OPTN | ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Policies

Contents

Policy 1: Administrative Rules and Definitions

1.1 Rules of Construction

The rules and definitions set forth in this Policy apply to all OPTN Policies.

1.1.A Time

A day ends at midnight Eastern Standard Time (EST).

1.1.B Headings, Notes, and History

All headings, notes, and history sections of these Policies are intended only as guidance and to supplement the OPTN Policies and are not part of the Policies. These sections and headings are nonbinding to members and should not be treated as policy or used to infer the intent of the Policies.

1.1.C Reporting of Information to the OPTN

Members must report requested information to the OPTN to fulfill membership requirements and to ensure compliance with OPTN Policies, Bylaws, and Management and Membership Policies. The OPTN will determine the required method and format for reporting any information required by OPTN Policies, Bylaws, and Management and Membership Policies, including the requirement to submit specific forms at defined times.

1.1.D Signature

Signatures necessary to meet OPTN Obligations may be handwritten or electronically produced, including digital or electronically imaged signatures.

1.2 Definitions

The definitions that follow are used to define terms specific to the OPTN Policies.

A

Active candidate
A candidate on the waiting list who is currently suitable for transplantation and eligible to receive organ offers.

Agent
A person legally authorized to act on behalf of another person.

Allocation MELD or PELD Score
The highest exception or calculated MELD or PELD score, including liver-intestine points, available to the candidate at the time of the match run for a liver or liver-intestine according to Policy.

Alternative allocation system
A type of variance that allows members who are permitted to join the variance to allocate organs differently than the OPTN Policies.

Alternative local unit (ALU)
A type of variance that creates a distinct geographic area for organ procurement and distribution.

Alternative point assignment system
A type of variance that allows members who are permitted to join the variance to assign points for organ allocation differently than required by the OPTN Policies.

Antigen mismatch
An antigen mismatch occurs when an identified deceased or living donor antigen is not recognized as equivalent to the recipient's own antigens. In cases where a donor or candidate only has one antigen identified at a human leukocyte antigen (HLA) locus (A, B, or DR), the antigens are considered to be identical at that locus.

Approved MELD or PELD Exception
A MELD or PELD exception or exception extension that met standardized criteria in OPTN policy or was reviewed and approved by the NLRB.

Assigned MELD or PELD Exception
A MELD or PELD exception or exception extension where the NLRB failed to make a decision within 21 days of the date of submission of the request and the candidate was assigned the requested score.

Authorization
The act of granting permission for a specific act. This is sometimes called consent, which is not to be confused with informed consent.

B

Backup offer
An organ offer made to a lower ranked candidate on a deceased donor match run after a transplant hospital accepts an organ on behalf of a higher ranked candidate, but before the organ is transplanted.

Bridge donor
A Kidney Paired Donation (KPD) donor at the end of a KPD Chain who chooses to participate in future KPD match runs.

Business days
Calendar days excluding Saturdays, Sundays, and federal holidays.

C

Calculated MELD or PELD Score
The highest non-exception MELD or PELD score available to the candidate according to Policy. Calculated MELD or PELD score excludes liver-intestine points.

Calculated Panel Reactive Antibody (CPRA)
The percentage of deceased donors expected to have one or more of the unacceptable antigens indicated on the waiting list for the candidate. The CPRA is derived from HLA antigen, allele, and epitope genotype frequencies for the different populations in proportion to their representation in the national deceased donor population.

Candidate
A person registered on the organ transplant waiting list. When a candidate appears on the match run, the candidate is then referred to as a potential transplant recipient (PTR).

Chain
A set of KPD matches that begins with a donation from a non-directed living donor to that KPD donor's matched candidate. This candidate's paired living donor then donates to the KPD donor's matched candidate. A chain continues until a living donor donates to an orphan candidate, a waiting list candidate or is a bridge donor.

Classification
A collection of potential transplant recipients grouped by similar characteristics and within a given geographical area. Classifications are used to rank potential recipients of deceased or living donor organs. A collection of ranked classifications of potential transplant recipients is also known as an organ allocation algorithm.

Closed variance
A variance that is not open for other members to join it.

Composite allocation score (CAS)
The scoring system used to prioritize candidates on the match run. It ranges from 0-100 and is an aggregate of separate goal level scores.

Covered Vascularized Composite Allograft body parts (covered VCAs)

Covered VCAs are VCAs that are subject to OPTN Policies, Bylaws, and Management and Membership Policies. Covered VCAs are categorized by type as follows:

Covered VCA(s)	Type:
Any group of vascularized body parts from the upper limb	Upper limb
Face, larynx, vascularized parathyroid gland, scalp, trachea, vascularized thyroid, and any other vascularized body parts from the head and neck	Head and neck
Abdominal wall, symphysis pubis, and any group of vascularized skeletal elements of the pelvis	Abdominal wall
Uterus, cervix, and vagina	Uterus
Penis and scrotum	External male genitalia
Internal male genitalia; external and internal female genitalia other than uterus, cervix, and vagina; and urinary bladder	Other genitourinary organ
Adrenal and thymus	Vascularized gland
Pelvic structures that are attached to the lower limb and transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, toe transfers, and any group of vascularized body parts from the lower limb	Lower limb
Spine axis, chest wall, and other composite graft of vascularized muscle, bone, nerve, or skin	Musculoskeletal composite graft segment
Spleen	Spleen

D

Day

Calendar day.

Deceased donor

An individual from whom at least one organ is recovered for the purpose of transplantation after declaration of death.

Directed donation

The allocation of a deceased or living donor organ to a specific candidate named by the person who authorized the donation.

Domino donor

An individual who has an organ removed as a component of medical treatment and who receives a replacement organ. The organ that was removed is transplanted into another person.

Donation after Circulatory Death (DCD)

Donation after Circulatory Death (DCD) describes the organ recovery process that may occur following death by irreversible cessation of circulatory and respiratory functions. A DCD donor may also be called a non-heart beating, asystolic, or donation after cardiac death donor.

Donation Service Area (DSA)

The geographic area designated by the Centers for Medicare and Medicaid Services (CMS) that is served by one organ procurement organization (OPO), one or more transplant hospitals, and one or more donor hospitals.

Donor hospital

The hospital where the deceased or living donor is admitted.

Donor ID

A unique identification assigned to each deceased and living donor by the OPTN.

Donor record

The record maintained by the OPO regarding an individual deceased donor.

E

Eligible death

For reporting purposes of DSA performance assessments, an eligible death for deceased organ donation is defined as the death of a patient who meets *all* the following characteristics:

- Is 75 years old or less
- Is legally declared dead by neurologic criteria according to state or local law
- Has body weight of 5 kg or greater
- Has a body mass index (BMI) of 50 kg/m^2 or less
- Has at least one kidney, liver, heart or lung that is deemed to meet the eligible data definition as defined below:
    - The kidney would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
        - Greater than 70 years old
        - Age 50-69 years with history of type 1 diabetes for more than 20 years
        - Polycystic kidney disease
        - Glomerulosclerosis greater than or equal to 20% by kidney biopsy
        - Terminal serum creatinine greater than 4.0 mg/dL
        - Chronic renal failure
        - No urine output for 24 hours or longer

- The liver would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
  - Cirrhosis
  - Terminal total bilirubin greater than or equal to 4 mg/dL
  - Portal hypertension
  - Macrosteatosis greater than or equal to 50% or fibrosis greater than or equal to stage II
  - Fulminant hepatic failure
  - Terminal AST/ALT greater than 700 U/L
- The heart would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
  - Greater than 60 years old
  - 45 years old or older with a history of 10 or more years of HTN or 10 or more years of type 1 diabetes
  - History of coronary artery bypass graft (CABG)
  - History of coronary stent/intervention
  - Current or past medical history of myocardial infarction (MI)
  - Severe vessel diagnosis as supported by cardiac catheterization (that is more than 50 percent occlusion or 2+ vessel disease)
  - Acute myocarditis or endocarditis, or both
  - Heart failure due to cardiomyopathy
  - Internal defibrillator or pacemaker
  - Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair
  - Serial echo results showing severe global hypokinesis
  - Myxoma
  - Congenital defects (surgically corrected or not)
- The lung would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
  - Greater than 65 years old
  - Diagnosed with COPD
  - Terminal PaO_2/FiO_2 less than 250 mmHg
  - Asthma (with daily prescription)
  - Asthma is the cause of death
  - Pulmonary fibrosis
  - Previous lobectomy
  - Multiple blebs documented on computed axial tomography (CAT) scan
  - Pneumonia as indicated on computed tomography (CT), X-ray, bronchoscopy, or cultures
  - Bilateral severe pulmonary contusions as per CT

If a deceased patient meets the above criteria they would be classified as an eligible death unless the donor meets *any* of the following criteria:

- The donor goes to the operating room with intent to recover organs for transplant and all organs are deemed not medically suitable for transplant
- The donor exhibits *any* of the following active infections (with a specific diagnosis):
  - Bacterial: tuberculosis, gangrenous bowel or perforated bowel or intra-abdominal sepsis

- Viral: HIV infection by serologic or molecular detection, rabies, reactive hepatitis B surface antigen, retroviral infections including viral encephalitis or meningitis, active herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia, acute Epstein Barr virus (mononucleosis), West Nile virus infection, or SARS. However, an organ procured from a donor with HIV for transplantation into a recipient living with HIV at a transplant hospital that meets the requirements in *Policy 15.7: Recovery and Transplantation of Organs from Donors with HIV* would still meet the requirements of an eligible death.
- Fungal: active infection with cryptococcus, aspergillus, histoplasma, coccidioides, active candidemia or invasive yeast infection
- Parasites: active infection with trypanosoma cruzi (Chagas'), Leishmania, strongyloides, or malaria (*plasmodium sp*.)
- Prion: Creutzfeldt-Jacob disease

The following are general exclusions:

- Aplastic anemia, agranulocytosis
- Current malignant neoplasms, except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease
- Previous malignant neoplasms with current evident metastatic disease
- A history of melanoma
- Hematologic malignancies: leukemia, Hodgkin's disease, lymphoma, multiple myeloma
- Active fungal, parasitic, viral, or bacterial meningitis or encephalitis
- No discernible cause of death

Emergency
Any situation that compromises telecommunications, transportation, function of or access to the OPTN computer match system.

Exchange
A set of KPD matches that form a chain, a two-way exchange, or a three-way exchange.

Extra vessels
Vessels taken during recovery of deceased or living donor organs with the intent to be used in organ transplantation only. Extra vessels are not connected to the organ. Extra vessels are subject to the same member requirements applying to the organ unless otherwise specified.

F

Final Rule
42 CFR § 121 *et seq*.

G

Geographical Area
A physical area used to group potential transplant recipients in a classification.

Glomerular Filtration Rate (GFR)
A measure of filtering capacity of the kidneys. GFR can be measured directly or estimated (eGFR) using various formulae. Formulae used to calculate an eGFR must not use a race-based variable.

Graft failure
For all organs except pancreas and covered VCAs, graft failure occurs when *any* of the following occurs:

- A recipient's transplanted organ is removed
- A recipient dies
- A recipient is placed on a chronic allograft support system

Pancreas graft failure occurs when *any* of the following occurs:

- A recipient's transplanted pancreas is removed
- A recipient re-registers for a pancreas
- A recipient registers for an islet transplant after receiving a pancreas transplant
- A recipient's total insulin use is greater than or equal to 0.5 units/kg/day for a consecutive 90 days
- A recipient dies

Covered VCA graft failure occurs when any of the following occurs:

- A recipient re-registers for the same covered VCA
- A recipient dies
- An unplanned removal of a covered VCA

H

Hepatitis B Virus (HBV)
Hepatitis B is a vaccine-preventable liver infection caused by the hepatitis B virus (HBV).

Hepatitis C Virus (HCV)
Hepatitis C is a liver infection caused by the hepatitis C virus (HCV).

Histocompatibility Laboratory
A histocompatibility laboratory is a member of the OPTN. A histocompatibility laboratory member is any histocompatibility laboratory that performs histocompatibility testing, including but not limited to, Human Leukocyte Antigen (HLA) typing, antibody screening, compatibility testing, or crossmatching, and serves at least one transplant hospital member or OPO. Histocompatibility laboratory members are either independent or hospital-based. See also Independent Histocompatibility Laboratory and Hospital-based Histocompatibility Laboratory definitions in the *OPTN Management and Membership Policies Appendix M: Definitions*.

Host Organ Procurement Organization (Host OPO)
The OPO responding to a deceased organ donor referral from a hospital.

Human Immunodeficiency Virus (HIV)

Human Immunodeficiency Virus (HIV) is a virus that attacks the body's immune system. If HIV is not treated, it can lead to Acquired Immunodeficiency Syndrome (AIDS).

I

Imminent neurological death

Imminent Neurological Death is defined as the death of a patient who meets *both* of the following criteria:

- Meets the eligible death definition with the exception that the patient has not been declared legally dead by neurologic criteria according to current standards of accepted medical practice and state or local law.
- Has a severe neurological injury requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has no observed spontaneous breathing and is lacking at least *two* of the additional brain stem reflexes that follow:

    - Pupillary reaction
    - Response to iced caloric
    - Gag Reflex
    - Cough Reflex
    - Corneal Reflex
    - Doll's eyes reflex
    - Response to painful stimuli

    A patient who is unable to be assessed neurologically due to administration of sedation or hypothermia protocol does not meet the definition of an imminent neurological death.

Inactive candidate

A candidate that is temporarily unavailable or unsuitable for transplantation, and appears as inactive on the waiting list.

Independent living donor advocate (ILDA)

A person available to assist potential living donors in the living donation process.

Intended incompatible

Donor and candidate primary blood types that are biologically incompatible, but transplantation is permissible according to OPTN policy.

Intestine

Stomach, small intestine, large intestine, or any portion of the gastro-intestinal tract as determined by the medical needs of individual candidates.

Islet infusion

An infusion of islets from a single deceased donor. If a recipient receives islets from multiple donors simultaneously, then each donor's islets must be counted as a separate infusion.

K

Kidney Paired Donation (KPD)
The donation and receipt of human kidneys under the following circumstances:

- An individual (the first living donor) desires to make a living donation of a kidney specifically to a particular patient (the first patient), but the first living donor is biologically incompatible as a donor for the first patient.
- A second individual (the second living donor) desires to make a living donation of a kidney specifically to a second particular patient (the second patient), but the second living donor is biologically incompatible as a donor for the second patient.
- The first living donor is biologically compatible as a donor of a kidney for the second patient, and the second living donor is biologically compatible as a donor of a kidney for the first patient. If there is any additional donor-patient pair as described above, each living donor in the group of donor-patient pairs is biologically compatible as a living donor of a kidney for a patient in the group.
- All donors and patients in the group of donor-patient pairs enter into a single agreement to donate and receive the kidneys, respectively, according to biological compatibility within the group.

Other than described as above, no valuable consideration is knowingly acquired, received, or otherwise transferred for the donation of the kidneys.

L

Living donor
A living individual from whom at least one organ is recovered for transplantation.

Living donor recipient
A transplant recipient that receives a living donor organ.

Living donor organ
An organ from a living donor.

Lower respiratory specimen
A sample taken from the respiratory system within the trachea or below. Sputum, tracheal aspirate, bronchial suction, bronchial wash, bronchoalveolar lavage (BAL), and lung biopsy are considered lower respiratory specimens.

M

Match
A donor and the donor's matched candidate. This includes deceased, living, and KPD donors.

Match run
A process that filters and ranks waiting list candidates based on deceased or non-directed living donor and candidate medical compatibility and organ-specific allocation criteria. A match run is also used to generate a set of potential exchanges for a KPD donor and candidate.

Match system
The computerized algorithm used to prioritize patients waiting for organs.

Matched candidate
The candidate that a KPD match run identifies as a potential transplant recipient of a living donor's kidney.

Matched donor
A living donor identified by a KPD match run as a potential donor for a candidate.

Matched recipient
A matched KPD candidate that has received a transplant.

Medical record
A chronological account of a patient's examination and treatment that includes the patient's medical history and complaints, the physician's physical findings, the results of diagnostic tests and procedures, and medications and therapeutic procedures.

Model for End Stage Liver Disease (MELD)
The scoring system used to measure illness severity in the allocation of livers to transplant candidates at least 12 years old.

Model-identified offer filter
A recommended offer filter generated based on a transplant program's previous organ offer acceptance.

Member
The OPTN membership categories are transplant hospital members, OPO members, histocompatibility laboratory members, medical/scientific members, public organization members, business members, and individual members.

Month
Calendar month.

Multi-organ candidate
A candidate registered on the waiting lists for more than one organ type.

N

National Organ Transplantation Act (NOTA)
42 U.S.C. § 273 *et seq*.

Non-Directed Donor (NDD)
A KPD donor that enters KPD without a paired candidate or a living donor who donates an organ and does not specify an intended recipient.

Non-domino therapeutic donor
An individual who has an organ removed as a component of medical treatment and whose organ is transplanted into another person. The donor does not receive a replacement organ.

Non-US citizen/Non-US resident
A non-citizen of the United States for whom the United States is not the primary place of residence.

Non-US citizen/US resident
A non-citizen of the United States for whom the United States is the primary place of residence.

O

Open variance
A variance that allows members other than the members that applied for the variance to join it.

OPTN computer match program
A set of computer-based instructions that compares data on a deceased organ donor with data on transplant candidates on the waiting list and ranks the candidates according to OPTN Policies to determine the priority for allocating the deceased donor organs.

OPTN Computer System
The software platform operated by the OPTN Contractor in performance of the OPTN Contract. This platform includes, but is not limited to, the OPTN Data System, the OPTN Waiting List, the OPTN Donor Data and Matching System, the OPTN Organ Labeling, Packaging, and Tracking system, the OPTN Patient Safety Reporting Portal, and OPTN Kidney Paired Donation Pilot Program (KPDPP).

OPTN Contractor
The corporation currently operating the Organ Procurement and Transplantation Network (OPTN) under contract with HHS. In 1984 NOTA directed the Secretary of HHS to establish by contract the OPTN which shall be a private, non-profit entity that has an expertise in organ procurement and transplantation. The United Network for Organ Sharing (UNOS) is the current OPTN Contractor.

OPTN obligations
Members agree to comply with all OPTN obligations. OPTN obligations include all the applicable provisions of NOTA, OPTN Final Rule, OPTN Charter, OPTN Bylaws,OPTN Policies, and OPTN Management and Membership Policies.

OPTN organ tracking system
A software application developed and distributed by the OPTN Contractor that uses barcode technology to generate printed labels for organ packaging and tracking.

Organ
A human kidney, liver, heart, lung, pancreas, intestine (including the esophagus, stomach, small or large intestine, or any portion of the gastrointestinal tract), or vascularized composite allograft. Blood vessels,

including extra vessels, recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of these Policies if the vessels are intended for use in organ transplantation and labeled ‘‘For use in organ transplantation only.’’

Organ allocation policies

OPTN Policies: *Policy 6: Allocation of Hearts and Heart-Lungs, Policy 7: Allocation of Intestines, Policy 8: Allocation of Kidneys, Policy 9: Allocation of Livers and Liver-Intestines, Policy 10: Allocation of Lungs, and Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets,* and *Policy 12: Allocation of Covered Vascularized Composite Allografts.*

Organ Center

The Organ Center is responsible for facilitating organ sharing among transplant centers, organ procurement organizations and histocompatibility laboratories across the U.S. The primary functions of the Organ Center are to: assist in placing donated organs for transplantation, assist organ procurement organizations with running the donor/recipient computer matching process, assist with transportation of organs and associated tissues for the purposes of transplantation, act as a resource to the transplant community regarding organ sharing policies. The Organ Center operates 24 hours a day, 365 days a year.

Organ offer acceptance

When the transplant hospital notifies the host OPO that it accepts the organ offer for an intended recipient, pending review of organ anatomy. For kidney, acceptance is also pending final crossmatch.

Organ offer refusal

When the transplant hospital notifies the OPTN or the host OPO that they are declining the organ offer.

Organ procurement organization (OPO)

An organization authorized by the Centers for Medicare and Medicaid Services, under *Section 1138(b)* of the Social Security Act, to procure organs for transplantation.

Organ Procurement and Transplantation Network (OPTN)

The network established according to *Section 372* of the Social Security Act.

Organ transplant

Organ transplants include solid organ transplants and islet infusions. An organ transplant begins at the start of organ anastomosis or the start of an islet infusion.

An organ transplant procedure is complete when *any* of the following occurs:

- The chest or abdominal cavity is closed and the final skin stitch or staple is applied.
- The transplant recipient leaves the operating room, even if the chest or abdominal cavity cannot be closed.
- The islet infusion is complete.

Orphan candidate

A KPD candidate who does not receive a kidney transplant from the matched donor for any reason after the candidate’s paired donor has donated.

Other antibody specificities
Antigens specified for a KPD candidate that may result in a positive or negative crossmatch. The rate of positive crossmatches would be expected to be higher against KPD donors who express these antigens.

P

Pair
A KPD donor and the KPD donor's paired KPD candidate.

Paired candidate
The KPD candidate to whom a KPD donor intended to donate his organ before entering into KPD.

Paired donor
A living donor who intended to donate his organ to his paired candidate before entering into KPD.

Paired donor's transplant hospital
The transplant hospital that enters the donor in a KPD program.

Paired recipient
A paired KPD candidate that has received a transplant.

Patient
Includes *all* of the following:

1. Potential deceased donors undergoing an OPO's potential donor evaluation, donor management and procurement processes
2. Potential candidates and potential living donors undergoing a transplant program's evaluation process
3. Candidates
4. Living donors being followed by a transplant program
5. Recipients being followed by a transplant program

Pediatric End Stage Liver Disease (PELD)
The scoring system used to measure illness severity in the allocation of livers to pediatric candidates under the age of 12.

PHS Guideline, see United States Public Health Service (PHS) Guideline.

Planned Removal of a Uterus
A planned removal of a uterus occurs when the graft is removed with the intent of removal recorded either pre-transplant or at time of transplant.

Potential transplant recipient (PTR)
A candidate who appears on a match run.

Primary potential transplant recipient
The first candidate according to match run sequence for whom an organ has been accepted.

Primary waiting time
The longest time period a candidate registered on the waiting list has been waiting for a specific organ transplant procedure, after having met qualifying criteria to accrue waiting time for that organ. Primary waiting time is based on the candidate's qualifying date, registration date, and waiting time accrued.

Privacy Incident
A suspected or confirmed incident involving the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses Personally Identifiable Information (PII) or (2) an authorized user accesses PII for an other than authorized purpose.

Provisional yes
When the transplant hospital notifies the OPTN or the host OPO that they have evaluated the offer and are interested in accepting the organ or receiving more information about the organ.

Q

Qualified health care professional
A person who is qualified to perform blood type reporting or verification requirements as defined in the OPO, transplant hospital, or recovery hospital written protocol.

Qualified specimen
A blood specimen without evidence of hemodilution.

Qualifying date
The date that a candidate began accruing waiting time.

Quality Assurance and Performance Improvement (QAPI)
Any quality assessment and improvement activities consistent with the definition of health care operations in the Health Insurance Portability and Accountability Act (HIPAA).

R

Receiving transplant program
The transplant program that receives a deceased or living donor organ from an OPO, transplant hospital, or recovery hospital.

Recipient
A candidate that has received an organ transplant.

Recovery hospital
A healthcare facility that recovers living donor organs.

Region
For administrative purposes, OPTN membership is divided into 11 geographic regions. Members belong to the Region in which they are located. The Regions are as follows:

Region 1: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Eastern Vermont
Region 2: Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, West Virginia, and the part of Northern Virginia in the Donation Service Area served by the Infinite Legacy (MDPC) OPO.
Region 3: Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, and Puerto Rico
Region 4: Oklahoma and Texas
Region 5: Arizona, California, Nevada, New Mexico, and Utah
Region 6: Alaska, Hawaii, Idaho, Montana, Oregon, and Washington
Region 7: Illinois, Minnesota, North Dakota, South Dakota, and Wisconsin
Region 8: Colorado, Iowa, Kansas, Missouri, Nebraska, and Wyoming
Region 9: New York and Western Vermont
Region 10: Indiana, Michigan, and Ohio
Region 11: Kentucky, North Carolina, South Carolina, Tennessee, and Virginia

Registration date
The date that the candidate registers on the waiting list.

S

Security incident
An event that is declared as jeopardizing the confidentiality, integrity, or availability of an information system or the information the system processes, stores, or transmits.

Sharing arrangements
A type of variance that permits two or more OPOs to share organs.

Source document
An original record of results, or a photocopy or digital copy of the original record.

T

Therapeutic donor
An individual who has an organ removed as a component of medical treatment and who receives a replacement organ. The organ that was removed is transplanted into another person.

Three-way exchange
A set of KPD matches that includes three living donor-candidate pairs where each living donor donates a kidney to a candidate in one of the other pairs.

Time-out
A period of time when action stops until some information is verified, or action is completed.

Transplant date
Determined by the start of the organ anastomosis during transplant or the start of the islet infusion.

Transplant hospital
A health care facility in which transplants of organs are performed.

Transplant program
A component within a transplant hospital that provides transplantation of a particular type of organ.

Two-way exchange
A set of matches that includes two living donor-candidate pairs where each living donor donates a kidney to the candidate in the other pair.

U

Unacceptable antigens
Antigens to which the patient is sensitized and would preclude transplantation with a deceased or living donor having any one of those antigens.

United States (U.S.) Public Health Service (PHS) Guideline
The Guideline issued by the U.S. Public Health Service in 2020 that provides recommendations for organ transplantation related to Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) transmission.

V

Variance
An experimental policy that tests methods of improving allocation.

Vascularized Composite Allograft (VCA)
A body part meeting *all* nine of the following criteria:

1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation.
2. Containing multiple tissue types.
3. Recovered from a human donor as an anatomical/structural unit.
4. Transplanted into a human recipient as an anatomical/structural unit.
5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement).
6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor).

7. Not combined with another article such as a device.
8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

Refer to "Covered Vascularized Composite Allograft body parts (covered VCAs)" for the list of body parts covered by OPTN Policies, Bylaws, and Management and Membership Policies.

W

Waiting list
A computerized list of candidates who are waiting to be matched with specific deceased donor organs for transplant.

Y

Year
Calendar year.

Z

0-ABDR mismatch
A candidate is considered a 0-ABDR mismatch with a deceased or living donor if *all* of the following conditions are met:
1. At least one donor antigen is identified for each of the A, B, and DR loci
2. At least one candidate antigen is identified for each of the A, B, and DR loci
3. The donor has zero non-equivalent A, B, or DR antigens with the candidate's antigens
4. The donor and the candidate have compatible or permissible blood types

In cases where a candidate or donor has only one antigen identified at an HLA locus (A, B, or DR), the antigens are considered to be identical at that locus. A 0-ABDR mismatch may also be referred to as a zero mismatch or zero-antigen mismatch.

1.3 Variances

1.3.A Acceptable Variances

Permissible variances include, but are not limited to:

- Alternative allocation systems
- Alternative local units
- Sharing arrangements
- Alternative point assignment systems

The following principles apply to *all* variances:

1. Variances must comply with the NOTA and the Final Rule.
2. Members participating in a variance must follow all rules and requirements of the OPTN Policies, Bylaws, and Management and Membership Policies.
3. If the Board later amends an OPTN Policy to contradict with a variance, the Policy amendment will not affect the existing variance.
4. If a member's application to create, amend, or join a variance will require other members to join the variance, the applicant must solicit their support.
5. The Board of Directors may extend, amend, or terminate a variance at any time.

1.3.B Creation of a Variance

Members wishing to create or amend a variance must submit an application to the OPTN. Completed applications will be considered through the policy development process described in *OPTN Management and Membership Policy E: Adoption of New Policies*. OPTN committees may also propose new variances without a member application.

Proposed new variances must address *all* of the following:

1. The purpose for the proposed variance and how the variance will further this purpose.
2. A defined expiration date or period of time when the variance will end, the participating members will report results, and the sponsoring Committee will evaluate the impact of the variance.
3. An evaluation plan with objective criteria to measure the variance's success achieving the variance's stated purpose.
4. Any anticipated difficulties in demonstrating whether the variance is achieving its stated purpose.
5. Whether this is an open variance or closed variance and, if this is an open variance, any additional conditions for members to join this variance.

1.3.C Joining an Open Variance

Members wishing to join an existing open variance must submit an application as dictated by the specific variance. When an open variance is created, it may set conditions for the OPTN Contractor to approve certain applications.

1.3.D Reporting Requirements for Variances

Members participating in a variance must submit data and status reports to the sponsoring Committee at the frequency defined by the variance, at least annually that does *all* of the following:

1. Evaluate whether the variance is achieving its stated purpose
2. Provide data for the performance measures in the variance application
3. Address any organ allocation problems caused by the variance

The sponsoring Committee must actively monitor and evaluate these reports to determine if the variance achieved of its stated purpose.

1.3.E Final Evaluation of Variances

Prior to the variance's expiration date, the sponsoring Committee must evaluate whether the variance achieved its stated purpose and make a final recommendation to the Board of Directors. The Board of Directors may take *any* of the following actions:

1. Direct the sponsoring Committee to develop a policy proposal based on the results of the variance
2. Amend the variance
3. Extend the variance for a set period of time
4. Terminate the variance

1.3.F Terminating Variances

Members participating in a variance may apply to the sponsoring Committee to withdraw from or terminate a variance. The applicant must solicit feedback from all other members participating in the variance. The sponsoring Committee must recommend to the Board of Directors whether to approve or deny the request. The Board of Directors may approve, modify, or deny the request.

1.3.G Appeals of Variance Decisions

Members participating in a variance or seeking to join an open variance may appeal a Committee or Board of Directors' decision on an existing variance. To appeal a decision of a Committee, the member must submit a written appeal to the sponsoring Committee within thirty days of notice of the decision and submit any new evidence not previously provided. The sponsoring Committee may request additional information from the member. The sponsoring Committee will then meet to consider the appeal. The member submitting the appeal may participate in this meeting. After this meeting, the sponsoring Committee will recommend action on the appeal to the Board of Directors.

Once the sponsoring Committee recommends action to the Board of Directors, a member cannot appeal again until the Policy Oversight Committee (POC) and Board of Directors decide on the variance. While evaluating the appeal, the POC may request additional information from the member. The sponsoring Committee must submit any information received from the member to the POC. The POC will recommend action on the variance to the Board of Directors.

The Board of Directors will consider the variance including the recommendations of the sponsoring Committee and the POC. The member may participate in this meeting of the Board of Directors.

1.4 Allocation of Organs during Emergencies

1.4.A Regional and National Emergencies

During a regional or national emergency, the OPTN Contractor will attempt to distribute instructions to all transplant hospitals and OPOs that describe the impact and how to proceed with organ allocation, distribution, and transplantation.

When the OPTN registers a candidate or modifies a candidate's registration due to an emergency, the transplant hospital must submit to the OPTN a statement explaining the event.

1.4.B Transportation Disruptions

If the transportation of organs is either not possible or severely impaired, affected members must contact the OPTN to determine proper operating procedures.

1.4.C Internet Outages

If the OPTN and members cannot communicate through the internet, affected members must contact the OPTN to determine the proper operating procedures.

1.4.D Telecommunications Outage

If the OPTN and members cannot communicate through telephone, affected members:

1. Must contact the OPTN by e-mail to determine operating procedures and to obtain assistance.
2. Must continue to use the OPTN computer match program for organ allocation and distribution.
3. Must document and report to the OPTN any variations in allocation or distribution during the telecommunications problems.

1.4.E OPTN Computer Match Program Outages

If the OPTN and members cannot communicate by any method and the OPTN computer match program is either not accessible or not operational, affected OPOs:

1. Must refer to recent matches of similar blood type and body size for ranking transplant candidates.
2. Must use transplant program waiting lists to match the best organ with waiting transplant candidates.
3. Must document and report to the OPTN their process for allocation during the outage.

1.5 Department of Defense Directive

Members may cooperate with U.S. military facilities that are bound by United States Department of Defense (DOD) organ allocation directives that conflict with *OPTN Policies*.

Policy 2: Deceased Donor Organ Procurement

2.1 OPO Organ Acceptance Criteria

Each organ procurement organization (OPO) must establish criteria for an acceptable deceased donor or deceased donor organ for the transplant programs in its Donation Service Area (DSA). If a host OPO rejects a deceased donor, the OPO must offer the organs to OPOs that have more liberal acceptance criteria.

2.2 OPO Responsibilities

The host OPO is responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Ensuring the clinical management of the deceased donor.
8. Ensuring that the necessary tissue-typing material is procured, divided, and packaged.

9. Assessing deceased donor organ quality.
10. Preserving, labeling, packaging, and transporting the organs. Labeling and packaging must be completed using the OPTN organ tracking system according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.
11. Executing the match run and using the resulting match for each deceased donor organ allocation.
12. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
13. Ensuring that all deceased donor information, according to *Policy 2.11: Required Deceased Donor Information,* is reported to the OPTN upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs.
14. Ensuring that documentation for *all* of the following deceased donor information is submitted to the OPTN upon receipt:
    a. ABO source documentation
    b. ABO subtype source documentation
    c. Infectious disease results source documentation
    d. Death pronouncement source documentation
    e. Authorization for donation source documentation
    f. HLA typing source documentation
15. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The samples must be collected within 24 hours prior to organ procurement. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

2.3 Evaluating and Screening Potential Deceased Donors

The host OPO must perform *all* of the following and report the resulting information to all receiving OPOs or transplant hospitals:

1. Attempt to obtain the deceased donor's medical and behavioral history from one or more individuals familiar with the donor according to *Policy 2.4: Deceased Donor Medical and Behavioral History*, to screen for medical conditions that may affect the decision to use the donated organ.
2. Review the deceased donor's medical record.
3. Complete a physical examination of the deceased donor, including the donor's vital signs.
4. Document in the deceased donor medical record if any of this information is not available and the reason it is not available.

2.4 Deceased Donor Medical and Behavioral History

The medical and behavioral history for each potential deceased donor must include *all* of the following:

1. Any testing and laboratory results used to identify the presence of transmissible diseases or malignancies, treated and untreated, or any other known condition that may be transmitted by the deceased donor organ and may reasonably impact the recipient.
2. Whether the potential deceased donor has any risk factors associated with disease transmission, including blood-borne pathogens. If the deceased donor has any risk criteria for acute HIV, HBV, or HCV infection according to the *U.S. Public Health Services (PHS) Guideline*, the host OPO must communicate this information to all transplant programs receiving organs from the deceased donor.
3. Whether the potential deceased donor has a history of prior exposure or treatment with non-recombinant Human Pituitary Derived Growth Hormone (HPDGH). If so, the potential deceased donor has an increased risk of prion disease and the host OPO must communicate this information to all transplant programs receiving organs from the donor.

2.5 Hemodilution Assessment

OPOs must use qualified (non-hemodiluted) blood samples for deceased donor screening tests if available. If a qualified sample is not available for testing, a hemodiluted sample may be used for deceased donor screening tests.

Prior to screening, the host OPO must assess all potential deceased donor blood samples that were obtained for screening tests for hemodilution using a hemodilution calculation. The host OPO must document in the deceased donor medical record a complete history of all blood products and intravenous fluid transfusions the deceased donor received since admission to the donor hospital.

Additionally, the host OPO must report *all* of the following to the accepting transplant programs when a hemodiluted specimen is used in deceased donor screening tests:

1. Any screening results from the hemodiluted specimens.
2. The tests completed on the hemodiluted specimens.
3. The hemodilution calculation used for the hemodiluted specimens, if requested.

2.6 Deceased Donor Blood Type Determination and Reporting

Host OPOs must develop and comply with a written protocol for blood type determination and reporting that includes *all* the requirements below.

2.6.A Deceased Donor Blood Type Determination

The host OPO must ensure that each deceased donor's blood type is determined by testing at least two donor blood samples prior to the match run.

The deceased donor blood samples must:

1. Be drawn on two separate occasions
2. Have different collection times
3. Be submitted as separate samples

The host OPO must include a process to address conflicting or indeterminate primary blood type results in their written protocol.

The host OPO must document:

1. That blood type determination was conducted according to the OPO's written protocol and
2. A complete history of all blood products the deceased donor received since admission to the donor hospital in the deceased donor medical record.

2.6.B Deceased Donor Blood Subtype Determination

Deceased donor blood subtyping must be completed according to the *Table 2-1* and the requirements below.

Table 2-1: Subtyping Requirements by Primary Blood Type and First Subtype Result

If the donor's primary blood type is:	Then subtyping is	A second subtyping must be completed if the first subtype result is:
A	Required	Blood type A, non-A_1
AB	Optional	Blood type AB, non-A_1B

Deceased donor blood samples for subtyping must:

1. Be tested using pre-red blood cell transfusion samples
2. Be drawn on two separate occasions
3. Have different collection times
4. Be submitted as separate samples

All subtype results reported to the OPTN must be from two separate tests indicating the same result. If there are conflicting or indeterminate subtype results, the subtype results must not be reported to the OPTN and the deceased donor must be allocated based on the primary blood type.

For all blood type A donors, the host OPO must document *either* that subtyping was completed or the reason it could not be completed.

2.6.C Reporting of Deceased Donor Blood Type and Subtype

The deceased donor is not eligible for a match run until the host OPO completes verification and reporting as follows:

1. Two different qualified health care professionals, as defined in the host OPO's protocol, must each make an independent report of the donor's blood type to the OPTN.
2. If the donor's blood subtype will be used for allocation, a qualified health care professional must report the subtype to the OPTN. This report must be verified by a different qualified health care professional according to the OPO's protocol.
3. Both qualified health care professionals must use all known available blood type and subtype determination source documents to verify they:
    a. Contain blood type and subtype (if used for allocation) results for the donor
    b. Indicate the same blood type and subtype (if used for allocation) on the test results. If the results are conflicting or indeterminate, the host OPO must refer to their written protocol as outlined in *Policy 2.6.A: Deceased Donor Blood Type Determination*.
    c. Match the result reported to the OPTN

The OPO must document that reporting was completed according to the OPO's protocol and the above requirements.

If donation must be accelerated to avoid organ waste, the host OPO may instead complete these requirements after the match run, but prior to organ release to a transplant hospital. The host OPO must document *all* of the following:

1. The reason that both blood type tests (and subtype tests, if used for allocation) could not be completed, verified, and reported prior to the match run.
2. If there are conflicting or indeterminate primary blood type test results, the host OPO must follow its protocol for resolving the discrepancy and must re-execute the match run if the final ABO result is different from the initial ABO on the original match run.
3. That all required blood type and subtype determinations, verification, and reporting were completed prior to organ release to a transplant hospital.

2.7 HIV Screening of Potential Deceased Donors

The host OPO must accurately document HIV test results for every deceased donor. All deceased donors must be tested for HIV according to *Policy 2.9: Required Deceased Donor Infectious Disease Testing*.

The host OPO must report the results of all HIV tests it performs directly to all receiving OPOs and transplant programs. Allocation of organs from deceased donors with HIV must follow the requirements in *Policy 5.5.C: OPO Requirements for Positive HIV Test Results* and *Policy 15.7.A: Requirements for Allocating Organs from Deceased Donors with HIV.*

2.7.A Informing Personnel

The host OPO must only inform health care personnel caring for potential deceased donors or deceased donors who test positive for HIV when it is necessary for making medical decisions.

2.8 Required Deceased Donor General Risk Assessment

The host OPO is responsible for evaluating each potential donor in order to obtain the following information:

1. Arterial blood gas results
2. Blood type determination and reporting according to *Policy 2.6: Deceased Donor Blood Type Determination and Reporting*, including sub-typing for blood type A donors
3. Chest x-ray
4. Complete blood count (CBC)
5. Electrolytes
6. Serum glucose
7. Urinalysis, within 24 hours before cross clamp

2.9 Required Deceased Donor Infectious Disease Testing

The host OPO is responsible for ensuring that *all* of the following infectious disease testing is completed in Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories, or in laboratories meeting equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS):

1. Blood and urine cultures
2. Infectious disease testing for all potential deceased organ donors using FDA licensed, approved or cleared tests, as listed below:
   a. HIV antibody (anti-HIV) donor screening test *or* HIV antigen/antibody (Ag/Ab) combination test
   b. HIV ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)
   c. Hepatitis B surface antigen (HBsAg) donor screening test
   d. Hepatitis B core antibody (total anti-HBc) donor screening test
   e. Hepatitis B deoxyribonucleic acid (DNA) by donor screening or diagnostic nucleic acid test (NAT)
   f. Hepatitis C antibody donor screening test (anti-HCV)
   g. Hepatitis C ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)
   h. Cytomegalovirus (CMV) antibody (anti-CMV) donor screening *or* diagnostic test
   i. Epstein-Barr Virus (EBV) antibody (anti-EBV) donor screening *or* diagnostic test
   j. Syphilis donor screening *or* diagnostic test
   k. Toxoplasma Immunoglobulin G (IgG) antibody test

   Donor samples for all required HIV, HBV, and HCV testing must be obtained within 96 hours prior to organ procurement.

3. Infectious disease testing for all potential deceased lung donors using an FDA licensed, approved, cleared, or emergency use authorized, lower respiratory specimen test for SARS-CoV-2 (COVID-19) by nucleic acid test (NAT)

   Lower respiratory specimen test results for SARS-CoV-2 by nucleic acid test (NAT) must be available pre-transplant of lungs.

4. Infectious disease testing for all potential deceased donors for *Strongyloides* antibody, using either
   - an FDA licensed, approved, cleared, or Class 1, 510(k)-exempt test or
   - a Laboratory Developed Test (LDT), as described by the FDA.

5. Infectious disease testing for all potential deceased donors whose donor history reflects the donor's birthplace was in a country classified as endemic for Chagas disease by the CDC at the time of testing. The OPTN maintains a list of countries currently classified as endemic for Chagas disease by the CDC. This testing must be performed using an FDA licensed, approved, or cleared donor screening test for *T. cruzi* antibody.

   Within 72 hours of receipt of a positive *T. cruzi* antibody donor screening test, the host OPO must submit a sample for confirmatory testing. Confirmatory testing requires either
   - submission through the CDC or
   - performance of at least two different FDA licensed, approved, or cleared antibody diagnostic tests.

2.10 Additional Deceased Donor Testing

If a host OPO completes any testing in addition to what is required for a potential donor, the results of these tests must be reported to all recipient transplant hospitals as soon as possible, but no later than 24 hours after receiving the test result.

2.11 Required Deceased Donor Information

The host OPO must report to the OPTN upon receipt *all* of the following information for each potential deceased donor:

1. Age
2. Diagnosis (or cause of brain death)
3. Donor behavioral and social history
4. Donor management information
5. Donor medical history
6. Donor evaluation information to include all laboratory testing, radiologic results, and injury to the organ
7. Ethnicity
8. Race

9. Height
10. Organ anatomy and recovery information
11. Sex
12. All vital signs, including blood pressure, heart rate, and temperature
13. Weight
14. SARS-CoV-2 (COVID-19) testing status. If COVID-19 testing was performed, the host OPO must report to the OPTN the date and time, type of specimen, testing method, and results

The potential transplant program team must have the opportunity to speak directly with responsible onsite OPO donor personnel to obtain current information about the deceased donor's physiology.

2.11.A Required Information for Deceased Kidney Donors

The host OPO must provide *all* the following additional information for all deceased donor kidney offers:

1. Anatomical description, including number of blood vessels, ureters, and approximate length of each
2. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, DPA1, and DPB1 antigens prior to organ offers
3. Injuries to or abnormalities of blood vessels, ureters, or kidney
4. Kidney perfusion information, if performed
5. Kidney laterality
6. Biopsy results, if performed. The host OPO must make reasonable efforts to perform a biopsy on deceased donor kidneys from donors that meet *at least one* of the following criteria, excluding donors less than 18 years old:
    - Anuria, or a urine output of less than 100ml in 24 hours during current hospital admission or in the course of donor management
    - Donor has received hemodialysis or other renal replacement therapy during current hospital admission or in the course of donor management
    - History of diabetes, or HbA1C of 6.5 or greater during donor evaluation or management
    - KDPI greater than 85% at the time of original match run.
    - Donor age 60 years or older
    - Donor age 50-59 years, and meets at least *two* of the following criteria:
        - History of hypertension
        - Manner of death: Cerebrovascular Accident (CVA)
        - Terminal serum creatinine greater than or equal to 1.5mg/dl

If the biopsy is not performed, the host OPO must document the reason and make this documentation available to the OPTN on request.

2.11.B Required Information for Deceased Liver Donors

The host OPO must provide *all* the following additional information for all deceased donor liver offers:

1. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, DPA1, and DPB1 antigens in the timeframe specified by the transplant program
2. Other laboratory tests within 12 hours of the offer:
   a. Alanine aminotransferase/asparate aminotransferase (ALT/AST)
   b. Alkaline phosphatase
   c. Total and direct bilirubin
   d. International normalized ration (INR) or Prothrombin (PT) if INR is not available
   e. Partial thromboplastin time (PTT)
3. Pre-procurement biopsy results, if performed
4. Pre-procurement CT imaging results, if performed

2.11.C Required Information for Deceased Heart Donors

The host OPO must provide *all* the following additional information for all deceased donor heart offers:

1. 12-lead electrocardiogram interpretation, if available
2. Arterial blood gas results and ventilator settings
3. Cardiology consult, if performed
4. Echocardiogram
5. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, DPA1, and DPB1 antigens prior to the final organ acceptance

2.11.D Required Information for Deceased Lung Donors

The host OPO must provide *all* the following additional information for all deceased lung donor offers:

1. Arterial blood gases and ventilator settings on 5 cm/H20/PEEP including PO2/FiO2 ratio and preferably 100% FiO2, within 2 hours prior to the offer
2. Bronchoscopy results, if performed
3. Chest x-ray interpreted by a radiologist or qualified physician within 3 hours prior to the offer
4. HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, DPA1, and DPB1 antigens prior to final organ acceptance
5. Sputum gram stain, with description of sputum
6. Lung laterality

If the host OPO cannot perform a bronchoscopy, it must document that it is unable to provide bronchoscopy results and the receiving transplant hospital may perform it. The lung recovery team may perform a confirmatory bronchoscopy provided unreasonable delays are avoided and deceased donor stability and the time limitations in *Policy 5.6.B: Time Limit for Review and Acceptance of Organ Offers* are maintained.

2.11.E Required Information for Deceased Pancreas Donors

The host OPO must provide *all* the following additional information for all deceased donor pancreas offers:

1. Family history of diabetes (including Type 1 and Type 2)
2. Hemoglobin A1C, if performed
3. HLA information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, DPA1, and DPB1 antigens prior to organ offers
4. Insulin protocol
5. Serum amylase
6. Serum lipase

2.12 Post Procurement Follow Up and Reporting

The host OPO is responsible for follow up and reporting of deceased donor test results received after procurement. The host OPO must develop and comply with written protocols to do *all* of the following:

1. Obtain and report all deceased donor test results to the OPTN
2. Report all positive test results and relevant information according to *Policy 15.4: Host OPO Requirements for Reporting Post-Procurement Test Results and Discovery of Potential Disease Transmissions*
3. Report relevant test results and other information to tissue banks receiving donor tissue

2.13 Deceased Donor Management

The host OPO must make reasonable efforts to manage the deceased donor by addressing *all* of the following:

1. Maintaining blood pressure for perfusion of vital organs
2. Monitoring vital signs
3. Administering IV therapy or drugs, as required
4. Administering antibiotic therapy, as required
5. Administering and monitoring fluid intake and output

The OPO must document that these efforts were made and report the results to the receiving OPOs or transplant hospitals.

2.14 Organ Procurement

2.14.A Conflicts of Interest

The organ recovery procedure and the transplantation of organs must *not* be performed by the donor hospital healthcare team member who declares the death of the potential deceased donor. Death is declared in accordance with hospital policy and applicable state and local statutes or regulation.

2.14.B Pre-Recovery Verification

Host OPOs must develop and comply with a written protocol to perform a pre-recovery verification for each organ recovered as required below. Qualified health care professionals, as defined in the host OPO's protocol, must perform all verifications. At least one of the individuals performing a verification must be an OPO staff member.

The host OPO must conduct the verification prior to organ recovery according to *Table 2-2* below. OPOs may use the OPTN organ tracking system to assist with completion of this verification.

Table 2-2: Pre-Recovery Verification Requirements

The host OPO must verify *all* of the following information:	Using at least *one* of the following:	By *both* of the following individuals:
Donor ID	• Donor identification band containing the donor ID • Donor identification band and OPTN computer system	1. On-site recovering surgeon 2. Qualified health care professional
Organ (and laterality, if applicable)	• Donor medical record • OPTN computer system	1. On-site recovering surgeon 2. Qualified health care professional
Donor blood type and subtype (if used for allocation)	• Donor blood type and subtype source documents	1. On-site recovering surgeon 2. Qualified health care professional

When the intended recipient is known prior to organ recovery, the host OPO must verify *all* of the additional information according to *Table 2-3* below.

Table 2-3: Additional Pre-Recovery Verification Requirements When the Intended Recipient is Known Prior to Organ Recovery

The host OPO must verify *all* of the following information:	Using the:	By the following individuals:
Intended recipient unique identifier	• OPTN computer system	Two qualified health care professionals
Intended recipient blood type	• OPTN computer system	Two qualified health care professionals
Donor and intended recipient are blood type compatible (or intended incompatible)	• OPTN computer system	Two qualified health care professionals

The host OPO must document that the verifications were completed according to the OPO's protocol and the above requirements.

2.14.C Organ Procurement Procedures

To ensure organ procurement quality, the host OPO must do *all* of the following:

1. Ensure that the deceased donor receives medications at appropriate times
2. Document in the deceased donor record any medications administered
3. Begin tissue typing and crossmatching as soon as possible
4. Use standard surgical techniques in a sterile environment
5. Maintain flush solutions, additives, and preservation media at appropriate temperatures
6. Document in the deceased donor record, flush solutions and additives with lot numbers, along with organ anatomy, organ flush characteristics, flush solution amount, and flush solution type
7. Document any organ abnormalities and surgical damage for all organs except extra vessels

2.14.D Required Tissue Typing and Blood Type Verification Materials

The host OPO must establish a written policy with a histocompatibility laboratory that includes specific details of the minimum tissue typing material, type of specimen, medium, and shipping requirements for these items. Extra vessels recovered for transplantation are excluded from minimum tissue typing material requirements. *Table 2-4* shows the minimum tissue typing material requirements for each organ.

Table 2-4: Minimum Typing Materials

The host OPO must provide:	For this organ:
One 7 to 10 mL clot red top tube	Any organ
Two acid-citrate-dextrose (ACD) yellow top tubes	Kidney or pancreas
If available, one 2 by 4 cm wedge of spleen in culture medium	Kidney or pancreas

The host OPO must provide:	For this organ:
Three to five lymph node samples	Each kidney or pancreas Any organ, if the receiving transplant hospital requests and they are available.

The host OPO will provide specimens for tissue typing for all other organs as requested.

2.14.E Deceased Donor Authorization Requirement

The host OPO may only recover organs that it has received authorization to recover. An authorized organ should be recovered if it is transplantable, or a potential transplant recipient is identified for the organ. If an authorized organ is not recovered, the host OPO must document the specific reason for non-recovery.

Extra vessels may only be recovered with at least one organ. To recover and use extra vessels in an organ transplant, the deceased donor authorization forms must include language indicating that the extra vessels will be used for transplant.

Recovery of covered VCAs for transplant must be specifically authorized from individuals authorizing donation, whether that be the donor or a surrogate donation decision-maker consistent with applicable state law. The specific authorization for covered VCAs must be documented by the host OPO.

2.14.F Non-renal Organ Procurement

Non-renal organ recovery teams have the option to remove the non-renal organ first unless extenuating circumstances dictate otherwise. All organ recovery teams must cooperate with each other.

2.14.G Start Time for Organ Procurement

After organs have been offered and accepted, recovery teams must agree on the time the procurement will begin. If they cannot agree on the start time for the procurement, the host OPO has the authority to withdraw the offer from the transplant hospital that cannot agree on the start time for procurement.

2.15 Requirements for Controlled Donation after Circulatory Death (DCD) Protocols

Donation after Circulatory Death (DCD) describes the organ recovery process that may occur following death by irreversible cessation of circulatory and respiratory functions. Potential DCD donors are limited to patients who have died, or whose death is imminent, whose medical treatment no longer offers a medical benefit to the patient as determined by the patient, the patient's authorized surrogate, or the patient's advance directive if applicable, in consultation with the healthcare team. Any planned withdrawal of life sustaining medical treatment/support will be carried out in accordance with hospital policy. Prior to the OPO initiating any discussion with the legal next-of-kin about organ donation for a potential DCD donor, the OPO must confirm that the legal next-of-kin has elected to withdraw life

sustaining medical treatment. The timing of a potential DCD donor evaluation and donation discussion will be coordinated with the OPO and the patient's healthcare team, in accordance with hospital policy. Death is declared by a healthcare team member in accordance with hospital policy and applicable state and local statutes or regulations. A DCD donor may also be called a non-heart beating, asystolic, or donation after cardiac death donor.

These policies will help OPOs and transplant hospitals develop necessary DCD protocols. These set the minimum requirements for DCD recovery but do not address local practices, cultural and resource issues, and therefore should not be the only resource consulted when developing DCD protocols. DCD protocols should continue to be developed through collaboration between OPOs, transplants hospitals, and donor hospitals.

2.15.A Agreement

The OPO must have a written agreement with all hospitals that participate in DCD recovery.

2.15.B Protocols

OPOs and donor hospitals must establish protocols that define the roles and responsibilities for the evaluation and management of potential DCD donors, organ recovery, and organ placement in compliance with OPTN Policy.

2.15.C Potential DCD Donor Evaluation

The primary healthcare team and the OPO must evaluate potential DCD donors to determine if the patient meets the OPO's criteria for DCD donation.

2.15.D Consent for DCD

Conditions involving a potential DCD donor being medically treated/supported in a conscious mental state will require that the OPO confirms that the healthcare team has assessed the patient's competency and capacity to make withdrawal/support and other medical decisions.

The OPO must confirm that consent has been obtained for any DCD related procedures or drug administration that occur prior to patient death.

2.15.E Authorization for DCD

For the purpose of obtaining authorization for a DCD recovery, "legal next of kin" can include *any* of the following:

1. The patient who authorizes deceased donation.
2. Persons defined by state/local laws to authorize organ donation.

2.15.F Withdrawal of Life Sustaining Medical Treatment or Support

Prior to the donor hospital withdrawing life-sustaining medical treatment or ventilated support, the OPO is required to conduct a timeout to confirm:

1. The patient's identification.
2. The process for withdrawing life-sustaining treatment or ventilated support.
3. Roles and responsibilities of the primary patient care team, the OPO team, and the organ recovery team.
4. The hospital's plan for continued patient care if the patient does not become a donor, and appropriate communication with the next of kin.

No recovery personnel (surgeons and other recovery practitioners) may be present for the withdrawal of life-sustaining medical treatment or ventilated support. No member of the organ recovery team or OPO staff may guide or administer palliative care or declare death.

2.15.G Pronouncement of Death

The donor hospital healthcare team member who declares the death of the potential deceased donor cannot be involved in any aspect of the organ recovery procedure or transplantation of that donor's organs. Death is declared in accordance with hospital policy and applicable state and local statutes or regulation.

2.15.H Organ Recovery

Organ recovery will only proceed after circulatory death is determined, inclusive of a predetermined waiting period of circulatory cessation to ensure no auto-resuscitation occurs.

2.15.I DCD Potential Donor Who Converts to Brain Death after an Organ Offer Has Been Made

When a DCD donor converts to brain death, the host OPO must re-execute the match system and allocate the organs according to the organ allocation policies. *Policy 5.4: Organ Offers* does not apply when a DCD donor converts to brain death. Additionally, OPOs should initiate allocation of organs that may have been ruled out due to the donor's initial DCD status.

However, the host OPO may choose not to reallocate organs from a DCD donor who converts to brain death for any *one* of the following reasons:

1. Donor instability
2. Lack of donor family approval and authorization
3. Other extraordinary circumstances

The host OPO must document the reason for not reallocating organs when a DCD donor converts to brain death and make this documentation available to the OPTN on request.

Policy 3: Candidate Registrations, Modifications, and Removals

3.1 Access to OPTN Computer System

Transplant hospital, organ procurement organization, and histocompatibility laboratory members are provided access to the OPTN Computer System as members of the OPTN for the purposes of facilitating organ transplants, quality assurance and performance improvement (QAPI), and fulfilling OPTN Obligations, as defined in OPTN *Management and Membership Policy Appendix M: Definitions*. Business members may be granted access to the OPTN Computer System for the purposes of facilitating organ transplants and fulfilling OPTN Obligations, as defined in OPTN *Management and Membership Policy Appendix M: Definitions,* on behalf of affiliated transplant hospitals, OPOs, or histocompatibility labs.

Transplant hospital, organ procurement organization, and histocompatibility laboratory members with access to the OPTN Computer System may authorize user access to the OPTN Computer System.

Representatives of HRSA, HHS, and other components of the federal government are provided access to the OPTN Computer System as requested by the HRSA COR.

Members must ensure that all users meet OPTN training requirements prior to establishing a user's access to the OPTN computer system and yearly thereafter. Members must also ensure that all users comply with the OPTN Contractor's system terms of use for the OPTN Computer System.

3.1.A Conditions for Access to and Interconnection with the OPTN Computer System

Members must have an active OPTN Interconnection Security Agreement (ISA) in order to interconnect with the OPTN Computer System, including interconnection via Application Programming Interface (API). The ISA must be executed by an individual authorized by the member organization within three months of being issued by the OPTN, reviewed annually, and renewed every three years.

The member must execute a new ISA with the OPTN:

- Upon change in any of the information provided by the member
- If additional interconnections are required
- If any of the requirements for interconnections change
- At the request of the OPTN

Members may not use the OPTN Computer System for non-members or allow non-members access to the OPTN Computer System.

Transplant hospitals, OPOs, and histocompatibility labs may grant business members permissions to their patient-identified data in the OPTN Computer System if *all* of the following requirements are met:

1. The business member is assisting the member with facilitating organ transplants or otherwise fulfilling OPTN Obligations, as defined in OPTN *Management and Membership Policy Appendix M: Definitions.*
2. The business member users are granted access to the OPTN Computer System according to *OPTN Policy 3.1.C.i: Business Member Users within the OPTN Computer System.*
3. The transplant hospital, OPO, or histocompatibility lab has a DUA with the business member with *all* of the following elements:
    a. Data confidentiality and security requirements
    b. Data rights
    c. Access to patient-identified data
    d. Data use
    e. Procedures for securing data confidentiality
    f. Storage or disposal of data upon completion of contracted task
    g. Procedures to protect patient-identified data in the event of a data breach, inadvertent or otherwise
    h. Remedies in the event of a violation of the DUA

The member must maintain copies of all DUAs with business members.

Business members accessing the OPTN Computer System must provide a list of all active OPTN members they are contracted with, update this list and report to the OPTN within 7 days of any changes, and verify the accuracy of this list upon request by the OPTN. Business members must also provide copies of their DUAs with each OPTN member they are contracted with to the OPTN upon request.

If the business member is no longer contracted with any active OPTN members they must notify the OPTN within 7 days prior to the contract ending and their access to the OPTN Computer System will be removed upon contract end.

Transplant hospitals, OPOs, and histocompatibility labs must notify the OPTN within 7 days prior to the contract ending when they are no longer contracted with a business member.

3.1.B Security Requirements for Systems Accessing the OPTN Computer System

Members must provide security for the computing environments and components thereof which are used to access the OPTN Computer System and the associated environments used to manage the member's computing environment used to access the OPTN Computer System.

Members must ensure that these environments adhere to a security framework that is either:

- The most recent revision of a National Institute of Standards in Technology (NIST) information security framework or
- A security framework with equivalent controls provided by the member and approved by the OPTN

Members who authorize access to users must ensure that the user agrees to access the OPTN Computer System through computing environments that adhere to either the most recent revision of a NIST information security framework or a security framework with equivalent controls.

Members must attest to their adherence to their security framework through an OPTN attestation. OPTN attestations must be submitted annually and upon request by the OPTN to maintain access to the OPTN Computer System.

Adherence to the security framework will be audited at least once every three years. Members must also respond to OPTN requests for information within the timeframe stated by the OPTN.

3.1.C Site Access Administrators

Organ procurement organization and histocompatibility laboratory members with access to the OPTN Computer System must designate at least two site access administrators to maintain access to the OPTN Computer System. Transplant hospital members with access to the OPTN Computer System must designate at least two site access administrators for each of its designated transplant programs.

Site access administrators are responsible for maintaining an accurate and current list of users and permissions, specific to the role of the user in their performance of duties related to OPTN Obligations. Permission levels must be granted according to the NIST principle of least privilege.

Site access administrators must review and update user accounts and permission levels:

- When a user is no longer associated with the member organization, as soon as possible, but no later than 24 hours after the user's last day of employment
- When the user's roles or responsibilities have changed, such that a different level of permission is necessitated, as soon as possible, but no later than 24 hours from the change in roles or responsibilities
- As directed by the OPTN, within the timeframe provided by the OPTN

3.1.C.i Business Member Users within the OPTN Computer System

Business member representatives are responsible for maintaining an accurate and current list of users. The list must include all organizations for which the user requires OPTN Computer System access. Business member representatives must review user accounts:

- When a user is no longer associated with the business member
- When a user's affiliated organizations have changed
- As directed by the OPTN

Business member representatives must report changes in user accounts to the OPTN:

- When a user is no longer associated with the business member, as soon as possible, but no later than 24 hours after the user's last day of employment
- As directed by the OPTN, within the timeframe provided by the OPTN

Business member users are granted access to the OPTN Computer System by the OPTN Contractor. Business member users are granted permissions to data within the OPTN Computer System by the site access administrators at each affiliated organization according to the NIST principle of least privilege.

3.1.D Security Incident and Privacy Incident Management and Reporting

Members with access to the OPTN Computer System must develop and comply with an incident response plan designed to identify, prioritize, contain and eradicate security incidents and privacy incidents. The incident response plan must include all of the following:

- Appointment of an information security contact, as detailed in OPTN *Policy 3.1.D.i: Information Security Contact*
- Notification to the OPTN Contractor of security incidents occurring in any environment outlined in *Policy 3.1.B: Security Requirements for Systems Accessing the OPTN Computer System,* as soon as possible, but no later than:
    - 24 hours following the member becoming aware of the security incident if a member does not disconnect the affected users and any impacted systems from the OPTN Computer System
    - 72 hours following the member becoming aware of the security incident if the member does disconnect the affected users and any impacted systems from the OPTN Computer System
- Notification to the OPTN Contractor of any privacy incident involving data obtained from the OPTN Computer System, except for data which a member incorporates into a member's own system for candidate, recipient, or donor medical records. Notification must occur as soon as possible, but no later than 48 hours following the member becoming aware of the privacy incident.
- Process for acquiring third party validation of proper containment, eradication, and successful recovery

Portions of the incident response plan involving access to the OPTN Computer System must be made available to the OPTN on request and will be considered confidential.

In the event of a security incident or privacy incident, members will be required to provide status updates to the OPTN on an agreed upon schedule and to meet control and verification requirements as provided by the OPTN based on the type of security incident or privacy incident. These requirements will be communicated directly to the member through the information security contact established in the member's incident response plan. Members may also be required to provide a final incident report.

Members may be required to take specific actions to appropriately ensure risk to the OPTN Computer System is managed and balanced with the need to ensure transplants continue. Specific actions may include on-site remediation, requiring the member's access to the OPTN Computer System be temporarily removed until the OPTN has determined the risk is mitigated, or other containment and recovery actions with oversight by the OPTN.

Any action that temporarily removes the member's access to the OPTN Computer System must be directed by the OPTN or the Secretary of HHS. The OPTN Contractor may take other actions necessary to secure the OPTN Computer System on behalf of the OPTN. Any actions taken by the OPTN Contractor to secure the OPTN Computer System on behalf of the OPTN must be reported to the OPTN within 48 hours.

3.1.D.i Information Security Contact

Members with access to the OPTN Computer System must identify an information security contact, who is responsible for maintaining and complying with a written protocol that includes how an information security contact will:

1. Provide 24/7 capability for incident response and communications
2. Receive relevant notifications of security incidents and privacy incidents from the member's information security staff
3. Communicate information regarding security incidents and privacy incidents to the OPTN
4. Facilitate development and fulfillment of OPTN Obligations outlined in *OPTN Policy 3.1.B: Security Requirements for Systems Accessing the OPTN Computer System*

3.2 Notifying Patients of Their Options

As part of the evaluation process, transplant programs must inform and provide each patient it evaluates with information and written materials explaining *all* of the following options:

1. Registering at multiple transplant hospitals
2. Transferring primary waiting time
3. Transferring their care to a different transplant hospital without losing accrued waiting time

Each transplant program must document that it fulfilled these requirements and maintain this documentation.

Transplant programs must inform the patient before or during the evaluation process if *either*:

1. The transplant program does not accept candidates with multiple registrations
2. The transplant program does not allow candidates to transfer waiting time to their program

3.3 Candidate Blood Type Determination and Reporting before Waiting List Registration

Transplant programs must develop and comply with a written protocol for blood type determination and reporting that includes *all* of the requirements below.

3.3.A Candidate Blood Type Determination

The transplant program must ensure that each candidate's blood type is determined by testing at least two candidate blood samples prior to registration on the waiting list.

Candidate blood samples must:

1. Be drawn on two separate occasions
2. Have different collection times
3. Be submitted as separate samples

The transplant program must include a process to address conflicting or indeterminate primary blood type results in their written protocol.

The transplant program must document that blood type determination was conducted according to the program's protocol and the above requirements.

3.3.B Reporting of Candidate Blood Type

The candidate is not eligible to appear on a match run until the transplant program completes verification and reporting as follows:

1. Two different qualified health care professionals, as defined in the transplant program's protocol, must each make an independent report of the candidate's blood type to the OPTN
2. Both qualified health care professionals must use all known available blood type determination source documents to verify they:
    a. Contain blood type results for the candidate
    b. Indicate the same blood type on the test results. If the results are conflicting or indeterminate, the transplant program must refer to their written protocol as outlined in *Policy 3.3.A: Candidate Blood Type Determination*.
    c. Match the result reported to the OPTN

The transplant program must document that reporting was completed according to the program's protocol and the above requirements.

3.4 Waiting List Registration

3.4.A Registration Fee

The registration fee of $868 for the registration of a transplant candidate is authorized by *42 C.F.R. § 121.5(c*) and *OPTN Management and Membership Policy F.2.D: Registration Fee*.

3.4.B Approved Transplant Program Requirement

Members are only permitted to register a candidate on the waiting list for an organ at a transplant program if the transplant program has current OPTN transplant program approval for that organ type.

3.4.C Candidate Registrations

Transplant programs must:

1. Register all recipients as candidates on the waiting list prior to transplant at the program that performs the organ transplant.
2. Complete all candidate registrations, modifications, and removals in the waiting list.
3. Register all multi-organ candidates on the waiting list for each required organ.

3.4.D Candidate Human Leukocyte Antigen (HLA) Requirements

The candidate's transplant program must report to the OPTN complete human leukocyte antigen (HLA) information (at least 1A, 1B, and 1DR antigen) according to *Table 3-1* below:

Table 3-1: HLA Requirements

If the candidate is registered for a…	Then, HLA information is…
Kidney alone	Required
Kidney–pancreas	Required
Kidney with any other non-renal organ	Not required
Pancreas alone	Required
Pancreas islet alone	Required

Transplant programs must report this HLA information using current World Health Organization (WHO) nomenclature when the candidate is registered on the waiting list.

3.4.E Inactive Status

If the candidate is temporarily unsuitable for transplant, then the candidate's transplant program may classify the candidate as inactive and the candidate will not receive any organ offers.

3.4.F Multiple Transplant Program Registrations

Candidates may be registered for an organ at multiple transplant programs within the same Donation Service Area (DSA) or different DSAs. A transplant program may choose whether or not to accept a candidate seeking multiple registrations for an organ.

Transplant hospitals may access a report from the OPTN that identifies any candidates that have multiple registrations for the same organ. This report will not include the identities of the other hospitals where the candidates are registered.

3.5 Patient Notification

Transplant hospitals must notify patients in writing according to *Table 3-2* below:

Table 3-2: Transplant Hospital Patient Notification Requirements

When:	The transplant hospital must send a notification within 10 business days with the following information:
The patient is registered on the waiting list	The date the patient was registered.
The patient's evaluation for transplant is complete and the patient is *not* registered on the waiting list	That the patient's evaluation has been completed and the patient will not be registered on the waiting list at this time.
The patient is removed from the waiting list for reasons *other than* transplant or death	That the patient has been removed from the waiting list.

Each written patient notification required in *Table 3-2* must also include and refer to the *OPTN Contractor's Patient Information Letter*, which provides the number for the toll-free Patient Services Line. The transplant hospital must document these notifications.

3.6 Waiting Time

3.6.A Waiting Time for Inactive Candidates

Candidates accrue waiting time while inactive according to *Table 3-3* below. Inactive candidates do not receive organ offers.

Table 3-3: Waiting Time for Inactive Candidates

If the candidate is registered for the following organ…	Then the candidate accrues waiting time while inactive as follows…
Heart	No time
Intestine	Up to 30 cumulative days
Kidney	Unlimited time
Kidney-pancreas	Unlimited time
Liver	No time
Lung	Unlimited time
Pancreas	Unlimited time
Pancreas islet	Unlimited time
Any covered VCA	Unlimited time

3.6.B Waiting Time Reinstatement for Non-Function of Transplanted Organ

The OPTN Contractor will reinstate waiting time to recipients according to the policies below, without interruption, when immediate and permanent non-function of any transplanted kidney, pancreas, or intestine occurs and the recipient is re-registered on the waiting list as a candidate for the same organ.

3.6.B.i Non-function of a Transplanted Kidney

Immediate and permanent non-function of a transplanted kidney is defined as *either*:

- Kidney graft removal within the first 90 days of transplant documented by an operative report of the removal of the transplanted kidney.
- Kidney graft failure within the first 90 days of transplant with documentation that the candidate is either on dialysis or has a glomerular filtration rate (GFR) or measured or estimated creatinine clearance (CrCl) less than or equal to 20 mL/min within 90 days after the candidate's kidney transplant.

Kidney waiting time will be reinstated when the OPTN receives a completed *Renal Waiting Time Reinstatement Form* and the supporting documentation required above. The Estimated Post Transplant Survival (EPTS) score will also be calculated without interruption. The OPTN will send a notice of waiting time reinstatement to the transplant hospital involved.

3.6.B.ii Non-function of a Transplanted Pancreas

Immediate and permanent non-function of a transplanted pancreas is defined as removal of the transplanted pancreas within 14 days after transplant.

Pancreas waiting time will be reinstated when the OPTN receives a completed *Pancreas Waiting Time Reinstatement Form* and *either* of the following:

- An operative report of the removal of the pancreas.
- A statement of intent from the transplant hospital to remove the transplanted pancreas, and a statement that there is documented, radiographic evidence indicating that the transplanted pancreas has failed.

The transplant hospital must maintain this documentation. The OPTN will send a notice of waiting time reinstatement to the transplant hospital involved.

3.6.B.iii Non-function of a Transplanted Intestine

Immediate and permanent non-function is defined as an intestinal organ graft failure resulting in removal of the transplanted organ within the first 7 days following transplant.

Intestine waiting time will be reinstated when the OPTN receives a completed *Intestinal Organ Waiting Time Reinstatement Form* and documentation, including but not limited to, the recipient's operative report of removal of the transplanted intestine. The OPTN will send a notice of waiting time reinstatement to the transplant hospital involved.

3.6.C Individual Waiting Time Transfers

A candidate may transfer primary waiting time from one transplant program to another if *all* of the following requirements are met:

The candidate must be registered at the new transplant program.
The candidate must currently be, or have previously been, registered at the earlier transplant program.
The candidate must sign a Wait Time Transfer Form, requesting transfer of primary waiting time to the new transplant program.
One of the transplant programs must submit a Wait Time Transfer Form to the OPTN.

The OPTN will transfer the primary qualifying date and waiting time accrued from the earlier transplant program to the new transplant program. However, time accrued simultaneously at more than one program is only counted once.

The OPTN will notify each of the transplant programs involved of the completed transfer of waiting time. The new transplant program must notify the candidate of the waiting time transfer status within 10 business days of receiving notification from the OPTN and must document that this notification was completed.

If the candidate chooses to have multiple registrations, the OPTN will exchange the primary qualifying date and waiting time accrued from the earlier transplant to the new transplant program.

If the candidate chooses not to have multiple registrations, then the OPTN will do *both* of the following:

1. Transfer the primary qualifying date and accrued waiting time from the earlier transplant program to the new transplant program.
2. Remove the candidate from the waiting list of the earlier transplant program.

If the candidate is removed from the waiting list at the earlier transplant program before being registered at the new transplant program, the OPTN will add the waiting time accrued at the earlier transplant program to the waiting time accrued at the new program.

The OPTN will not include time between removal at the earlier transplant program and registration at the new program in the candidate's waiting time.

3.7 Waiting Time Modifications

3.7.A Applications for Modifications of Waiting Time

To apply for a waiting time modification, the candidate's transplant program must submit an application to the OPTN with *all* of the following information:

1. The requested listing date and documentation showing an intent to register the candidate at the requested listing date.
2. Documentation or a statement showing that the candidate qualified for the waiting time according to the organ-specific *OPTN Policies 6* through *12*.
3. A corrective action plan, if the application is due to an error.
4. The name and signature of the candidate's physician or surgeon.
5. Signatures indicating agreement from all applicable transplant programs in the OPO. If a signature cannot be obtained from a transplant program, the submitting program must explain the efforts it made to obtain a signature and include any stated reasons for disagreement with the request.

Upon receipt of a complete application and required documentation, the OPTN will forward the application, without person-identified data, according to *Table 3-4* that follows:

Table 3-4: Waiting Time Modification Application Review

If the candidate requests a waiting time modification for the following organ:	Then the application will be reviewed by the:
Kidney	Kidney Waiting Time Modifications Subcommittee
Liver	A subcommittee of the Liver and Intestinal Organ Transplantation Committee, appointed by the Chair of the Liver and Intestinal Organ Transplantation Committee
Heart	A subcommittee of the Heart Transplantation Committee, appointed by the Chair of the Heart Transplantation Committee
Lung	A subcommittee of the Lung Transplantation Committee, appointed by the Chair of the Lung Transplantation Committee
Pancreas	Kidney or Pancreas Waiting Time Modifications Subcommittee
Intestine	A subcommittee of the Liver and Intestinal Organ Transplantation Committee, appointed by the Chair of the Liver and Intestinal Organ Transplantation Committee

Waiting list modification applications will be reviewed as follows:

1. The reviewer will determine if it is appropriate to modify the candidate's waiting time as requested in the application and will notify the OPTN of the decision.
2. Upon notice, the OPTN will implement the waiting time modification.
3. The reviewer will report the modification, without person-identified data, to the relevant organ specific Committee.
4. The Committee will report the modification, without person-identified data, to the Board of Directors.

3.7.B Required Expedited Modifications of Waiting Time

An application for waiting time modifications must follow the procedures for expedited modifications of waiting time if it meets *any* of the following criteria according to *Table 3-5* below:

Table 3-5: Applications Requiring Expedited Modifications of Waiting Time

When:	And the candidate is registered for:	And the transplant program is requesting reinstatement of waiting time including:
An error occurred in removing the candidate's waiting list record	The same organ	Time accrued under the previous registration and any time lost by the error.
An error occurred in registering, modifying, or renewing the candidate's waiting list record	Status 1 liver, pediatric status 1A heart, adult status 1,2, 3, or 4 heart, or priority 1 pediatric lung	Any time lost by the error.
The candidate was removed from the waiting list for medical reasons, other than receiving a transplant	The same organ with the same diagnosis	Time accrued under the previous registration without the time interval when the candidate was removed from the waiting list.
An islet recipient has re-registered on the islet waiting list	An islet infusion	Any previously accrued waiting time according to *Policy 11.3.C: Islet Waiting Time Criteria*.
The candidate needs a second organ	Heart, liver, or lung	Modified waiting time for the second organ that includes the waiting time accrued for the first organ.

When:	And the candidate is registered for:	And the transplant program is requesting reinstatement of waiting time including:
The candidate needs a second organ, routine alternative therapies are not possible, and the other transplant programs within the OPO and the OPO itself agree to the modified waiting time	Kidney, pancreas, or intestine	Modified waiting time for the second organ that includes the waiting time for the first organ.

Additionally, applications must meet any additional requirements outlined in the organ-specific allocation policies. If an application does not comply with the requirements of *Policy 3.7: Waiting Time Modifications*, then the OPTN will not implement the requested waiting time modifications or forward the application for review.

Applications eligible for expedited modifications of waiting time must use the following process:

1. Upon receipt of a complete application, including the name and signature of the candidate's physician or surgeon, the OPTN will implement the waiting time modification.
2. The OPTN will report the modification, without person-identified data, to the relevant organ-specific Committee.
3. The Committee will report the modification, without person-identified data, to the Board of Directors.

3.7.C Waiting Time Modifications for Heart, Lung, and Heart-Lung Candidates

The OPTN may assign heart, lung, and heart-lung candidates waiting time from one waiting list to another waiting list according to *Table* 3-6 below.

Table 3-6: Waiting Time Modifications for Heart, Lung, and Heart-Lung Candidates

From this registration:	To this registration:
Heart	Heart-lung
Heart-lung	Heart
Heart-lung	Lung

3.7.D Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations

Transplant hospitals must develop and comply with a written protocol that includes processes for meeting the requirements of *Policy 3.7.D*, including:

- Confirming candidate race
- Fulfilling notification requirements
- Seeking supporting documentation including at a minimum, what sources will be reviewed

The transplant hospital must document that above processes were completed, including the results of the review of sources, in the candidate's medical record.

3.7.D.i Notification Requirement

All designated kidney transplant programs must notify candidates, of the following:

1. Programs are required to submit eGFR waiting time modifications for candidates affected by race inclusive eGFR calculations (education notification).
2. Whether or not candidates are eligible for an eGFR modification (eligibility notification).
3. The outcome of the eGFR modification submission, for applicable candidates (outcome notification).
    - Programs must notify candidates within 10 business days following the program's receipt of modification outcome from the OPTN.

3.7.D.ii Determination of Eligible Candidates

All designated kidney transplant programs must determine eligibility for a Waiting Time Modification for Kidney Candidates affected by Race-Inclusive eGFR Calculations for each candidate registered at the transplant program. A candidate is eligible for a waiting time modification if the candidate is registered as Black or African American in the OPTN Computer System and has documentation establishing that the candidate had an eGFR that was over 20 mL/min and would have been 20 mL/min or less if a race-neutral calculation had been used. Every kidney transplant candidate needs to be assessed for eligibility regardless of waiting time criteria or status, including candidates registered for multi-organ transplant.

3.7.D.iii Application for Waiting Time Modification

Transplant programs must submit an eGFR waiting time modification for each eligible candidate registered at their transplant program. The application for an eGFR waiting time modification must include the qualifying eGFR value, as well as:

1. Documentation of one of the following, and
    - The candidate's eGFR values for Black and non-Black candidates or
    - The estimation of GFR with a race-inclusive calculation and a re-estimation of GFR with a race-neutral calculation.
2. The name and signature of the candidate's physician or surgeon.

Upon receipt of a complete application the OPTN will implement the waiting time modification.

3.8 Collective Patient Transfers

The OPTN may collectively transfer patients from transplant programs with a status of long-term inactive, withdrawal, or termination, and in other circumstances upon request to one or more transplant programs according to *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of the

OPTN Management and Membership Policies. Candidates transferred as part of a collective transfer will retain waiting time according to *Appendix K.6: Transferred Candidates Waiting Time.*

3.9 Removing Candidates from the Waiting List

If a candidate receives a transplant or dies while awaiting a transplant then the registering transplant hospitals must remove the candidate from the hospital's organ waiting lists and notify the OPTN within 24 hours of the event. If the candidate has multiple-registrations for the same organ, each transplant hospital where the candidate is registered must meet these requirements.

The OPTN will notify other transplant hospitals when a multiple registered candidate receives a transplant or another transplant hospital reports the candidate as deceased. Upon notification, all other transplant hospitals involved can investigate and remove the candidate from the transplant hospital's waiting list.

If the transplant recipient re-registers for another organ to replace a transplanted organ, then waiting time will begin as of the date and time the candidate re-qualifies. The waiting time from the previous registration may be added to the new registration according to *Policy 3.6.B: Waiting Time Reinstatement for Non-Function of Transplanted Organ*.

3.9.A Removing Liver Candidates from the Waiting List

For a liver candidate, the data necessary to calculate the candidate's current MELD or PELD score is required to remove the candidate from the waiting list.

3.9.B Removing Pancreas Islets Candidates from the Waiting List

The transplant hospital must remove the candidate from the waiting list within 24 hours of the candidate receiving each islet infusion.

Policy 4: Histocompatibility

4.1 Requirements for Laboratory Review of Reports

Reports must be reviewed by the laboratory director, technical supervisor, or a staff member who meets at least the minimum requirements of a general supervisor prior to release. All deceased donor HLA typing and crossmatch reports must be reviewed during the next day of regular laboratory operation.

4.2 Requirements for Waiting List Data Verification

All histocompatibility laboratories must review and verify the waiting list histocompatibility data for every patient whose test results the laboratory completed. Documentation of the review must be kept for at least three years or the period required by local, state and federal regulations, whichever is longer. This document must be available to the OPTN on request.

4.3 Requirements for Performing and Reporting HLA Typing

Laboratories must ensure that all HLA typing is accurately determined and report HLA typing results to the OPO or Transplant Program according to the deadlines specified in the written agreement between the laboratory and the OPO or transplant program. Laboratories must report HLA typing results to the OPTN Contractor. HLA typing results that are entered manually must be verified by reporting each result twice.

4.3.A Deceased Donor HLA Typing

If the laboratory performs HLA typing on a deceased donor, the laboratory must perform molecular typing and report results at the level of serological splits to the OPO for all required HLA types on deceased donors according to *Table 4-1: Deceased Donor HLA Typing Requirements*.

Table 4-1 below provides the requirements of HLA typing of HLA A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, DPA1, and DPB1 antigens.

Table 4-1: Deceased Donor HLA Typing Requirements

If a Laboratory Performs HLA Typing on a:	Then the Laboratory Must Report Results to the OPO at the Following Times:
Deceased Kidney, Kidney-Pancreas, Pancreas, or Pancreas Islet Donor	Prior to organ offers
Deceased Heart, Heart-Lung, or Lung Donors	Prior to final acceptance, if required by the transplant program
Deceased Liver Donors	Within the period specified by the transplant program

4.3.B HLA Typing for Candidates

Laboratories must perform HLA typing on a kidney, kidney-pancreas, pancreas, or pancreas islet candidate and report results for HLA A, B, Bw4, Bw6, and DR to the transplant program prior to registration on the waiting list.

4.4 Critical HLA Discrepancies in Candidate, Donor, and Recipient HLA Typing Results

A human leukocyte antigen (HLA) critical discrepancy is a difference among non-equivalent values at one or more loci in a candidate's, donor's, or recipient's HLA typing.

- For typing recorded from a low-resolution method by serologic nomenclature, values within the same serologic split antigen group or within the same P group according to IPD-IMGT/HLA are considered equivalent.
- For typing reported at the two-field resolution, values within the same P group according to IPD-IMGT/HLA are considered equivalent.

4.4.A Requirement to Notify Transplant Programs and OPOs

4.4.A.i Donor HLA Critical Discrepancies

If a laboratory becomes aware of a critical discrepancy in a deceased donor's HLA typing, the laboratory must notify the host OPO of the discrepancy. Notification and supporting documentation must be provided as soon as possible, but no later than one hour following determination of the correct HLA typing.

Upon independent discovery or receipt of documentation of the discrepancy, the OPO must do the following:

- If the discrepancy is discovered prior to procurement, the OPO must notify and provide supporting documentation to all accepting transplant programs as soon as possible, but

no later than 12 hours following discovery of the discrepancy or prior to procurement, whichever occurs first.

- If the discrepancy is discovered post-procurement, the OPO must notify and provide supporting documentation to all accepting transplant programs within 24 hours following the discovery.

4.4.A.ii Candidate and Recipient HLA Critical Discrepancies

If a laboratory discovers a critical HLA discrepancy in a candidate's or recipient's HLA typing, the laboratory must notify the listing transplant program and provide documentation of the discrepancy as soon as possible, but within 5 days following determination of the correct HLA typing.

4.4.B Requirement to Resolve and Report to the OPTN Critical Discrepant Donor and Recipient HLA Typing Results

The laboratory director of ~~e~~ach laboratory involved in a candidate, donor, or recipient critical HLA typing discrepancy, or their designee, must identify the correct HLA typing. The laboratory director of the laboratory who discovers the critical HLA typing discrepancy, or their designee, must report the critical HLA typing discrepancy to the OPTN via the OPTN Improving Patient Safety Portal within 72 hours of discovery of the discrepancy. Each laboratory director involved in the critical HLA typing discrepancy, or their designee, must report the reason for the discrepancy to the OPTN within 60 days of the initial report.

4.5 Antibody Screening and Reporting

The laboratory must screen a patient for the presence of anti-HLA antibodies if requested by a physician or other authorized individuals.

When a laboratory performs an antibody screening, the laboratory must do *all* of the following:

1. Report anti-HLA antibodies identified to the candidate's requesting provider
2. Use at least one solid phase immunoassay using purified HLA molecules

4.6 Calculated Panel Reactive Antibody (CPRA) Calculation

CPRA for a candidate will be calculated automatically when a transplant hospital reports unacceptable antigens to the OPTN.

The equation for CPRA calculation is

$$\text{CPRA} = \sum_i [G_F \times D_i]$$

Table 4-2: CPRA Calculation Values

Where…	Is defined as…
i	The racial or ethnic base population, as reported to the OPTN for deceased donors
G_F	The frequency of HLA genotypes in each specific racial or ethnic population i equivalent to the unacceptable HLA antigens, alleles, and epitopes reported on the waiting list
D_i	The proportion of donors in each specific racial or ethnic population i in the OPTN deceased donor population

The CPRA derived from this calculation will be rounded to the sixth decimal place. The maximum CPRA is 100%.

The determination of the HLA genotype frequencies G_F used in the CPRA calculation includes all donor alleles equivalent to a candidate's reported unacceptable antigens, alleles, or epitopes according to OPTN *Policy 4.10: Reference Tables of HLA Antigen Values and Split Equivalences*. The antigens in *Table 4-3* will have combined frequencies for the purpose of CPRA calculation.

Table 4-3: Unacceptable Antigens with Combined Frequencies for CPRA Calculation

Locus	Antigens with combined frequencies for CPRA calculation
DQA1	01:01, 01:04, 01:05
DQA1	01:02, 01:11
DQA1	03:02, 03:03
DQA1	05:01, 05:05, 05:09, 05:11
DQA1	05:03, 05:07

The OPTN maintains a list of genotype frequencies (G_F) for each reportable unacceptable antigen, allele, and epitope.

4.7 Crossmatching

4.7.A Crossmatching for Kidney Transplants

Laboratories performing histocompatibility testing for kidney transplants or multi-organ transplants in which a kidney is to be transplanted must perform a final crossmatch and report the results to the Transplant Program before transplant.

4.7.B General Crossmatching Requirements

When a laboratory performs a physical crossmatch, the laboratory must do *all* of the following:

1. Perform a crossmatch according to the terms specified in the written agreement between the laboratory and the OPO or transplant program if a physician or other authorized individual requests it.
2. Perform crossmatches with potential donor T lymphocytes to identify class I anti-HLA antibodies.
3. Perform crossmatches with potential donor B lymphocytes to identify class I and class II anti-HLA antibodies using a method that distinguishes between reactions with T and B lymphocytes.
4. Use a crossmatching technique with increased sensitivity.

4.8 Blood Type Determination

If a laboratory performs blood type testing, the laboratory must:

1. Follow manufacturer's directions for materials and equipment used in testing.
2. Perform testing in compliance with federal regulations.

4.9 Preservation of Excess Specimens

If a laboratory performs testing to determine histocompatibility between a donor and recipient, then the laboratory must preserve enough specimen from the deceased donor to perform subsequent testing for at least five years after the transplant.

4.10 HLA Value Updates

The Histocompatibility Committee must review the HLA matching and unacceptable antigen equivalency tables and the proportions of donors (D_i) used in CPRA calculation on an annual basis. Changes to the equivalency tables in Policy 4.11 and proportions of donors (D_i) are eligible for future expedited updates pursuant to *OPTN Management and Membership Policy 5.8: Expedited Actions*.

4.11 Reference Tables of HLA Antigen Values and Split Equivalences

4.11.A: HLA Matching Equivalences

Tables 4-2, 4-3, and *4-4* show candidate-donor antigen equivalencies. All of the candidate and donor antigens that are considered equivalent to each other for the purposes of HLA matching are listed within each row. All other combinations are considered mismatches for the purposes of HLA matching.

Table 4-2: HLA A Matching Antigen Equivalences

Candidate and Donor A-Locus Antigens Equivalent to Each Other
1, 01:01P, 01:01, 01:02P, 01:02, 01:03P
2, 02:01P, 02:01, 02:02P, 02:02, 02:03P, 02:03, 02:04P, 02:05P, 02:05, 02:06P, 02:06, 02:07P, 02:07, 02:10P, 02:10, 02:11P,

Candidate and Donor A-Locus Antigens Equivalent to Each Other
02:14P, 02:16P, 02:18, 02:20P, 02:22P, 02:29P, 02:49P, 02:65P, 02:81P
3, 03:01P, 03:01, 03:02P, 03:02, 03:04P, 32:04
9
10
11, 11:01P, 11:01, 11:02P, 11:02, 11:03P, 11:05P
19
23, 23:01P
24, 24:02P, 24:02, 24:03P, 24:03, 24:05P, 24:07P, 24:10P, 24:26P
25, 25:01P
26, 26:01P, 26:01, 26:02, 26:03P, 26:03
28
29, 29:01P, 29:01, 29:02P, 29:02
30, 30:01P, 30:01, 30:02P, 30:02, 30:04P
31, 31:01P
32, 32:01P
33, 33:01P, 33:01, 33:03P, 33:03
34, 34:01P, 34:01, 34:02
36, 36:01P
43
66, 66:01P, 66:01, 66:02P, 66:02
68, 68:01P, 68:01, 68:02P, 68:02, 68:03P
69
74, 74:01P, 74:06P
80, 80:01P

Table 4-3: HLA B Matching Antigen Equivalences

Candidate and Donor B-Locus Antigens Equivalent to Each Other
5
7, 07:02P, 07:02, 07:03, 07:05P, 07:14
8, 08:01P, 08:01, 08:02, 08:03, 08:04
12
13, 13:01P, 13:01, 13:02P, 13:02
14
15
16
17
18, 18:01P

Candidate and Donor B-Locus Antigens Equivalent to Each Other
21
22
27, 27:02P, 27:03, 27:04P, 27:04, 27:05P, 27:05, 27:06P, 27:06, 27:07P
27:08
35, 35:01P, 35:01, 35:02P, 35:02, 35:03P, 35:03, 35:05P, 35:08P, 35:14P, 35:08, 35:12P, 35:12, 35:43P, 35:137P
37, 37:01P
38, 38:01P, 38:01, 38:02P, 38:02
39, 39:01P, 39:01, 39:02P, 39:02, 39:03P, 39:04, 39:05P, 39:05, 39:06P, 39:06, 39:09P, 39:10P, 39:13, 39:15P
40, 40:40P, 40:213P
41, 41:01P, 41:01, 41:02P, 41:02
42, 42:01P, 42:01, 42:02
44, 44:02P, 44:02, 44:03P, 44:03, 44:05P, 44:29P, 44:53P, 51:42P
45, 45:01P, 50:02P, 50:02
46, 46:01P
47, 47:01P
48, 48:01P, 48:01, 48:02, 48:04P
49, 49:01P
50, 50:01P, 50:01, 40:05
51, 51:01P, 51:01, 51:02, 51:08P, 51:09P, 51:143P
52, 52:01P
53, 53:01P
54, 54:01P
55, 55:01P, 55:01, 55:02P, 55:02, 55:04
56, 56:01P, 56:01, 56:03
57, 57:01P, 57:01, 57:03P, 57:03
58, 58:01P, 58:02P
59, 59:01P
60, 40:01P, 40:01
61, 40:02P, 40:02, 40:03P, 40:03, 40:04, 40:06P, 40:06
62, 15:01P, 15:01, 15:04, 15:06, 15:07P, 15:07, 15:20P, 15:20, 15:25P, 15:27, 15:28P, 15:30P, 15:32P, 15:35P, 15:39P
63, 15:16P, 15:16, 15:17P, 15:17
64, 14:01P, 14:01
65, 14:02P, 14:02
67, 67:01P
70, 15:123P
71, 15:10P, 15:10, 15:18P, 15:18
72, 15:03P, 15:03
73, 73:01P
75, 15:02P, 15:02, 15:11P, 15:11, 15:21P, 15:21

Candidate and Donor B-Locus Antigens Equivalent to Each Other
76, 15:12P, 15:12, 15:14P
77, 15:13, 15:24
78
81, 81:01P
82
83:01

Table 4-4: HLA DR Matching Antigen Equivalences

Candidate and Donor DR-Locus Antigens Equivalent to Each Other
1, 01:01P, 01:01, 01:02P, 01:02
2
3
4, 04:01P, 04:01, 04:02P, 04:02, 04:03P, 04:03, 04:04P, 04:04, 04:05P, 04:05, 04:06P, 04:06, 04:07P, 04:08P, 04:10P, 04:10, 04:11
5
6
7, 07:01P
8, 08:01P, 08:01, 08:02P, 08:02, 08:03P, 08:03, 08:04P, 08:07
9, 09:01P, 09:01, 09:02
10, 10:01P
11, 11:01P, 11:01, 11:02P, 11:03P, 11:03, 11:04P, 11:04, 11:06P, 11:11P
12, 12:01P, 12:01, 12:02P, 12:02
13, 13:01P, 13:01, 13:02P, 13:02, 13:03P, 13:03, 13:05, 13:12P
14, 14:01P, 14:01, 14:02P, 14:02, 14:03P, 14:03, 14:04P, 14:04, 14:05, 14:06, 14:08P, 14:24P, 14:54
15, 15:01P, 15:01, 15:02P, 15:02, 15:03P, 15:03, 15:04P, 15:07P
16, 16:01P, 16:01, 16:02P, 16:02
17, 03:01P, 03:01
18, 03:02P, 03:02, 03:03
103, 01:03P, 01:03

4.11.B: HLA Unacceptable Antigen Equivalences

At the time of the match run, if an antigen or epitope is entered as unacceptable for a candidate, then the candidate will not appear on the match run for donors reported with any of the equivalent antigens described in *4-5, 4-6, 4-7, 4-8, 4-9, 4-10, 4-11, 4-12, 4-13, 4-14, 4-15, and 4-16 below.*

CPRA calculations include all donor alleles equivalent to a candidate's reported unacceptable antigens, alleles, and epitopes.

Table 4-5: HLA A Unacceptable Antigen Equivalences

If this A-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
1	1, 01:01P, 01:01, 01:02P, 01:02, 01:03P
01:01	01:01
01:02	01:02
2	2, 02:01P, 02:01, 02:02P, 02:02, 02:03P, 02:03, 02:04P, 02:05P, 02:05, 02:06P, 02:06, 02:07P, 02:07, 02:10P, 02:10, 02:11P, 02:14P, 02:16P, 02:18, 02:20P, 02:22P, 02:29P, 02:49P, 02:65P, 02:81P
02:01	02:01
02:02	02:02
02:03	02:03
02:05	02:05
02:06	02:06
02:07	02:07
02:10	02:10
02:18	02:18
3	3, 03:01P, 03:01, 03:02P, 03:02, 03:04P, 32:04
03:01	03:01
03:02	03:02
9	9, 23, 23:01P, 24, 24:02P, 24:02, 24:03P, 24:03, 24:05P, 24:07P, 24:10P, 24:26P
10	10, 25, 25:01P, 26, 26:01P, 26:01, 26:02, 26:03P, 26:03, 34, 34:01P, 34:01, 34:02, 66, 66:01P, 66:01, 66:02P, 66:02, 43
11	11, 11:01P, 11:01, 11:02P, 11:02, 11:03P, 11:05P
11:01	11:01
11:02	11:02
19	19, 29, 29:01P, 29:01, 29:02P, 29:02, 30, 30:01P, 30:01, 30:02P, 30:02, 30:04P, 31, 31:01P, 32, 32:01P, 33, 33:01P, 33:01, 33:03P, 33:03, 74, 74:01P, 74:06P
23	23, 23:01P
24	24, 24:02P, 24:02, 24:03P, 24:03, 24:05P, 24:07P, 24:10P, 24:26P
24:02	24:02
24:03	24:03
25	25, 25:01P
26	26, 26:01P, 26:01, 26:02, 26:03P, 26:03
26:01	26:01
26:02	26:02

If this A-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
26:03	26:03
28	28, 68, 69, 68:01P, 68:01, 68:02P, 68:02, 68:03P
29	29, 29:01P, 29:01, 29:02P, 29:02
29:01	29:01
29:02	29:02
30	30, 30:01P, 30:01, 30:02P, 30:02, 30:04P
30:01	30:01
30:02	30:02
31	31, 31:01P
32	32, 32:01P
32:04	32:04
33	33, 33:01P, 33:01, 33:03P, 33:03
33:01	33:01
33:03	33:03
34	34, 34:01P, 34:01, 34:02
34:01	34:01
34:02	34:02
36	36, 36:01P
43	43
66	66, 66:01P, 66:01, 66:02P, 66:02
66:01	66:01
66:02	66:02
68	68, 68:01P, 68:01, 68:02P, 68:02, 68:03P
68:01	68:01
68:02	68:02
69	69
74	74, 74:01P, 74:06P
80	80, 80:01P

Table 4-6 HLA B Unacceptable Antigen Equivalences

If this B-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
5	5, 51, 51:01P, 51:01, 51:02, 51:08P, 51:09P, 51:143P, 52, 52:01P
7	7, 07:02P, 07:02, 07:03, 07:05P, 07:14
07:02	07:02
07:03	07:03
07:14	07:14
8	8, 08:01P, 08:01, 08:02, 08:03, 08:04
08:01	08:01

If this B-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
08:02	08:02
08:03	08:03
08:04	08:04
12	12, 44, 44:02P, 44:02, 44:03P, 44:03, 44:05P, 44:29P, 44:53P, 51:42P, 45, 50:02P, 50:02
13	13, 13:01P, 13:01, 13:02P, 13:02
13:01	13:01
13:02	13:02
14	14, 64, 65, 14:01P, 14:01, 14:02P, 14:02
14:01	14:01, 64
14:02	14:02, 65
15	15, 62, 63, 70, 71, 72, 75, 76, 77, 15:01P, 15:01, 15:02P, 15:02, 15:03P, 15:03, 15:04, 15:06, 15:07P, 15:07, 15:10P, 15:10, 15:11P, 15:11, 15:12P, 15:12, 15:13, 15:14P, 15:16P, 15:16, 15:17P, 15:17, 15:18P, 15:18, 15:20P, 15:20, 15:21P, 15:21, 15:24, 15:25P, 15:27, 15:28P, 15:30P, 15:32P, 15:35P, 15:39P, 15:123P
15:01	15:01
15:02	15:02
15:03	15:03
15:04	15:04
15:06	15:06
15:07	15:07
15:10	15:10
15:11	15:11
15:12	15:12
15:13	15:13
15:16	15:16
15:17	15:17
15:18	15:18
15:20	15:20
15:21	15:21
15:24	15:24
15:27	15:27
16	16, 38, 38:01P, 38:01, 38:02P, 38:02, 39, 39:01P, 39:01, 39:02P, 39:02, 39:03P, 39:04, 39:05P, 39:05, 39:06P, 39:06, 39:09P, 39:10P, 39:13, 39:15P
17	17, 57, 57:01P, 57:01, 57:03P, 57:03, 58, 58:01P, 58:02P
18	18, 18:01P
21	21, 49, 49:01P, 50, 40:05, 50:01P, 50:01
22	22, 54, 54:01P, 55, 55:01P, 55:01, 55:02P, 55:02, 55:04, 56, 56:01P, 56:01, 56:03
27	27, 27:02P, 27:03, 27:04P, 27:04, 27:05P, 27:05, 27:06P, 27:06, 27:07P
27:03	27:03

If this B-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
27:04	27:04
27:05	27:05
27:06	27:06
27:08	27:08
35	35, 35:01P, 35:01, 35:02P, 35:02, 35:03P, 35:03, 35:05P, 35:08P, 35:08, 35:12 35:14P, 35:43P, 35:137P
35:01	35:01
35:02	35:02
35:03	35:03
35:08	35:08
35:12	35:12
37	37, 37:01P
38	38, 38:01P, 38:01, 38:02P, 38:02
38:01	38:01
38:02	38:02
39	39, 39:01P, 39:01, 39:02P, 39:02, 39:03P, 39:04, 39:05P, 39:05, 39:06P, 39:06, 39:09P, 39:10P, 39:13, 39:15P
39:01	39:01
39:02	39:02
39:04	39:04
39:05	39:05
39:06	39:06
39:13	39:13
40	40, 60, 61, 40:01P, 40:01, 40:02P, 40:02, 40:03P, 40:03, 40:04, 40:06P, 40:06, 40:40P, 40:213P
40:01	40:01
40:02	40:02
40:03	40:03
40:04	40:04
40:05	40:05
40:06	40:06
41	41, 41:01P, 41:01, 41:02P, 41:02
41:01	41:01
41:02	41:02
42	42, 42:01P, 42:01, 42:02
42:01	42:01
42:02	42:02
44	44, 44:02P, 44:02, 44:03P, 44:03, 44:05P, 44:29P, 44:53P, 51:42P
44:02	44:02
44:03	44:03
45	45, 45:01P, 50:02P, 50:02
46	46, 46:01P
47	47, 47:01P
48	48, 48:01P, 48:01, 48:02, 48:04P

If this B-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
48:01	48:01
48:02	48:02
49	49, 49:01P
50	50, 40:05, 50:01P, 50:01
50:01	50:01
50:02	50:02
51	51, 51:01P, 51:01, 51:02, 51:08P, 51:09P, 51:143P
51:01	51:01
51:02	51:02
52	52, 52:01P
53	53, 53:01P
54	54, 54:01P
55	55, 55:01P, 55:01, 55:02P, 55:02, 55:04
55:01	55:01
55:02	55:02
55:04	55:04
56	56, 56:01P, 56:01, 56:03
56:01	56:01
56:03	56:03
57	57, 57:01P, 57:01, 57:03P, 57:03
57:01	57:01
57:03	57:03
58	58, 58:01P, 58:02P
59	59, 59:01P
60	60, 40:01P, 40:01
61	61, 40:02P, 40:02, 40:03P, 40:03, 40:04, 40:06P, 40:06
62	62, 15:01P, 15:01, 15:04, 15:06, 15:07P, 15:07, 15:20P, 15:20, 15:25P, 15:27, 15:28P, 15:30P, 15:32P, 15:35P, 15:39P
63	63, 15:16P, 15:16, 15:17P, 15:17
64	64, 14:01P, 14:01
65	65, 14:02P, 14:02
67	67, 67:01P
70	70, 71, 72, 15:03P, 15:03, 15:10P, 15:10, 15:18P, 15:18, 15:123P
71	71, 15:10P, 15:10, 15:18P, 15:18
72	72, 15:03P, 15:03
73	73, 73:01P
75	75, 15:02P, 15:02, 15:11P, 15:11, 15:21P, 15:21
76	76, 15:12P, 15:12, 15:14P
77	77, 15:13
78	78
81	81, 81:01P
82	82
83:01	83:01

If this B-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
Bw4	Bw4, 08:02, 08:03, 5, 13, 13:01P, 13:01, 13:02P, 13:02, 15:13, 15:16P, 15:16, 15:17P, 15:17, 15:24, 17, 27, 27:02P, 27:03, 27:04P, 27:04, 27:05P, 27:05, 27:06P, 27:06, 27:07P, 37, 37:01P, 38, 38:01P, 38:01, 38:02P, 38:02, 44, 44:02P, 44:02, 44:03P, 44:03, 44:05P, 44:29P, 44:53P, 47, 47:01P, 49, 49:01P, 51, 51:01P, 51:01, 51:02, 51:08P, 51:09P, 51:42P, 51:143P, 52, 52:01P, 53, 53:01P, 57, 57:01P, 57:01, 57:03P, 57:03, 58, 58:01P, 58:02P, 59, 59:01P, 63, 77
Bw6	Bw6, 7, 07:02P, 07:02, 07:03, 07:05P, 07:14, 8, 08:01P, 08:01, 08:04, 14, 14:01P, 14:01, 14:02P, 14:02, 15:01P, 15:01, 15:02P, 15:02, 15:03P, 15:03, 15:04, 15:06, 15:07P, 15:07, 15:10P, 15:10, 15:11P, 15:11, 15:12P, 15:12, 15:14P, 15:18P, 15:18, 15:20P, 15:20, 15:21P, 15:21, 15:25P, 15:27, 15:28P, 15:30P, 15:32P, 15:35P, 15:39P, 15:123P, 18, 18:01P, 22, 27:08, 35, 35:01P, 35:01, 35:02P, 35:02, 35:03P, 35:03, 35:05P, 35:08P, 35:08, 35:12P, 35:12, 35:14P, 35:43P, 35:137P, 39, 39:01P, 39:01, 39:02P, 39:02, 39:03P, 39:04, 39:05P, 39:05, 39:06P, 39:06, 39:09P, 39:10P, 39:13, 39:15P, 40, 40:01P, 40:01, 40:02P, 40:02, 40:03P, 40:03, 40:04, 40:05, 40:06P, 40:06, 40:40P, 40:213P, 41, 41:01P, 41:01, 41:02P, 41:02, 42, 42:01P, 42:01, 42:02, 45, 45:01P, 48, 48:01P, 48:01 48:02, 48:04P, 50, 50:01P, 50:01, 50:02P, 50:02, 54, 54:01P, 55, 55:01P, 55:01, 55:02P, 55:02, 55:04, 56, 56:01P, 56:01, 56:03, 60, 61, 62, 64, 65, 67, 67:01P, 70, 71, 72, 75, 76, 78, 81, 81:01P, 82

Table 4-7: HLA C Unacceptable Antigen Equivalences

If this C-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
01	01, 01:02P, 01:02, 01:03P, 01:03, 01:63P
01:02	01:02
01:03	01:03
02	02, 02:02P, 02:02, 02:10, 02:14P, 02:16P, 02:134P, 02:159P, 02:182P
02:02	02:02
02:10	02:10
03	03, 03:02P, 03:02, 03:03P, 03:03, 03:04P, 03:04, 03:05P, 03:05, 03:06, 03:14P, 03:40P, 09, 10
03:02	03:02
03:03	03:03
03:04	03:04
03:05	03:05
03:06	03:06
04	04, 04:01P, 04:01, 04:03P, 04:03, 04:04, 04:06P, 04:07, 04:09L, 04:10P, 04:59P, 04:355P, 04:360P
04:01	04:01
04:03	04:03

If this C-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
04:04	04:04
04:07	04:07
05	05, 05:01P, 05:01
05:01	05:01
06	06, 06:02P, 06:02, 06:06P, 06:87P
06:02	06:02
07	07, 07:01P, 07:01, 07:02P, 07:02, 07:04P, 07:04, 07:06, 07:18, 07:19P, 07:22P, 07:26P, 07:27P, 07:28P, 07:165P, 07:450P, 07:919P
07:01	07:01
07:02	07:02
07:04	07:04
07:06	07:06
07:18	07:18
08	08, 08:01P, 08:01, 08:02P, 08:02, 08:03P, 08:03, 08:04
08:01	08:01
08:02	08:02
08:03	08:03
08:04	08:04
09	09, 03:03P, 03:03
10	10, 03:02P, 03:02, 03:04P, 03:04, 03:06
12	12, 12:02P, 12:02, 12:03P, 12:03, 12:04, 12:14P
12:02	12:02
12:03	12:03
12:04	12:04
14	14, 14:02P, 14:02, 14:03P, 14:03
14:02	14:02
14:03	14:03
15	15, 15:02P, 15:02, 15:04P, 15:04, 15:05P, 15:05, 15:06, 15:09, 15:103P
15:02	15:02
15:04	15:04
15:05	15:05
15:06	15:06
15:09	15:09
16	16, 16:01P, 16:01, 16:02P, 16:02, 16:04, 16:15P
16:01	16:01
16:02	16:02
16:04	16:04
17	17, 17:01P, 17:01, 17:03
17:01	17:01
17:03	17:03
18	18, 18:01P, 18:01, 18:02
18:01	18:01

If this C-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
18:02	18:02

Table 4-8: HLA DR Unacceptable Antigen Equivalences

If this DR-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
1	1, 01:01P, 01:01, 01:02P, 01:02
01:01	01:01
01:02	01:02
01:03	01:03, 103
2	2, 15, 15:01P, 15:01, 15:02P, 15:02, 15:03P, 15:03, 15:04P, 15:07P, 16, 16:01P, 16:01, 16:02P, 16:02
3	3, 17, 18, 03:01P, 03:01, 03:02P, 03:02, 03:03
03:01	03:01
03:02	03:02
03:03	03:03
4	4, 04:01P, 04:01, 04:02P, 04:02, 04:03P, 04:03, 04:04P, 04:04, 04:05P, 04:05, 04:06P, 04:06, 04:07P, 04:07, 04:08P, 04:10P, 04:10, 04:11
04:01	04:01
04:02	04:02
04:03	04:03
04:04	04:04
04:05	04:05
04:06	04:06
04:07	04:07
04:10	04:10
04:11	04:11
5	5, 11, 11:01P, 11:01, 11:02P, 11:03P, 11:04P, 11:04, 11:06P, 11:11P, 12, 12:01P, 12:01, 12:02P, 12:02
6	6, 13, 13:01P, 13:01,13:02P, 13:02, 13:03P, 13:03, 13:05, 13:12P, 14, 14:01P, 14:01, 14:02P, 14:02, 14:03P, 14:03, 14:04P, 14:04, 14:05, 14:06, 14:08P, 14:24P
7	7, 07:01P
8	8, 08:01P, 08:01, 08:02P, 08:02, 08:03P, 08:03, 08:04P, 08:07
08:01	08:01
08:02	08:02
08:03	08:03
08:07	08:07
9	9, 09:01P, 09:01, 09:02
09:01	09:01
09:02	09:02
10	10, 10:01P
11	11, 11:01P, 11:01, 11:02P, 11:03P, 11:03, 11:04P, 11:04, 11:06P, 11:11P

If this DR-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
11:01	11:01
11:03	11:03
11:04	11:04
12	12, 12:01P, 12:01, 12:02P, 12:02
12:01	12:01
12:02	12:02
13	13, 13:01P, 13:01, 13:02P, 13:02, 13:03P, 13:03, 13:05, 13:12P
13:01	13:01
13:02	13:02
13:03	13:03
13:05	13:05
14	14, 14:01P, 14:01, 14:02P, 14:02, 14:03P, 14:03, 14:04P, 14:04, 14:05, 14:06, 14:08P, 14:24P, 14:54
14:01	14:01
14:02	14:02
14:03	14:03
14:04	14:04
14:05	14:05
14:06	14:06
14:54	14:54
15	15, 15:01P, 15:01, 15:02P, 15:02, 15:03P, 15:03, 15:04P, 15:07P
15:01	15:01
15:02	15:02
15:03	15:03
16	16, 16:01P, 16:01, 16:02P, 16:02
16:01	16:01
16:02	16:02
17	17, 03:01P, 03:01
18	18, 03:02P, 03:02, 03:03
103	103, 01:03P, 01:03

Table 4-9: HLA DR51 Unacceptable Antigen Equivalences

If this DR51-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
5*01	5*01, 5*01:01P, 5*01:01, 5*01:02P, 5*01:02
5*01:01	5*01:01
5*01:02	5*01:02
5*02	5*02, 5*02:02P, 5*02:02
5*02:02	5*02:02
51	51, 5*01:01P, 5*01:01, 5*01:02P, 5*01:02, 5*02:02P, 5*02:02, 5*01, 5*02

Table 4-10: HLA DR52 Unacceptable Antigen Equivalences

If this DR52-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigens:
3*01	3*01, 3*01:01P, 3*01:01
3*01:01	3*01:01
3*02	3*02, 3*02:01P, 3*02:01, 3*02:02P, 3*02:02, 3*02:100P
3*02:01	3*02:01
3*02:02	3*02:02
3*03	3*03, 3*03:01P, 3*03:01, 3*03:22P
3*03:01	3*03:01
52	52, 3*01:01P, 3*01:01, 3*02:01P, 3*02:01, 3*02:02P, 3*02:02, 3*02:100P, 3*03:01P, 3*03:01, 3*03:22P, 3*01, 3*02, 3*03

Table 4-11: HLA DR53 Unacceptable Antigen Equivalences

If this DR-53 Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
4*01	4*01, 4*01:01P, 4*01:01, 4*01:03, 4*01:75P, 4*01:78P
4*01:01	4*01:01
4*01:03	4*01:03
53	53, 4*01:01P, 4*01:01, 4*01:03, 4*01:75P, 4*01:78P, 4*01

Table 4-12: HLA DQA1 Unacceptable Antigen Equivalences

If this DQA1-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
01	01, 01:01P, 01:01, 01:02P, 01:02, 01:03P, 01:03, 01:04, 01:05, 01:06, 01:07P, 01:07, 01:08, 01:09, 01:10, 01:11, 01:12
01:01	01:01
01:02	01:02
01:03	01:03
01:04	01:04
01:05	01:05
01:06	01:06
01:07	01:07
01:08	01:08
01:09	01:09
01:10	01:10
01:11	01:11
01:12	01:12

If this DQA1-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
02	02, 02:01P, 02:01
02:01	02:01
03	03, 03:01P, 03:01, 03:02, 03:03
03:01	03:01
03:02	03:02
03:03	03:03
04	04, 04:01P, 04:01, 04:02, 04:04
04:01	04:01
04:02	04:02
04:04	04:04
05	05, 05:01P, 05:01, 05:02, 05:03, 05:04, 05:05, 05:06, 05:07, 05:08, 05:09, 05:10, 05:11, 05:23P
05:01	05:01
05:02	05:02
05:03	05:03
05:04	05:04
05:05	05:05
05:06	05:06
05:07	05:07
05:08	05:08
05:09	05:09
05:10	05:10
05:11	05:11
06	06, 06:01P, 06:01, 06:02
06:01	06:01
06:02	06:02

Table 4-13: HLA DQB1 Unacceptable Antigen Equivalences

If this DQB1-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
2	2, 02:01P, 02:01, 02:02, 02:03P, 02:57P, 02:135P
02:01	02:01
02:02	02:02
3	3, 7, 8, 9, 03:01P, 03:01, 03:02P, 03:02, 03:03P, 03:03, 03:04P, 03:05P, 03:10P, 03:19, 03:71P, 03:113P
03:01	03:01

If this DQB1-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
03:02	03:02
03:03	03:03
03:19	03:19
4	4, 04:01P, 04:01, 04:02P, 04:02
04:01	04:01
04:02	04:02
5	5, 05:01P, 05:01, 05:02P, 05:02, 05:03P, 05:03, 05:04P
05:01	05:01
05:02	05:02
05:03	05:03
6	6, 06:01P, 06:01, 06:02P, 06:02, 06:03P, 06:03, 06:04P, 06:04, 06:08P, 06:09P, 06:09, 06:46P, 06:92P
06:01	06:01
06:02	06:02
06:03	06:03
06:04	06:04
06:09	06:09
7	7, 03:01P, 03:01, 03:04P, 03:19
8	8, 03:02P, 03:02, 03:05P, 03:10P
9	9, 03:03P, 03:03

Table 4-14: HLA DPA1 Unacceptable Antigen Equivalences

If this DPA1-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
01	01, 01:03P, 01:03, 01:04, 01:05P, 01:05, 01:06, 01:07, 01:08, 01:09, 01:10, 01:11, 01:12
01:03	01:03
01:04	01:04
01:05	01:05
01:06	01:06
01:07	01:07
01:08	01:08
01:09	01:09
01:10	01:10
01:11	01:11
01:12	01:12
02	02, 02:01P, 02:01,02:02P, 02:02, 02:03, 02:04, 02:07, 02:21P, 02:54P
02:01	02:01
02:02	02:02
02:03	02:03

If this DPA1-Locus Unacceptable Antigen is reported:	The following HLA values are considered equivalent to the reported unacceptable antigen:
02:04	02:04
02:07	02:07
03	03, 03:01P, 03:01, 03:02, 03:03, 03:07P
03:01	03:01
03:02	03:02
03:03	03:03
04	04, 04:01P, 04:01
04:01	04:01

Table 4-15: HLA DPB1 Unacceptable Antigen Equivalences

In addition to the alleles and p-groups displayed in this table, all non-null HLA-DPB1 alleles as of IPD-IMGT/HLA version 3.52.0 are available for reporting candidate, donor, or recipient HLA typing.

If this DPB1-Locus Unacceptable Antigen is reported:	All of the following HLA values are considered equivalent to the unacceptable antigen reported and to all the values within the row:
01:01	01:01P, 01:01, 162:01, 417:01, 462:01, 616:01, 733:01, 807:01, 810:01, 853:01, 931:01, 953:01, 979:01, 998:01, 999:01, 1024:01, 1038:01, 1050:01, 1068:01, 1076:01, 1151:01, 1162:01, 1183:01, 1287:01, 1314:01, 1361:01, 1392:01, 1406:01, 1443:01

If this DPB1-Locus Unacceptable Antigen is reported:	All of the following HLA values are considered equivalent to the unacceptable antigen reported and to all the values within the row:
02:01	02:01P, 02:01, 141:01, 352:01, 414:01, 416:01, 461:01, 617:01, 640:01, 678:01, 723:01, 783:01, 799:01, 819:01, 845:01, 857:01, 861:01, 955:01, 967:01, 975:01, 1036:01, 1051:01, 1055:01, 1077:01, 1082:01, 1094:01, 1102:01, 1115:01, 1160:01, 1175:01, 1198:01, 1227:01, 1243:01, 1248:01, 1266:01, 1290:01, 1298:01, 1307:01, 1312:01, 1315:01, 1320:01, 1323:01, 1326:01, 1344:01, 1352:01, 1360:01, 1363:01, 1369:01, 1372:01, 1405:01, 1417:01, 1419:01, 1456:01
02:02	02:02P, 02:02, 547:01,721:01, 766:01, 1188:01, 1376:01, 1437:01
03:01	03:01P, 03:01, 104:01, 124:01, 351:01, 669:01, 675:01, 676:01, 704:01, 706:01, 728:01, 829:01, 855:01, 938:01, 946:01, 948:01, 952:01, 1000:01, 1014:01, 1021:01, 1049:01, 1114:01, 1134:01, 1157:01, 1245:01, 1246:01, 1254:01, 1263:01, 1295:01, 1382:01, 1388:01, 1401:01, 1407:01, 1429:01

If this DPB1-Locus Unacceptable Antigen is reported:	All of the following HLA values are considered equivalent to the unacceptable antigen reported and to all the values within the row:
04:01	04:01P, 04:01, 126:01, 350:01, 415:01, 459:01, 464:01, 534:01, 615:01, 618:01, 670:01, 677:01, 699:01, 702:01, 755:01, 757:01, 765:01, 767:01, 784:01, 804:01, 806:01, 813:01, 820:01, 824:01, 826:01, 849:01, 850:01, 859:01, 880:01, 882:01, 926:01, 932:01, 939:01, 978:01, 988:01, 989:01, 992:01, 997:01, 1001:01, 1002:01, 1003:01, 1004:01, 1010:01, 1011:01, 1023:01, 1033:01, 1074:01, 1086:01, 1091:01, 1100:01, 1129:01, 1132:01, 1144:01, 1146:01, 1148:01, 1152:01, 1155:01, 1161:01, 1164:01, 1173:01, 1181:01, 1184:01, 1196:01, 1206:01, 1207:01, 1217:01, 1225:01, 1226:01, 1231:01, 1237:01, 1238:01, 1241:01, 1242:01, 1244:01, 1249:01, 1268:01, 1271:01, 1284:01, 1297:01, 1300:01, 1304:01, 1308:01, 1316:01, 1317:01, 1321:01, 1322:01, 1327:01, 1328:01, 1345:01, 1362:01, 1374:01, 1377:01, 1379:01, 1387:01, 1390:01, 1391:01, 1409:01, 1412:01, 1413:01, 1436:01, 1444:01, 1446:01, 1450:01, 1459:01, 1465:01, 1472:01, 1476:01
04:02	04:02P, 04:02, 105:01, 463:01, 571:01, 647:01, 665:01, 674:01, 701:01, 725:01, 726:01, 730:01, 731:01, 734:01, 735:01, 763:01, 809:01, 818:01, 823:01, 858:01, 881:01, 927:01, 933:01, 954:01, 958:01, 981:01, 1005:01, 1013:01, 1020:01, 1025:01, 1031:01, 1035:01, 1037:01, 1072:01, 1075:01, 1083:01, 1085:01, 1124:01, 1153:01, 1171:01, 1194:01, 1197:01, 1235:01, 1239:01, 1267:01, 1270:01, 1283:01, 1331:01, 1346:01, 1380:01, 1404:01, 1424:01, 1425:01, 1460:01
05:01	05:01P, 05:01, 135:01, 668:01, 729:01, 744:01, 764:01, 790:01, 847:01, 848:01, 851:01, 860:01, 923:01, 951:01, 1015:01, 1018:01, 1117:01, 1118:01, 1119:01, 1120:01, 1143:01, 1172:01, 1199:01, 1213:01, 1273:01, 1289:01, 1318:01, 1438:01, 1457:01, 1462:01, 1473:01
06:01	06:01P, 06:01,737:01, 906:01, 914:01, 1022:01, 1087:01, 1111:01, 1259:01, 1471:01
08:01	08:01
09:01	09:01P, 09:01, 797:01, 899:01, 1149:01, 1258:01, 1303:01, 1313:01, 1378:01
10:01	10:01P, 10:01, 650:01, 673:01, 902:01, 1126:01, 1261:01, 1470:01
11:01	11:01P, 11:01, 649:01, 654:01, 672:01, 707:01, 907:01, 937:01, 1063:01
13:01	13:01P, 13:01, 107:01, 133:01, 518:01, 519:01, 888:01, 924:01, 947:01, 996:01, 1065:01, 1069:01, 1105:01, 1123:01, 1131:01, 1185:01, 1232:01, 1294:01, 1451:01

If this DPB1-Locus Unacceptable Antigen is reported:	All of the following HLA values are considered equivalent to the unacceptable antigen reported and to all the values within the row:
14:01	14:01P, 14:01, 498:01, 572:01, 651:01, 671:01, 705:01, 834:01, 854:01, 949:01, 1187:01, 1348:01, 1354:01, 1384:01, 1395:01, 1414:01
15:01	15:01P, 15:01, 585:01, 896:01, 910:01, 1054:01, 1192:01, 1250:01, 1336:01, 1434:01
16:01	16:01P, 16:01, 652:01, 653:01, 864:01, 886:01, 940:01, 968:01, 1386:01
17:01	17:01P, 17:01, 131:01, 168:01, 460:01, 846:01, 956:01, 1032:01, 1052:01, 1233:01, 1265:01, 1367:01, 1394:01, 1397:01, 1431:01, 1435:01, 1475:01
18:01	18:01P, 18:01, 897:01, 942:01, 1165:01
19:01	19:01P, 19:01, 106:01, 533:01, 535:01, 785:01, 965:01, 1101:01, 1255:01, 1282:01
20:01	20:01P, 20:01, 905:01, 1389:01, 1426:01
21:01	21:01P, 21:01, 1019:01, 1186:01, 1190:01
22:01	22:01P, 22:01, 1026:01
23:01	23:01P, 23:01, 138:01
24:01	24:01
25:01	25:01P, 25:01, 1469:01
26:01	26:01P, 26:01, 1088:01
27:01	27:01
28:01	28:01P, 28:01, 296:01, 1286:01, 1324:01
29:01	29:01P, 29:01, 909:01
30:01	30:01
31:01	31:01P, 31:01, 945:01
34:01	34:01P, 34:01, 835:01, 913:01
35:01	35:01
38:01	38:01P, 38:01, 1099:01
39:01	39:01P, 39:01, 584:01
40:01	40:01P, 40:01, 745:01
45:01	45:01P, 45:01, 832:01
51:01	51:01P, 51:01, 736:01
55:01	55:01P, 55:01, 1353:01
57:01	57:01P, 57:01, 648:01
59:01	59:01P, 59:01,782:01

If this DPB1-Locus Unacceptable Antigen is reported:	All of the following HLA values are considered equivalent to the unacceptable antigen reported and to all the values within the row:
80:01	80:01P, 80:01, 762:01
81:01	81:01P, 81:01, 1383:01
85:01	85:01P, 85:01, 713:01, 901:01, 1034:01, 1441:01
90:01	90:01P, 90:01, 1012:01
100:01	100:01P, 100:01, 1483:01
104:01	104:01
105:01	105:01
106:01	106:01
107:01	107:01
124:01	124:01
126:01	126:01
130:01	130:01P, 130:01, 1211:01
131:01	131:01
132:01	132:01P, 132:01, 1027:01
135:01	135:01
137:01	137:01P, 137:01, 791:01
152:01	152:01P, 152:01, 944:01
184:01	184:01P, 184:01, 1224:01
233:01	233:01P, 233:01, 1428:01
398:01	398:01P, 398:01, 922:01
1096:01	1096:01P, 1096:01, 1133:01
1371:01	1371:01P, 1371:01, 1445:01

Table 4-16: Epitope based Unacceptable Antigen Assignment for DPB1

If this Candidate Unacceptable Epitope is reported:	The following HLA values are considered equivalent to the reported unacceptable epitope:
55AAE	01:01, 04:01, 11:01, 13:01, 15:01, 23:01, 26:01, 27:01, 31:01, 33:01, 34:01, 39:01, 40:01, 52:01, 55:01, 56:01, 58:01, 62:01, 63:01, 65:01, 66:01, 67:01, 71:01, 72:01, 74:01, 85:01, 87:01, 89:01, 90:01, 95:01, 96:01, 99:01, 102:01, 103:01, 107:01, 110:01, 112:01, 117:01, 118:01, 121:01, 125:01, 126:01, 127:01, 128:01, 133:01, 134:01, 138:01, 142:01, 147:01, 149:01, 150:01, 158:01, 160:01, 162:01, 169:01, 173:01, 174:01, 175:01, 176:01, 177:01, 178:01, 179:01, 180:01, 181:01, 192:01, 193:01, 194:01, 195:01, 199:01, 201:01, 202:01, 206:01, 207:01, 209:01, 212:01, 213:01, 220:01, 224:01, 225:01, 227:01, 228:01, 230:01, 231:01, 232:01, 240:01, 244:01, 246:01, 247:01, 250:01, 253:01, 255:01, 262:01, 264:01, 267:01, 268:01, 272:01, 275:01, 276:01, 278:01, 279:01, 280:01, 281:01, 282:01, 283:01, 290:01, 294:01, 295:01, 298:01, 299:01, 303:01, 304:01, 305:01, 306:01, 314:01, 318:01, 319:01, 320:01, 322:01, 323:01, 325:01, 326:01, 327:01, 333:01, 334:01, 335:01, 336:01, 340:01, 341:01, 345:01, 346:01, 348:01, 350:01, 353:01, 354:01, 356:01, 360:01, 362:01, 370:01, 371:01, 372:01, 375:01, 376:01, 377:01, 378:01, 387:01, 388:01, 389:01, 392:01, 393:01, 396:01, 397:01, 398:01, 399:01, 411:01, 412:01, 415:01, 417:01, 418:01, 425:01, 426:01, 428:01, 434:01, 435:01, 436:01, 437:01, 438:01, 440:01, 449:01, 451:01, 453:01, 454:01, 456:01, 458:01, 459:01, 462:01, 464:01, 465:01, 468:01, 471:01, 474:01, 475:01, 476:01, 479:01, 480:01, 481:01, 482:01, 483:01, 485:01, 486:01, 487:01, 490:01, 493:01, 497:01, 500:01, 503:01, 512:01, 516:01, 517:01, 518:01, 519:01, 520:01, 521:01, 522:01, 523:01, 524:01, 529:01, 531:01, 534:01, 538:01, 542:01, 543:01, 544:01, 553:01, 554:01, 556:01, 559:01, 561:01, 562:01, 563:01, 564:01, 565:01, 569:01, 575:01, 576:01, 578:01, 580:01, 583:01, 584:01, 585:01, 591:01, 592:01, 593:01, 597:01, 599:01, 600:01, 607:01, 609:01, 612:01, 614:01, 615:01, 616:01, 618:01, 623:01, 625:01, 626:01, 631:01, 632:01, 634:01, 635:01, 636:01, 643:01, 644:01, 649:01, 654:01, 658:01, 666:01, 667:01, 670:01, 672:01, 677:01, 679:01, 682:01, 683:01, 686:01, 687:01, 694:01, 695:01, 699:01, 702:01, 703:01, 707:01, 708:01, 709:01, 713:01, 716:01, 722:01, 733:01, 739:01, 742:01, 745:01, 747:01, 749:01, 750:01, 753:01, 755:01, 757:01, 758:01, 761:01, 765:01, 767:01, 768:01, 769:01, 772:01, 773:01, 784:01, 787:01, 788:01, 789:01, 795:01, 803:01, 804:01, 806:01, 807:01, 808:01, 810:01, 811:01, 812:01, 813:01, 814:01, 820:01, 822:01, 824:01, 826:01, 828:01, 830:01, 835:01, 837:01, 840:01, 842:01, 849:01, 850:01, 852:01, 853:01, 856:01, 859:01, 879:01,

If this Candidate Unacceptable Epitope is reported:	The following HLA values are considered equivalent to the reported unacceptable epitope:
	880:01, 882:01, 888:01, 893:01, 895:01, 896:01, 901:01, 904:01, 907:01, 908:01, 910:01, 912:01, 913:01, 915:01, 916:01, 921:01, 922:01, 924:01, 926:01, 930:01, 931:01, 932:01, 934:01, 937:01, 945:01, 947:01, 953:01, 957:01, 966:01, 969:01, 972:01, 976:01, 978: 01, 979:01, 988:01, 989:01, 991:01, 992:01, 993:01, 996:01, 997:01, 998:01, 999:01, 1001:01, 1002:01, 1003:01, 1004:01, 1010:01, 1011:01, 1012:01, 1016:01, 1023:01, 1024:01, 1033:01, 1034:01, 1038:01, 1040:01, 1042:01, 1046:01, 1048:01, 1050:01, 1054:01, 1057:01, 1060:01, 1062:01, 1063:01, 1064:01, 1065:01, 1066:01, 1068:01, 1069:01, 1073:01, 1074:01, 1076:01, 1078:01, 1080:01, 1081:01, 1086:01, 1088:01, 1091:01, 1097:01, 1100:01, 1105:01, 1108:01, 1109:01, 1113:01, 1122:01, 1123:01, 1129:01, 1131:01, 1132:01, 1137:01, 1138:01, 1139:01, 1141:01, 1144:01, 1145:01, 1146:01, 1147:01, 1148:01, 1151:01, 1152:01, 1155:01, 1161:01, 1162:01, 1164:01, 1166:01, 1167:01, 1170:01, 1173:01, 1177:01, 1181:01, 1183:01, 1184:01, 1185:01, 1192:01, 1195:01, 1196:01, 1204:01, 1205:01, 1206:01, 1207:01, 1208:01, 1212:01, 1214:01, 1215:01, 1216:01, 1217:01, 1218:01, 1220:01, 1221:01, 1222:01, 1225:01, 1226:01, 1231:01, 1232:01, 1234:01, 1237:01, 1238:01, 1241:01, 1242:01, 1244:01, 1249:01, 1250:01, 1252:01, 1262:01, 1264:01, 1268:01, 1271:01, 1274:01, 1277:01, 1284:01, 1287:01, 1292:01, 1294:01, 1297:01, 1300:01, 1301:01, 1304:01, 1306:01, 1308:01, 1309:01, 1310:01, 1314:01, 1316:01, 1317:01, 1321:01, 1322:01, 1327:01, 1328:01, 1329:01, 1333:01, 1336:01, 1337:01, 1341:01, 1342:01, 1343:01, 1345:01, 1353:01, 1356:01, 1358:01, 1361:01, 1362:01, 1370:01, 1374:01, 1377:01, 1379:01, 1385:01, 1387:01, 1390:01, 1391:01, 1392:01, 1399:01, 1406:01, 1409:01, 1412:01, 1413:01, 1420:01, 1421:01, 1427:01, 1433:01, 1434:01, 1436:01, 1441:01, 1443:01, 1444:01, 1446:01, 1447:01, 1450:01, 1451:01, 1453:01, 1454:01, 1459:01, 1464:01, 1465:01, 1472:01, 1476:01, 01:01P, 04:01P, 11:01P, 13:01P, 15:01P, 23:01P, 26:01P, 31:01P, 34:01P, 39:01P, 40:01P, 55:01P, 85:01P, 90:01P, 398:01P
55DED	03:01, 06:01, 09:01, 14:01, 17:01, 20:01, 29:01, 35:01, 44:01, 46:01, 50:01, 57:01, 69:01, 70:01, 76:01, 78:01, 80:01, 86:01, 88:01, 91:01, 92:01, 98:01, 104:01, 108:01, 111:01, 119:01, 124:01, 130:01, 131:01, 132:01, 152:01, 156:01, 157:01, 164:01, 166:01, 168:01, 182:01, 197:01, 203:01, 205:01, 208:01, 214:01, 221:01, 222:01, 234:01, 235:01, 241:01, 242:01, 243:01, 245:01, 248:01, 249:01, 251:01, 259:01, 266:01, 270:01, 287:01, 288:01, 289:01, 292:01, 293:01, 329:01, 332:01, 343:01, 351:01, 355:01, 361:01, 363:01, 379:01, 383:01, 384:01, 385:01, 386:01, 391:01, 394:01, 404:01, 405:01, 407:01, 409:01, 413:01, 439:01, 442:01, 445:01, 446:01, 447:01, 460:01, 472:01, 484:01, 491:01, 492:01, 498:01, 504:01, 505:01, 506:01,

If this Candidate Unacceptable Epitope is reported:	The following HLA values are considered equivalent to the reported unacceptable epitope:
	508:01, 509:01, 530:01, 536:01, 540:01, 541:01, 545:01, 546:01, 548:01, 555:01, 566:01, 567:01, 568:01, 572:01, 581:01, 601:01, 610:01, 613:01, 620:01, 621:01, 629:01, 630:01, 645:01, 648:01, 651:01, 662:01, 664:01, 669:01, 671:01, 675:01, 676:01, 684:01, 688:01, 689:01, 698:01, 704:01, 705:01, 706:01, 714:01, 719:01, 727:01, 728:01, 737:01, 760:01, 762:01, 797:01, 801:01, 815:01, 829:01, 833:01, 834:01, 839:01, 846:01, 854:01, 855:01, 883:01, 899:01, 905:01, 906:01, 909:01, 914:01, 920:01, 935:01, 938:01, 944:01, 946:01, 948:01, 949:01, 952:01, 956:01, 970:01, 977:01, 983:01, 987:01, 990:01, 994:01, 1000:01, 1009:01, 1014:01, 1017:01, 1021:01, 1022:01, 1027:01, 1030:01, 1032:01, 1043:01, 1047:01, 1049:01, 1052:01, 1067:01, 1071:01, 1087:01, 1090:01, 1093:01, 1103:01, 1104:01, 1111:01, 1114:01, 1116:01, 1125:01, 1127:01, 1128:01, 1130:01, 1134:01, 1149:01, 1157:01, 1158:01, 1174:01, 1178:01, 1182:01, 1187:01, 1203:01, 1211:01, 1233:01, 1245:01, 1246:01, 1251:01, 1254:01, 1258:01, 1259:01, 1263:01, 1265:01, 1278:01, 1295:01, 1303:01, 1311:01, 1313:01, 1330:01, 1339:01, 1340:01, 1348:01, 1354:01, 1355:01, 1359:01, 1365:01, 1366:01, 1367:01, 1373:01, 1378:01, 1382:01, 1384:01, 1388:01, 1389:01, 1394:01, 1395:01, 1396:01, 1397:01, 1401:01, 1407:01, 1411:01, 1414:01, 1418:01, 1422:01, 1426:01, 1429:01, 1431:01, 1432:01, 1435:01, 1448:01, 1452:01, 1458:01, 1466:01, 1467:01, 1471:01, 1474:01, 1475:01, 1480:01, 03:01P, 06:01P, 09:01P, 14:01P, 17:01P, 20:01P, 29:01P, 57:01P, 80:01P, 130:01P, 132:01P, 152:01P
55DEE	02:01, 04:02, 08:01, 10:01, 16:01, 18:01, 25:01, 28:01, 37:01, 41:01, 45:01, 48:01, 49:01, 51:01, 53:01, 59:01, 60:01, 68:01, 73:01, 75:01, 77:01, 79:01, 81:01, 82:01, 83:01, 93:01, 94:01, 105:01, 109:01, 113:01, 115:01, 116:01, 122:01, 123:01, 129:01, 136:01, 137:01, 141:01, 143:01, 144:01, 145:01, 146:01, 151:01, 153:01, 155:01, 163:01, 165:01, 167:01, 172:01, 183:01, 184:01, 185:01, 186:01, 187:01, 188:01, 189:01, 191:01, 196:01, 198:01, 200:01, 204:01, 210:01, 211:01, 217:01, 219:01, 229:01, 236:01, 237:01, 238:01, 239:01, 252:01, 256:01, 257:01, 258:01, 260:01, 261:01, 263:01, 265:01, 269:01, 271:01, 273:01, 274:01, 277:01, 285:01, 286:01, 296:01, 297:01, 307:01, 308:01, 309:01, 310:01, 311:01, 312:01, 313:01, 316:01, 321:01, 324:01, 338:01, 339:01, 342:01, 344:01, 347:01, 349:01, 352:01, 359:01, 364:01, 365:01, 366:01, 367:01, 368:01, 369:01, 373:01, 374:01, 380:01, 381:01, 402:01, 410:01, 414:01, 416:01, 419:01, 420:01, 421:01, 422:01, 423:01, 424:01, 429:01, 430:01, 431:01, 432:01, 433:01, 441:01, 443:01, 444:01, 448:01, 452:01, 457:01, 461:01, 463:01, 466:01, 467:01, 469:01, 470:01, 477:01, 488:01, 489:01, 494:01, 499:01, 501:01, 502:01, 510:01, 511:01, 513:01, 514:01, 515:01, 525:01,

If this Candidate Unacceptable Epitope is reported:	The following HLA values are considered equivalent to the reported unacceptable epitope:
	526:01, 528:01, 532:01, 537:01, 539:01, 549:01, 552:01, 557:01, 571:01, 574:01, 577:01, 579:01, 582:01, 586:01, 594:01, 595:01, 596:01, 602:01, 603:01, 604:01, 606:01, 608:01, 617:01, 622:01, 624:01, 627:01, 628:01, 633:01, 637:01, 639:01, 640:01, 641:01, 646:01, 647:01, 650:01, 652:01, 653:01, 655:01, 656:01, 659:01, 660:01, 663:01, 665:01, 673:01, 674:01, 678:01, 680:01, 681:01, 685:01, 690:01, 692:01, 701:01, 711:01, 723:01, 725:01, 726:01, 730:01, 731:01, 734:01, 735:01, 736:01, 740:01, 741:01, 751:01, 752:01, 759:01, 763:01, 770:01, 771:01, 774:01, 775:01, 776:01, 780:01, 781:01, 782:01, 783:01, 791:01, 799:01, 805:01, 809:01, 816:01, 817:01, 818:01, 819:01, 823:01, 827:01, 832:01, 836:01, 841:01, 843:01, 845:01, 857:01, 858:01, 861:01, 863:01, 864:01, 881:01, 884:01, 885:01, 886:01, 887:01, 889:01, 890:01, 891:01, 892:01, 897:01, 898:01, 900:01, 902:01, 903:01, 918:01, 927:01, 933:01, 936:01, 940:01, 942:01, 943:01, 954:01, 955:01, 958:01, 963:01, 964:01, 967:01, 968:01, 973:01, 975:01, 981:01, 1005:01, 1006:01, 1007:01, 1013:01, 1020:01, 1025:01, 1028:01, 1031:01, 1035:01, 1036:01, 1037:01, 1039:01, 1051:01, 1053:01, 1055:01, 1056:01, 1059:01, 1072:01, 1075:01, 1077:01, 1082:01, 1083:01, 1085:01, 1089:01, 1092:01, 1094:01, 1102:01, 1106:01, 1107:01, 1110:01, 1115:01, 1124:01, 1126:01, 1136:01, 1140:01, 1142:01, 1150:01, 1153:01, 1159:01, 1160:01, 1163:01, 1165:01, 1168:01, 1171:01, 1175:01, 1176:01, 1179:01, 1194:01, 1197:01, 1198:01, 1200:01, 1201:01, 1210:01, 1219:01, 1224:01, 1227:01, 1230:01, 1235:01, 1236:01, 1239:01, 1243:01, 1247:01, 1248:01, 1253:01, 1261:01, 1266:01, 1267:01, 1270:01, 1276:01, 1280:01, 1281:01, 1283:01, 1286:01, 1290:01, 1296:01, 1298:01, 1307:01, 1312:01, 1315:01, 1319:01, 1320:01, 1323:01, 1324:01, 1326:01, 1331:01, 1335:01, 1344:01, 1346:01, 1347:01, 1352:01, 1360:01, 1363:01, 1368:01, 1369:01, 1371:01, 1372:01, 1380:01, 1381:01, 1383:01, 1386:01, 1393:01, 1402:01, 1404:01, 1405:01, 1408:01, 1410:01, 1417:01, 1419:01, 1424:01, 1425:01, 1445:01, 1456:01, 1460:01, 1461:01, 1468:01, 1469:01, 1470:01, 1479:01, 02:01P, 04:02P, 10:01P, 16:01P, 18:01P, 25:01P, 28:01P, 45:01P, 51:01P, 59:01P, 81:01P, 137:01P, 184:01P, 1371:01P
55EAE	02:02, 05:01, 19:01, 21:01, 22:01, 24:01, 30:01, 36:01, 38:01, 47:01, 54:01, 97:01, 100:01, 106:01, 114:01, 135:01, 139:01, 140:01, 170:01, 171:01, 223:01, 233:01, 284:01, 291:01, 300:01, 301:01, 302:01, 317:01, 330:01, 337:01, 358:01, 390:01, 395:01, 400:01, 406:01, 408:01, 473:01, 495:01, 496:01, 527:01, 533:01, 535:01, 547:01, 550:01, 558:01, 573:01, 587:01, 588:01, 589:01, 590:01, 611:01, 619:01, 638:01, 746:01, 697:01, 715:01, 717:01, 718:01, 720:01, 721:01, 729:01, 744:01,

If this Candidate Unacceptable Epitope is reported:	The following HLA values are considered equivalent to the reported unacceptable epitope:
	847:01, 764:01, 766:01, 778:01, 779:01, 785:01, 790:01, 798:01, 802:01, 962:01, 848:01, 851:01, 860:01, 923:01, 928:01, 929:01, 951:01, 961:01, 1026:01, 965:01, 971:01, 980:01, 982:01, 1008:01, 1015:01, 1018:01, 1019:01, 1143:01, 1061:01, 1095:01, 1099:01, 1101:01, 1117:01, 1118:01, 1119:01, 1120:01, 1209:01, 1156:01, 1172:01, 1180:01, 1186:01, 1188:01, 1189:01, 1190:01, 1199:01, 1289:01, 1213:01, 1229:01, 1240:01, 1255:01, 1257:01, 1272:01, 1273:01, 1282:01, 1293:01, 1302:01, 1318:01, 1349:01, 1376:01, 1400:01, 1403:01, 1428:01, 1437:01, 1438:01, 1457:01, 1462:01, 1473:01, 1477:01, 1481:01, 1483:01, 02:02P, 05:01P, 19:01P, 21:01P, 22:01P, 38:01P, 100:01P, 233:01P
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If this Candidate Unacceptable Epitope is reported:	The following HLA values are considered equivalent to the reported unacceptable epitope:
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Policy 5: Organ Offers, Acceptance, and Verification

5.1 Minimum Acceptance Criteria

5.1.A Kidney Minimum Acceptance Criteria

Kidney transplant programs must report to the OPTN annually minimum kidney acceptance criteria for offers for deceased donor kidneys more than 250 nautical miles away from the transplant program. The kidney minimum acceptance criteria will not apply to imported 0-ABDR mismatch offers or offers to candidates with a CPRA of 99% or above.

5.1.B Minimum Acceptance Criteria for Other Transplant Programs

All other transplant hospitals may report minimum organ-specific acceptance criteria to the OPTN, including multi-organ combinations.

5.2 Maximum Mismatched Antigens

A transplant program may also specify the maximum number of mismatched antigens it will accept and any unacceptable antigens for any of its candidates. If a transplant program specifies these mismatched antigens, the OPTN will only offer organs from deceased donors with mismatched antigens equal to or less than the maximum specified. This policy does not apply to VCA transplants.

5.3 Additional Acceptance and Screening Criteria

5.3.A Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA)

In order to list an unacceptable antigen for a candidate on the waiting list, the transplant program must do at least *one* of the following:

1. Define the criteria for unacceptable antigens that are considered as contraindications for transplant. This may include clarification of unacceptable antigens based on solid phase testing, consideration of prior donor antigens or non-self antigens involved in pregnancies, prior blood transfusion, and unexpected positive crossmatches.
2. Base unacceptable antigens on laboratory detection of human leukocyte antigen (HLA) specific antibodies using at least one solid phase immunoassay with purified HLA molecules.

Transplant programs may establish criteria for additional unacceptable antigens including, but not limited to, multiple unexpected positive crossmatches.

5.3.B Infectious Disease Screening Criteria

A transplant hospital may specify whether a candidate is willing to accept an organ from a donor known to have certain infectious diseases, according to *Table 5-1* below:

Table 5-1: Donor Infectious Disease Screening Options

If the donor tests positive for:	Then candidates may choose not to receive offers on the following match runs:
Cytomegalovirus (CMV)	Intestine
Hepatitis B core antibody (HBcAb)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, VCA
Hepatitis B Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, VCA
Hepatitis C (HCV) Antibody	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, VCA
Hepatitis C Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, VCA
Human Immunodeficiency Virus (HIV); Organs from donors with HIV may only be recovered and transplanted according to the requirements in *Policy 15.7: Recovery and Transplantation of Organs from Donors with HIV*	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, VCA

5.3.C Informed Consent for Kidneys Based on KDPI Greater than 85%

Prior to receiving an offer for a kidney with a Kidney Donor Profile Index (KDPI) score greater than 85%, transplant programs must obtain written, informed consent from each kidney candidate willing to receive offers for kidneys in this category. This requirement also applies to multi-organ offers that include a kidney; however, this informed consent may be obtained any time prior to transplant.

5.3.D Liver Acceptance Criteria

The responsible transplant surgeon must determine the acceptable deceased donor weight for each of its liver candidates, and the determined acceptable weight must be reported to the OPTN.

Liver transplant programs may also specify additional liver acceptance criteria, including *any* of the following:

1. The maximum number of mismatched antigens it will accept for any of its liver candidates
2. Minimal acceptance criteria for livers
3. Acceptance criteria for expedited offers as outlined in OPTN *Policy 9.10.A: Expedited Liver Placement Acceptance Criteria*
4. If a blood type O candidate will accept a liver from a deceased donor with blood type A, non-A_1
5. For status 1A or 1B candidates, if they will accept a liver from a deceased donor with any blood type
6. If a candidate with a Model for End-Stage Liver Disease (MELD) or Pediatric End Stage Liver Disease (PELD) score of at least 30 will accept a liver from a deceased donor with any blood type
7. If a candidate will accept a liver for other methods of hepatic support
8. If a candidate is willing to accept a segmental graft
9. If a candidate living with HIV is willing to accept a liver from a donor with HIV

5.3.E Pediatric Heart Acceptance Criteria to Receive Intended Incompatible Blood Type Hearts

A transplant hospital may specify whether a candidate registered before 18 years of age is willing to accept a heart or heart-lungs from an intended incompatible blood type deceased donor.

5.3.F Pancreas Candidates after Kidney Transplant Acceptance Criteria

When listing a candidate for a pancreas after a kidney transplant, the transplant program may enter the candidate's prior deceased or living kidney donor's antigens, which will then be considered self antigens in pancreas match runs. If a candidate's prior kidney donor's antigens are entered, the pancreas match run will take into account the candidate's antigens and all of the kidney donor's mismatched antigens that are reported to the OPTN.

Antigens that are common to a candidate's prior deceased or living kidney donor and a subsequent deceased pancreas donor are considered as matches and the candidate will appear on the match run for all deceased pancreas donors who meet these mismatch criteria. Use of these modified mismatch criteria is optional.

5.3.G Dual and En Bloc Kidney Acceptance Criteria

In order for a kidney candidate to receive offers of both kidneys from a single deceased donor, a transplant hospital must specify to the OPTN that the candidate is willing to accept these kidneys.

5.3.H Kidney Offer Filters

The OPTN generates model-identified offer filters for all kidney transplant programs based off of a program's transplantation behavior within the most recently available 365 days of data. New model-identified filters will be generated and enabled for each transplant program every six months. A model-identified offer filter is generated for a program if all of the following criteria are met:

- The program declined all kidney offers on at least 20 donors that met the filter criteria,
- The program transplanted 0 donors that met the filter criteria, and
- The kidneys that meet the filter criteria were transplanted elsewhere

All model-identified offer filters will automatically not apply to candidates with any of the following criteria at the time of the match run:

- Greater than 90% CPRA,
- 0-ABDR mismatch,
- in medically urgent status, or
- less than 18 years old

Model-identified offer filters will be applied to all adult kidney transplant programs. Pediatric alone programs may manually apply model-identified filters.

All programs may remove their model-identified filters or modify automatic candidate exclusion criteria of their model-identified filters. Any program may create their own program-identified filters.

Model-identified and program-identified offer filters will not be applied to kidney match runs from a donor with HIV.

5.4 Organ Offers

5.4.A Nondiscrimination in Organ Allocation

A candidate's citizenship or residency status in the United States must not be considered when allocating deceased donor organs to candidates for transplantation. Allocation of deceased donor organs must not be influenced positively or negatively by political influence, national origin, ethnicity, race, sex, religion, or financial status.

5.4.B Order of Allocation

The process to allocate deceased donor organs occurs with these steps:

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.

3. OPOs must first offer organs to potential transplant recipients (PTRs) in the order that the PTRs appear on a match run.
4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update candidates' data with the OPTN. The host OPO must re-execute the match run to allocate the organ.
5. Extra vessels allocated with an organ but not required for its transplant can be shared according to OPTN *Policy 16.6.A: Extra Vessels Use and Sharing*.
6. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all PTRs on the match run. Members must submit the *Organ Export Verification Form* to the OPTN prior to exporting deceased donor organs.

5.4.C Liver Offers

The host OPO must make the initial liver offer using only a match run that is less than eight hours old. The host OPO may only re-execute the match run for use in allocation sooner than eight hours if *one* of the following occurs:

- A previously accepted liver is later refused because there is a change in specific medical information related to the deceased liver donor
- The deceased donor liver has not been allocated within two hours of procurement
- New donor information is received that would screen any potential recipient from appearing on the match run due to donor acceptance criteria according to OPTN *Policy 5.5: Re-Execution of the Match Run Due to New Information*

5.4.D Backup Organ Offers

OPOs may make backup offers for all organs. Transplant programs must treat backup offers the same as actual organ offers and must respond within one hour of receiving the required deceased donor information for an organ. If a transplant program refuses to consider or does not respond to a backup offer, the offer will be considered refused.

If a transplant program accepts a backup offer, it may later refuse to accept the organ based on medical or logistical criteria. Transplant programs must be promptly notified of any change in deceased donor status or organ availability.

5.4.E Allocation to Candidates Not on the Match Run

When a candidate does not appear on at least one of the deceased donor's match runs for at least one organ type, the transplant hospital must document the reason the candidate does not appear and ensure that the organ is safe and appropriate for the candidate. Acceptable reasons for allocation to the candidate may include, but are not limited to, directed donations or to prevent organ waste.

In such an event, the transplant hospital must document *all* of the following:

1. The reason for transplanting an organ into a candidate who did not appear on the match run
2. The reason the candidate did not appear on the match run

3. Whether the transplant hospital is willing to accept a kidney from a deceased donor with a KDPI score greater than 85% or from a donation after circulatory death (DCD) donor, if applicable
4. Prior to transplant, the transplant hospital must verify the medical suitability between the deceased donor organ and recipient in at least, but not limited to, *all* the following areas according to organ type:

    - Blood type
    - Blood subtype, when used for allocation
    - Donor HLA and candidate's unacceptable antigens
    - Donor height
    - Donor weight
    - Infectious disease test results
    - For deceased donors with HIV, the OPO and transplant program must also do *both* of the following:

        a. Verify that the potential recipient is living with HIV and willing to accept an organ from a donor with HIV
        b. Meet the requirements in OPTN *Policy 15.7: Recovery and Transplantation of Organs from Donors with HIV*

The transplant hospital must maintain all related documentation.

5.4.F Local Conflicts

If any member believes there is an inequity or has a conflict with an OPO policy regarding the allocation of organs that cannot be resolved, the member may submit the issue to the appropriate organ-specific committee and Board of Directors for review and a final decision.

5.4.G Open Variance for Expedited Placement

This variance allows participating members to allocate organs in a manner consistent with any expedited placement protocol approved by the Executive Committee. This variance supersedes OPTN *Policies 5.4.B: Order of Allocation*, *5.6.B: Time Limit for Review and Acceptance of Organ Offers for all participating members*, and *5.9: Released Organs*.

The Executive Committee will approve protocols for expedited placement of organs. Each protocol must include 1) criteria for organs eligible for expedited placement; 2) criteria for candidates eligible to receive expedited placement offers; 3) conditions for the use of expedited placement; and 4) OPO and transplant hospital responsibilities.

Approved expedited placement protocols will be made available to the public. Protocols can last no longer than six months unless amended by the Executive Committee.

This variance will be monitored for the following metrics:

- For kidney and liver transplants, Percent of weekly transplants that went to pediatric candidates among the participating members compared to the median percent of

weekly transplants that went to pediatric candidates among the participating members for the last six months.
- Percent of weekly transplants that went to female candidates among the participating members compared to the median percent of weekly transplants that went to female candidates among the participating members for the last six months.
- Percent of weekly transplants that went to non-white ethnicity candidates among the participating members compared to the median percent of weekly transplants that went to non-white ethnicity candidates among the participating members for the last six months.

Expedited placement protocols for a given organ will expire if any of the below respective organ specific conditions occur for any of the above monitoring metrics:

- One or more points below the 3-sigma limits; however, if the average sample size over a six month period is less than ten this rule does not apply.
- Two out of three successive points below a 2-sigma limit; however, if the average sample size over a six month period is less than ten this rule will not apply.
- Four out of five successive points below a 1-sigma limit.
- A run of eight successive points below the center line.

Each participating member must report to the OPTN expedited placements with the date, time, and match run when they initiate an expedited placement protocol. Participating members must meet monthly to review the results of this variance.

This variance will expire on December 31, 2025.

5.5 Re-Execution of the Match Run Due to New Information

5.5.A (*Reserved*)

5.5.B Host OPO and Transplant Hospital Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results

If a host OPO executes a match run with negative or pending results for any of the infectious diseases listed in *Table 5-1: Donor Infectious Disease Screening Options* and subsequently receives a positive result for any of these tests, then it must report the updated information to the OPTN and do the following:

1. When a deceased donor organ has *not* been accepted for a potential transplant recipient, then the OPO must do *all* of the following for each organ being allocated:
    a. Stop allocation on the original match run for this donor
    b. Re-execute the match run according to the infectious disease screening options as follows:
        i. A new positive Cytomegalovirus (CMV) result will apply to re-execution of the intestine match run

ii. A new positive hepatitis B (HBcAb or HBV NAT) or hepatitis C (HCV Ab or HCV NAT) result will apply to re-execution of *all* organ types

c. Allocate the organ using this updated match run

2. When a deceased donor organ has already been accepted for a potential transplant recipient, the host OPO must do *all* of the following for each organ being allocated:

   a. Report this new infectious disease test result to the first transplant hospital on the match run that accepted the organ as soon as possible, but within one hour, of receipt of the new test result
   b. Re-execute the match run for use as follows:
      i. For re-allocation of the organ if the offer to the primary potential transplant recipient is declined after receipt of the positive infectious disease test
      ii. For back-up organ offers based upon the new positive test result

When the transplant hospital is notified by the host OPO of these new positive infectious disease results, it must notify the host OPO whether the organ will be accepted or declined, within one hour of receipt of the new test result.

5.5.C OPO Requirements for Positive HIV Test Results

If a donor is found to have a positive test result for HIV after any match run has been executed, the host OPO must report the updated information on the donor with HIV to the OPTN and do *all* of the following for each organ being allocated:

1. Stop allocation on the original match run for this donor
2. Re-execute match runs in order to include *only* kidney, liver, or liver-kidney candidates living with HIV who are willing to accept organs from donors with HIV, and on-kidney or non-liver candidates living with HIV who are participating in an institutional review board (IRB) approved research protocol that meets the requirements in the National Institutes of Health (NIH) Final Notice regarding the recovery and transplantation of organs from donors with HIV and the requirements outlined in *Policy 15.7.D: Open Variance for the Recovery and Transplantation of Non-Kidney and Non-Liver Organs from Donors with HIV*.
3. Withdraw any pending offers to candidates who are not living with HIV and willing to accept an organ from a donor with HIV.
4. Withdraw any pending offers to non-kidney and non-liver candidates who are not also participating in an IRB- approved research protocol that meets the requirements in the NIH Final Notice and the requirements outlined in *Policy 15.7.D: Open Variance for the Recovery and Transplantation of Non-Kidney and Non-Liver Organs from Donors with HIV*
5. Continue allocating organs using the re-executed match run. Only recover and send extra vessels from this donor with an organ allocated from this donor.

5.6 Receiving and Accepting Organ Offers

5.6.A Receiving and Reviewing Organ Offers

Transplant hospitals must view organ offers and respond to these offers through the match system.

The transplanting surgeon at the receiving transplant hospital is responsible for ensuring the medical suitability of organs offered for transplant to potential recipients, including whether deceased donor and candidate blood types (and donor subtype, when used for allocation) are compatible or intended incompatible.

5.6.B Time Limit for Review and Acceptance of Organ Offers

This policy does not apply to expedited liver offers as outlined in OPTN *Policy 9.10.B: Expedited Liver Offers.*

A transplant hospital has a total of one hour after receiving the initial organ offer notification to access the deceased donor information and submit a provisional yes or an organ offer refusal.

Once the host OPO has provided all the required deceased donor information according to OPTN *Policy 2.11: Required Deceased Donor Information*, with the exception of organ anatomy and recovery information, the transplant hospital for the initial primary potential transplant recipient must respond to the host OPO within one hour with *either* of the following:

- An organ offer acceptance
- An organ offer refusal

All other transplant hospitals who have entered a provisional yes must respond to the host OPO within 30 minutes of receiving notification that their offer is for the primary potential transplant recipient with *either* of the following:

- An organ offer acceptance
- An organ offer refusal

The transplant hospital must respond as required by these timeframes or it is permissible for the host OPO to offer the organ to the transplant hospital for the candidate that appears next on the match run.

5.6.C Organ Offer Acceptance Limit

For any one candidate, the transplant hospital can only have one organ offer acceptance for each organ type. The host OPO must immediately report transplant hospital organ offer acceptances to the OPTN.

5.6.D Effect of Acceptance

When a transplant hospital accepts an OPO's organ offer without conditions, this acceptance binds the transplant hospital and OPO unless they mutually agree on an alternative allocation of the organ.

If an organ has been accepted by a transplant program for a primary potential transplant recipient, the organ is not required to be offered according to *Policy 5.10: Allocation of Multi-Organ Combinations*.

5.7 Organ Check-In

Transplant hospitals must develop and comply with a written protocol to perform organ check-ins as required below.

The transplant hospital must complete an organ check-in any time an organ is recovered outside the facility where the transplant will take place. The organ check-in must be completed upon arrival at the transplant hospital prior to opening the organ's external transport container.

The transplant hospital must use the OPTN external organ label to confirm that the label contains the expected:

1. Donor ID
2. Organ type and laterality (if applicable)

Assistance using an OPTN-approved electronic method is permitted. If the transplant hospital determines that the donor ID, organ type or laterality label information conflicts with the expected information, then the transplant hospital must notify the host OPO as soon as possible, but within one hour, of the determination.

The transplant hospital must document that the organ check-in was completed.

5.8 Pre-Transplant Verification

Transplant hospitals must develop and comply with a written protocol to perform pre-transplant verifications as required below.

5.8.A Pre-Transplant Verification Prior to Organ Receipt

If the recipient surgery will begin prior to organ receipt in the operating room, the transplant hospital must conduct a pre-transplant verification that meets *all* of the following requirements:

1. The intended recipient must be present in the operating room
2. The verification must occur *either*:
   a. Prior to induction of general anesthesia
   b. Prior to incision if the patient has been receiving continuous sedation prior to arrival in the operating room

3. Transplant hospitals must use at least one of the acceptable sources during the pre-transplant verification prior to organ receipt to verify all of the following information according to *Table 5-2* below. Transplant hospitals may use the OPTN organ tracking system to assist with completion of this verification.

Table 5-2: Pre-Transplant Verification Prior to Organ Receipt Requirements

The transplant hospital must verify all of the following information:	Using at least *one* of the following:	By *both* of the following individuals:
Expected donor ID	• OPTN computer system • Recipient medical record	Two licensed health care professionals
Expected organ (and lung laterality if applicable)	• OPTN computer system • Recipient medical record	Two licensed health care professionals
Expected donor blood type and subtype (if used for allocation)	• Donor blood type and subtype source documents • OPTN computer system	Two licensed health care professionals
Recipient unique identifier	• Recipient identification band	Two licensed health care professionals
Recipient blood type	• OPTN computer system • Recipient blood type and subtype source documents • Recipient medical record	Two licensed health care professionals
Expected donor and recipient are blood type compatible (or intended incompatible).	• OPTN computer system • Recipient medical record • Attestation following verification of donor and recipient blood types	Two licensed health care professionals
For kidneys and livers from donors with HIV, that the recipient is living with HIV and willing to accept an organ from a donor with HIV	• OPTN computer system • Recipient medical record • Attestation following verification of HIV status of donor and candidate	1. Transplant surgeon 2. Licensed health care professional

If a pre-transplant verification was conducted prior to organ receipt, the transplant hospital must document that the verification was completed according to the hospital's protocol and the above requirements.

5.8.B Pre-Transplant Verification Upon Organ Receipt

At the time of organ receipt in the operating room, the transplant hospital must conduct a pre-transplant verification with *all* the following requirements:

1. The intended recipient must be present in the operating room
2. The verification must occur after the organ arrives in the operating room, but prior to

anastomosis of the first organ

3. Transplant hospitals must use at least one of the acceptable sources during the pre-transplant verification upon organ receipt to verify all of the following information according to *Table 5-3* below. Transplant hospitals may use the OPTN organ tracking system to assist with completion of this verification.

Table 5-3: Pre-Transplant Verification Upon Organ Receipt Requirements

The transplant hospital must verify all of the following information:	Using at least *one* of the following:	By *both* of the following individuals:
Donor ID	• External and internal organ package labels • Documentation with organ	Transplant surgeon Licensed health care professional
Organ (and laterality if applicable)	• Organ received	1. Transplant surgeon 2. Licensed health care professional
Donor blood type and subtype (if used for allocation)	• Donor blood type and subtype source documents	1. Transplant surgeon 2. Licensed health care professional
Recipient unique identifier	• Recipient identification band	1. Transplant surgeon 2. Licensed health care professional
Recipient blood type	• Recipient blood type source documents • Recipient medical record	1. Transplant surgeon 2. Licensed health care professional
Donor and recipient are blood type compatible (or intended incompatible)	• OPTN computer system • Recipient medical record • Attestation following verification of donor and recipient blood types	1. Transplant surgeon 2. Licensed health care professional
Correct donor organ has been identified for the correct recipient	• Recipient medical record • OPTN computer system • Attestation following verification of donor ID, organ, and recipient unique identifier	1. Transplant surgeon 2. Licensed health care professional
For kidneys and livers from donors with HIV, that the recipient is living with HIV and willing to accept an organ from a donor with HIV	• OPTN computer system • Recipient medical record • Attestation following verification of HIV status of donor and candidate	1. Transplant surgeon 2. Licensed health care professional

The transplant hospital must document that the pre-transplant verification upon organ receipt

was completed according to the hospital's protocol and the above requirements.

5.8.C Additional Pre-Transplant Verification Requirements for Extra Vessels

If *any* of the following occurs:

- Deceased donor extra vessels recovered with an organ will be used in the transplantation of a different organ
- Extra vessels will be used in the modification of a transplanted organ

Then, prior to transplant of the extra vessels, transplant hospitals must complete *all* of the following:

1. Meet the requirements according to OPTN *Policy 5.8: Pre-Transplant Verification*
2. Verify the extra vessels are within 14 days of the recovery date
3. Verify the extra vessels donor's infectious disease testing results for HIV, hepatitis B (HBV), and hepatitis C (HCV)
4. Document and maintain these verifications in the recipient medical record

5.9 Released Organs

The transplant surgeon or physician responsible for the care of a candidate will make the final decision whether to transplant the organ.

The transplant program must transplant all accepted, deceased donor organs into the original intended recipient or release the deceased donor organs back to and immediately notify the host OPO or the OPTN for further distribution. If a transplant program released an organ, it must explain to the OPTN the reason for refusing the organ for that candidate. The host OPO or OPTN must then allocate the organ to other candidates according to the organ-specific policies. The host OPO may contact the OPTN for assistance allocating the organs. The host OPO may delegate the responsibility to the OPO serving the candidate transplant programs's DSA, except in the cases of released kidneys, pancreata, and islets.

If extra vessels are not used for the recipient, then the transplant hospital may use, share, or store extra vessels, according to OPTN *Policy 16: Organ and Extra Vessels Packaging, Labeling, Shipping, and Storage.*

5.10 Allocation of Multi-Organ Combinations

5.10.A Allocation of Heart-Lungs

Heart-lung combinations are allocated according to OPTN *Policy 6.6.F: Allocation of Heart-Lungs*.

5.10.B Allocation of Liver-Kidneys

Liver-kidney combinations are allocated according to OPTN *Policy 9.9: Liver-Kidney Allocation*.

5.10.C Allocation of Kidney-Pancreas

Kidney-pancreas combinations are allocated according to OPTN *Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets.*

5.10.D Allocation of Liver-Intestines

Liver-intestine combinations are allocated according to OPTN *Policy 9: Allocation of Livers and Liver-Intestines.*

5.10.E: Allocation of Heart-Kidneys

When an OPO is offering a heart, and a kidney is also available from the same deceased donor, then the OPO must offer the kidney to a potential transplant recipient (PTR) who is registered for a heart and a kidney at the same transplant hospital, and who meets either of the following criteria:

- PTR is registered at a transplant hospital at or within 500 NM of the donor hospital and is any active pediatric status, or
- PTR is registered at a transplant hospital at or within 500 NM of the donor hospital and heart adult status 1, 2, 3, 4, or 5, and meets the eligibility criteria established in *Table 5-4: Medical Eligibility Criteria for Heart-Kidney Allocation*

If a host OPO is offering a kidney and a heart from the same deceased donor, then before allocating the kidney to kidney-alone candidates, the host OPO must offer the kidney with the heart to candidates who meet either of the eligibility criteria described in OPTN Policy 5.10.E.

Table 5-4: Medical Eligibility Criteria for Heart-Kidney Allocation

If the candidate's transplant nephrologist confirms a diagnosis of:	Then the transplant program must report to the OPTN and document in the candidate's medical record:
Chronic kidney disease (CKD) with a measured or estimated glomerular filtration rate (GFR) less than or equal to 60 mL/min for greater than 90 consecutive days	At least *one* of the following: • That the candidate has begun regularly administered dialysis as an end-stage renal disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting. • At the time of registration on the kidney waiting list, that the candidate's most recent measured or estimated creatinine clearance (CrCl) or GFR is less than or equal to 30 mL/min. • On a date after registration on the kidney waiting list, that the candidate's measured or estimated CrCl or GFR is less than or equal to 30 mL/min.

If the candidate's transplant nephrologist confirms a diagnosis of:	Then the transplant program must report to the OPTN and document in the candidate's medical record:
Sustained acute kidney injury	At least one of the following, or a combination of both of the following, for the last 6 weeks: • That the candidate has been on dialysis at least once every 7 days. • That the candidate has a measured or estimated CrCl or GFR less than or equal to 25 mL/min at least once every 7 days. If the candidate's eligibility is not confirmed at least once every seven days for the last 6 weeks, the candidate is not eligible to receive a heart and a kidney from the same donor.

5.10.F: Allocation of Lung-Kidneys

When an OPO is offering a lung, and a kidney is also available from the same deceased donor, then the OPO must offer the kidney to a potential transplant recipient (PTR) who is registered for a lung and a kidney at the same transplant hospital, and who meets either of the following criteria:

- PTR was less than 18 years old when registered on the lung waiting list, or
- PTR has a Lung Composite Allocation Score of 25[1] or greater, and meets eligibility according to *Table 5-5: Medical Eligibility Criteria for Lung-Kidney Allocation*

If a host OPO is offering a kidney and a lung from the same deceased donor, then before allocating the kidney to kidney-alone candidates, the host OPO must offer the kidney with the lung to candidates who meet either of the eligibility criteria described in OPTN Policy 5.10.F.

[1] When this proposal was approved by the OPTN Board of Directors on June 27, 2022, this policy required a Lung Composite Allocation Score of 28 or greater. A subsequent proposal approved by the OPTN Board of Directors on December 5, 2022, changed the requirement to a Lung Composite Allocation Score of 25 or greater. See: https://optn.transplant.hrsa.gov/media/ai4npr5x/policy-notice_mot-for-cd_lung.pdf.

Table 5-5: Medical Eligibility Criteria for Lung-Kidney Allocation

If the candidate's transplant nephrologist confirms a diagnosis of:	Then the transplant program must report to the OPTN and document in the candidate's medical record:
Chronic kidney disease (CKD) with a measured or estimated glomerular filtration rate (GFR) less than or equal to 60 mL/min for greater than 90 consecutive days	At least *one* of the following: • That the candidate has begun regularly administered dialysis as an end-stage renal disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting. • At the time of registration on the kidney waiting list, that the candidate's most recent measured or estimated creatinine clearance (CrCl) or GFR is less than or equal to 30 mL/min. • On a date after registration on the kidney waiting list, that the candidate's measured or estimated CrCl or GFR is less than or equal to 30 mL/min.
Sustained acute kidney injury	At least *one* of the following, or a combination of *both* of the following, for the last 6 weeks: • That the candidate has been on dialysis at least once every 7 days. • That the candidate has a measured or estimated CrCl or GFR less than or equal to 25 mL/min at least once every 7 days. If the candidate's eligibility is not confirmed at least once every seven days for the last 6 weeks, the candidate is not eligible to receive a lung and a kidney from the same donor.

5.10.G Allocation of Heart-Liver and Lung-Liver

When an OPO is offering a heart or lung, and a liver is also available from the same deceased donor, PTRs who meet the criteria in *Table 5-6: When Offering a Heart or Lung and Second Organ Is a Liver* must be offered the liver. When an OPO is offering a heart or lung and two PTRs meet the criteria in *Table 5-6*, the OPO has the discretion to offer the liver to either PTR.

Table 5-6: When Offering a Heart or Lung and Second Organ Is a Liver

If an OPO is offering a heart or lung, and a PTR is also registered for a liver:	The OPO must offer the liver if the PTR meets the following criteria:
Heart	• Registered at a transplant hospital at or within 500 NM of the donor hospital • Heart Adult Status 1, 2, 3 or any active pediatric status
Lung	Has a Lung Composite Allocation Score of 25[2] or greater

It is permissible for the OPO to offer the liver to other PTRs who do not meet the criteria in OPTN Policy 5.10.G.

[2] When this proposal was approved by the OPTN Board of Directors on June 27, 2022, this policy required a Lung Composite Allocation Score of 28 or greater. A subsequent proposal approved by the OPTN Board of Directors on December 5, 2022, changed the requirement to a Lung Composite Allocation Score of 25 or greater. See: https://optn.transplant.hrsa.gov/media/ai4npr5x/policy-notice_mot-for-cd_lung.pdf

Policy 6: Allocation of Hearts and Heart-Lungs

6.1 Adult Status Assignments and Update Requirements

Each adult heart transplant candidate at least 18 years old at the time of registration is assigned a status that reflects the candidate's medical urgency for transplant. The candidate's transplant program must submit a heart status justification form to the OPTN to assign a candidate the status for which the candidate qualifies. Transplant programs must assign candidates on the waiting list that are not currently suitable for transplant to the inactive status.

If a candidate's transplant program does not submit a heart status justification form or the status expires and the transplant program does not submit a new heart status justification form, the candidate is assigned to status 6, or status 5 if the candidate is registered for another organ.

When registering a candidate, the transplant program must submit to the OPTN *all* of the following clinical data:

- Hemodynamic assessment results
- Functional status or exercise testing results
- Heart failure severity or end organ function indicators
- Heart failure therapies
- Mechanical support
- Sensitization risk, including CPRA, peak PRA, and number of prior sternotomies
- Current diagnosis

These clinical data must be submitted every time the transplant program submits a justification form unless a test needed to obtain the data has not been performed since the last justification form was submitted. The transplant program must maintain source documentation for all laboratory values reported to the OPTN.

6.1.A Adult Heart Status 1 Requirements

To assign a candidate adult status 1, the candidate's transplant program must submit a *Heart Status 1 Justification Form* to the OPTN. A candidate is not assigned adult status 1 until this form is submitted.

If the candidate is at least 18 years old at the time of registration, then the candidate's transplant program may assign the candidate adult status 1 if the candidate has at least *one* of the following conditions:

- Is supported by veno-arterial extracorporeal membrane oxygenation (VA ECMO), according to OPTN *Policy 6.1.A.i* below.
- Is supported by a non-dischargeable, surgically implanted, non-endovascular biventricular support device according to *Policy 6.1.A.ii* below.
- Is supported by a mechanical circulatory support device (MCSD) and has a life-threatening ventricular arrhythmia according to *Policy 6.1.A.iii* below.

6.1.A.i Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)

A candidate's transplant program may assign a candidate to adult status 1 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and is supported by VA ECMO for cardiogenic shock as evidenced by *either* of the following:

- Within 7 days prior to VA ECMO support, *all* of the following are true within one 24 hour period:
  a. Systolic blood pressure less than 90 mmHg
  b. Cardiac index less than 1.8 L/min/m^2 if the candidate is not supported by inotropes or less than 2.0 L/min/m^2 if the candidate is supported by at least one inotrope
  c. Pulmonary capillary wedge pressure greater than 15 mmHg
- If hemodynamic measurements could not be obtained within 7 days prior to VA ECMO support, at least *one* of the following is true within 24 hours prior to VA ECMO support:
  - CPR was performed on the candidate
  - Systolic blood pressure less than 70 mmHg
  - Arterial lactate greater than 4 mmol/L
  - Aspartate transaminase (AST) or alanine transaminase (ALT) greater than 1,000 U/L

Candidates that meet either of the criteria above will remain in this status for up to 7 days from submission of the *Heart Status 1 Justification Form*.

Every 7 days, the transplant program may apply to the regional review board (RRB) to extend the candidate at this status if the candidate remains hospitalized and is supported by VA ECMO. The transplant program must provide to the RRB objective evidence of *both* of the following:

1. The candidate demonstrated a contraindication to being supported by a durable device
2. Within 48 hours prior to the status expiring, the transplant program failed at weaning the candidate from VA ECMO as evidenced by at least *one* of the following:
   - Mean arterial pressure (MAP) less than 60 mmHg

- Cardiac index less than 2.0 L/min/m^2
- Pulmonary capillary wedge pressure greater than 15 mmHg
- SvO_2 less than 50 percent measured by central venous catheter

The RRB will retrospectively review extension requests. If the candidate is still supported by VA ECMO after 7 days and either the extension request is not granted or the transplant program does not request an extension, then the transplant program may assign the candidate to status 3.

6.1.A.ii Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device

A candidate's transplant program may assign a candidate to adult status 1 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by a surgically implanted, non-endovascular biventricular support device and must remain hospitalized because the device is not FDA-approved for out of hospital use. This status is valid for up to 7 days from submission of *the Heart Status 1 Justification Form*.

A candidate's transplant program may extend the candidate's status every 7 days if the candidate continues to meet the above criteria and the transplant program submits another *Heart Status 1 Justification Form.*

6.1.A.iii Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia

A candidate's transplant program may assign a candidate to adult status 1 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by an MCSD, and is experiencing recurrent or sustained ventricular tachycardia or ventricular fibrillation as evidenced by at least *one* of the following:

- Placement of a biventricular mechanical circulatory support device for the treatment of sustained ventricular arrhythmias
- That the patient was not considered a candidate for other treatment alternatives, such as ablation, by an electrophysiologist, and has experienced three or more episodes of ventricular fibrillation or ventricular tachycardia separated by at least an hour, over the previous 7 days that *both:*
    1. Occurred in the setting of normal serum magnesium and potassium levels
    2. Required electrical cardioversion despite receiving continuous intravenous antiarrhythmic therapies

This status is valid for up to 7 days from submission of *the Heart Status 1 Justification Form*. This status can be extended by the transplant program every 7 days by submission of another *Heart Status 1 Justification Form* if the candidate remains hospitalized on continuous intravenous antiarrhythmic therapy.

After 7 days, if the candidate remains hospitalized and the transplant program does not request an extension, then the transplant program may assign the candidate to status 3.

6.1.B Adult Heart Status 2 Requirements

To assign a candidate adult status 2, the candidate's transplant program must submit a *Heart Status 2 Justification Form* to the OPTN. A candidate is not assigned adult status 2 until this form is submitted.

If the candidate is at least 18 years old at the time of registration then the candidate's transplant program may assign the candidate to adult status 2 if the candidate has at least *one* of the following conditions:

- Is supported by a non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD), according to OPTN *Policy 6.1.B.i* below.
- Is supported by a total artificial heart (TAH), biventricular assist device (BiVAD), right ventricular assist device (RVAD), or ventricular assist device (VAD) for single ventricle patients, according to OPTN *Policy 6.1.B.ii* below.
- Is supported by a mechanical circulatory support device (MCSD) that is malfunctioning, according to OPTN *Policy 6.1.B.iii* below.
- Is supported by a percutaneous endovascular mechanical circulatory support device, according to OPTN *Policy 6.1.B.iv* below.
- Is supported by an intra-aortic balloon pump (IABP), according to OPTN *Policy 6.1.B.v* below.
- Is experiencing recurrent or sustained ventricular tachycardia or ventricular fibrillation according to OPTN *Policy 6.1.B.vi* below.

6.1.B.i Non-Dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD)

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by a surgically implanted, non-endovascular LVAD, and must remain hospitalized because the device is not FDA-approved for out of hospital use.

Candidates that meet the criteria above will remain in this status for up to 14 days from submission of *the Heart Status 2 Justification Form*. Every 14 days, the transplant program may apply to the RRB to extend the candidate's registration if the candidate remains supported by the non-dischargeable surgically implanted, non-endovascular LVAD. The transplant program must provide to the RRB objective evidence of *both* of the following:

1. The candidate demonstrated a contraindication to being supported by a durable device
2. Within 48 hours prior to the status expiring, the transplant program failed at weaning the candidate from the non-dischargeable surgically implanted, non-endovascular LVAD as evidenced by at least *one* of the following:
    - Mean arterial pressure (MAP) less than 60 mmHg
    - Cardiac index less than 2.0 L/min/m^2

- Pulmonary capillary wedge pressure greater than15
- SvO_2 less than 50 percent measured by central venous catheter

The RRB will retrospectively review extension requests. If the candidate is still supported by the non-dischargeable surgically implanted, non-endovascular LVAD after 14 days and either the extension request is not granted or the transplant program does not request an extension, then the transplant program may assign the candidate to status 3.

6.1.B.ii Total Artificial Heart (TAH), BiVAD, Right Ventricular Assist Device (RVAD), or Ventricular Assist Device (VAD) for Single Ventricle Patients

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is supported by *any* of the following:

- A TAH
- An RVAD alone
- A BiVAD
- A VAD, for single ventricle patients only

This status is valid for up to 14 days from submission of *the Heart Status 2 Justification Form*. This status can be extended by the transplant program every 14 days by submission of another *Heart Status 2 Justification Form*.

6.1.B.iii Mechanical Circulatory Support Device (MCSD) with Malfunction

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list and is supported by an MCSD that is experiencing device malfunction as evidenced by *all* of the following:

1. Malfunction of at least one of the components of the MCSD
2. Malfunction cannot be fixed without an entire device replacement
3. Malfunction is currently causing inadequate mechanical circulatory support or places the candidate at imminent risk of device stoppage

This status is valid for up to 14 days from submission of *the Heart Status 2 Justification Form*. This status can be extended by the transplant program every 14 days by submission of another *Heart Status 2 Justification Form*.

6.1.B.iv Percutaneous Endovascular Mechanical Circulatory Support Device

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and is supported by a percutaneous endovascular mechanical circulatory support device without an oxygenator for cardiogenic shock as evidenced by *either* of the following:

- Within 7 days prior to percutaneous endovascular mechanical circulatory support, *both* of the following are true:
    1. *All* of the following hemodynamic measurements were obtained for the candidate within one 24-hour period, and:
        a. Systolic blood pressure of less than 90 mmHg
        b. Cardiac index of less than 2.0 L/min/m^2
        c. Pulmonary capillary wedge pressure of greater than 15 mmHg
    2. The candidate *either*:
        a. Was being supported by inotropic therapy according to either of the following qualifying doses, or
            - A continuous infusion of at least one high-dose intravenous inotrope, or:
                - Dobutamine greater than or equal to 7.5 mcg/kg/min
                - Milrinone greater than or equal to 0.50 mcg/kg/min
                - Epinephrine greater than or equal to 0.02 mcg/kg/min
            - A continuous infusion of at least two intravenous inotropes:
                - Dobutamine greater than or equal to 3 mcg/kg/min
                - Milrinone greater than or equal to 0.25 mcg/kg/min
                - Epinephrine greater than or equal to 0.01 mcg/kg/min
                - Dopamine greater than or equal to 3 mcg/kg/min
        b. Developed ventricular tachycardia lasting at least 30 seconds or required cardioversion, defibrillation, or antitachycardia pacing after inotropic therapy was initiated in an attempt to reach the qualifying doses

- If hemodynamic measurements could not be obtained within 7 days prior to percutaneous endovascular mechanical circulatory support, at least *one* of the following was true within 24 hours prior to percutaneous endovascular mechanical circulatory support:
    - CPR was performed on the candidate
    - Systolic blood pressure less than 70 mmHg
    - Arterial lactate greater than 4 mmol/L
    - Aspartate transaminase (AST) or alanine transaminase (ALT) greater than 1,000 U/L

Candidates that meet the criteria above will remain in this status for up to 14 days from submission of *the Heart Status 2 Justification Form*. Every 14 days, the transplant program may apply to the RRB to extend the candidate's status if the candidate remains supported by the percutaneous endovascular mechanical circulatory support device.

The transplant program must provide to the RRB objective evidence of *both* of the following:

1. The candidate demonstrated a contraindication to being supported by a durable device, and
2. Either
    a. Within 48 hours prior to the status expiring, the transplant program demonstrated a failure to wean the candidate from the percutaneous endovascular mechanical circulatory support device evidenced by *at least one* of the following while being supported by inotropic therapy at a qualifying dose, or:
        - Mean arterial pressure (MAP) less than 60 mmHg
        - Cardiac index less than 2.0 L/min/m^2
        - Pulmonary capillary wedge pressure greater than 15 mmHg
        - SvO_2 less than 50 percent measured by central venous catheter
    b. The candidate had qualified for status 2 after requiring a percutaneous endovascular mechanical circulatory support device due to failure to be supported on inotropes related to ventricular tachycardia lasting at least 30 seconds, or requiring cardioversion, defibrillation, or antitachycardia pacing.

The RRB will retrospectively review extension requests. If the candidate is still supported by the percutaneous endovascular mechanical circulatory support device after 14 days and either the extension request is not granted or the transplant program does not request an extension, then the transplant program may assign the candidate to status 3.

6.1.B.v Intra-Aortic Balloon Pump (IABP)

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and is supported by an IABP for cardiogenic shock as evidenced by *either* of the following:

- Within 7 days prior to IABP support, *both* of the following are true:
    1. *All* of the following hemodynamic measurements were obtained for the candidate within one 24-hour period, and:
        a. Systolic blood pressure of less than 90 mmHg
        b. Cardiac index of less than 2.0 L/min/m^2
        c. Pulmonary capillary wedge pressure of greater than 15 mmHg
    2. The candidate *either*:
        a. Was being supported by inotropic therapy according to either of the following qualifying doses, or
            - A continuous infusion of at least one high-dose intravenous inotrope, or:
                - Dobutamine greater than or equal to 7.5 mcg/kg/min
                - Milrinone greater than or equal to 0.50 mcg/kg/min

        - Epinephrine greater than or equal to 0.02 mcg/kg/min
    - A continuous infusion of at least two intravenous inotropes:
        - Dobutamine greater than or equal to 3 mcg/kg/min
        - Milrinone greater than or equal to 0.25 mcg/kg/min
        - Epinephrine greater than or equal to 0.01 mcg/kg/min
        - Dopamine greater than or equal to 3 mcg/kg/min

    b. Developed ventricular tachycardia lasting at least 30 seconds or required cardioversion, defibrillation, or antitachycardia pacing after inotropic therapy was initiated in an attempt to reach the qualifying doses

- If hemodynamic measurements could not be obtained within 7 days prior to IABP support, at least *one* of the following was true within 24 hours prior to IABP support:
    - CPR was performed on the candidate
    - Systolic blood pressure less than 70 mmHg
    - Arterial lactate greater than 4 mmol/L
    - AST or ALT greater than 1,000 U/L

Candidates that meet the criteria above will remain in this status for up to 14 days from submission of *the Heart Status 2 Justification Form*. Every 14 days, the transplant program may apply to the RRB to extend the candidate's status if the candidate remains supported by the IABP. The transplant program must provide to the RRB objective evidence of *both* of the following:

1. The candidate demonstrated a contraindication to being supported by a durable device, and
2. Either
    a. Within 48 hours prior to the status expiring, the transplant program demonstrated a failure to wean the candidate from the IABP evidenced by *at least one* of the following, while being supported by inotropic therapy at a qualifying dose, or:
        - Mean arterial pressure (MAP) less than 60 mmHg
        - Cardiac index less than 2.0 L/min/m^2
        - Pulmonary capillary wedge pressure greater than 15 mmHg
        - SvO_2 less than 50 percent measured by central venous catheter

    b. The candidate had qualified for status 2 after requiring the IABP due to failure to be supported on inotropes related to ventricular tachycardia lasting at least 30 seconds, or requiring cardioversion, defibrillation, or antitachycardia pacing.

The RRB will retrospectively review extension requests. If the candidate is still supported by the IABP after 14 days and either the extension request is not granted or the transplant program does not request an extension, then the transplant program may assign the candidate to status 3.

6.1.B.vi Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF)

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is not considered a candidate for other treatment alternatives, such as ablation, by an electrophysiologist, and is experiencing recurrent or sustained VT or VF with at least three episodes separated by at least one hour within a period of 14 days. The VT or VF episodes must have *both* of the following:

1. Occurred in the setting of normal serum magnesium and potassium levels
2. Required electrical cardioversion despite receiving intravenous antiarrhythmic therapies

This status is valid for up to 14 days from submission of *the Heart Status 2 Justification Form*. This status can be extended by the transplant program every 14 days by submission of another *Heart Status 2 Justification Form*.

6.1.C Adult Heart Status 3 Requirements

To assign a candidate to adult status 3, the candidate's transplant program must submit a *Heart Status 3 Justification Form* to the OPTN. A candidate is not assigned adult status 3 until this form is submitted.

If the candidate is at least 18 years old at the time of registration, then the candidate's transplant program may assign the candidate adult status 3 if the candidate has at least *one* of the following conditions:

- Is supported by a dischargeable left ventricular assist device and is exercising 30 days of discretionary time, according to OPTN *Policy 6.1.C.i* below.
- Is supported by multiple inotropes or a single high dose inotrope and has hemodynamic monitoring, according to OPTN *Policy 6.1.C.ii* below.
- Is supported by a mechanical circulatory support device (MCSD) with hemolysis, according to OPTN *Policy 6.1.C.iii* below.
- Is supported by an MCSD with pump thrombosis, according to OPTN *Policy 6.1.C.iv* below.
- Is supported by an MCSD and has right heart failure, according to OPTN *Policy 6.1.C.v* below.
- Is supported by an MCSD and has a device infection, according to OPTN *Policy 6.1.C.vi* below.
- Is supported by an MCSD and has bleeding, according to OPTN *Policy 6.1.C.vii* below.
- Is supported by an MCSD and has aortic insufficiency, according to OPTN *Policy 6.1.C.viii* below.
- Is supported by veno-arterial extracorporeal membrane oxygenation (VA ECMO) after 7 days, according to OPTN *Policy 6.1.C.ix* below.

- Is supported by a non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD) after 14 days, according to OPTN *Policy 6.1.C.x* below.
- Is supported by a percutaneous endovascular mechanical circulatory support device after 14 days, according to OPTN *Policy 6.1.C.xi* below.
- Is supported by an intra-aortic balloon pump (IABP) after 14 days, according to OPTN *Policy 6.1.C.xii* below.
- Is supported by a MCSD and has life threatening ventricular arrhythmia after 7 days, according to OPTN *Policy 6.1.C.xiii* below.

6.1.C.i Dischargeable Left Ventricular Assist Device (LVAD) for Discretionary 30 Days

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by a dischargeable LVAD. The OPTN maintains a list of OPTN-approved, qualifying devices.

The candidate may be registered as status 3 for 30 days at any point after being implanted with the dischargeable LVAD and once the attending physician determines the candidate is medically stable. Regardless of whether the candidate has a single transplant program registration or multiple transplant program registrations, the candidate receives a total of 30 days discretionary time for each dischargeable LVAD implanted across all registrations. Each day used by any of the transplant programs counts towards the cumulative 30 days.

The 30 days do not have to be consecutive and if the candidate undergoes a procedure to receive another replacement dischargeable LVAD, then the candidate qualifies for a new term of 30 days. When a candidate receives a replacement device, the 30 day period begins again, and the candidate cannot use any time remaining from the previous period.

6.1.C.ii Multiple Inotropes or a Single High Dose Inotrope and Hemodynamic Monitoring

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is admitted to the hospital that registered the candidate on the waiting list, and within 7 days prior to inotrope administration or while on inotropes meets *all* of the following:

1. Has *one* of the following:
   - Invasive pulmonary artery catheter
   - Daily hemodynamic monitoring to measure cardiac output and left ventricular filling pressures
2. Is in cardiogenic shock, as evidenced by *all* of the following within one 24 hour period:
   a. Systolic blood pressure less than 90 mmHg
   b. Pulmonary Capillary Wedge Pressure greater than 15 mmHg
   c. Cardiac index of *either*:

- Less than 1.8 L/min/m^2 for candidates without inotropic or mechanical support within 7 days prior to inotrope administration
- Less than 2.2 L/min/m^2 for candidates with inotropic or mechanical support

3. Is supported by *one* of the following:
   - A continuous infusion of *at least one* high-dose intravenous inotrope:
     - Dobutamine greater than or equal to 7.5 mcg/kg/min
     - Milrinone greater than or equal to 0.50 mcg/kg/min
     - Epinephrine greater than or equal to 0.02 mcg/kg/min
   - A continuous infusion of *at least two* intravenous inotropes:
     - Dobutamine greater than or equal to 3 mcg/kg/min
     - Milrinone greater than or equal to 0.25 mcg/kg/min
     - Epinephrine greater than or equal to 0.01 mcg/kg/min
     - Dopamine greater than or equal to 3 mcg/kg/min

This status is valid for up to 14 days from submission of *the Heart Status 3 Justification Form*. After the initial 14 days, this status can be extended by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form* if the candidate remains admitted to the hospital that registered the candidate on the waiting list, and the candidate remains supported by ongoing use of a qualifying inotrope therapy and meets *all* of the following:

1. O*ne* of the following hemodynamic monitoring:
    - Invasive pulmonary artery catheter
    - Daily hemodynamic monitoring to measure cardiac output and left ventricular filling pressures
2. Within 48 hours prior to the status expiring, must meet *either* of the following:
    - Cardiac index less than 2.2 L/min/m^2 on the current medical regimen
    - Failed attempt to wean the inotrope support documented by at least *one* of the following:
        - Cardiac index less than 2.2 L/min/m^2 during dose reduction
        - Increase in serum creatinine by 20 percent over the value immediately prior to, and within 24 hours of, inotrope dose reduction
        - Increase in arterial lactate to greater than 2.5 mmol/L
        - SvO_2 less than 50 percent measured by central venous catheter

6.1.C.iii Mechanical Circulatory Support Device (MCSD) with Hemolysis

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD and is not experiencing device malfunction, but is experiencing hemolysis, as evidenced by *both* of the following:

1. Two separate samples collected within 48 hours of each other confirming markers of active hemolysis as evidenced by *at least two* of the following criteria:
    - Blood lactate dehydrogenase (LDH) at least 2.5 times the upper limit of normal at the laboratory reference range
    - Plasma free hemoglobin greater than 20 mg/dL
    - Hemoglobinuria
2. Documentation of at least one attempt to treat the condition using an intravenous anticoagulant, intravenous anti-platelet agent, or thrombolytic, with persistent or recurrent hemolysis

This status is valid for up to 14 days from submission of *the Heart Status 3 Justification Form*. After the initial 14 days, this status can be extended by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form*.

6.1.C.iv Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is admitted to the transplant hospital that registered the candidate on the

waiting list, is supported by MCSD and the transplant program has identified a suspected pump thrombosis in either an implanted LVAD or a discharged paracorporeal device and *both* of the following criteria are met:

- The candidate has one of the following conditions:
    - Transient Ischemic Attack (TIA) lasting less than 24 hours or Reversible Ischemic Neurologic Deficit (RIND) lasting less than 72 hours (as observed by symptoms such as, but not limited to unilateral facial weakness, vision problems, and/or slurred speech), Cerebrovascular Accident (CVA), or a peripheral thromboembolic event in the absence of intracardiac thrombus or significant carotid artery disease,
    - A condition that requires inotropic support and presence of left-sided heart failure not explained by structural heart disease such as Aortic Insufficiency (AI) [as defined *Policy 6.1.C.vii: MCSD with Mucosal Bleeding*], as demonstrated by
        - Pulmonary Capillary Wedge Pressure (PCWP) greater than 15, and
        - Mean Arterial Pressure (MAP) less than 90
    - Abnormal pump parameters, such as significant and persistent increase in pump power and low flow despite good blood pressure control
    - Visually detected thrombus in a paracorporeal ventricular device (VAD)
- The candidate is supported by one of the following treatments in the hospital:
    - Intravenous anticoagulation (e.g. heparin)
    - Intravenous thrombolytics (e.g. tPA)
    - Intravenous antiplatelet therapy (e.g. eptifibatide or tirofiban)

This status is valid for up to 30 days from submission of *the Heart Status 3 Justification Form*.

After the initial 30 days, a candidate's transplant program may extend the candidate's status every 90 days if the candidate continues to meet the above criteria and the transplant program submits another *Heart Status 3 Justification Form*.

6.1.C.v Mechanical Circulatory Support Device (MCSD) with Right Heart Failure

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD and has at least moderate right ventricular malfunction in the absence of left ventricular assist device (LVAD) malfunction, and *both* of the following:

1. Has been treated with at least *one* of the following therapies for at least 14 consecutive days, and requires ongoing treatment with at least *one* of the following therapies:
    - Dobutamine greater than or equal to 5 mcg/kg/min
    - Dopamine greater than or equal to 4 mcg/kg/min
    - Epinephrine greater than or equal to 0.05 mcg/kg/min

- Inhaled nitric oxide
- Intravenous prostacyclin
- Milrinone greater than or equal to 0.35 mcg/kg/min

2. Has, within 7 days prior to initiation of any of the therapies above, pulmonary capillary wedge pressure less than 20 mmHg and central venous pressure greater than 18 mmHg within one 24 hour period.

This status is valid for up to 14 days from submission of *the Heart Status 3 Justification Form*.
After the initial 14 days, a candidate's transplant program may extend the candidate's status every 90 days if the candidate continues to meet the above criteria and the transplant program submits another *Heart Status 3 Justification Form*.

6.1.C.vi Mechanical Circulatory Support Device (MCSD) with Device Infection

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD and is experiencing a pump-related local or systemic infection, with *at least one* of the symptoms according to *Table 6-1: Evidence of Device Infection* below.

Table 6-1: Evidence of Device Infection

If the candidate has evidence of:	Then this status is valid for up to:
Erythema and pain along the driveline, requiring IV antibiotics and *either*: • Positive bacterial or fungal cultures from the driveline exit site within the last 14 days • A culture-positive fluid collection between the driveline exit site and the device	14 days from submission of *the Heart Status 3 Justification Form*.
Debridement of the driveline with positive cultures from sites between the driveline exit site and the device requiring IV antibiotics	14 days from submission of *the Heart Status 3 Justification Form*.
Recurrent debridement	90 days from submission of *the Heart Status 3 Justification Form.*
Positive culture of material from the pump pocket of an implanted device	90 days from submission of *the Heart Status 3 Justification Form*.
Bacteremia treated with antibiotics	42 days from submission of *the Heart Status 3 Justification Form*.
Recurrent bacteremia that recurs from the same organism within four weeks	90 days from submission of *the Heart Status 3 Justification Form*.

If the candidate has evidence of:	Then this status is valid for up to:
of completing antibiotic treatment to which the bacteria is susceptible	

After the initial qualifying time period, a candidate's transplant program may extend the candidate's stay according to the time periods established in Table 6-1: Evidence of Device Infection if the candidate continues to meet the above criteria or the candidate continues to require intravenous (IV) antibiotics, and the transplant program submits another *Heart Status 3 Justification Form*.

6.1.C.vii Mechanical Circulatory Support Device (MCSD) with Mucosal Bleeding

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by an MCSD, has been hospitalized for mucosal bleeding at least two times within the past six months, excluding the candidate's hospitalization for implantation of the MCSD, and meets the requirements according to *Table 6-2: Evidence of Mucosal Bleeding* below:

Table 6-2: Evidence of Mucosal Bleeding

If *all* of the following occurred:	Then this status is valid for *either*
1. The candidate received blood transfusions of at least two units of packed red blood cells per hospitalization during at least two hospitalizations for mucosal bleeding 2. The candidate's international normalized ratio (INR) was less than 3.0 at the time of at least one of the bleeds 3. The candidate's hematocrit upon admission is less than or equal to 0.20 or decreased by 20 percent or more relative to the last measured value at any time during the bleeding episode	• Up to 14 days from submission of *the Heart Status 3 Justification Form*, if the candidate has been hospitalized for mucosal bleeding at least two times within the past six months • Up to 90 days from submission of *the Heart Status 3 Justification Form*, if the candidate has been hospitalized for mucosal bleeding at least three times within the past six months

After the initial qualifying time period, this status can be extended by the transplant program by submission of another *Heart Status 3 Justification Form*.

6.1.C.viii Mechanical Circulatory Support Device (MCSD) with Aortic Insufficiency (AI)

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD and is not exhibiting evidence of device malfunction, but is experiencing AI, with *all* of the following:

1. At least moderate AI by any imaging modality in the setting of the mean arterial pressure (MAP) less than or equal to 80 mmHg
2. Pulmonary capillary wedge pressure greater than 20 mmHg
3. New York Heart Association (NYHA) Class III-IV symptoms

This status is valid for up to 90 days from submission of *the Heart Status 3 Justification Form*. After the initial 90 days, this status can be extended by the transplant program every 90 days by submission of another *Heart Status 3 Justification Form*.

6.1.C.ix VA ECMO after 7 Days

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by VA ECMO, and has already been assigned to status 1 according to OPTN *Policy 6.1.A.i: Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)* for 7 days.

This status is valid for up to 7 days from submission of *the Heart Status 3 Justification Form*. After the initial 7 days, this status can be extended by the transplant program every 7 days by submission of another *Heart Status 3 Justification Form*.

6.1.C.x Non-Dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD) after 14 Days

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by a non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD) and has already been assigned to status 2 according to OPTN *Policy 6.1.B.i: Non-Dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD)* for 14 days.

This status is valid for up to 14 days from submission of the *Heart Status 3 Justification Form*. After the initial 14 days, this status can be extended by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form*.

6.1.C.xi Percutaneous Endovascular Mechanical Circulatory Support Device after 14 Days

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by a percutaneous endovascular mechanical circulatory support device and has already been assigned to status 2 according to OPTN *Policy 6.1.B.iv: Percutaneous Endovascular Mechanical Circulatory Support Device* for 14 days.

This status is valid for up to 14 days from submission of *the Heart Status 3 Justification Form*. After the initial 14 days, this status can be extended by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form*.

6.1.C.xii Intra-Aortic Balloon Pump (IABP) after 14 Days

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by an IABP, and has already been assigned to status 2 according to OPTN *Policy 6.1.B.v: Intra-Aortic Balloon Pump (IABP)* for 14 days.

This status is valid for up to 14 days from submission of *the Heart Status 3 Justification Form*. After the initial 14 days, this status can be extended by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form*.

6.1.C.xiii Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia After 7 Days

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by placement of a biventricular mechanical circulatory support device for the treatment of sustained ventricular arrhythmias or receiving continuous intravenous antiarrhythmic therapy, and has already been assigned to status 1 according to OPTN *Policy 6.1.A.iii: Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia* for 7 days. This status is valid for up to 7 days from the submission of *the Heart Status 3 Justification Form.*

A candidate's transplant program may extend the candidate's status every 7 days if the candidate continues to meet the above criteria and the transplant program submits another *Heart Status 3 Justification Form*.

6.1.D Adult Heart Status 4 Requirements

To assign a candidate adult status 4, the candidate's transplant program must submit a *Heart Status 4 Justification Form* to the OPTN. A candidate is not assigned adult status 4 until this form is submitted.

If the candidate is at least 18 years old at the time of registration then the candidate's transplant program may assign the candidate adult status 4 if the candidate has at least *one* of the following conditions:

- Is supported by a dischargeable left ventricular assist device (LVAD), according to OPTN *Policy 6.1.D.i* below.
- Is supported by inotropes without continuous hemodynamic monitoring, according to OPTN *Policy 6.1.D.ii* below.
- Is diagnosed with congenital heart disease, according to OPTN *Policy 6.1.D.iii* below.
- Is diagnosed with ischemic heart disease with intractable angina, according to OPTN *Policy 6.1.D.iv* below.
- Is diagnosed with amyloidosis, hypertrophic cardiomyopathy or restrictive cardiomyopathy, according to OPTN *Policy 6.1.D.v* below.
- Is a re-transplant, according to OPTN *Policy 6.1.D.vi* below.

6.1.D.i Dischargeable Left Ventricular Assist Device (LVAD) without Discretionary 30 Days

A candidate's transplant program may assign a candidate to adult status 4 if the candidate is supported by a dischargeable LVAD. The OPTN maintains a list of OPTN-approved, qualifying devices.

This status is valid for up to 90 days from submission of *the Heart Status 4 Justification Form*. After the initial 90 days, this status can be extended by the transplant program every 90 days by submission of another *Heart Status 4 Justification Form*.

6.1.D.ii Inotropes without Hemodynamic Monitoring

A candidate's transplant program may assign a candidate to adult status 4 if the candidate is supported by a continuous infusion of a positive inotropic agent, and meets *all* of the following:

1. Cardiac index of less than 2.2 L/min/m^2 within 7 days prior to inotropic administration or while on inotrope infusion as specified below
2. Pulmonary Capillary Wedge Pressure greater than 15 mmHg
3. Requires at least *one* of the following intravenous inotropes:
    - Dobutamine greater than or equal to 3 mcg/kg/min
    - Milrinone greater than or equal to 0.25 mcg/kg/min
    - Epinephrine greater than or equal to 0.01 mcg/kg/min
    - Dopamine greater than or equal to 3 mcg/kg/min

This status is valid for up to 180 days from submission of *the Heart Status 4 Justification Form*. After the initial 180 days, this status can be extended by the transplant program every 180 days by submission of another *Heart Status 4 Justification Form*.

6.1.D.iii Congenital Heart Disease

A candidate's transplant program may assign a candidate to adult status 4 if the candidate is diagnosed with a hemodynamically significant congenital heart disease. The OPTN maintains a list of OPTN-approved qualifying congenital heart disease diagnoses.

This status is valid for up to 90 days from submission of *the Heart Status 4 Justification Form*. After the initial 90 days, this status can be extended by the transplant program every 90 days by submission of another *Heart Status 4 Justification Form*.

6.1.D.iv Ischemic Heart Disease with Intractable Angina

A candidate's transplant program may assign a candidate to adult status 4 if the candidate is diagnosed with ischemic heart disease and has intractable angina, with *all* of the following:

1. Coronary artery disease
2. Canadian Cardiovascular Society Grade IV angina pectoris that cannot be treated by a combination of medical therapy, and percutaneous or surgical revascularization
3. Myocardial ischemia shown by imaging

This status is valid for up to 90 days from submission of *the Heart Status 4 Justification Form*. After the initial 90 days, this status can be extended by the transplant program every 90 days by submission of another *Heart Status 4 Justification Form*.

6.1.D.v Amyloidosis, or Hypertrophic or Restrictive Cardiomyopathy

A candidate's transplant program may assign a candidate to adult status 4 if the candidate is diagnosed with amyloidosis, hypertrophic cardiomyopathy or restrictive cardiomyopathy, with at least *one* of the following:

- Canadian Cardiovascular Society Grade IV angina pectoris that cannot be controlled by medical therapy
- New York Heart Association (NYHA) Class III-IV symptoms with *either*:
  - Cardiac index less than 2.2 L/min/m^2
  - Left or right atrial pressure, left or right ventricular end-diastolic pressure, or pulmonary capillary wedge pressure greater than 20 mmHg
- Ventricular tachycardia lasting at least 30 seconds
- Ventricular fibrillation
- Ventricular arrhythmia requiring electrical cardioversion
- Sudden cardiac death

This status is valid for up to 90 days from submission of *the Heart Status 4 Justification Form*. After the initial 90 days, this status can be extended by the

transplant program every 90 days by submission of another *Heart Status 4 Justification Form*.

6.1.D.vi Re-transplant

A candidate's transplant program may assign a candidate to adult status 4 if the candidate has a previous heart transplant, and there is evidence of International Society of Heart and Lung Transplantation (ISHLT) coronary allograft vasculopathy (CAV) grade 2-3, or New York Heart Association (NYHA) Class III-IV heart failure symptoms.

This status is valid for up to 90 days from submission of *the Heart Status 4 Justification Form*. After the initial 90 days, this status can be extended by the transplant program every 90 days by submission of another *Heart Status 4 Justification Form*.

6.1.E Adult Heart Status 5 Requirements

If the candidate is at least 18 years old at the time of registration then the candidate's transplant program may assign the candidate to adult status 5 if the candidate is registered on the heart waiting list and is also registered on the waiting list for at least one other organ at the same hospital.

This status is valid for up to 180 days from submission of *the Heart Status 5 Justification Form* as long as the candidate is registered for another organ at the same hospital. After the initial 180 days, this status can be extended by the transplant program every 180 days by submission of another *Heart Status 5 Justification Form* as long as the candidate is registered for another organ at the same hospital.

6.1.F Adult Heart Status 6 Requirements

If the candidate is at least 18 years old at the time of registration and is suitable for transplant, then the transplant program may assign the candidate to adult status 6.

This status is valid for up to 180 days from submission of *the Heart Status 6 Justification Form* as long as the candidate remains suitable for transplant. After the initial 180 days, this status can be extended by the transplant program every 180 days by submission of another *Heart Status 6 Justification Form* as long as the candidate remains suitable for transplant.

6.2 Pediatric Status Assignments and Update Requirements

Heart candidates less than 18 years old at the time of registration may be assigned any of the following:

- Pediatric status 1A
- Pediatric status 1B
- Pediatric status 2
- Inactive status

A candidate registered on the waiting list before turning 18 years old remains eligible for pediatric status until the candidate has been removed from the waiting list.

6.2.A Pediatric Heart Status 1A Requirements

To register a candidate as pediatric status 1A, the candidate's transplant program must submit a *Heart Status 1A Justification Form* to the OPTN. A candidate is not classified as pediatric status 1A until this form is submitted.

The candidate's transplant program may assign the candidate pediatric status 1A if the candidate is less than 18 years old at the time of registration and meets at least *one* of the following criteria:

1. Requires continuous mechanical ventilation and is admitted to the hospital that registered the candidate.
2. Requires assistance of an intra-aortic balloon pump and is admitted to the hospital that registered the candidate.
3. Has ductal dependent pulmonary or systemic circulation, with ductal patency maintained by stent or prostaglandin infusion, and is admitted to the transplant hospital that registered the candidate.
4. Has a hemodynamically significant congenital heart disease diagnosis, requires infusion of multiple intravenous inotropes or a high dose of a single intravenous inotrope, and is admitted to the transplant hospital that registered the candidate. The OPTN maintains a list of OPTN-approved congenital heart disease diagnoses and qualifying inotropes and doses that qualify a candidate for pediatric status 1A.
5. Requires assistance of a mechanical circulatory support device.

Pediatric status 1A is valid for 14 days from the date of the candidate's initial registration as pediatric status 1A. After the initial 14 days, status 1A must be recertified by the transplant program every 14 days to extend the status 1A registration.

When a candidate's pediatric status 1A expires, the candidate will be assigned pediatric status 1B. Within 24 hours of the status change, the transplant program must report to the OPTN the criterion that qualifies the candidate to be registered as status 1B. The transplant program must classify the candidate as pediatric status 2 or inactive status if the candidate's medical condition does not qualify for pediatric status 1B.

6.2.B Pediatric Heart Status 1B Requirements

To assign a candidate pediatric heart status 1B, the candidate's transplant program must submit a *Heart Status 1B Justification Form* to the OPTN. A candidate is not assigned pediatric status 1B until this form is submitted.

The candidate's transplant program may assign the candidate pediatric status 1B if the candidate is less than 18 years old at the time of registration and meets at least *one* of the following criteria:

1. Requires infusion of one or more inotropic agents but does not qualify for pediatric status 1A. The OPTN maintains a list of the OPTN-approved status 1B inotropic agents and doses.
2. Is less than one year old at the time of the candidate's initial registration and has a diagnosis of hypertrophic or restrictive cardiomyopathy.

The candidate may retain pediatric status 1B for an unlimited period and this status does not require any recertification, unless the candidate's medical condition changes and the criteria used to justify that candidate's status are no longer accurate as described in *Policy 6.2*.

6.2.C Pediatric Heart Status 2 Requirements

If the candidate is less than 18 years old at the time of registration and does not meet the criteria for pediatric status 1A or 1B but is suitable for transplant, then the candidate may be assigned pediatric status 2.

A candidate's pediatric status 2 does not require any recertification.

6.2.D Inactive Adult and Pediatric Candidates

If an adult or pediatric candidate is temporarily unsuitable for transplant, then the candidate's transplant program may assign the candidate inactive status and the candidate will not receive any heart offers.

6.3 Status Updates

If a candidate's medical condition changes and the criteria used to justify that candidate's status is no longer accurate, then the candidate's transplant program must update the candidate's status and report the updated information to the OPTN within 24 hours of the change in medical condition.

6.4 Adult and Pediatric Status Exceptions

A heart candidate can receive a status by qualifying for an exception according to *Table 6-3* below.

Table 6-3: Exception Qualification and Periods

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Adult status 1	1. Candidate is admitted to the transplant hospital that registered the candidate on the waiting list 2. Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for status 1 exceptions	14 days	• Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Adult status 2	1. Candidate is admitted to the transplant hospital that registered the candidate on the waiting list 2. Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for status 2 exceptions	14 days	• Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively
Adult status 3	1. Candidate is admitted to the transplant hospital that registered the candidate on the waiting list 2. Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for status 3 exceptions	14 days	• Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Adult status 1, 2, or 3	1. Candidate's implanted mechanical circulatory support device, or an implanted component within, has a U.S. Food and Drug Administration recall that the transplant physician determines is a risk to patient safety that cannot be sufficiently mitigated without replacement of the device or the component, and 2. Transplant physician believes, using acceptable medical criteria, that the heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for exceptions associated with a heart device recall	14 days	• Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively
Adult status 4	Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for status 4 exceptions	90 days	• Require RRB approval for each successive 90 day period • RRB will review and decide extension requests retrospectively

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Pediatric status 1A	a. Candidate is admitted to the transplant hospital that registered the candidate on the waiting list b. Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	The National Heart Review Board (NHRB) retrospectively reviews requests for Status 1A-exceptions	14 days	• Require the NHRB approval for each successive 14 day period • The NHRB will review and decide extension requests retrospectively • If no extension request is submitted, the candidate will be assigned pediatric status 1B
Pediatric status 1B	Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	The NHRB retrospectively review requests for Status 1B exceptions	Indefinite	• Not required as long as candidate's medical condition remains the same

The candidate's transplant physician must submit a justification form with the requested status and the rationale for granting the status exception.

6.4.A Review Board and Committee Review of Status Exceptions

The heart RRB reviews applications for adult status exceptions and extensions retrospectively. The national heart review board (NHRB) reviews applications for pediatric status exceptions and extensions retrospectively.

If the candidate is transplanted and the relevant review board does not approve the initial exception or extension request or any appeal, then the case will be referred to the Heart Transplantation Committee. If the Heart Transplantation Committee agrees with the review board's decision, then the Heart Transplantation Committee may refer the case to Membership & Professional Standards Committee (MPSC) for review according to *Appendix L* of the *OPTN Management and Membership Policies*.

6.4.A.i. Review Board Appeals

If the review board denies an exception or extension request, the candidate's transplant program must either appeal to the relevant review board within 1 day of receiving notification of the review board denial or assign the candidate to the

status for which the candidate qualifies within 1 day of receiving notification of the review board denial.

6.4.A.ii Committee Appeals

If the review board denies the appeal, the candidate's transplant program must within 1 day of receiving notification of the denied appeal either appeal to the Heart Transplantation Committee or assign the candidate to the status for which the candidate qualifies. If the Heart Transplantation Committee agrees with the review board's decision, the candidate's transplant program must assign the candidate to the status for which the candidate qualifies within 1 day of receiving notification of the denied Committee appeal. If the transplant program does not assign the candidate to the status for which the candidate qualifies within 1 day of receiving notification of the denied Committee appeal, then the Committee will refer the case to the MPSC.

6.5 Waiting Time

Waiting time for heart candidates begins when the candidate is first registered as an active heart candidate on the waiting list and is calculated within each heart status.

If a candidate's status is upgraded, waiting time accrued while assigned to a lower status is not transferred to the higher status. Conversely, waiting time accrued while assigned at a higher status is transferred to a lower status if the candidate is assigned to a lower status.

Waiting time does not accrue while the candidate is inactive.

6.6 Heart Allocation Classifications and Rankings

6.6.A Blood Type Matching Priority for Heart Offers

Hearts are prioritized according to the blood type matching requirements in *Table 6-4: Blood Type Matching Prioritization for Heart Allocation*. Pediatric candidates who are eligible for intended incompatible blood type offers are prioritized according to OPTN *Policy 6.6.B.ii: Blood Type Prioritization for Intended Incompatible Offers.*

Table 6-4: Blood Type Matching Prioritization for Heart Allocation

Hearts from Deceased Donors with:	Are Allocated to Primary Candidates defined as:	Then to Secondary Candidates, defined as:
Blood Type O	Blood type O *or* blood type B	Blood type A or blood type AB
Blood Type A	Blood type A or blood type AB	Not applicable
Blood Type B	Blood type B or blood type AB	Not applicable
Blood Type AB	Blood type AB	Not applicable

6.6.B Intended Incompatible Blood Type Heart Offers Eligibility and Prioritization

6.6.B.i Eligibility for Intended Incompatible Blood Type Heart Offers

Pediatric heart and pediatric heart-lung candidates are eligible for an intended incompatible blood type heart offer if *all* of the following conditions are met:

- The transplant program specifies the candidate is willing to accept an intended incompatible blood type heart according to OPTN *Policy 5.3.E: Pediatric Heart Acceptance Criteria to Receive Intended Incompatible Blood Type Heart*, and reports isohemagglutinin titer(s) information according to *Table 6-5: Isohemagglutinin Titer(s) Reporting Requirements for Pediatric Candidates Willing to Receive an Intended Incompatible Blood Type Heart*
- The transplant program reports updated isohemagglutinin titer information every 30 days
- And the candidate meets one of the following conditions:
    - Is less than one year old at the time of the match run
    - Is at least one year old at the time of the match run, and has titers less than or equal to 1:16, and has not received treatments that may have reduced isohemagglutinin titers to 1:16 or less within 30 days of when this blood sample was collected.

Table 6-5: Isohemagglutinin Titer Reporting Requirements for a Candidate Who is Willing to Receive an Intended Incompatible Blood Type Heart

If the candidate's blood type is:	Then the transplant program must report the following isohemagglutinin titers to the OPTN:
A	Anti-B
B	Anti-A
O	Anti-A and Anti-B

6.6.B.ii Blood Type Matching Priority for Intended Incompatible Blood Type Heart Offers

An eligible pediatric candidate who is less than one year old at the time of the match run is classified as a primary blood type match candidate.

An eligible pediatric candidate who is at least one year old at the time of the match run is classified as a secondary blood type match candidate, unless they are a primary blood type match candidate according to *Table 6-4*.

6.6.B.iii Reporting Requirements for Recipients of Intended Incompatible Blood Type Hearts

Isohemagglutinin titers must be reported for recipients of an intended incompatible blood type heart, according to *Table 6-6*, as follows:

1. At transplant from a blood sample taken within 24 hours prior to transplant.

2. If graft loss occurs within one year after transplant from the most recent blood sample, if available.
3. If recipient death occurs within one year after transplant from the most recent blood sample, if available.

Table 6-6: Isohemagglutinin Titer Reporting Requirements for a Recipient of an Intended Incompatible Blood Type Heart

Deceased donor's blood type:	Recipient's blood type:	Isohemagglutinin titer reporting requirement:
A	B or O	Anti-A
B	A or O	Anti-B
AB	A	Anti-B
AB	B	Anti-A
AB	O	Anti-A and Anti-B

If a laboratory provides more than one isohemagglutinin titer value for a tested blood sample, the transplant program must report to the OPTN the highest titer value.

6.6.C Sorting Within Each Classification

Candidates are sorted within each classification by the total amount of waiting time that the candidate has accumulated at that status, according to OPTN *Policy 6.5: Waiting Time*.

6.6.D Allocation of Hearts from Donors at Least 18 years Old

Hearts from deceased donors at least 18 years old are allocated to candidates according to *Table 6-7* below.

Table 6-7: Allocation of Hearts from Deceased Donors At Least 18 Years Old

Classification	Candidates that are within the	And registered at a transplant hospital that is at or within this distance from the donor hospital
1	Adult status 1 or pediatric status 1A and primary blood type match with the donor	500NM
2	Adult status 1 or pediatric status 1A and secondary blood type match with the donor	500NM
3	Adult status 2 and primary blood type match with the donor	500NM
4	Adult status 2 and secondary blood type match with the donor	500NM

Classification	Candidates that are within the	And registered at a transplant hospital that is at or within this distance from the donor hospital
5	Adult status 3 or pediatric status 1B and primary blood type match with the donor	250NM
6	Adult status 3 or pediatric status 1B and secondary blood type match with the donor	250NM
7	Adult status 1 or pediatric status 1A and primary blood type match with the donor	1000NM
8	Adult status 1 or pediatric status 1A and secondary blood type match with the donor	1000NM
9	Adult status 2 and primary blood type match with the donor	1000NM
10	Adult status 2 and secondary blood type match with the donor	1000NM
11	Adult status 4 and primary blood type match with the donor	250NM
12	Adult status 4 and secondary blood type match with the donor	250NM
13	Adult status 3 or pediatric status 1B and primary blood type match with the donor	500NM
14	Adult status 3 or pediatric status 1B and secondary blood type match with the donor	500NM
15	Adult status 5 and primary blood type match with the donor	250NM
16	Adult status 5 and secondary blood type match with the donor	250NM
17	Adult status 3 or pediatric status 1B and primary blood type match with the donor	1000NM
18	Adult status 3 or pediatric status 1B and secondary blood type match with the donor	1000NM
19	Adult status 6 or pediatric status 2 and primary blood type match with the donor	250NM
20	Adult status 6 or pediatric status 2 and secondary blood type match with the donor	250NM

Classification	Candidates that are within the	And registered at a transplant hospital that is at or within this distance from the donor hospital
21	Adult status 1 or pediatric status 1A and primary blood type match with the donor	1500NM
22	Adult status 1 or pediatric status 1A and secondary blood type match with the donor	1500NM
23	Adult status 2 and primary blood type match with the donor	1500NM
24	Adult status 2 and secondary blood type match with the donor	1500NM
25	Adult status 3 or pediatric status 1B and primary blood type match with the donor	1500NM
26	Adult status 3 or pediatric status 1B and secondary blood type match with the donor	1500NM
27	Adult status 4 and primary blood type match with the donor	500NM
28	Adult status 4 and secondary blood type match with the donor	500NM
29	Adult status 5 and primary blood type match with the donor	500NM
30	Adult status 5 and secondary blood type match with the donor	500NM
31	Adult status 6 or pediatric status 2 and primary blood type match with the donor	500NM
32	Adult status 6 or pediatric status 2 and secondary blood type match with the donor	500NM
33	Adult status 1 or pediatric status 1A and primary blood type match with the donor	2500NM
34	Adult status 1 or pediatric status 1A and secondary blood type match with the donor	2500NM
35	Adult status 2 and primary blood type match with the donor	2500NM
36	Adult status 2 and secondary blood type match with the donor	2500NM
37	Adult status 3 or pediatric status 1B and primary blood type match with the donor	2500NM

Classification	Candidates that are within the	And registered at a transplant hospital that is at or within this distance from the donor hospital
38	Adult status 3 or pediatric status 1B and secondary blood type match with the donor	2500NM
39	Adult status 4 and primary blood type match with the donor	1000NM
40	Adult status 4 and secondary blood type match with the donor	1000NM
41	Adult status 5 and primary blood type match with the donor	1000NM
42	Adult status 5 and secondary blood type match with the donor	1000NM
43	Adult status 6 or pediatric status 2 and primary blood type match with the donor	1000NM
44	Adult status 6 or pediatric status 2 and secondary blood type match with the donor	1000NM
45	Adult status 1 or pediatric status 1A and primary blood type match with the donor	Nation
46	Adult status 1 or pediatric status 1A and secondary blood type match with the donor	Nation
47	Adult status 2 and primary blood type match with the donor	Nation
48	Adult status 2 and secondary blood type match with the donor	Nation
49	Adult status 3 or pediatric status 1B and primary blood type match with the donor	Nation
50	Adult status 3 or pediatric status 1B and secondary blood type match with the donor	Nation
51	Adult status 4 and primary blood type match with the donor	1500NM
52	Adult status 4 and secondary blood type match with the donor	1500NM
53	Adult status 5 and primary blood type match with the donor	1500NM
54	Adult status 5 and secondary blood type match with the donor	1500NM
55	Adult status 6 or pediatric status 2 and primary blood type match with the donor	1500NM

Classification	Candidates that are within the	And registered at a transplant hospital that is at or within this distance from the donor hospital
56	Adult status 6 or pediatric status 2 and secondary blood type match with the donor	1500NM
57	Adult status 4 and primary blood type match with the donor	2500NM
58	Adult status 4 and secondary blood type match with the donor	2500NM
59	Adult status 5 and primary blood type match with the donor	2500NM
60	Adult status 5 and secondary blood type match with the donor	2500NM
61	Adult status 6 or pediatric status 2 and primary blood type match with the donor	2500NM
62	Adult status 6 or pediatric status 2 and secondary blood type match with the donor	2500NM
63	Adult status 4 and primary blood type match with the donor	Nation
64	Adult status 4 and secondary blood type match with the donor	Nation
65	Adult status 5 and primary blood type match with the donor	Nation
66	Adult status 5 and secondary blood type match with the donor	Nation
67	Adult status 6 or pediatric status 2 and primary blood type match with the donor	Nation
68	Adult status 6 or pediatric status 2 and secondary blood type match with the donor	Nation

6.6.E Allocation of Hearts from Donors Less Than 18 Years Old

A heart from a pediatric donor will be allocated to a pediatric heart candidate by status and geographical location before being allocated to a candidate at least 18 years old according to *Table 6-8* below.

Table 6-8: Allocation of Hearts from Donors Less Than 18 Years Old

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
1	Pediatric status 1A and primary blood type match with the donor	500NM
2	Pediatric status 1A and secondary blood type match with the donor	500NM
3	Adult status 1 and primary blood type match with the donor	250NM
4	Adult status 1 and secondary blood type match with the donor	250NM
5	Adult status 2 and primary blood type match with the donor	250NM
6	Adult status 2 and secondary blood type match with the donor	250NM
7	Pediatric status 1B and primary blood type match with the donor	500NM
8	Pediatric status 1B and secondary blood type match with the donor	500NM
9	Adult status 1 and primary blood type match with the donor	500NM
10	Adult status 1 and secondary blood type match with the donor	500NM
11	Adult status 2 and primary blood type match with the donor	500NM
12	Adult status 2 and secondary blood type match with the donor	500NM
13	Adult status 3 and primary blood type match with the donor	250NM
14	Adult status 3 and secondary blood type match with the donor	250NM
15	Adult status 4 and primary blood type match with the donor	250NM

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
16	Adult status 4 and secondary blood type match with the donor	250NM
17	Adult status 5 and primary blood type match with the donor	250NM
18	Adult status 5 and secondary blood type match with the donor	250NM
19	Adult status 3 and primary blood type match with the donor	500NM
20	Adult status 3 and secondary blood type match with the donor	500NM
21	Adult status 4 and primary blood type match with the donor	500NM
22	Adult status 4 and secondary blood type match with the donor	500NM
23	Adult status 5 and primary blood type match with the donor	500NM
24	Adult Status 5 and secondary blood type match with the donor	500NM
25	Pediatric status 2 and primary blood type match with the donor	250NM
26	Pediatric status 2 and secondary blood type match with the donor	250NM
27	Adult status 6 and primary blood type match with the donor	250NM
28	Adult status 6 and secondary blood type match with the donor	250NM
29	Pediatric status 1A and primary blood type match with the donor	1000NM
30	Pediatric status 1A and secondary blood type match with the donor	1000NM
31	Adult status 1 and primary blood type match with the donor	1000NM

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
32	Adult status 1 and secondary blood type match with the donor	1000NM
33	Adult status 2 and primary blood type match with the donor	1000NM
34	Adult status 2 and secondary blood type match with the donor	1000NM
35	Pediatric status 1B and primary blood type match with the donor	1000NM
36	Pediatric status 1B and secondary blood type match with the donor	1000NM
37	Adult status 3 and primary blood type match with the donor	1000NM
38	Adult status 3 and secondary blood type match with the donor	1000NM
39	Adult status 4 and primary blood type match with the donor	1000NM
40	Adult status 4 and secondary blood type match with the donor	1000NM
41	Adult status 5 and primary blood type match with the donor	1000NM
42	Adult status 5 and secondary blood type match with the donor	1000NM
43	Pediatric status 2 and primary blood type match with the donor	500NM
44	Pediatric status 2 and secondary blood type match with the donor	500NM
45	Adult status 6 and primary blood type match with the donor	500NM
46	Adult status 6 and secondary blood type match with the donor	500NM
47	Pediatric status 2 and primary blood type match with the donor	1000NM

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
48	Pediatric status 2 and secondary blood type match with the donor	1000NM
49	Adult status 6 and primary blood type match with the donor	1000NM
50	Adult status 6 and secondary blood type match with the donor	1000NM
51	Pediatric status 1A and primary blood type match with the donor	1500NM
52	Pediatric status 1A and secondary blood type match with the donor	1500NM
53	Adult status 1 and primary blood type match with the donor	1500NM
54	Adult status 1 and secondary blood type match with the donor	1500NM
55	Adult status 2 and primary blood type match with the donor	1500NM
56	Adult status 2 and secondary blood type match with the donor	1500NM
57	Pediatric status 1B and primary blood type match with the donor	1500NM
58	Pediatric status 1B and secondary blood type match with the donor	1500NM
59	Adult status 3 and primary blood type match with the donor	1500NM
60	Adult status 3 and secondary blood type match with the donor	1500NM
61	Adult status 4 and primary blood type match with the donor	1500NM
62	Adult status 4 and secondary blood type match with the donor	1500NM

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
63	Adult status 5 and primary blood type match with the donor	1500NM
64	Adult status 5 and secondary blood type match with the donor	1500NM
65	Pediatric status 2 and primary blood type match with the donor	1500NM
66	Pediatric status 2 and secondary blood type match with the donor	1500NM
67	Adult status 6 and primary blood type match with the donor	1500NM
68	Adult status 6 and secondary blood type match with the donor	1500NM
69	Pediatric status 1A and primary blood type match with the donor	2500NM
70	Pediatric status 1A and secondary blood type match with the donor	2500NM
71	Adult status 1 and primary blood type match with the donor	2500NM
72	Adult status 1 and secondary blood type match with the donor	2500NM
73	Adult status 2 and primary blood type match with the donor	2500NM
74	Adult status 2 and secondary blood type match with the donor	2500NM
75	Pediatric status 1B and primary blood type match with the donor	2500NM
76	Pediatric status 1B and secondary blood type match with the donor	2500NM
77	Adult status 3 and primary blood type match with the donor	2500NM

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
78	Adult status 3 and secondary blood type match with the donor	2500NM
79	Adult status 4 and primary blood type match with the donor	2500NM
80	Adult status 4 and secondary blood type match with the donor	2500NM
81	Adult status 5 and primary blood type match with the donor	2500NM
82	Adult status 5 and secondary blood type match with the donor	2500NM
83	Pediatric status 2 and primary blood type match with the donor	2500NM
84	Pediatric status 2 and secondary blood type match with the donor	2500NM
85	Adult status 6 and primary blood type match with the donor	2500NM
86	Adult status 6 and secondary blood type match with the donor	2500NM
87	Pediatric status 1A and primary blood type match with the donor	Nation
88	Pediatric status 1A and secondary blood type match with the donor	Nation
89	Adult status 1 and primary blood type match with the donor	Nation
90	Adult status 1 and secondary blood type match with the donor	Nation
91	Adult status 2 and primary blood type match with the donor	Nation
92	Adult status 2 and secondary blood type match with the donor	Nation
93	Pediatric status 1B and primary blood type match with the donor	Nation

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
94	Pediatric status 1B and secondary blood type match with the donor	Nation
95	Adult status 3 and primary blood type match with the donor	Nation
96	Adult status 3 and secondary blood type match with the donor	Nation
97	Adult status 4 and primary blood type match with the donor	Nation
98	Adult status 4 and secondary blood type match with the donor	Nation
99	Adult status 5 and primary blood type match with the donor	Nation
100	Adult status 5 and secondary blood type match with the donor	Nation
101	Pediatric status 2 and primary blood type match with the donor	Nation
102	Pediatric status 2 and secondary blood type match with the donor	Nation
103	Adult status 6 and primary blood type match with the donor	Nation
104	Adult status 6 and secondary blood type match with the donor	Nation

6.6.F Allocation of Heart-Lungs

6.6.F.i Allocation of Heart-Lungs from Deceased Donors at Least 18 Years Old

If a host OPO is offering a heart and lung from the same deceased donor, then the host OPO must offer the heart and lung in the following order:

1. To all heart and heart-lung PTRs in allocation classifications 1 through 4 according to OPTN *Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old*
2. To all lung and heart-lung PTRs according to OPTN *Policy 10.1 Lung Composite Allocation Score* until offers have been made to all heart-lung PTRs with a lung composite allocation score of 25 or higher
3. To heart and heart-lung PTRs in classifications 5 or later according to OPTN *Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old*.

The host OPO must follow the order on each match run, including heart-lung, heart, and lung candidates.

6.6.F.ii Allocation of Heart-Lungs from Deceased Donors Less Than 18 Years Old

If a host OPO is offering a heart and lung from the same deceased donor, then the host OPO must offer:

1. To all heart and heart-lung PTRs in allocation classifications 1 through 12 according to OPTN *Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old*
2. To all lung and heart-lung PTRs according to OPTN *Policy 10.1 Lung Composite Allocation Score* until offers have been made to all heart-lung PTRs with a lung composite allocation score of 25 or higher
3. To heart and heart-lung PTRs in classifications 13 or later according to OPTN *Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old*

The host OPO must follow the order on each match run, including heart-lung, heart, and lung candidates.

Policy 7: Allocation of Intestines

7.1 Status Assignments

Each intestine candidate is assigned a status that reflects the candidate's medical condition. Candidates may be assigned *any* of the following:

- Status 1
- Status 2
- Inactive status

7.1.A Status 1 Requirements

To assign an intestine candidate status 1, the candidate's transplant program must submit a *Status 1 Justification Form* to the OPTN. A candidate may be assigned status 1 if the candidate has *any* of the following conditions:

- Liver function test abnormalities
- No vascular access through the subclavian, jugular, or femoral veins for intravenous feeding
- Medical indications that warrant intestinal organ transplantation on an urgent basis

7.1.B Status 2 Requirements

Any active candidate that does not meet the criteria for status 1 must be registered as status 2.

7.1.C Inactive Status

If the candidate is temporarily unsuitable for transplant, then the candidate's transplant program may classify the candidate as inactive, and the candidate will not receive any intestine offers.

7.2 Waiting Time

Inactive candidates will accrue waiting time while inactive for up to a maximum of 30 cumulative days.

7.3 Intestine Allocation Classifications and Rankings

7.3.A Sorting Within Each Classification

Within each allocation classification, candidates are sorted by waiting time (longest to shortest).

7.3.B Allocation of Intestines

Intestines are allocated to candidates according to *Table 7-1* below.

Table 7-1: Allocation of Intestines

Classification	Candidates registered at a transplant hospital that is at or within this distance from the donor hospital	Who are:
1	500NM	Status 1 and a blood type identical to the donor
2	500NM	Status 1 and a blood type compatible with the donor
3	Nation	Status 1 and a blood type identical to the donor
4	Nation	Status 1 and a blood type compatible with the donor
5	500NM	Status 2 and a blood type identical to the donor
6	500NM	Status 2 and a blood type compatible with the donor
7	Nation	Status 2 and a blood type identical to the donor
8	Nation	Status 2 and a blood type compatible with the donor

Policy 8: Allocation of Kidneys

8.1 Exceptions

8.1.A Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings

Allocation of deceased donor kidneys is based on the HLA typing identified by the donor histocompatibility laboratory. If the recipient HLA laboratory identifies a different HLA type for the deceased donor and the intended recipient cannot be transplanted, the kidney must be allocated according to OPTN *Policy 5.9: Released Organs*. When reallocating the kidney, the OPO has the discretion to use either the HLA typing identified by the donor histocompatibility laboratory or the recipient HLA laboratory.

8.2 Kidney Allocation Score

Candidates receive an allocation score according to the total of all points assigned in *Table 8-1.*

Table 8-1: Kidney Points

If the candidate is:	And the following allocation sequence is used:	Then the candidate receives this many points:
Registered for transplant and meets the qualifying criteria described in *Policy 8.3: Waiting Time*	8.4.I, 8.4.J, 8.4.K, or 8.4.L	1/365 points for each day since the qualifying criteria in *Policy 8.3: Waiting Time*
Aged 0-10 at time of match and a 0-ABDR mismatch with the donor	8.4.I, 8.4.J, or 8.4.K	4 points
Aged 11-17 at time of match and a 0-ABDR mismatch with the donor	8.4.I, 8.4.J, or 8.4.K	3 points
Aged 0-10 at time of match and donor has a KDPI score <35%	8.4.I, 8.4.J	1 point

If the candidate is:	And the following allocation sequence is used:	Then the candidate receives this many points:
A prior living donor	8.4.I, 8.4.J, or 8.4.K	4 points
Sensitized (CPRA at least 20%)	8.4.I, 8.4.J, or 8.4.K	*See Table 8-2: Points for CPRA*
A single HLA-DR mismatch with the donor*	8.4.I, 8.4.J, or 8.4.K	1 point
A zero HLA-DR mismatch with the donor*	8.4.I, 8.4.J, or 8.4.K	2 points
Meets the qualifying criteria described in *Table 8-3: Points for Allocation of Kidneys based on Proximity to Donor Hospital*	8.4.I, 8.4.J, 8.4.K, or 8.4.L	*See Table 8-3: Points for Allocation of Kidneys based on Proximity to Donor Hospital*

*****Donors with only one antigen identified at an HLA locus (A, B, and DR) are presumed "homozygous" at that locus.

Table 8-2: Points for CPRA

If the candidate's CPRA score is:	Then the candidate receives this many points:
0	0.00
1-9	0.00
10-19	0.00
20-29	0.08
30-39	0.21
40-49	0.34
50-59	0.48
60-69	0.81
70-74	1.09
75-79	1.58
80-84	2.46
85-89	4.05
90-94	6.71
95	10.82
96	12.17
97	17.30
98	24.40
99	50.09
100	202.10

Table 8-3: Points for Allocation of Kidneys based on Proximity to Donor Hospital

For purposes of this section, distance is calculated in nautical miles between candidate's hospital of registration and the donor hospital.

If the candidate is:	Then the candidate receives this many points:
Registered at a transplant program that is 250 nautical miles or less away from the donor hospital	$2 - \left[\left(\frac{2}{250-0}\right) \times distance\right]$
Registered at a transplant program that is more than 250 nautical miles away from but 2500 nautical miles or less away from the donor hospital	$4 - \left[\left(\left(\frac{4}{2500-250}\right) \times distance\right) - \left(4 \times \frac{250}{2500-250}\right)\right]$
Registered at a transplant program that is more than 2500 nautical miles away from the donor hospital	0

Table 8-4: Points for Released Kidneys based on Proximity to Transplant Hospital that Originally Accepted the Organ

For purposes of this section, distance is calculated in nautical miles between the candidate's hospital of registration and the transplant hospital that released the kidney.

If the candidate is:	Then the candidate receives this many points:
Registered at a transplant hospital that is 250 nautical miles or less away from the transplant hospital that originally accepted the kidney	$2 - \left[\left(\frac{2}{250-0}\right) \times distance\right]$
Registered at a transplant hospital that is more than 250 nautical miles but 2,500 nautical miles or less away from the transplant hospital that originally accepted the kidney	$4 - \left[\left(\left(\frac{4}{2500-250}\right) \times distance\right) - \left(4 \times \frac{250}{2500-250}\right)\right]$
Registered at a transplant hospital that is more than 2,500 nautical miles away from the transplant hospital that originally accepted the kidney	0

8.3 Waiting Time

8.3.A Waiting Time for Candidates Registered at Age 18 Years or Older

If a kidney candidate is 18 years or older on the date the candidate is registered for a kidney, then the candidate's waiting time is based on the earliest of the following:

1. The candidate's registration date with a glomerular filtration rate (GFR) or measured or estimated creatinine clearance (CrCl) less than or equal to 20 mL/min.
2. The date after registration that a candidate's GFR or measured or estimated CrCl becomes less than or equal to 20 mL/min.
3. The date that the candidate began regularly administered dialysis as an End Stage Renal Disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting.

8.3.B Waiting Time for Candidates Registered prior to Age 18

If a kidney candidate is less than 18 years old at the time of registration on the waiting list, then the candidate's waiting time is based on the earlier of the following:

1. The date that the candidate registered on the waiting list regardless of clinical criteria.
2. The date that the candidate began regularly administered dialysis as an ESRD patient in a hospital based, independent non-hospital based, or home setting.

8.3.C Time at Medically Urgent Status

For registered kidney candidates that also qualify for medically urgent status according to *Policy 8.4.A.i*, the candidate accrues time at medically urgent status while active on the waiting list, based on the date the transplant program first indicates the candidate's qualification for medically urgent status to the OPTN.

8.3.D Waiting Time for Kidney Recipients

If a kidney recipient returns to the kidney waiting list, waiting time will be based only on the dates after the most recent kidney transplant, unless the candidate qualifies for reinstatement of waiting time according to OPTN *Policy 3.6.B.i: Non-function of a Transplanted Kidney*.

8.4 Kidney Allocation Classifications and Rankings

8.4.A Candidate Classifications

Each candidate on the kidney waiting list after turning 18 years old receives an Estimated Post Transplant Survival (EPTS) score. A candidate's EPTS score represents the percentage of kidney candidates in the nation with a longer expected post-transplant survival time. EPTS is based on *all* of the following:

1. Candidate time on dialysis
2. Whether or not the candidate has a current diagnosis of diabetes
3. Whether or not the candidate has had any prior solid organ transplant

4. Candidate age

If a kidney recipient returns to the kidney waiting list, only time on dialysis after the most recent kidney transplant applies for number 1 above, candidate time on dialysis, as defined in OPTN *Policy 8.3: Waiting Time*.

Each candidate's EPTS score is calculated when the candidate is registered on the waiting list. The OPTN will update EPTS scores as follows:

- All candidate EPTS scores are updated once each day
- A candidate's EPTS score will be updated anytime the transplant hospital reports changes to any EPTS factor for a candidate

A candidate's raw EPTS score is equal to:

0.047 * MAX(Age - 25, 0) +
-0.015 * Diabetes * MAX(Age - 25, 0) +
0.398 * Prior Solid Organ Transplant +
-0.237 * Diabetes * Prior Solid Organ Transplant +
0.315 * log (Years on Dialysis + 1) +
-0.099 * Diabetes * log(Years on Dialysis + 1) +
0.130 * (Years on Dialysis = 0) +
-0.348 * Diabetes * (Years on Dialysis = 0) +
1.262 * Diabetes

The EPTS calculation uses all the following as binary indicators:

1. Diabetes,
2. Prior solid organ transplant
3. Years on dialysis=0

If a binary indicator is true, then it is replaced by a value of 1.0 in the calculation; otherwise, it is replaced by 0. Fractional calendar years are used for candidate's age and years on dialysis.

The OPTN's EPTS mapping table is used to convert a candidate's raw EPTS score into an EPTS score. All EPTS scores are rounded to the nearest integer.

The reference population used to determine the top 20% EPTS threshold is reviewed annually by the Kidney Transplantation Committee and updated by the OPTN on or before June 1 of each calendar year.

8.4.A.i Medically Urgent Status for Adult and Pediatric Candidates

To qualify for medically urgent status the candidate must be:

1. An active candidate
2. Accruing waiting time, according to OPTN *Policy 8.3: Waiting Time* and

3. Certified by a transplant nephrologist and transplant surgeon as medically urgent, based on meeting the following criteria:

   First, the candidate must have exhausted, or has a contraindication to, all dialysis access via all of the following methods:
   - Vascular access in the upper left extremity
   - Vascular access in the upper right extremity
   - Vascular access in the lower left extremity
   - Vascular access in the lower right extremity
   - Peritoneal access in the abdomen

   After exhaustion or contraindication to all dialysis via the methods listed above, the candidate must also either have exhausted dialysis, be currently dialyzed, or have a contraindication to dialysis via one of the following methods:
   - Transhepatic IVC Catheter
   - Translumbar IVC Catheter
   - Other method of dialysis (must specify)

   The candidate's transplant surgeon and transplant nephrologist must review and sign a written approval of the candidate's qualification for medical urgency status. Programs must consider clinical characteristics specific to adult and pediatric candidates when indicating contraindications to the criteria above. The transplant hospital must document this medical urgency qualification in the candidate's medical record and submit supporting documentation to the OPTN within seven business days of indicating medical urgency status.

   The Kidney Transplantation Committee will review a transplant program's use of the medical urgency status retrospectively. Cases may be referred to Membership & Professional Standards Committee (MPSC) for review according to *Appendix L* of the *OPTN Management and Membership Policies*.

8.4.B Deceased Donor Classifications

Kidneys from deceased donors are classified according to the Kidney Donor Profile Index (KDPI). The KDPI score is derived directly from the Kidney Donor Risk Index (KDRI) score. The KDPI is the percentage of donors in the reference population that have a KDRI less than or equal to this donor's KDRI.

The donor characteristics used to calculate KDRI are provided in *Table 8-5* below.

Table 8-5: KDRI Factors

This deceased donor characteristic:	Applies to:	KDRI score component:
Age (integer years)	All donors	0.0092*(age-40)
	Donors with age < 18	0.0113*(age-18)
	Donors with age > 50	0.0067*(age-50)
Creatinine (mg/dL)	All donors	0.2128*(creatinine - 1)
	Donors with creatinine > 1.5	-0.2199*(creatinine - 1.5)
History of Hypertension	Hypertensive donors	0.1106
History of Diabetes	Diabetic donors	0.2577
Cause of Death	Donors with cerebrovascular accident as cause of death	0.0743
Height (cm)	All donors	-0.0557*(height - 170) / 10
Weight (kg)	All donors with weight < 80 kg	-0.0333*(weight - 80) / 5
Donor type	DCD donors	0.1966

To calculate KDRI, follow these steps:

1. Sum each of the applicable KDRI score components in *Table 8-5*
2. Apply the antilog (base e) function to this sum
3. Divide the KDRI by the median KDRI value of the most recent donor reference population
4. Determine the KDPI using the OPTN's KDRI-to-KDPI mapping table

The KDPI score is rounded to the nearest integer.

The KDPI used for allocation is based on the most recent values of donor characteristics reported to the OPTN before executing a match run.

The reference population used to determine the KDRI-to-KDPI mapping is reviewed annually by the Kidney Transplantation Committee and updated by the OPTN on or before June 1 of each calendar year.

8.4.C Sorting Within Each Classification

For candidates within classifications 1 through 7 according to *Tables 8-7* and *8-8*; classifications 1 through 6 according to *Table 8-9*, and classifications 1 through 5 according to *Table 8-10*, candidates are sorted in the following order:

1. Medical urgency status
2. Total time at medically urgent status for current medically urgent candidates only (highest to lowest)
3. Total points (highest to lowest)
4. Date and time of the candidate's registration (oldest to most recent)

For candidates within all other classifications, candidates are sorted in the following order:

1. Total points (highest to lowest)
2. Date and time of the candidate's registration (oldest to most recent)

8.4.D Allocation of Kidneys by Blood Type

Transplants are restricted by blood type in certain circumstances. Kidneys will be allocated to candidates according to the blood type matching requirements in *Table 8-6* below:

Table 8-6: Allocation of Kidneys by Blood Type

Kidneys from Donors with:	Are Allocated to Candidates with:
Blood Type O	Blood type O. For offers made to candidates in 0-ABDR mismatch categories, blood type O kidneys may be transplanted into candidates who have blood types other than O.
Blood Type A	Blood type A or blood type AB.
Blood Type B	Blood type B. For offers made to candidates in 0-ABDR mismatch categories, blood type B kidneys may be transplanted into candidates who have blood types other than B.
Blood Type AB	Blood type AB.
Blood Types A, non-A_1 and AB, non-A_1B	Kidneys may be transplanted into candidates with blood type B who meet *all* of the following criteria: 1. The transplant program obtains written informed consent from each blood type B candidate regarding their willingness to accept a blood

Kidneys from Donors with:	Are Allocated to Candidates with:
	type A, non-A_1 or blood type AB, non-A_1B blood type kidney. 2. The transplant program establishes a written policy regarding its program's titer threshold for transplanting blood type A, non-A_1 and blood type AB, non-A_1B kidneys into candidates with blood type B. The transplant program must confirm the candidate's eligibility every 90 days (+/- 20 days).

8.4.E Prior Living Organ Donors

A kidney candidate will be classified as a prior living donor if *all* of the following conditions are met:

1. The candidate donated for transplantation, within the United States or its territories, at least *one* of the following:
    - Kidney
    - Liver segment
    - Lung segment
    - Partial pancreas
    - Small bowel segment.

2. The candidate's physician reports *all* of the following information to the OPTN:
    a. The name of the recipient or intended recipient of the donated organ or organ segment
    b. The recipient's or intended recipient's transplant hospital
    c. The date the donated organ was procured

8.4.F Prioritization for Liver Recipients on the Kidney Waiting List

If a kidney candidate received a liver transplant, but not a liver and kidney transplant from the same deceased donor, the candidate will be classified as a prior liver recipient. This classification gives priority to a kidney candidate if *both* of the following criteria are met:

1. The candidate is registered on the kidney waiting list prior to the one-year anniversary of the candidate's most recent liver transplant date
2. On a date that is at least 60 days but not more than 365 days after the candidate's liver transplant date, at least *one* of the following criteria is met:
    - The candidate has a GFR or measured or estimated CrCl less than or equal to 20 mL/min.
    - The candidate is on dialysis.

When the transplant program reports that the candidate meets the criteria for this classification, the candidate will remain at this classification for 30 days from the date of the qualifying test or treatment. If the transplant program reports additional qualifying tests or

treatments, then the candidate will remain at this classification for 30 days from the most recent date of the test or treatment. If the transplant program reports that the candidate meets the criteria for 90 consecutive days, the candidate will remain at this classification until the candidate is removed from the kidney waiting list. If the candidate transfers kidney waiting time according to *Policy 3.6.C: Individual Waiting Time Transfers* and has met the criteria for 90 consecutive days, then the candidate's classification will be included in the transfer.

If a liver recipient receives a kidney using this priority classification and returns to the kidney waiting list after the most recent kidney transplant, the candidate must again meet the criteria for this classification, unless the candidate qualifies for kidney waiting time reinstatement according to OPTN *Policy 3.6.B.i: Non-function of a Transplanted Kidney.* If the candidate qualifies for kidney waiting time reinstatement, the candidate will be classified as qualifying for the classification.

If a kidney candidate received a liver and kidney transplant from the same deceased donor, the candidate will only qualify for this classification if the candidate qualifies for kidney waiting time reinstatement according to OPTN *Policy 3.6.B.i: Non-function of a Transplanted Kidney*

8.4.G Prioritization for Heart Recipients on the Kidney Waiting List

If a kidney candidate received a heart transplant, but not a heart and kidney transplant from the same deceased donor, the candidate will be classified as a prior heart recipient. This classification gives priority to a kidney candidate if *both* of the following criteria are met:

1. The candidate is registered on the kidney waiting list prior to the one-year anniversary of the candidate's most recent heart transplant date
2. On a date that is at least 60 days but not more than 365 days after the candidate's heart transplant date, at least *one* of the following criteria is met:
    - The candidate has a measured or estimated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 20 mL/min.
    - The candidate is on dialysis.

When the transplant program reports that the candidate meets the criteria for this classification, the candidate will remain at this classification for 30 days from the date of the qualifying test or treatment. If the transplant program reports additional qualifying tests or treatments, then the candidate will remain at this classification for 30 days from the most recent date of the test or treatment. If the transplant program reports that the candidate meets the criteria for 90 consecutive days, the candidate will remain at this classification until the candidate is removed from the kidney waiting list. If the candidate transfers kidney waiting time according to OPTN *Policy 3.6.C: Individual Waiting Time Transfers* and has met the criteria for 90 consecutive days, then the candidate's classification will be included in the transfer.

If a heart recipient receives a kidney using this priority classification and returns to the kidney waiting list after the most recent kidney transplant, the candidate must again meet the criteria for this classification, unless the candidate qualifies for kidney waiting time reinstatement according to OPTN *Policy 3.6.B.i: Non-function of a Transplanted Kidney.* If the candidate qualifies for kidney waiting time reinstatement, the candidate will be classified as qualifying for the classification.

If a kidney candidate received a heart and kidney transplant from the same deceased donor, the candidate will only qualify for this classification if the candidate qualifies for kidney waiting time reinstatement according to OPTN *Policy 3.6.B.i: Non-function of a Transplanted Kidney.*

8.4.H Prioritization for Lung Recipients on the Kidney Waiting List

If a kidney candidate received a lung transplant, but not a lung and kidney transplant from the same deceased donor, the candidate will be classified as a prior lung recipient. This classification gives priority to a kidney candidate if *both* of the following criteria are met:

1. The candidate is registered on the kidney waiting list prior to the one-year anniversary of the candidate's most recent lung transplant date
2. On a date that is at least 60 days but not more than 365 days after the candidate's lung transplant date, at least *one* of the following criteria is met:
    - The candidate has a measured or estimated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 20 mL/min.
    - The candidate is on dialysis.

When the transplant program reports that the candidate meets the criteria for this classification, the candidate will remain at this classification for 30 days from the date of the qualifying test or treatment. If the transplant program reports additional qualifying tests or treatments, then the candidate will remain at this classification for 30 days from the most recent date of the test or treatment. If the transplant program reports that the candidate meets the criteria for 90 consecutive days, the candidate will remain at this classification until the candidate is removed from the kidney waiting list. If the candidate transfers kidney waiting time according to OPTN *Policy 3.6.C: Individual Waiting Time Transfers* and has met the criteria for 90 consecutive days, then the candidate's classification will be included in the transfer.

If a lung recipient receives a kidney using this priority classification and returns to the kidney waiting list after the most recent kidney transplant, the candidate must again meet the criteria for this classification, unless the candidate qualifies for kidney waiting time reinstatement according to OPTN *Policy 3.6.B.i: Non-function of a Transplanted Kidney.* If the candidate qualifies for kidney waiting time reinstatement, the candidate will be classified as qualifying for the classification.

If a kidney candidate received a lung and kidney transplant from the same deceased donor, the candidate will only qualify for this classification if the candidate qualifies for kidney waiting time reinstatement according to OPTN *Policy 3.6.B.i: Non-function of a Transplanted Kidney.*

8.4.I Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%

Kidneys from deceased donors with a kidney donor profile index (KDPI) score of less than or equal to 20% are allocated to candidates according to *Table 8-7* below. For the purposes of *Table 8-7*, distribution will be based on the distance from the candidate's transplant hospital to the donor hospital, unless the kidney is allocated according to OPTN *Policy 8.7: Allocation of*

Released Kidneys. For kidneys that are released and the host OPO or the OPTN executes a released kidney match run, distribution will be based on the distance from the candidate's transplant hospital to the transplant hospital that released the organ.

Table 8-7: Allocation of Kidneys from Deceased Donors with KDPI Less Than or Equal To 20%

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	250NM	Any
2	CPRA equal to 100%, blood type identical or permissible	250NM	Any
3	0-ABDR mismatch, CPRA equal 100%, blood type identical or permissible	Nation	Any
4	CPRA equal to 100%, blood type identical or permissible	Nation	Any
5	Prior living donor, blood type identical or permissible	250NM	Any
6	Registered prior to 18 years old, blood type identical or permissible	250NM	Any
7	Medically Urgent	250NM	Any
8	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	250NM	Any
9	CPRA equal to 99%, blood type identical or permissible	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
10	0-ABDR mismatch, CPRA equal to 98%, blood type identical or permissible	250NM	Any
11	CPRA equal to 98%, blood type identical or permissible	250NM	Any
12	0-ABDR mismatch, top 20% EPTS, and blood type identical	250NM	Any
13	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
14	0-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
15	0-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type identical	Nation	Any
16	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
17	0-ABDR mismatch, top 20% EPTS, and blood type B	250NM	O

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
18	0-ABDR mismatch, top 20% EPTS or less than 18 years at time of match run, CPRA greater than or equal to 80%, and blood type B	Nation	O
19	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
20	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type B	Nation	O
21	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
22	0-ABDR mismatch, top 20% EPTS, and blood type permissible	250NM	Any
23	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
24	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
25	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type permissible	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
26	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
27	Top 20% EPTS, blood type B	250NM	A2 or A2B
28	Top 20% EPTS, blood type identical or permissible	250NM	Any
29	0-ABDR mismatch, EPTS greater than 20%, blood type identical	250NM	Any
30	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
31	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
32	0-ABDR mismatch, EPTS greater than 20%, and blood type B	250NM	O
33	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type B	Nation	O
34	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
35	0-ABDR mismatch, EPTS greater than 20%, and blood type permissible	250NM	Any
36	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
37	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
38	EPTS greater than 20%, blood type B	250NM	A2 or A2B
39	All remaining candidates, blood type identical or permissible	250NM	Any
40	Registered prior to 18 years old, blood type identical or permissible	Nation	Any
41	Top 20% EPTS, blood type B	Nation	A2 or A2B
42	Top 20% EPTS, blood type identical or permissible	Nation	Any
43	All remaining candidates, blood type identical or permissible	Nation	Any

8.4.J Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%

Kidneys from deceased donors with KDPI scores greater than 20% but less than 35% are allocated to candidates according to *Table 8-8* below. For the purposes of *Table 8-8*, distribution will be based on the distance from the candidate's transplant hospital to the donor hospital, unless the kidney is allocated according to OPTN *Policy 8.7: Allocation of Released Kidneys*. For kidneys that are released and the host OPO or the OPTN executes a released kidney match run, distribution will be based on the distance from the candidate's transplant hospital to the transplant hospital that released the organ.

Table 8-8: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	250NM	Any
2	CPRA equal to 100%, blood type identical or permissible	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	Nation	Any
4	CPRA equal to 100%, blood type identical or permissible	Nation	Any
5	Prior living donor, blood type identical or permissible	250NM	Any
6	Registered prior to 18 years old, blood type identical or permissible	250NM	Any
7	Medically Urgent	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
8	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	250NM	Any
9	CPRA equal to 99%, blood type identical or permissible	250NM	Any
10	0-ABDR mismatch, CPRA equal to 98%, blood type identical or permissible	250NM	Any
11	CPRA equal to 98%, blood type identical or permissible	250NM	Any
12	0-ABDR mismatch, blood type identical	250NM	Any
13	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
14	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Nation	Any
15	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Nation	Any
16	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
17	0-ABDR mismatch, blood type B	250NM	O
18	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
19	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	Nation	O
20	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	Nation	O
21	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
22	0-ABDR mismatch, blood type permissible	250NM	Any
23	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
24	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
25	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible	Nation	Any
26	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
27	Prior liver, heart, and lung recipients who meet the qualifying criteria according to OPTN *Policies 8.4.F: Prioritization for Liver Recipients on the Kidney Waiting List*, *8.4.G: Prioritization for Heart Recipients on the Kidney Waiting List*, or *8.4.H: Prioritization of Lung Recipients on the Kidney Waiting List*, blood type permissible or identical	250NM	Any
28	Blood type B	250NM	A2 or A2B
29	All remaining candidates, blood type identical or permissible	250NM	Any
30	Registered prior to 18 years old, blood type identical or permissible	Nation	Any
31	Blood type B	Nation	A2 or A2B

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
32	All remaining candidates, blood type identical or permissible	Nation	Any

8.4.K Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%

Kidneys from donors with KDPI scores greater than or equal to 35% but less than or equal to 85% are allocated to candidates according to *Table 8-9* below and the following:

- Classifications 1 through 30 for one deceased donor kidney
- Classification 31 and 32 for both kidneys from a single deceased donor

For the purposes of *Table 8-9*, distribution will be based on the distance from the candidate's transplant hospital to the donor hospital, unless the kidney is allocated according to OPTN *Policy 8.7: Allocation of Released Kidneys*. For kidneys that are released and the host OPO or the OPTN executes a released kidney match run, distribution will be based on the distance from the candidate's transplant hospital to the transplant hospital that released the organ.

Table 8-9: Allocation of Kidneys from Deceased Donors with KDPI Greater Than or Equal To 35% and Less Than or Equal To 85%

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	250NM	Any
2	CPRA equal to 100%, blood type identical or permissible	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
4	CPRA equal to 100%, blood type identical or permissible	Nation	Any
5	Prior living donor, blood type identical or permissible	250NM	Any
6	Medically Urgent	250NM	Any
7	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	250NM	Any
8	CPRA equal to 99%, blood type identical or permissible	250NM	Any
9	0-ABDR mismatch, CPRA equal to 98%, blood type identical or permissible	250NM	Any
10	CPRA equal to 98%, blood type identical or permissible	250NM	Any
11	0-ABDR mismatch, blood type identical	250NM	Any
12	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
13	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
14	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Nation	Any
15	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
16	0-ABDR mismatch, and blood type B	250NM	O
17	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
18	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	Nation	O
19	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	Nation	O
20	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
21	0-ABDR mismatch, blood type permissible	250NM	Any
22	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
23	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type permissible	Nation	Any
24	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type permissible	Nation	Any
25	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
26	Prior liver, heart, and lung recipients who meet the qualifying criteria according to *Policy 8.4.F: Prioritization for Liver Recipients on the Kidney Waiting List*, *Policy 8.4.G: Prioritization for Heart Recipients on the Kidney Waiting List*, or *Policy 8.4.H: Prioritization for Lung Recipients on the Kidney Waiting List*, blood type permissible or identical	250NM	Any
27	Blood type B	250NM	A2 or A2B
28	All remaining candidates, blood type identical or permissible	250NM	Any
29	Blood type B	Nation	A2 or A2B

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
30	All remaining candidates, blood type identical or permissible	Nation	Any
31	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type identical or permissible	250NM	Any
32	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type identical or permissible	Nation	Any

8.4.L Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%

With the exception of 0-ABDR mismatches, kidneys from deceased donors with KDPI scores greater than 85% are allocated to adult candidates according to *Table 8-10* below and the following:

- Classifications 1 through 21, 23, and 24 for one deceased donor kidney
- Classifications 22 and 25 for both kidneys from a single deceased donor

For the purposes of *Table 8-10*, distribution will be based on the distance from the candidate's transplant hospital to the donor hospital, unless the kidney is allocated according to OPTN *Policy 8.7: Allocation of Released Kidneys*. For kidneys that are released and the host OPO or the OPTN executes a released kidney match run, distribution will be based on the distance from the candidate's transplant hospital to the transplant hospital that released the organ.

Table 8-10: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 85%

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	250NM	Any
2	CPRA equal to 100%, blood type identical or permissible	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	Nation	Any
4	CPRA equal to 100%, blood type identical or permissible	Nation	Any
5	Medically Urgent	250NM	Any
6	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	250NM	Any
7	CPRA equal to 99%, blood type identical or permissible	250NM	Any
8	0-ABDR mismatch, CPRA equal to 98%, blood type identical or permissible	250NM	Any
9	CPRA equal to 98%, blood type identical or permissible	250NM	Any
10	0-ABDR mismatch, blood type identical or permissible	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
11	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
12	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
13	0-ABDR mismatch, blood type B	250NM	O
14	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
15	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
16	0-ABDR mismatch, blood type permissible	250NM	Any
17	0-ABDR mismatch, CPRA greater than or equal to 80% , and blood type permissible	Nation	Any
18	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
19	Prior liver, heart, and lung recipients who meet the qualifying criteria according to *Policy 8.4.F: Prioritization for Liver Recipients on the Kidney Waiting List, Policy 8.4.G: Prioritization for Heart Recipients on the Kidney Waiting List, or Policy 8.4.H: Prioritization of Lung Recipients on the Kidney Waiting List*, blood type permissible or identical	250NM	Any
20	Blood type B	250NM	A2 or A2B
21	All remaining candidates, blood type identical or permissible	250NM	Any
22	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type identical or permissible	250NM	Any
23	Blood type B	Nation	A2 or A2B
24	All remaining candidates, blood type identical or permissible	Nation	Any
25	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type identical or permissible	Nation	Any

8.5 Allocation of Both Kidneys from a Single Deceased Donor to a Single Candidate

8.5.A Allocation of Dual Kidneys

If a host OPO procures both kidneys with a KDPI score greater than or equal to 35% from a single deceased donor who weighs greater than or equal to 18 kg, those kidneys will be offered to candidates according to OPTN *Policy 8.4.K: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%* or OPTN *Policy 8.4.L: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 85%*.

8.5.B Allocation of En Bloc Kidneys

If a host OPO procures both kidneys from a single deceased donor less than 18 kg, the host OPO must offer both kidneys en bloc according to OPTN *Policy 8.4.I: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%.*

8.5.C Transplanting Kidneys Individually after Allocation of Both Kidneys from a Single Deceased Donor to a Single Candidate

If the transplanting surgeon determines, based on medical judgment, that kidneys procured together from a single donor should instead be transplanted individually, then the receiving transplant program must do *one* of the following:

- Transplant one of the kidneys into the originally designated recipient and document the reason for not transplanting the kidneys together. The receiving transplant program will decide which of the two kidneys to transplant into the originally designated recipient and release the other kidney according to OPTN *Policy 5.9: Released Organs*.
- Release both kidneys to be allocated according to the KDPI score of the deceased donor, pursuant to OPTN *Policy 5.9: Released Organs*. Kidneys originally allocated en bloc and then split can no longer be allocated as en bloc.

8.6 Administrative Rules

8.6.A Choice of Right versus Left Donor Kidney

If both kidneys from a deceased donor are able to be transplanted, the transplant hospital that received the offer for the candidate with higher priority on the waiting list will get to choose first which of the two kidneys it will receive.

However, when a kidney is offered to a 0-ABDR mismatched candidate, a candidate with a CPRA greater than or equal to 99% (classifications 1 through 4, 8 or 9 *in Tables 8-7 and 8-8*; classifications 1 through 4, 7 or 8 *in Table 8-9*; and classifications 1 through 4, 6 or 7 *in Table 8-10*) or to a combined kidney and non-renal organ candidate, the host OPO determines whether to offer the left or the right kidney.

8.6.B National Kidney Offers

The host OPO must allocate deceased donor kidneys according to *Table 8-11* below. For purposes of this section, national candidates are those candidates registered at transplant programs more than 250 nautical miles from the donor hospital.

Table 8-11: National Kidney Offers

If the organ offer is for:	Then the host OPO must:
A national 0-ABDR mismatch candidate	Allocate the kidney or contact the Organ Center for assistance allocating the kidney
A national 100% CPRA candidate in match classifications 1 through 4 in allocation sequences according to *Tables 8-7* through *8-10*	Allocate the kidney or contact the Organ Center for assistance allocating the kidney
Any other national candidates	Contact the Organ Center for assistance allocating the kidney

8.6.C Kidney Allocation in Multi-Organ Combinations

If a host OPO procures a kidney along with other organs, the host OPO must first offer the kidney according to one of the following policies before allocating the kidney to kidney alone candidates according to *OPTN Policy 8: Allocation of Kidneys*:

- *OPTN Policy 5.10.E: Allocation of Heart-Kidneys*
- *OPTN Policy 5.10.F: Allocation of Lung-Kidneys*
- *OPTN Policy 9.9: Liver-Kidney Allocation*
- *OPTN Policy 11.4.A: Kidney-Pancreas Allocation Order*

8.6.D Multi-Organ Combinations Allocated but Not Transplanted

If a multi-organ combination that includes a kidney is allocated but the kidney transplant is not performed, the kidney must be reallocated according to OPTN *Policy 5.9: Released Organs*.

8.6.E Location of Donor Hospitals

For the purpose of determining the location of the donor hospital, kidneys procured in Alaska will be considered procured from the Sea-Tac Airport, Seattle, Washington.

8.7 Allocation of Released Kidneys

For kidneys allocated according to OPTN *Policy 5.9: Released Organs*, the host OPO may

1. Continue allocation according to the original match run
2. Allocate the kidney using the released kidney match run in accordance with *Tables 8-7, 8-8, 8-9,* and *8-10* or
3. Contact the OPTN for assistance allocating the kidney

Policy 9: Allocation of Livers and Liver-Intestines

9.1 Status and Score Assignments

Each liver transplant candidate is assigned a score that reflects the probability of death within a 3-month period as determined by the Model for End-Stage Liver Disease (MELD) scoring system or the Pediatric End Stage Liver Disease (PELD) scoring system. Liver candidates can also be assigned a priority status if the candidate meets the requirements for that status.

Liver candidates at least 18 years old at the time of registration may be assigned *any* of the following:

- Adult status 1A
- Calculated MELD score
- Exception MELD score
- Inactive status

Liver candidates less than 18 years old at the time of registration may be assigned *any* of the following:

- Pediatric status 1A
- Pediatric status 1B
- Calculated MELD or PELD score
- Exception MELD or PELD score
- Inactive status

Liver candidates less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, will be classified as a 12 to 17 year old for the purposes of allocation in:

- OPTN *Policy 9.8.F: Allocation of Livers from Non- DCD Deceased Donors 11 to 17 Years Old*
- OPTN *Policy 9.8.G: Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old*
- OPTN *Policy 9.8.J: Allocation of Liver-Intestines from Non-DCD Donors Less than 11 Years Old*

If the candidate is removed from the waiting list at any time and returns to the waiting list after turning 18 years old, the candidate must then be registered as an adult.

9.1.A Adult Status 1A Requirements

To assign a candidate adult status 1A, the candidate's transplant hospital must submit a *Liver Status 1A Justification Form* to the OPTN. A candidate is not registered as status 1A until this form is submitted. When reporting laboratory values to the OPTN, transplant hospitals must submit the most recent results including the dates of the laboratory tests.

The candidate's transplant program may assign the candidate adult status 1A if *all* the following conditions are met:

1. The candidate is at least 18 years old at the time of registration
2. The candidate has a life expectancy without a liver transplant of less than 7 days and has at least *one* of the following conditions:

    a. Fulminant liver failure, defined as the onset of hepatic encephalopathy within 56 days of the first signs or symptoms of liver disease. In addition, the candidate:
        i. Must not have a pre-existing diagnosis of liver disease. For purposes of this section, any diagnoses of liver disease that occurred prior to a subsequent liver transplant do not constitute pre-existing liver disease.
        ii. Must currently be admitted in the intensive care unit
        iii. Must meet at least *one* of the following conditions:
            1. Is ventilator dependent
            2. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
            3. Has an international normalized ratio (INR) greater than 2.0

    b. Anhepatic

    c. Primary non-function of a transplanted whole liver within 7 days of transplant, with aspartate aminotransferase (AST) greater than or equal to 3,000 U/L and at least *one* of the following:
        - International normalized ratio (INR) greater than or equal to 2.5
        - Arterial pH less than or equal to 7.30
        - Venous pH less than or equal to 7.25
        - Lactate greater than or equal to 4 mmol/L

        All laboratory results reported for the tests required above must be from the same blood draw taken 24 hours to 7 days after the transplant.

d. non-function within 7-days of transplant of a transplanted liver segment from a deceased or living donor, evidenced by at least *one* of the following:
   - INR greater than or equal to 2.5
   - Arterial pH less than or equal to 7.30
   - Venous pH less than or equal to 7.25
   - Lactate greater than or equal to 4 mmol/L

e. Hepatic artery thrombosis (HAT) within 7-days of transplant, with AST greater than or equal to 3,000 U/L and at least *one* of the following:
   - INR greater than or equal to 2.5
   - Arterial pH less than or equal to 7.30
   - Venous pH less than or equal to 7.25
   - Lactate greater than or equal to 4 mmol/L

   All laboratory results reported for the tests required above must be from the same blood draw taken 24 hours to 7 days after the transplant.

f. Acute decompensated Wilson's disease

9.1.B Pediatric Status 1A Requirements

To assign a candidate pediatric status 1A, the candidate's transplant hospital must submit a *Liver Status 1A Justification Form* to the OPTN. A candidate is not assigned pediatric status 1A until this form is submitted.

The candidate's transplant program may assign the candidate pediatric status 1A if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of registration. This includes candidates less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, but does not include candidates removed from the waiting list at any time who then return to the waiting list after turning 18 years old.
2. The candidate has at least *one* of the following conditions:

   a. Fulminant liver failure and the candidate:
      i. Must not have a pre-existing diagnosis of liver disease. For purposes of this section, any diagnoses of liver disease that occurred prior to a subsequent liver transplant do not constitute pre-existing liver disease.
      ii. Must meet at least *one* of the following criteria:
         1. Is ventilator dependent
         2. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
         3. Has an international normalized ratio (INR) greater than or equal to 1.5 and less than 2.0 and a diagnosis of hepatic encephalopathy within 56 days of the first signs or symptoms of liver disease
         4. Has an INR greater than or equal to 2.0

b. Diagnosis of primary non-function of a transplanted liver within 7 days of transplant, evidenced by at least *two* of the following:
   i. Alanine aminotransferase (ALT) greater than or equal to 2,000 U/L
   ii. INR greater than or equal to 2.5
   iii. Total bilirubin greater than or equal to 10 mg/dL
   iv. Acidosis, defined as *one* of the following:
      - Arterial pH less than or equal to 7.30
      - Venous pH less than or equal to 7.25
      - Lactate greater than or equal to 4 mmol/L

   All laboratory results reported for any tests required for the primary non-function of a transplanted liver diagnosis above must be from the same blood draw taken between 24 hours and 7 days after the transplant.

c. Diagnosis of hepatic artery thrombosis (HAT) in a transplanted liver within 14 days of transplant

d. Acute decompensated Wilson's disease

9.1.C Pediatric Status 1B Requirements

To assign a candidate pediatric status 1B, the candidate's transplant hospital must submit a *Liver Status 1B Justification Form* to the OPTN. A candidate is not registered as status 1B until this form is submitted.

The candidate's transplant program may assign the candidate pediatric status 1B if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of registration. This includes candidates less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, but does not include candidates removed from the waiting list at any time who then return to the waiting list after turning 18 years old.

2. The candidate has *one* of the following conditions:

   a. The candidate has a biopsy-proven hepatoblastoma without evidence of metastatic disease.
   b. The candidate has an organic acidemia or urea cycle defect and an approved MELD or PELD exception meeting standard criteria for metabolic disease for at least 30 days.
   c. Chronic liver disease and meets at least *one* of the following criteria due to complications of chronic liver disease:
      i. Is on a mechanical ventilator
      ii. Has gastrointestinal bleeding requiring red blood cell replacement of at least 30 mL/kg within the previous 96 hours or 20 mL/kg within the previous 24 hours
      iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)

d. Chronic liver disease and is a combined liver-intestine candidate and meets at least *one* of the following criteria due to complications of chronic liver disease:
    i. Is on a mechanical ventilator
    ii. Has gastrointestinal bleeding requiring at least 10 mL/kg of red blood cell replacement within the previous 24 hours
    iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)

9.1.D MELD Score

Candidates who are at least 18 years old at the time of registration receive a MELD score equal to:

MELD = 1.33 (if female) + [4.56 x $\log_e$(bilirubin)] + [0.82 x (137-sodium)] – [0.24 x (137-sodium) x $\log_e$(bilirubin)] + [9.09 x $\log_e$(INR)] + [11.14 x $\log_e$(creatinine)] + [1.85 x (3.5-albumin)] – [1.83 x (3.5 – albumin) x $\log_e$(creatinine)] + 6

Candidates who are currently at least 12 years old and were less than 18 years old at the time of registration receive a MELD score equal to:

MELD = [4.56 x $\log_e$(bilirubin)] + [0.82 x (137-sodium)] – [0.24 x (137-sodium) x $\log_e$(bilirubin)] + [9.09 x $\log_e$(INR)] + [11.14 x $\log_e$(creatinine)] + [1.85 x (3.5-albumin)] – [1.83 x (3.5 – albumin) x $\log_e$(creatinine)] + 7.33

Bilirubin, INR, and creatinine values less than 1.0 will be set to 1.0 when calculating a candidate's MELD score.

The following candidates will receive a creatinine value of 3.0 mg/dL when calculating a candidate's MELD score:

- Candidates with a creatinine value greater than 3.0 mg/dL
- Candidates who received two or more dialysis treatments within the 7 days prior to the serum creatinine test
- Candidates who received 24 hours of continuous veno-venous hemodialysis (CVVHD) within the 7 days prior to the serum creatinine test

Sodium values less than 125 mmol/L will be set to 125 mmol/L, and values greater than 137 mmol/L will be set to 137 mmol/L.

Albumin values less than 1.5 g/dL will be set to 1.5 g/dL, and values greater than 3.5 g/dL will be set to 3.5 g/dL.

The minimum MELD score is 6. The maximum MELD score is 40. The MELD score derived from this calculation will be rounded to the nearest whole number.

9.1.E PELD Score

Candidates who are under the age of 12 receive a PELD score equal to:

Table 9-1: PELD Score Calculation

	If the value is:	Then the value's contribution to PELD is:
Candidate Age (fractional calendar year)	<1	-0.1967 * 1
	1 to 5.5	-0.1967 * age at the time of the most recent lab reported for use in the PELD score
	> 5.5 and < 12	-0.1967 * 5.5
Albumin (g/dL)	1 to 1.9	-1.842 * ln(albumin)
	> 1.9	-1.842 * ln(1.9)
Total bilirubin (mg/dL)	1 to 4	0.7854 * ln(bilirubin) + 0.3434 * ln(4)
	> 4 to 40	0.7854 * ln(4) + 0.3434 * ln(bilirubin)
	> 40	0.7854 * ln(4) + 0.3434 * ln(40)
INR	1 to 2	1.981 * ln(INR) + 0.7298 * ln(2)
	> 2 to 10	1.981 * ln(2) + 0.7298 * ln(INR)
	> 10	1.981 * ln(2) + 0.7298 * ln(10)
Minimum of CDC height or weight Z-score	< -5.0	-0.1807 * (-5)
	-5.0 to -2.1	-0.1807 * (minimum z-score)
	> -2.1	-0.1807 * (-2.1)
Creatinine (mg/dL)	< 0.2	1.453 * ln(.02)
	0.2 to 1.3	1.453 * ln(creatinine)
	> 1.3	1.453 * ln(1.3)

A candidate's PELD score will then be calculated as follows:

PELD = (sum of all terms as outlined in **Table 9-1: PELD Score Calculation** + 1.5287) x 10 + 2.82

The minimum of Center for Disease Control and Prevention's (CDC) height or weight Z-score uses the lambda-mu-alpha (LMS) method and is based on the 2000 CDC Growth Charts for the United States. The calculation uses the candidate's birth sex, most recent values submitted for

height and weight, and the candidate's age in months at the time the height and weight values used in the PELD calculation were measured.

Albumin, bilirubin, and INR values less than 1.0 will be set to 1.0 when calculating a candidate's PELD score.

The following candidates will receive a creatinine value of 1.3 mg/dL when calculating a candidate's PELD score:

- Candidates with a creatinine value greater than 1.3 mg/dL
- Candidates who received two or more dialysis treatments within the 7 days prior to the serum creatinine test
- Candidates who received 24 hours of continuous veno-venous hemodialysis (CVVHD) within the 7 days prior to the serum creatinine test

The minimum PELD score is 6. The PELD score derived from this calculation will be rounded to the nearest whole number.

9.1.F Liver-Intestine Candidates

Liver candidates who are registered on the waiting list after turning 18 years old and are also registered and active on the waiting list for an intestine transplant at that transplant hospital will automatically receive an additional increase in their MELD or PELD score equivalent to a 10 percentage point increase in risk of 3-month mortality. Liver candidates who are registered on the waiting list before turning 18 years old and are also registered and active on the waiting list for an intestine transplant at that transplant hospital will receive 23 additional points to their calculated MELD or PELD score. The transplant hospital must document in the candidate's medical record the medical justification for the combined liver-intestine transplant and that the transplant was completed.

9.2 Status and Laboratory Values Update Schedule

The OPTN will notify the transplant hospital within 2 days of the deadline for recertification when a candidate's laboratory values need to be updated. Transplant hospitals must recertify a candidate's values according to *Table 9-2*.

When reporting laboratory values to the OPTN, transplant hospitals must submit the most recent results including the dates of the laboratory tests. In order to change a MELD or PELD score voluntarily, all laboratory values must be obtained within the same 2 day period.

Table 9-2: Liver Status Update Schedule

If the candidate is:	The new laboratory values must be reported every:	And when reported, the new laboratory values must be no older than :
Status 1A or 1B	7 days	2 days
MELD 25 or greater (ages 18 or older)	7 days	2 days
MELD or PELD 25 or greater (less than 18 years old)	14 days	3 days
MELD or PELD 19 to 24	30 days	7 days
MELD or PELD 11 to 18	90 days	14 days
MELD or PELD 10 or less	365 days	30 days

Status 1B candidates have these further requirements for certification:

- Candidates with a gastrointestinal bleed as the reason for the initial status 1B upgrade criteria must have had another bleed in the past 7 days immediately before the upgrade in order to recertify as status 1B.
- Candidates indicating a metabolic disease or a hepatoblastoma require recertification every 90 days with lab values no older than 14 days.

If a candidate is not recertified by the deadline according to *Table 9-2*, the candidate will be re-assigned to their previous lower MELD or PELD score. The candidate may remain at that previous lower score for the period allowed based on the recertification schedule for the previous lower score, minus the time spent in the uncertified score.

If the candidate remains uncertified past the recertification due date for the previous lower score, the candidate will be assigned a MELD or PELD score of 6. If a candidate has no previous lower MELD or PELD score, and is not recertified according to the schedule, the candidate will be reassigned to a MELD or PELD score of 6.

9.2.A Recertification of Status 1A or 1B

Transplant hospitals must submit a completed *Liver Status 1A or 1B Justification Form* to the OPTN for *each* recertification as a status 1A or 1B. A request to continue as status 1A or 1B beyond 14 days accumulated time will result in a review of all status 1A or 1B liver candidate registrations at the transplant hospital. A review will not occur if the request was for a candidate meeting the requirements for hepatoblastoma in OPTN *Policy 9.1.C: Pediatric Status 1B Requirements* or a metabolic disease in OPTN *Policy 9.5.F: Requirements for Metabolic Disease MELD or PELD Score Exceptions*.

9.2.B Reporting of Final Laboratory Value at Removal from Waiting List

The transplant hospital must report final laboratory values reported for certification to the OPTN before removing the candidate from the waiting list as transplanted or deceased.

9.3 Status Exceptions

The Liver and Intestinal Organ Transplantation Committee establishes guidelines for review of status and MELD or PELD score exception requests.

If a candidate's transplant program believes that a candidate's current status does not appropriately reflect the candidate's medical urgency for transplant, the transplant program may register a candidate at an exceptional status. However, the Liver and Intestinal Organ Transplantation Committee will retrospectively review all exception candidates registered as status 1A or 1B and may refer these cases to the Membership and Professional Standards Committee (MPSC) for review according to *Appendix L* of the *OPTN Management and Membership Policies*.

9.4 MELD or PELD Score Exceptions

If a candidate's transplant program believes that a candidate's current MELD or PELD score does not appropriately reflect the candidate's medical urgency for transplant, the transplant program may submit a MELD or PELD score exception request to the National Liver Review Board (NLRB).

9.4.A MELD or PELD Score Exception Requests

A MELD or PELD score exception request must include:

1. A request for either:
   a. An adjustment of a certain amount of points higher or lower than MMaT or MPaT or
   b. A specific MELD or PELD score of 40 or higher
2. A justification that outlines how a candidate's medical condition warrants an exception and the specific score being requested.

MELD or PELD exceptions are valid for 90 days from the date the exception is approved or assigned.

9.4.B NLRB and Committee Review of MELD or PELD Exceptions

The NLRB must review exception or extension requests within 21 days of the date the request is submitted to the OPTN. If the NLRB fails to make a decision on the initial exception or extension request by the end of the 21 day review period, the candidate will be assigned the requested MELD or PELD exception score.

9.4.B.i NLRB Appeals

If the NLRB denies an exception or extension request, the candidate's transplant program may appeal to the NLRB within 14 days of receiving the denial.

The NLRB must review appeals within 21 days of the date the appeal is submitted to the OPTN. If the NLRB fails to make a decision on the appeal by the end of the 21 day appeal period, the candidate will be assigned the requested MELD or PELD exception score.

9.4.B.ii Appeals Review Team (ART) Conference

If the NLRB denies the appeal for an exception or extension request, the candidate's transplant program may further appeal to the Appeals Review Team (ART) within 7 days of receiving notification of the denial. If the transplant program appeals the exception or extension request to the ART, the ART must review the request within 14 days of the date the appeal is submitted to the OPTN. If the ART fails to make a decision on the appealed request by the end of the 14 day ART appeal review period, the candidate will be assigned the requested MELD or PELD exception score.

9.4.B.iii Committee Appeals

If the ART denies the appeal for an exception or extension request, the candidate's transplant program may appeal to the Liver and Intestinal Organ Transplantation Committee within 7 days of receiving notification of the denial.

9.4.C MELD or PELD Exception Extensions

9.4.C.i Hepatocellular Carcinoma (HCC) MELD or PELD Score Exception Extensions

A candidate with an approved exception for HCC is eligible for automatic approval of an extension according to OPTN *Policy 9.5.I.vii Extensions of HCC Exceptions*, even if the initial exception was not a standardized MELD or PELD score exception.

9.4.C.ii Other MELD or PELD Score Exception Extensions

A candidate's approved or assigned exception will be maintained if the transplant program enters a MELD or PELD Exception Score Extension Request before the due date, even if the NLRB does not act before the due date. If the extension request is denied or if no MELD or PELD Exception Score Extension Request is submitted before the due date, then the candidate will be assigned the calculated MELD or PELD score based on the most recent reported laboratory values.

Each approved or assigned MELD or PELD exception extension is valid for an additional 90 days beginning from the day that the previous exception or extension expired.

9.4.D Calculation of Median MELD or PELD at Transplant

For each donor hospital, the OPTN will calculate the MMaT based on a cohort of recipients transplanted at programs at or within 150 nautical miles of the donor hospital in a prior 365 day period. If there are either less than two active liver transplant programs or less than 10 qualifying transplants within 150 nautical miles of the donor hospital, the geographic area used to calculate the MMaT will increase in 50 nautical mile increments until two active liver transplant programs and 10 qualifying transplants are included in the MMaT cohort.

The MMaT is calculated by using the median of the MELD scores at the time of transplant of all recipients within the geographic area defined above that are at least 12 years old at the time of transplant. Recipients are excluded who are either of the following:

1. Transplanted with livers from living donors, DCD donors, or donors from donor hospitals more than 500 nautical miles away from the recipient's transplant program or
2. Status 1A or 1B at the time of transplant.

If a transplant program has not performed at least one transplant included in the MMaT calculation, the program is not included in the MMaT cohort.

If there are less than 10 qualifying transplants within 250 nautical miles of a donor hospital in Hawaii or Puerto Rico, the MMaT will be calculated based on a total of 730 days. There does not need to be two transplant programs within 250 nautical miles of donor hospitals in Hawaii or Puerto Rico.

Median PELD at transplant (MPaT) is calculated by using the median of the PELD scores at the time of transplant of all recipients less than 12 years old at the time of transplant in the nation. Recipients are excluded who are either of the following:

1. Transplanted with livers from living donors, DCD donors, or donors from donor hospitals more than 500 nautical miles away from the recipient's transplant program or
2. Status 1A or 1B at the time of transplant.

The OPTN will recalculate the MMaT and MPaT twice a year based on an updated cohort. The updated cohort will include transplants over a prior 365 day period.

9.4.E MELD or PELD Exception Scores Relative to Median MELD or PELD at Transplant

A match run will provide MELD exception candidates on the match run a MELD exception score relative to the MMaT for the donor hospital. PELD exception candidates are provided a PELD exception score relative to the MPaT for the nation. If a candidate's exception score relative to MMaT or MPaT would be lower than 15, the candidate's exception score will be 15.

The following exception scores are not awarded relative to MMaT or MPaT:

1. Exception scores of 40 or higher awarded by the NLRB according to OPTN *Policy 9.4.A: MELD or PELD Score Exception Requests*
2. Any exception awarded according to OPTN *Policy 9.5.D: Requirements for Hepatic Artery Thrombosis (HAT) MELD or PELD Score Exceptions*

3. Exceptions awarded to candidates less than 18 years old at time of registration according to OPTN *Policy 9.5.I: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions*

9.5 Specific Standardized MELD or PELD Score Exceptions

Candidates are eligible for MELD or PELD score exceptions or extensions that do not require evaluation by the NLRB if they meet *any* of the following requirements for a specific diagnosis of *any* of the following:

- Hilar Cholangiocarcinoma (CCA), according to OPTN *Policy 9.5.A: Requirements for Hilar Cholangiocarcinoma MELD or PELD Score Exceptions*
- Cystic fibrosis, according to OPTN *Policy 9.5.B: Requirements for Cystic Fibrosis MELD or PELD Score Exceptions*
- Familial amyloid polyneuropathy, according to OPTN *Policy 9.5.C: Requirements for Familial Amyloid Polyneuropathy (FAP) MELD or PELD Score Exceptions*
- Hepatic artery thrombosis, according to OPTN *Policy 9.5.D: Requirements for Hepatic Artery Thrombosis (HAT) MELD Score Exceptions*
- Hepatopulmonary syndrome, according to OPTN *Policy 9.5.E: Requirements for Hepatopulmonary Syndrome (HPS) MELD or PELD Score Exceptions*
- Metabolic disease, according to OPTN *Policy 9.5.F: Requirements for Metabolic Disease MELD or PELD Score Exceptions*
- Portopulmonary hypertension, according to OPTN *Policy 9.5.G: Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions*
- Primary hyperoxaluria, according to OPTN *Policy 9.5.H: Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions*
- Hepatocellular carcinoma, according to OPTN *Policy 9.5.I: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exception*

9.5.A Requirements for Hilar Cholangiocarcinoma (CCA) MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for Hilar CCA, if the candidate's transplant program meets *all* the following qualifications:

1. Submits a written protocol for patient care to the Liver and Intestinal Organ Transplantation Committee for review and approval. The written protocol must include *all* of the following:
   i. Candidate selection criteria
   ii. Administration of neoadjuvant therapy before transplantation
   iii. Operative staging to exclude any patient with regional hepatic lymph node metastases, intrahepatic metastases, or extrahepatic disease
   iv. Any data requested by the Liver and Intestinal Organ Transplantation Committee

2. Documents that the candidate meets the diagnostic criteria for Hilar CCA with a malignant appearing stricture on cholangiography and at least *one* of the following:
   - Biopsy or cytology results demonstrating malignancy
   - Carbohydrate antigen 19-9 greater than 100 U/mL in absence of cholangitis

- Aneuploidy
- Hilar mass, which is less than 3 cm in radial diameter.

The tumor must be considered un-resectable because of technical considerations or underlying liver disease.

3. Submits cross-sectional imaging studies. If cross-sectional imaging studies demonstrate a mass, the mass must be single and less than three cm in radial (perpendicular to the duct) diameter. The longitudinal extension of the stricture along the bile duct is not considered in the measurement of a mass.

4. Documents the exclusion of intrahepatic and extrahepatic metastases by cross-sectional imaging studies of the chest and abdomen within 90 days prior to submission of the initial exception request.

5. Assesses regional hepatic lymph node involvement and peritoneal metastases by operative staging after completion of neoadjuvant therapy and before liver transplantation. Endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable to exclude patients with obvious metastases before neo-adjuvant therapy is initiated.

6. Transperitoneal aspiration or biopsy of the primary tumor (either by endoscopic ultrasound, operative or percutaneous approaches) must be avoided because of the high risk of tumor seeding associated with these procedures.

A candidate who meets the requirements for a standardized MELD or PELD score exception will receive a score according to *Table 9-2*.

Table 9-2: Hilar CCA Exception Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

In order to be approved for an extension of this MELD or PELD score exception, transplant programs must submit an exception extension request according to OPTN *Policy 9.4.C: MELD or PELD Exception Extensions,* and provide cross-sectional imaging studies of the chest and abdomen that exclude intrahepatic and extrahepatic metastases. These required imaging studies must have been completed within 30 days prior to the submission of the extension request.

9.5.B Requirements for Cystic Fibrosis (CF) MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for cystic fibrosis if the candidate's diagnosis has been confirmed by genetic analysis, and the candidate has a forced expiratory volume at one second (FEV1) below 40 percent of predicted FEV1 within 30 days prior to submission of the initial exception request.

A candidate who meets the requirements for a standardized MELD or PELD score exception will receive a score according to *Table 9-3*.

Table 9-3: Cystic Fibrosis Exception Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

In order to be approved for an extension of this MELD or PELD score exception, transplant programs must submit an exception extension request according to OPTN *Policy 9.4.C: MELD or PELD Exception Extensions.*

9.5.C Requirements for Familial Amyloid Polyneuropathy (FAP) MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for FAP if the candidate's transplant program submits evidence of *all* of the following:

1. Either that the candidate is also registered and active on the waiting list for a heart transplant at that transplant hospital, or has an echocardiogram performed within 30 days prior to submission of the initial exception request showing the candidate has an ejection fraction greater than 40 percent.
2. That the candidate can walk without assistance.
3. That a transthyretin (TTR) gene mutation has been confirmed.
4. A biopsy-proven amyloid.

A candidate who meets the requirements for a standardized MELD or PELD score exception will receive a score according to *Table 9-4*.

Table 9-4: FAP Exception Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

In order to be approved for an extension of this MELD or PELD score exception, transplant programs must submit an exception extension request according to OPTN *Policy 9.4.C: MELD or PELD Exception Extensions* and meet one of the following criteria:

1. An echocardiogram that shows that the candidate has an ejection fraction greater than 40 percent within the last 120 days
2. Registered and active on the waiting list for a heart transplant at that hospital

9.5.D Requirements for Hepatic Artery Thrombosis (HAT) MELD Score Exceptions

A candidate will receive a MELD score exception for HAT if the candidate is at least 18 years old at registration and has HAT within 14 days of transplant but does not meet criteria for status 1A in OPTN *Policy 9.1.A: Adult Status 1A Requirements*.

Candidates who meet these requirements will receive a MELD score of 40.

In order to be approved for an extension of this MELD score exception, transplant programs must submit an exception extension request according to OPTN *Policy 9.4.C: MELD or PELD Exception Extensions.*

9.5.E Requirements for Hepatopulmonary Syndrome (HPS) MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for HPS if the candidate's transplant program submits evidence of *all* of the following:

1. Ascites, varices, splenomegaly, or thrombocytopenia.
2. A shunt, shown by either contrast echocardiogram or lung scan.
3. PaO_2 less than 60 mmHg on room air within 30 days prior to submission of the initial exception request.
4. No clinically significant underlying primary pulmonary disease.

A candidate who meets the requirements for a standardized MELD or PELD exception will receive a score according to *Table 9-5*.

Table 9-5: HPS Exception Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

In order to be approved for an extension of this MELD or PELD score exception, transplant programs must submit an exception extension request according to OPTN *Policy 9.4.C: MELD or PELD Exception Extensions,* with evidence that the candidate's PaO_2 remained at less than 60 mmHg on room air within the 30 days prior to submission of the extension request.

9.5.F Requirements for Metabolic Disease MELD or PELD Score Exceptions

A liver candidate less than 18 years old at the time of registration will receive a MELD or PELD score exception for metabolic disease if the candidate's transplant program submits evidence of urea cycle disorder or organic acidemia.

A candidate who meets the requirements for a standardized MELD or PELD score exception will receive a score according to *Table 9-6*.

Table 9-6: Metabolic Disease Exception Scores

Age	Age at registration	Score
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

If the candidate does not receive a transplant within 30 days of being registered with the exception score, then the candidate's transplant physician may register the candidate as a status 1B.

In order to be approved for an extension of this MELD or PELD score exception, transplant programs must submit an exception extension request according to OPTN *Policy 9.4.C: MELD or PELD Exception Extensions.*

9.5.G Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for portopulmonary hypertension if the transplant program submits evidence of *all* of the following:

1. Document via heart catheterization initial mean pulmonary arterial pressure (MPAP) level greater than or equal to 35 mmHg and initial pulmonary vascular resistance (PVR) level greater than or equal to 240 dynes*sec/cm^5 (or greater than or equal to 3 Wood units (WU)). These values must be from the same test date.
2. Other causes of pulmonary hypertension have been assessed and determined to not be a significant contributing factor
3. Initial transpulmonary gradient to correct for volume overload
4. Documentation of treatment
5. Document via heart catheterization within 90 days prior to submission of the initial exception either of the following:
    - Post-treatment MPAP less than 35 mmHg and post-treatment PVR less than 400 dynes*sec/cm^5 (or less than 5 Wood units (WU)). These values must be from the same test date.
    - Post-treatment MPAP greater than or equal to 35 mmHg and less than 45 mmHg and post-treatment PVR less than 240 dynes*sec/cm^5 (or less than 3 Wood units (WU)). These values must be from the same test date.
6. Documentation of portal hypertension at the time of initial exception

A candidate who meets the requirements for a standardized MELD or PELD score exception will receive a score according to *Table 9-7*.

Table 9-7: Portopulmonary Hypertension Exception Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

In order to be approved for an extension of this MELD or PELD score exception, transplant programs must submit an exception extension request according to OPTN *Policy 9.4.C: MELD or PELD Exception Extensions* with evidence of a heart catheterization since the last exception or extension request that confirms either of the following:

- MPAP less than 35 mmHg and PVR less than 400 dynes*sec/cm^5 (or less than 5 Wood units (WU)). These values must be from the same test date.
- MPAP greater than or equal to 35 mmHg and less than 45 mmHg and PVR less than 240 dynes*sec/cm^5 (or less than 3 Wood units (WU)). These values must be from the same test date.

9.5.H Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for primary hyperoxaluria if the candidate's transplant program submits evidence of all of the following:

1. The liver candidate is registered on the waiting list for a kidney transplant at that transplant hospital
2. Alanine glyoxylate aminotransferase (AGT) deficiency proven by liver biopsy using sample analysis or genetic analysis
3. Glomerular filtration rate (GFR) less than or equal to 25 mL/min on 2 occasions at least 42 days apart

A candidate who meets the requirements for a standardized MELD or PELD score exception will receive an exception score according to *Table 9-8*.

Table 9-8: Primary Hyperoxaluria Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	Equal to MMaT
At least 12 years old	Less than 18 years old	3 points above MMaT
Less than 12 years old	Less than 12 years old	3 points above MPaT

In order to be approved for an extension of this MELD or PELD score exception, transplant programs must submit an exception extension request according to OPTN OPTN *Policy 9.4.C: MELD or PELD Exception Extensions* with evidence that the candidate is registered on the waiting list for a kidney transplant at that hospital.

9.5.I Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions

Upon submission of the first exception request, a candidate with hepatocellular carcinoma (HCC) will receive a score according to *OPTN Policy 9.5.I.vii: Extensions of HCC Exceptions* if the candidate meets the criteria according to *OPTN Policies 9.5.I.i through 9.5.I.vi.*

9.5.I.i Initial Assessment and Requirements for HCC Exception Requests

Prior to applying for a standardized MELD or PELD exception, the candidate must undergo a thorough assessment that includes *all* of the following:

1. An evaluation of the number and size of lesions using multiphase contrast-enhanced computer tomography (CT) or magnetic resonance imaging (MRI) before locoregional therapy.
2. An evaluation that the lesions meet Class 5 criteria according to *Table 9-9* using a multiphase contrast-enhanced (CT), (MRI), or ultrasound (CEUS).
3. A CT of the chest to rule out metastatic disease. This is only required prior to applying for an initial exception. A CT of the chest is not required for exception extensions.
4. A CT or MRI to rule out any other sites of extrahepatic spread or macrovascular involvement
5. An indication that the candidate is not eligible for resection
6. An indication whether the candidate has undergone locoregional therapy
7. The candidate's alpha-fetoprotein (AFP) level

The transplant hospital must maintain documentation of the radiologic images and assessments of all OPTN Class 5 lesions in the candidate's medical record. If growth criteria are used to classify a lesion as HCC, the radiology report must contain the prior and current dates of imaging, type of imaging, and measurements of the lesion.

For those candidates who receive a liver transplant while receiving additional priority under the HCC exception criteria, the transplant hospital must submit the *Post-Transplant Explant Pathology Form* to the OPTN within 60 days of transplant. If the *Post-Transplant Explant Pathology Form* does not show evidence of HCC or liver-directed therapy for HCC, the transplant program must also submit documentation or imaging studies confirming HCC at the time of assignment.

The Liver and Intestinal Organ Transplantation Committee will review the submitted documentation or imaging studies when more than 10 percent of the *Post-Transplant Explant Pathology Forms* submitted by a transplant program in a one year period do not show evidence of HCC or liver-directed therapy for HCC.

9.5.I.ii Eligible Candidates Definition of T2 Stage

Candidates with hepatic lesions that meet T2 stage are eligible for a standardized MELD or PELD exception if they have an alpha-fetoprotein (AFP) level less than or equal to 1000 ng/mL. T2 stage is defined as candidates with *either* of the following:

- One Class 5 lesion greater than or equal to 2 cm and less than or equal to 5 cm in size.
- Two or three Class 5 lesions each greater than or equal to 1 cm and less than or equal to 3 cm in size.

A candidate who has previously had an AFP level greater than 1000 ng/mL at any time must qualify for a standardized MELD or PELD exception according to OPTN *Policy 9.5.I.iv: Candidates with Alpha-fetoprotein (AFP) Levels Greater than 1000.*

9.5.I.iii Lesions Eligible for Downstaging Protocols

Candidates are eligible for a standardized MELD or PELD exception if, before completing locoregional therapy, they have lesions that meet *one* of the following criteria:

- One Class 5 lesion greater than 5 cm and less than or equal to 8 cm
- Two or three Class 5 lesions that meet all of the following:
  - at least one lesion greater than 3 cm
  - each lesion less than or equal to 5 cm, and
  - a total diameter of all lesions less than or equal to 8 cm
- Four or five Class 5 lesions each less than 3 cm, and a total diameter of all lesions less than or equal to 8 cm

For candidates who meet the downstaging criteria above and then complete locoregional therapy, the viable lesions must subsequently meet the size requirements for T2 stage according to OPTN *Policy 9.5.I.ii: Eligible Candidates Definition of T2 Stage* to be eligible for a standardized MELD or PELD exception. Downstaging to meet eligibility requirements for T2 stage must be demonstrated by multiphase contrast-enhanced CT or MRI performed after locoregional therapy. Candidates with lesions that do not initially meet the downstaging protocol inclusion criteria who are later downstaged and then meet eligibility for T2 stage are not automatically eligible for a standardized MELD or PELD exception and must be referred to the NLRB for consideration of a MELD or PELD exception.

9.5.I.iv Candidates with Alpha-fetoprotein (AFP) Levels Greater than 1000

Candidates with lesions meeting T2 stage according to OPTN *Policy 9.5.I.ii Eligible Candidates Definition of T2 Stage* but with an alpha-fetoprotein (AFP) level greater than 1000 ng/mL may be treated with locoregional therapy. If the candidate's AFP level falls below 500 ng/mL after treatment, the candidate is eligible for a standardized MELD or PELD exception as long as the candidate's AFP level remains

below 500 ng/mL. Candidates with an AFP level greater than or equal to 500 ng/mL following locoregional therapy at any time must be referred to the NLRB for consideration of a MELD or PELD exception.

9.5.I.v Requirements for Multiphase Contrast-enhanced CT or MRI of the Liver

CT scans or MRIs performed for a HCC MELD or PELD score exception request must be interpreted by a radiologist at a transplant hospital. If the lesion cannot be categorized due to image degradation or omission, then the lesion will be classified as Not categorizable (NC) and imaging must be repeated or completed to receive an HCC MELD or PELD exception. If the lesion cannot be fully categorized due to image degradation or omission, then imaging must be repeated or completed. Contrast-enhanced ultrasound (CEUS) can be used to determine class 5 classification, in accordance with *Table 9-9*.

9.5.I.vi Imaging Requirements for Class 5 Lesions

Lesions found on imaging in candidates at risk for HCC are classified according to *Table 9-9*. The imaging criteria within the table apply only to observations which do not represent benign lesions or non-HCC malignancy (i.e. targetoid or LR-M) by imaging.

Table 9-9: Classification System for Lesions Seen on Imaging of Livers

Class	Description
NC – Not Categorizable	Incomplete or technically inadequate study due to image degradation or omission
5A	Must meet *all* of the following: • Maximum diameter of at least 1 cm and less than 2 cm, as measured on late arterial or portal phase images • Either of the following: o LI-RADS 5 classification on CT, MRI, or CEUS o Biopsy
5B	Must meet *all* of the following: • Maximum diameter of at least 2 cm and less than or equal to 5 cm, as measured on late arterial or portal phase images • Either of the following: o LI-RADS 5 classification on CT, MRI, or CEUS o Biopsy
5T	a. Any Class 5A, 5B lesion that was automatically approved upon initial request or extension and has subsequently been treated by locoregional therapy

9.5.I.vii Extensions of HCC Exceptions

A candidate with an approved exception for HCC is eligible for automatic approval of an extension if the transplant program enters a MELD or PELD Exception Score Extension Request that contains the following:

1. Documentation of the tumor stage using multiphase contrast-enhanced CT or MRI
2. The type of treatment if the number of tumors decreased since the last request
3. The candidate's alpha-fetoprotein (AFP) level

A CT of the chest to rule out metastatic disease is not required after the initial exception request.

The candidate's exception extension will then be automatically approved unless *any* of the following occurs:

- The candidate's lesions progress beyond T2 criteria, according to OPTN *9.5.I.ii: Eligible Candidates Definition of T2 Stage*
- The candidate's alpha-fetoprotein (AFP) level was less than or equal to 1,000 ng/mL on the initial request but subsequently rises above 1,000 ng/mL
- The candidate's AFP level was greater than 1,000 ng/mL, the AFP level falls below 500 ng/mL after treatment but before the initial request, then the AFP level subsequently rises to greater than or equal to 500 ng/mL
- The candidate's tumors have been resected since the previous request
- The program requests a score different from the scores assigned in Table 9-10.

When a transplant program submits either an initial exception request or the first extension request for a liver candidate at least 18 years old at the time of registration that meets the requirements for a standardized MELD score exception, the candidate will appear on the match run according to the calculated MELD score.

A candidate who meets these requirements for a MELD or PELD score exception for HCC will receive a score according to *Table 9-10* below.

Table 9-10: HCC Exception Scores

Age	Age at registration	Exception Request	Score
At least 18 years old	At least 18 years old	Initial and first extension	Calculated MELD
At least 18 years old	At least 18 years old	Any extension after the first extension	3 points below MMaT
At least 12 years old	Less than 18 years old	Any	40
Less than 12 years old	Less than 12 years old	Any	40

9.6 Waiting Time

9.6.A Waiting Time for Liver Candidates

Liver transplant candidates on the waiting list accrue waiting time within status 1A or 1B or any MELD or PELD score.

Status 1A or 1B candidates will receive waiting time points based on their waiting time in that status, according to OPTN *Policy 9.7.A: Points for Waiting Time*. Status 1A candidates begin accruing waiting time at status 1A upon submission of the earliest *Liver Status 1A or 1B Justification Form* for the status 1A. Status 1B candidates begin accruing waiting time at status 1B upon submission of the earliest *Liver Status 1A or 1B Justification Form* for status 1B.

Candidates with a MELD or PELD score begin accruing waiting time when the candidate is first registered as an active liver candidate on the waiting list.

Allocation MELD or PELD score waiting time is accrued as follows:

- If the candidate's allocation MELD or PELD score is based on a calculated MELD or PELD score, then allocation MELD or PELD score waiting time includes all waiting time at current or higher calculated MELD or PELD score, including liver-intestine points. Waiting time at current or higher calculated MELD or PELD score includes *all* of the following:
    1. Waiting time at current calculated MELD or PELD score, including liver-intestine points
    2. Previous waiting time accrued during an earlier period at current calculated MELD or PELD sore, including liver-intestine points
    3. Previous total waiting time accrued at any calculated MELD or PELD score higher than the current calculated MELD or PELD score, including liver-intestine points
    4. Previous total waiting time accrued at status 1A and status 1B

- If the candidate's allocation MELD or PELD score is an exception MELD or PELD score, then allocation MELD or PELD score waiting time equals time since submission of earliest approved or assigned MELD or PELD exception request, including time at an inactive status.

9.6.B Waiting Time for Liver-Intestine Candidates

Waiting time accrued by a candidate for an isolated intestinal organ transplant while waiting on the waiting list may also be applied for a combine liver-intestine transplant, when it is determined that the candidate requires both organs.

9.7 Liver Allocation Points

Points are used for sorting liver candidates according to OPTN *Policy 9.8.D: Sorting Within Each Classification*.

9.7.A Points for Waiting Time

Points are assigned so that the status 1A or 1B candidate with the longest waiting time receives the most points as follows:

- 10 points for the candidate with the greatest total status 1A or status 1B waiting time within each classification
- A fraction of 10 points divided up among the remaining status 1A or status 1B candidates within each classification, based on the potential recipient's total waiting time

9.7.B Points Assigned by Blood Type

For status 1A and 1B transplant candidates, those with the same blood type as the deceased liver donor will receive 10 points. Candidates with compatible but not identical blood types will receive 5 points, and candidates with incompatible types will receive 0 points. Blood type O candidates who will accept a liver from a blood type A, non-A1 blood type donor will receive 5 points for blood type incompatible matching.

9.7.C Points Assigned by Diagnosis

Status 1B candidates will be assigned points based on diagnosis as follows:

- If the candidate's diagnosis is chronic liver disease, the candidate will receive 15 points.
- If the candidate's diagnosis is hepatoblastoma, the candidate will receive 5 points.
- If the candidate's diagnosis is an organic acidemia or urea cycle defect, the candidate will receive 0 points.
- If the candidate has any other diagnosis, the candidate will receive 0 points.

9.8 Liver Allocation, Classifications, and Rankings

Unless otherwise stated, all mentions of MELD or PELD in this section reference a candidate's allocation MELD or PELD score.

9.8.A Segmental Transplant and Allocation of Liver Segments

If a transplant program accepts a liver and performs a segmental transplant, the host OPO must make reasonable attempts to offer the remaining segment according to the adult deceased donor liver match run. If the remaining segment has not been allocated by the time the deceased donor organ procurement has started, the transplant hospital must offer it to candidates registered with the transplant program, or any medically appropriate candidate on the waiting list.

The match run will identify a donor's liver as one with the potential to be split if the donor meets *all* the following criteria:

1. Less than 40-years old
2. On a single vasopressor or less
3. Transaminases no greater than three times the normal level
4. Body mass index (BMI) of 28 or less

The deceased donor liver match run will also indicate if potential transplant recipients are willing to accept a segmental liver transplant.

If the potential transplant recipient that receives the primary whole liver offer ultimately declines the liver, any subsequent segmental allocation must be relinquished so that the host OPO may reallocate the whole liver using the liver match run that corresponds to the deceased donor's age.

The transplant hospital that receives the primary whole liver offer will determine how the liver will be split.

9.8.B Allocation of Livers for Other Methods of Hepatic Support

A liver must be offered first for transplantation according to the match run before it is offered for use in other methods of hepatic support. If the liver is not accepted for transplant within 6 hours of attempted allocation by the OPTN, the OPTN will offer the liver for other methods of hepatic support, according to *Tables 9-11, 9-12, 9-13, 9-14, 9-15,* and *9-16* below.

9.8.C Allocation of Livers by Blood Type

Livers from blood type O donors must be offered in the following order:

1. Status 1A and 1B candidates, blood type O candidates, and blood type B candidates with a MELD or PELD score of at least 30
2. Blood type B candidates with a MELD or PELD score less than 30
3. Any remaining blood type compatible candidates

For status 1A or 1B candidates or candidates with a MELD or PELD score ≥ 30, transplant hospitals may specify on the waiting list if those candidates will accept a liver from a deceased donor of any blood type. Candidates are given points depending on their blood type according to OPTN *Policy 9.7.B: Points Assigned by Blood Type*.

9.8.D Sorting Within Each Classification

Within each status 1A allocation classification, candidates are sorted in the following order:

1. The sum of waiting time and blood type compatibility points, according to OPTN *Policy 9.7: Liver Allocation Points* (highest to lowest)
2. Total waiting time at status 1A (highest to lowest)

Within each status 1B allocation classification, candidates are sorted in the following order:

1. The sum of waiting time, blood type compatibility, and diagnosis points according to OPTN *Policy 9.7: Liver Allocation Points* (highest to lowest)
2. Total waiting time at status 1B (highest to lowest)

Within each MELD or PELD score allocation classification, all candidates are sorted in the following order:

1. Allocation MELD or PELD score (highest to lowest)
2. Blood type compatibility (identical, compatible, then incompatible)

3. Age at time of registration on the liver waitlist (less than 18 years old followed by 18 years or older)
4. Allocation MELD or PELD score type (calculated, including liver-intestine points, then exception)
5. Allocation MELD or PELD score waiting time (highest to lowest)
6. Total waiting time (highest to lowest)

9.8.E Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Livers from non-DCD deceased donors at least 18 years old and less than 70 years old are allocated to candidates according to *Table 9-11* below.

Table 9-11: Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
1	Status 1A	500NM	Any	Any
2	Status 1B	500NM	Any	Any
3	Status 1A	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
4	Status 1B	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
5	37	150NM	O	O or B
6	37	150NM	Non-O	Any
7	37	250NM	O	O or B
8	37	250NM	Non-O	Any
9	37	500NM	O	O or B
10	37	500NM	Non-O	Any

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
11	37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	O	O or B
12	37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Non-O	Any
13	33	150NM	O	O or B
14	33	150NM	Non-O	Any
15	33	250NM	O	O or B
16	33	250NM	Non-O	Any
17	33	500NM	O	O or B
18	33	500NM	Non-O	Any
19	30	150NM	O	O or B
20	29	150NM	O	O
21	29	150NM	Non-O	Any
22	30	250NM	O	O or B
23	29	250NM	O	O
24	29	250NM	Non-O	Any
25	30	500NM	O	O or B
26	29	500NM	O	O
27	29	500NM	Non-O	Any

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
28	15	150NM	O	O
29	15	150NM	Non-O	Any
30	15	250NM	O	O
31	15	250NM	Non-O	Any
32	15	500NM	O	O
33	15	500NM	Non-O	Any
34	Status 1A	Nation	Any	Any
35	Status 1B	Nation	Any	Any
36	30	Nation	O	O or B
37	15	Nation	O	O
38	15	Nation	Non-O	Any
39	Any	150NM	O	O
40	Any	150NM	Non-O	Any
41	Any	250NM	O	O
42	Any	250NM	Non-O	Any
43	Any	500NM	O	O
44	Any	500NM	Non-O	Any
45	Any	Nation	O	O
46	Any	Nation	Non-O	Any
47	29	150NM	O	B
48	29	250NM	O	B

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
49	29	500NM	O	B
50	15	150NM	O	B
51	15	250NM	O	B
52	15	500NM	O	B
53	15	Nation	O	B
54	Any	150NM	O	B
55	Any	250NM	O	B
56	Any	500NM	O	B
57	Any	Nation	O	B
58	37	150NM	O	A or AB
59	37	250NM	O	A or AB
60	37	500NM	O	A or AB
61	33	150NM	O	A or AB
62	33	250NM	O	A or AB
63	33	500NM	O	A or AB
64	29	150NM	O	A or AB
65	29	250NM	O	A or AB
66	29	500NM	O	A or AB
67	15	150NM	O	A or AB
68	15	250NM	O	A or AB
69	15	500NM	O	A or AB

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
70	15	Nation	O	A or AB
71	Any	150NM	O	A or AB
72	Any	250NM	O	A or AB
73	Any	500NM	O	A or AB
74	Any	Nation	O	A or AB
75	Status 1A, for other method of hepatic support	Nation	Any	Any
76	Status 1B, for other method of hepatic support	Nation	Any	Any
77	Any MELD or PELD for other method of hepatic support	Nation	Any	Any

9.8.F Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old

Livers from non-DCD deceased donors 11 to 17 years old are allocated to candidates according to *Table 9-12* below.

Table 9-12: Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
1	Pediatric Status 1A	500NM	Any	Any
2	Adult Status 1A	500NM	Any	Any

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
3	Pediatric Status 1B	500NM	Any	Any
4	Pediatric Status 1A	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
5	Adult Status 1A	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
6	Pediatric Status 1B	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
7	PELD of at least 37	500NM	O	O or B
8	PELD of at least 37	500NM	Non-O	Any

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
9	PELD of at least 37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	O	O or B
10	PELD of at least 37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Non-O	Any
11	PELD of at least 30	500NM	O	O or B
12	Any PELD	500NM	O	O
13	Any PELD	500NM	Non-O	Any
14	MELD of at least 37 and candidate is less than 18 years old at registration	500NM	O	O or B
15	MELD of at least 37 and candidate is less than 18 years old at registration	500NM	Non-O	Any
16	MELD of at least 37 and candidate is less than 18 years old at registration	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	O	O or B
17	MELD of at least 37 and candidate is less than 18 years old at registration	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Non-O	Any

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
18	MELD of at least 30 and candidate is less than 18 years old at registration	500NM	O	O or B
19	Any MELD and candidate is less than 18 years old at registration	500NM	O	O
20	Any MELD and candidate is less than 18 years old at registration	500NM	Non-O	Any
21	Pediatric Status 1A	Nation	Any	Any
22	Adult Status 1A	Nation	Any	Any
23	Pediatric Status 1B	Nation	Any	Any
24	PELD score of at least 30	Nation	O	O or B
25	Any PELD	Nation	O	O
26	Any PELD	Nation	Non-O	Any
27	MELD of at least 30 and candidate is less than 18 years old at registration	Nation	O	O or B
28	Any MELD and candidate is less than 18 years old at registration	Nation	O	O
29	Any MELD and candidate is less than 18 years old at registration	Nation	Non-O	Any

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
30	MELD of at least 30 and candidate is at least 18 years old at registration	500NM	O	O or B
31	Any MELD and candidate is at least 18 years old at registration	500NM	O	O
32	Any MELD and candidate is at least 18 years old at registration	500NM	Non-O	Any
33	MELD of at least 30 and candidate is at least 18 years old at registration	Nation	O	O or B
34	Any MELD and candidate is at least 18 years old at registration	Nation	O	O
35	Any MELD and candidate is at least 18 years old at registration	Nation	Non-O	Any
36	Any PELD	500NM	O	B
37	Any MELD and candidate is less than 18 years old at registration	500NM	O	B
38	Any PELD	Nation	O	B

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
39	Any MELD and candidate is less than 18 years old at registration	Nation	O	B
40	Any MELD and candidate is at least 18 years old at registration	500NM	O	B
41	Any MELD and candidate is at least 18 years old at registration	Nation	O	B
42	Any PELD	500NM	O	A or AB
43	Any MELD and candidate is less than 18 years old at registration	500NM	O	A or AB
44	Any PELD	Nation	O	A or AB
45	Any MELD and candidate is less than 18 years old at registration	Nation	O	A or AB
46	Any MELD and candidate is at least 18 years old at registration	500NM	O	A or AB
47	Any MELD and candidate is at least 18 years old at registration	Nation	O	A or AB

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
48	Adult or Pediatric Status 1A, for other method of hepatic support	Nation	Any	Any
49	Pediatric Status 1B, for other method of hepatic support	Nation	Any	Any
50	Any MELD or PELD for other method of hepatic support	Nation	Any	Any

9.8.G Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old

Livers from non-DCD donors less than 11 years old are allocated to candidates according to *Table 9-13* below.

Table 9-13: Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
1	Pediatric Status 1A	500NM	Any	Any
2	Pediatric Status 1A and candidate is less than 12 years old	Nation	Any	Any
3	Adult Status 1A	500NM	Any	Any
4	Pediatric Status 1B	500NM	Any	Any
5	Pediatric Status 1A and candidate is at least 12 years old	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
6	Adult Status 1A	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
7	Pediatric Status 1B	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
8	PELD of at least 37	500NM	O	O or B
9	PELD of at least 37	500NM	Non-O	Any
10	PELD of at least 37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	O	O or B
11	PELD of at least 37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Non-O	Any
12	PELD of at least 30	500NM	O	O or B
13	Any PELD	500NM	O	O
14	Any PELD	500NM	Non-O	Any
15	MELD of at least 37 and candidate is less than 18 years old at registration	500NM	O	O or B

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
16	MELD of at least 37 and candidate is less than 18 years old at registration	500NM	Non-O	Any
17	MELD of at least 37 and candidate is less than 18 years old at registration	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	O	O or B
18	MELD of at least 37 and candidate is less than 18 years old at registration	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Non-O	Any
19	MELD of at least 30 and candidate is less than 18 years old at registration	500NM	O	O or B
20	Any MELD and candidate is less than 18 years old at registration	500NM	O	O
21	Any MELD and candidate is less than 18 years old at registration	500NM	Non-O	Any
22	Pediatric Status 1A and candidate is at least 12 years old	Nation	Any	Any
23	Adult Status 1A	Nation	Any	Any
24	Pediatric Status 1B	Nation	Any	Any
25	PELD of at least 30	Nation	O	O or B

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
26	Any PELD	Nation	O	O
27	Any PELD	Nation	Non-O	Any
28	MELD of at least 30 and candidate is less than 18 years old at registration	Nation	O	O or B
29	Any MELD and candidate is less than 18 years old at registration	Nation	O	O
30	Any MELD and less than 18 years old at registration	Nation	Non-O	Any
31	MELD of at least 30 and candidate is at least 18 years old at registration	500NM	O	O or B
32	Any MELD and candidate is at least 18 years old at registration	500NM	O	O
33	Any MELD and at least 18 years old at registration	500NM	Non-O	Any
34	MELD of at least 30 and at least 18 years old at registration	Nation	O	O or B
35	Any MELD and at least 18 years old at registration	Nation	O	O

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
36	Any MELD and at least 18 years old at registration	Nation	Non-O	Any
37	Any PELD	500NM	O	B
38	Any MELD and candidate is less than 18 years old at registration	500NM	O	B
39	Any PELD	Nation	O	B
40	Any MELD and candidate is less than 18 years old at registration	Nation	O	B
41	Any MELD and candidate is at least 18 years old at registration	500NM	O	B
42	Any MELD and candidate is at least 18 years old at registration	Nation	O	B
43	Any PELD	500NM	O	A or AB
44	Any MELD and candidate is less than 18 years old at registration	500NM	O	A or AB
45	Any PELD	Nation	O	A or AB
46	Any MELD and candidate is less than 18 years old at registration	Nation	O	A or AB

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
47	Any MELD and candidate is at least 18 years old at registration	500NM	O	A or AB
48	Any MELD and candidate is at least 18 years old at registration	Nation	O	A or AB
49	Status 1A, for other method of hepatic support	Nation	Any	Any
50	Status 1B, for other method of hepatic support	Nation	Any	Any
51	Any MELD or PELD for other method of hepatic support	Nation	Any	Any

9.8.H Allocation of Livers and Liver-Intestines from DCD Donors or Donors at Least 70 Years Old

Livers and liver-intestines from DCD donors or donors at least 70 years old are allocated to candidates according to *Table 9-14*.

Table 9-14: Allocation of Livers and Liver-Intestines from DCD Donors or Donors at Least 70 Years Old

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
1	Status 1A	500NM	Any	Any
2	Status 1B	500NM	Any	Any
3	30	150NM	O	O or B
4	15	150NM	O	O
5	15	150NM	Non-O	Any
6	30	250NM	O	O or B
7	15	250NM	O	O
8	15	250NM	Non-O	Any
9	30	500NM	O	O or B
10	15	500NM	O	O
11	15	500NM	Non-O	Any
12	Status 1A	Nation	Any	Any
13	Status 1B	Nation	Any	Any
14	30	Nation	O	O or B
15	15	Nation	O	O
16	15	Nation	Non-O	Any
17	Any	150NM	O	O
18	Any	150NM	Non-O	Any
19	Any	250NM	O	O
20	Any	250NM	Non-O	Any
21	Any	500NM	O	O
22	Any	500NM	Non-O	Any
23	Any	Nation	O	O
24	Any	Nation	Non-O	Any
25	15	150NM	O	B

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
26	15	250NM	O	B
27	15	500NM	O	B
28	15	Nation	O	B
29	Any	150NM	O	B
30	Any	250NM	O	B
31	Any	500NM	O	B
32	Any	Nation	O	B
33	15	150NM	O	A or AB
34	15	250NM	O	A or AB
35	15	500NM	O	A or AB
36	15	Nation	O	A or AB
37	Any	150NM	O	A or AB
38	Any	250NM	O	A or AB
39	Any	500NM	O	A or AB
40	Any	Nation	O	A or AB
41	Status 1A, for other method of hepatic support	Nation	Any	Any
42	Status 1B, for other method of hepatic support	Nation	Any	Any
43	Any MELD or PELD for other method of hepatic support	Nation	Any	Any

9.8.I Allocation of Liver-Intestines from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Livers and intestines from non-DCD deceased donors at least 18 years old and less than 70 years old are allocated to candidates according to *Table 9-15* below:

Table 9-15: Allocation of Liver-Intestines from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
1	Status 1A	500NM	Any	Any
2	Status 1B	500NM	Any	Any
3	Status 1A	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
4	Status 1B	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
5	37	150NM	O	O or B
6	37	150NM	Non-O	Any
7	37	250NM	O	O or B
8	37	250NM	Non-O	Any
9	37	500NM	O	O or B
10	37	500NM	Non-O	Any
11	37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	O	O or B

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
12	37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Non-O	Any
13	33	150NM	O	O or B
14	33	150NM	Non-O	Any
15	33	250NM	O	O or B
16	33	250NM	Non-O	Any
17	33	500NM	O	O or B
18	33	500NM	Non-O	Any
19	30	150NM	O	O or B
20	29	150NM	O	O
21	29	150NM	Non-O	Any
22	30	250NM	O	O or B
23	29	250NM	O	O
24	29	250NM	Non-O	Any
25	30	500NM	O	O or B
26	29	500NM	O	O
27	29	500NM	Non-O	Any
28	Status 1A and also registered for an intestine	Nation	Any	Any

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
29	Status 1B and also registered for an intestine	Nation	Any	Any
30	30 and also registered for an intestine	Nation	O	O or B
31	Any and also registered for an intestine	Nation	O	O
32	Any and also registered for an intestine	Nation	Non-O	Any
33	15	150NM	O	O
34	15	150NM	Non-O	Any
35	15	250NM	O	O
36	15	250NM	Non-O	Any
37	15	500NM	O	O
38	15	500NM	Non-O	Any
39	Status 1A	Nation	Any	Any
40	Status 1B	Nation	Any	Any
41	30	Nation	O	O or B
42	15	Nation	O	O
43	15	Nation	Non-O	Any
44	Any	150NM	O	O
45	Any	150NM	Non-O	Any

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
46	Any	250NM	O	O
47	Any	250NM	Non-O	Any
48	Any	500NM	O	O
49	Any	500NM	Non-O	Any
50	Any	Nation	O	O
51	Any	Nation	Non-O	Any
52	29	150NM	O	B
53	29	250NM	O	B
54	29	500NM	O	B
55	Any and also registered for an intestine	Nation	O	B
56	15	150NM	O	B
57	15	250NM	O	B
58	15	500NM	O	B
59	15	Nation	O	B
60	Any	150NM	O	B
61	Any	250NM	O	B
62	Any	500NM	O	B
63	Any	Nation	O	B
64	37	150NM	O	A or AB
65	37	250NM	O	A or AB

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
66	37	500NM	O	A or AB
67	33	150NM	O	A or AB
68	33	250NM	O	A or AB
69	33	500NM	O	A or AB
70	29	150NM	O	A or AB
71	29	250NM	O	A or AB
72	29	500NM	O	A or AB
73	Any and also registered for an intestine	Nation	O	A or AB
74	15	150NM	O	A or AB
75	15	250NM	O	A or AB
76	15	500NM	O	A or AB
77	15	Nation	O	A or AB
78	Any	150NM	O	A or AB
79	Any	250NM	O	A or AB
80	Any	500NM	O	A or AB
81	Any	Nation	O	A or AB
82	Status 1A, for other method of hepatic support	Nation	Any	Any
83	Status 1B, for other method of hepatic support	Nation	Any	Any

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
84	Any MELD or PELD for other method of hepatic support	Nation	Any	Any

9.8.J Allocation of Liver-Intestines from Non-DCD Donors 11 to 17 Years Old

For combined liver-intestine allocation from non-DCD donors 11 to 17 years old, the liver must first be offered as follows:

- According to OPTN *Policy 9.8.F: Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old*
- Sequentially to *each* liver candidate, including all MELD and PELD candidates, through national status 1A and 1B offers

The liver may then be offered to combined liver-intestine potential recipients sequentially according to the intestine match run.

9.8.K Allocation of Liver-Intestines from Non-DCD Donors Less than 11 Years Old

Livers and intestines from non-DCD donors less than 11 years old are allocated to candidates according to *Table 9-16.*

Table 9-16: Allocation of Combined Liver-Intestines from Donors Less than 11 Years Old

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
1	Pediatric Status 1A	500NM	Any	Any
2	Pediatric Status 1A and candidate is less than 12 years old	Nation	Any	Any

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
3	Pediatric Status 1A, candidate is at least 12 years old, and candidate is also registered for an intestine	Nation	Any	Any
4	Adult Status 1A	500NM	Any	Any
5	Pediatric Status 1B	500NM	Any	Any
6	Pediatric Status 1A and candidate is at least 12 years old	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
7	Adult Status 1A	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
8	Pediatric Status 1B	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
9	PELD of at least 37	500NM	O	O or B
10	PELD of at least 37	500NM	Non-O	Any
11	PELD of at least 37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	O	O or B

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
12	PELD of at least 37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Non-O	Any
13	PELD 30	500NM	O	O or B
14	PELD 20	500NM	O	O
15	PELD 20	500NM	Non-O	Any
16	Pediatric Status 1B, and candidate is also registered for an intestine	Nation	Any	Any
17	PELD of at least 30 and candidate is also registered for an intestine	Nation	O	O or B
18	PELD of at least 20 and candidate is also registered for an intestine	Nation	O	O
19	PELD of at least 20 and candidate is also registered for an intestine	Nation	Non-O	Any
20	Any PELD	500NM	O	O
21	Any PELD	500NM	Non-O	Any
22	MELD of at least 37 and candidate is less than 18 years old at registration	500NM	O	O or B

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
23	MELD of at least 37 and candidate is less than 18 years old at registration	500NM	Non-O	Any
24	MELD of at least 37 and candidate is less than 18 years old at registration	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	O	O or B
25	MELD of at least 37 and candidate is less than 18 years old at registration	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Non-O	Any
26	MELD of at least 30 and less than 18 years old at registration	500NM	O	O or B
27	Any MELD and less than 18 years old at registration	500NM	O	O
28	Any MELD, candidate is less than 18 years old at registration	500NM	Non-O	Any
29	Pediatric Status 1A and at least 12 years old	Nation	Any	Any
30	Adult Status 1A	Nation	Any	Any
31	Pediatric Status 1B	Nation	Any	Any
32	PELD at least 30	Nation	O	O or B
33	Any PELD	Nation	O	O

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
34	Any PELD	Nation	Non-O	Any
35	MELD of at least 30 and less than 18 years old at registration	Nation	O	O or B
36	Any MELD and less than 18 years old at registration	Nation	O	O
37	Any MELD and less than 18 years old at registration	Nation	Non-O	Any
38	MELD of at least 30 and at least 18 years old at registration	500NM	O	O or B
39	Any MELD and at least 18 years old at registration	500NM	O	O
40	Any MELD and at least 18 years old at registration	500NM	Non-O	Any
41	MELD of at least 30 and at least 18 years old at registration	Nation	O	O or B
42	Any MELD and at least 18 years old at registration	Nation	O	O
43	Any MELD and at least 18 years old at registration	Nation	Non-O	Any
44	PELD 20	500NM	O	B

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
45	PELD of at least 20 and candidate is also registered for an intestine	Nation	O	B
46	Any PELD	500NM	O	B
47	Any MELD and candidate is less than 18 years old at registration	500NM	O	B
48	Any PELD	Nation	O	B
49	Any MELD and candidate is less than 18 years old at registration	Nation	O	B
50	Any MELD and candidate is at least 18 years old at registration	500NM	O	B
51	Any MELD and candidate is at least 18 years old at registration	Nation	O	B
52	PELD 20	500NM	O	A or AB
53	PELD of at least 20 and candidate is also registered for an intestine	Nation	O	A or AB
54	Any PELD	500NM	O	A or AB
55	Any MELD and candidate is less than 18 years old at registration	500NM	O	A or AB

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
56	Any PELD	Nation	O	A or AB
57	Any MELD, candidate is less than 18 years old at registration	Nation	O	A or AB
58	Any MELD, candidate is at least 18 years old at registration	500NM	O	A or AB
59	Any MELD, candidate is at least 18 years old at registration	Nation	O	A or AB
60	Adult or Pediatric Status 1A, for other method of hepatic support	Nation	Any	Any
61	Pediatric Status 1B, for other method of hepatic support	Nation	Any	Any
62	Any MELD or PELD for other method of hepatic support	Nation	Any	Any

9.9 Liver-Kidney Allocation

Unless otherwise stated, all mentions of MELD in this section reference a candidate's allocation MELD score.

When an OPO is offering a liver, and a kidney is also available from the same deceased donor, then before allocating the kidney to kidney alone candidates, the OPO must offer the kidney to a potential transplant recipient (PTR) who is registered for a liver and a kidney at the same transplant hospital, and who meets one of the following criteria:

a) PTR was less than 18 years old when registered on the liver waiting list
b) PTR is registered at a transplant hospital at or within 150 nautical miles of the donor hospital and has a MELD of 15 or greater and meets eligibility criteria according to *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*

c) PTR is registered at a transplant hospital at or within 500 nautical miles of the donor hospital and has a MELD of 29 or greater and meets eligibility criteria according to *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*
d) PTR is registered at a transplant hospital at or within 500 nautical miles of the donor hospital and is adult status 1A and meets eligibility criteria according to *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*

The OPO may then offer the kidney and liver to any PTRs who meet eligibility in *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation,* or offer the liver and the kidney separately according to policy.

Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation

If the candidate's transplant nephrologist confirms a diagnosis of:	Then the transplant program must report to the OPTN and document in the candidate's medical record:
Chronic kidney disease (CKD) with a GFR less than or equal to 60 mL/min for greater than 90 consecutive days	At least *one* of the following: • That the candidate has begun regularly administered dialysis as an end-stage renal disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting. • At the time of registration on the kidney waiting list, that the candidate's most recent GFR or measured or estimated creatinine clearance (CrCl) is less than or equal to 30 mL/min. • On a date after registration on the kidney waiting list, that the candidate's GFR or measured or estimated CrCl is less than or equal to 30 mL/min.
Sustained acute kidney injury	At least *one* of the following, or a combination of *both* of the following, for the last 6 weeks: • That the candidate has been on dialysis at least once every 7 days. • That the candidate has a GFR or measured or estimated CrCl less than or equal to 25 mL/min at least once every 7 days. If the candidate's eligibility is not confirmed at least once every seven days for the last 6 weeks, the candidate is not eligible to receive a liver and a kidney from the same donor.
Metabolic disease	A diagnosis of at least *one* of the following: • Hyperoxaluria • Atypical hemolytic uremic syndrome (HUS) from mutations in factor H or factor I • Familial non-neuropathic systemic amyloidosis • Methylmalonic aciduria

9.10 Expedited Placement of Livers

9.10.A Expedited Liver Placement Acceptance Criteria

In order for a liver candidate to receive expedited offers as outlined in OPTN *Policy 9.10.B: Expedited Liver Offers*, the transplant hospital must report *all* of the following information to the OPTN:

1. Agreement to accept a liver recovered by any procurement team
2. The following liver acceptance criteria:
    - Minimum and maximum age
    - Maximum body mass index (BMI)
    - Maximum distance from the donor hospital
    - Minimum and maximum height
    - Percentage of macrosteatosis
    - Minimum and maximum weight

9.10.B Expedited Liver Offers

The host OPO or the Organ Center is permitted to make expedited liver offers if *both* of the following conditions are met:

1. The donor has entered the operating room or, in the case of a DCD donor, withdrawal of life sustaining medical support has been initiated, whichever occurs first.
2. The host OPO or Organ Center is notified by the primary transplant hospital that the primary potential transplant recipient will no longer accept the liver.

Prior to sending expedited liver offers, the host OPO or Organ Center must report *all* of the following information to the OPTN:

1. Date and time donor entered the operating room or withdrawal of life sustaining medical support was initiated, whichever occurs first.
2. Date and time host OPO was notified by the primary transplant hospital that they will no longer accept the liver offer for the primary potential transplant recipient.
3. Reason for organ offer refusal by the primary potential transplant recipient.

Expedited liver offers will be made to potential transplant recipients on the match run who are eligible to receive expedited liver offers as described in OPTN *Policy 9.10.A: Expedited Liver Placement Acceptance Criteria.*

Transplant hospitals must accept an expedited offer within 30 minutes of notification to be eligible to receive the liver. Once this time limit has expired, the host OPO or Organ Center must place the liver with the potential transplant recipient with the provisional yes that appears highest on the match run.

9.11 Administrative Rules

9.11.A Registration Accuracy

If a member questions the accuracy or appropriateness of a liver allocation or candidate status, the member may report it with reasons for the concern to the national liver review board (NLRB). The NLRB will retrospectively review the allocation or status.

If the NLRB receives two or more reports about a member within any one year period, the NLRB will report it to the Membership and Professional Standards (MPSC) Committee and request an on-site review of the member.

9.11.B Review of Status 1A and 1B Candidate Registrations

If three or more status 1A or 1B candidate registrations at a transplant program are rejected and each of the candidates receives a transplant while registered at the rejected status, then the OPTN will conduct an on-site review of the transplant program's status 1A and 1B candidate registrations. If the OPTN finds a Policy violation or inappropriate registrations, the transplant program will reimburse all necessary and reasonable expenses incurred by the OPTN in performing this review.

9.11.C Location of Donor Hospitals

For the purposes of determining the location of the donor hospital, livers, intestine, and liver-intestine organs procured in Alaska will be considered procured from the Seattle Tacoma Airport, Seattle Washington.

9.12 Variances

9.12.A Open Variance for Segmental Liver Transplantation

This variance only applies when a transplant program transplants a right lobe or right tri-segment of the liver.

Under this variance, a transplant program may offer the remaining left lobe or left-lateral segment into a different, medically suitable, potential recipient registered at the same transplant hospital or an affiliated pediatric institution instead of offering the remaining segment to potential recipients at other transplant programs. The transplant program must determine potential recipient for the second segment by using the same match run used to allocate the right lobe or tri-segment. Additionally, the transplant program must document all refusals of potential transplant recipients that are prioritized ahead of the potential transplant recipient that received the second segment.

Each participating region or DSA must meet to review the results of the first ten segmental liver transplants performed as a result of this variance, and each ten thereafter. If the re-transplant rate for segmental liver transplant recipients at any liver transplant program participating in the variance exceeds three within any sequential twenty transplants, the variance at that transplant program will be put on hold until the transplant program can review results and surgical practices.

9.12.B Closed Variance for Allocation of Blood Type O Deceased Donor Livers

This is a closed variance that applies only to liver and liver-intestine organs allocated by the OPOs in Hawaii and Puerto Rico to potential transplant recipients registered at transplant programs in Hawaii and Puerto Rico, respectively due to geographic location. This variance supersedes the treatment of blood type O donors according to OPTN *Policy 9.8.C Allocation of Livers by Blood Type*, and instead the OPO will allocate these blood type O organs to potential transplant recipients with any blood type within the same classification.

9.12.C Closed Variance for Any Segment Liver Transplantation

This is a closed variance. The OPTN maintains a list of participating transplant programs.

If a participating transplant program chooses to split an accepted liver, the program will decide which segment of the liver to transplant into the intended recipient. The transplant program must notify the host OPO of the remaining segment prior to transplanting the remaining segment. The OPO must then offer the remaining segment to the following potential transplant recipients, using the same match run used to allocate the liver:

- Lower-ranked status 1A and 1B potential transplant recipients registered at any transplant hospital within 500 nautical miles of the donor hospital
- Lower-ranked potential transplant recipients with a MELD or PELD of 33 or higher that are registered at any transplant hospital within 500 nautical miles of the donor hospital

If the remaining segment is not accepted for any of the potential transplant recipients in the bulleted classifications listed above, the OPO must notify the participating transplant program that accepted the liver. The participating transplant program may then transplant the remaining segment into a different, medically suitable, candidate registered at the same transplant hospital or an affiliated transplant program with an active pediatric liver component. If the first segment is accepted for a pediatric potential transplant recipient, the participating transplant program may transplant the remaining segment into a different, medically suitable, candidate at the same transplant hospital or an affiliated transplant program. For purposes of this variance, participating transplant programs may only have one affiliated transplant program and must identify the program they are affiliated with in their application for the variance.

If the participating transplant program declines the remaining segment, the OPO may offer the remaining segment to any lower ranked potential transplant recipients off the same match run used to allocate the liver to the recipient of the first segment.

9.12.D Closed Variance for Liver Transplantation in Hawaii and Puerto Rico

This is a closed variance that applies only to liver and liver-intestine candidates registered at transplant programs in Hawaii or Puerto Rico, due to geographic location. This variance provides for additional classifications in the allocation sequences in OPTN *Policies 9.8.E-9.8.J*. The additional classifications apply to the following:

- Candidates registered at transplant programs in Hawaii when the transplant hospital is at or within 2,400 NM of the donor hospital.

- Candidates registered at transplant programs in Puerto Rico when the transplant hospital is at or within 1,100 NM of the donor hospital.

Policy 10: Allocation of Lungs

10.1 Lung Composite Allocation Score

The lung composite allocation score is the combined total of the candidate's lung medical urgency score, lung post-transplant outcomes score, lung biological disadvantages score, lung patient access score and lung placement efficiency score. The lung composite allocation score is awarded on a scale from 0 to 100.

Candidates will be rank-ordered by lung composite allocation score. If two or more candidates have the same lung composite allocation score, the tied candidates will be ranked by order of their registration date (oldest to newest).

10.1.A Prioritizing Medically Urgent Candidates

The lung medical urgency score is equal to the candidate's lung waitlist survival points.

10.1.A.1. Waitlist Survival Points for Candidates at least 12 Years Old

For candidates at least 12 years old at the time of the match run lung waitlist survival points are awarded based on the candidate's waiting list survival probability, based on the following factors:

- Age at the time of the match run (fractional calendar years)
- Bilirubin (mg/dL) value with the most recent test date and time
- Body mass index (BMI) (kg/m2)
- Assisted ventilation
- Creatinine (serum) (mg/dL) with the most recent test date and time
- Diagnosis Group (A, B, C, or D), as defined in OPTN *Policy 10.1.F Lung Disease Diagnosis Groups*
- Whether the candidate has one of the following specific diagnoses within Diagnosis Group A:
    - Bronchiectasis
    - Sarcoidosis with pulmonary artery (PA) mean pressure of 30 mm Hg or less
    - Sarcoidosis with PA mean pressure missing
- Whether the candidate has one of the following specific diagnoses within Diagnosis Group D:
    - COVID-19: pulmonary fibrosis
    - Pulmonary fibrosis, other specify cause
    - Sarcoidosis with PA mean pressure greater than 30 mm Hg
- Functional Status

- Amount of supplemental oxygen required to maintain adequate oxygen saturation (88% or greater) at rest (L/min)
- PCO2 (mm Hg): current
- PCO2 increase of at least 15%
- PA systolic pressure (mm Hg) at rest, prior to any exercise
- Six-minute-walk distance (feet)

Lung waitlist survival points are awarded on a scale of 0-25. OPTN *Policy 21.1.A: Waiting List Survival Formulas* details the calculation of lung waitlist survival points.

10.1.A.2 Waitlist Survival Points for Candidates Less than 12 Years Old

Lung candidates assigned pediatric priority 1 receive 1.9073 waitlist survival points based on the candidate's waitlist survival probability.

Lung candidates assigned pediatric priority 2 receive 0.4406 waitlist survival points based on the candidate's waitlist survival probability.

10.1.A.2.a Candidates Less than 12 Years Old - Priority 1

A lung candidate less than 12 years old may be assigned priority 1 if at least *one* of the following requirements is met:

1. Candidate has respiratory failure, evidenced by at least *one* of the following:
    - Requires continuous mechanical ventilation
    - Requires supplemental oxygen delivered by any means to achieve FiO_2 greater than 50% in order to maintain oxygen saturation levels greater than 90%
    - Has an arterial or capillary PCO_2 greater than 50 mm Hg
    - Has a venous PCO_2 greater than 56 mm Hg

2. Candidate has pulmonary hypertension, evidenced by at least *one* of the following:
    - Has pulmonary vein stenosis involving 3 or more vessels
    - Exhibits *any* of the following, in spite of medical therapy:
        - Cardiac index less than 2 L/min/M^2
        - Syncope
        - Hemoptysis
        - Suprasystemic PA pressure on cardiac catheterization or by echocardiogram estimate

10.1.A.2.b Candidates Less than 12 Years Old - Priority 2

If a lung candidate less than 12 years old does not meet any of the above criteria to qualify for priority 1, then the candidate is assigned priority 2.

10.1.B Improving Post-Transplant Outcomes

Each lung candidate is assigned a lung post-transplant outcomes score. The lung post-transplant outcomes score is equal to the candidate's lung post-transplant outcomes points.

10.1.B.1 Post-Transplant Outcomes Points for Candidates at Least 12 Years Old

For candidates at least 12 years old at the time of the match run, lung post-transplant outcomes points are awarded based on the candidate's post-transplant survival probability, based on the following factors:

- Age at the time of the match run (fractional calendar years)
- Creatinine (serum) (mg/dL) with the most recent test date and time
- Cardiac index (L/min/m2) at rest, prior to any exercise
- Assisted ventilation
- Diagnosis Group (A, B, C, or D), as defined in OPTN *Policy 10.1.F: Lung Disease Diagnosis Groups*
- Whether the candidate has one of the following specific diagnoses within Diagnosis Group A:
    - Bronchiectasis
    - Lymphangioleiomyomatosis
    - Sarcoidosis with PA mean pressure of 30 mm Hg or less
    - Sarcoidosis with PA mean pressure missing
- Whether the candidate has one of the following specific diagnoses within Diagnosis Group D:
    - COVID-19: pulmonary fibrosis
    - Obliterative bronchiolitis (non-retransplant)
    - Constrictive bronchiolitis
    - Sarcoidosis with PA mean pressure greater than 30 mm Hg
    - Pulmonary fibrosis, other specify cause
- Functional Status
- Six-minute-walk-distance (feet)

Lung post-transplant outcomes points are awarded on a scale of 0-25. OPTN *Policy 21.1.B: Post-Transplant Outcomes Formulas* details the calculation of lung post-transplant outcomes points.

10.1.B.2 Post-Transplant Outcomes Points for Candidates Less than 12 years Old

Lung candidates who are less than 12 years old are assigned 18.6336 post-transplant outcomes points based on the candidate's post-transplant survival probability.

10.1.C Reducing Biological Disadvantages

Each lung candidate is assigned a lung biological disadvantages score. The lung biological disadvantages score is equal to the total of the candidate's lung blood type points, lung CPRA points, and lung height points.

10.1.C.1 Blood Type

Each lung candidate is assigned lung blood type points determined based on the proportion of donors the candidate could accept based on blood type compatibility, according to *Table 10-1: Points by Blood Type.* Candidates who are eligible to accept blood group incompatible donors according to OPTN *Policy 10.4.A Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Lungs* receive the same blood type points as other candidates in their blood group.

Table 10-1: Points by Blood Type

A candidate with a blood type of	Will receive this many lung blood type points
AB	0
A	0.3032
B	2.2382
O	5.0000

10.1.C.2 CPRA

Each lung candidate is assigned lung CPRA points based on the proportion of donors the candidate could accept based on antigen acceptability. Lung CPRA points are awarded on a scale of 0-5. OPTN *Policy 21.1.C.1: Lung CPRA Points* details the calculation of lung CPRA points.

10.1.C.3 Height

Each lung candidate is assigned lung height points based on the proportion of donors the candidate could accept based on height compatibility. Lung height points are awarded on a scale of 0-5. OPTN *Policy 21.1.C.2: Lung Height Points* details the calculation of lung height points.

10.1.D Promoting Patient Access

The lung patient access score is equal to the total of the candidate's lung pediatric points and lung living donor points.

10.1.D.1 Pediatric Candidates

A candidate who was less than 18 years old at the time of registration on the lung waiting list will receive 20 lung pediatric points.

10.1.D.2 Prior Living Donors

A candidate who is a prior living organ donor will receive 5 lung living donor points.

A lung candidate will be classified as a prior living donor if the candidate donated for transplantation, within the United States or its territories, at least one organ and the candidate's physician reports all of the following information to the OPTN:

a. The name of the recipient or intended recipient of the donated organ or organ segment

b. The recipient's or intended recipient's transplant hospital

c. The date the donated organ was procured

10.1.E Promoting the Efficient Management of the Organ Placement System

The lung placement efficiency score is the total of the candidate's lung travel efficiency and lung proximity efficiency points.

10.1.E.1 Travel Efficiency

A candidate's lung travel efficiency points are determined based on the straight-line distance between the donor hospital and the transplant hospital where the candidate is listed. Lung travel efficiency points are awarded on a scale of 0-5. OPTN Policy *21.1.D.1: Lung Travel Efficiency Points* details the calculation of lung proximity efficiency points.

10.1.E.2 Proximity Efficiency

A candidate's lung proximity efficiency points are determined based on the straight-line distance between the donor hospital and the transplant hospitals where the candidate is listed. Lung proximity efficiency points are awarded on a scale of 0-5. OPTN *Policy 21.1.D.2: Lung Proximity Efficiency Points* details the calculation of lung travel efficiency points.

10.1.F Lung Disease Diagnosis Groups

Each candidate is assigned a diagnosis group, based on their lung disease diagnosis, which is used in the calculation of their medical urgency score and their post-transplant survival score.

Group A
A candidate is in Group A if the candidate has *any* of the following diagnoses:

- Allergic bronchopulmonary aspergillosis
- Alpha-1 antitrypsin deficiency
- Bronchiectasis
- Bronchopulmonary dysplasia
- Chronic obstructive pulmonary disease/emphysema
- Ehlers-Danlos syndrome
- Granulomatous lung disease
- Inhalation burns/trauma
- Kartagener's syndrome
- Lymphangioleiomyomatosis
- Obstructive lung disease
- Primary ciliary dyskinesia;
- Sarcoidosis with either:

    - Pulmonary artery (PA) mean pressure of 30 mm Hg or less
    - PA mean pressure missing
- Tuberous sclerosis
- Wegener's granuloma – bronchiectasis

Group B
A candidate is in Group B if the candidate has *any* of the following diagnoses:

- Congenital malformation
- CREST – pulmonary hypertension
- Eisenmenger's syndrome: atrial septal defect (ASD)
- Eisenmenger's syndrome: multi-congenital anomalies
- Eisenmenger's syndrome: other specify
- Eisenmenger's syndrome: patent ductus arteriosus (PDA)
- Eisenmenger's syndrome: ventricular septal defect (VSD)
- Portopulmonary hypertension
- Pulmonary hypertension/pulmonary arterial hypertension
- Pulmonary capillary hemangiomatosis
- Pulmonary telangiectasia – pulmonary hypertension
- Pulmonary thromboembolic disease
- Pulmonary vascular disease
- Pulmonary veno-occlusive disease
- Pulmonic stenosis
- Right hypoplastic lung
- Scleroderma – pulmonary hypertension
- Secondary pulmonary hypertension
- Thromboembolic pulmonary hypertension

Group C
A candidate is in Group C if the candidate has *any* of the following diagnoses:

- Common variable immune deficiency
- Cystic fibrosis
- Fibrocavitary lung disease
- Hypogammaglobulinemia
- Schwachman-Diamond syndrome

Group D
A candidate is in Group D if the candidate has *any* of the following diagnoses:

- ABCA3 transporter mutation
- Alveolar proteinosis
- Amyloidosis
- Acute respiratory distress syndrome or pneumonia
- Bronchioloalveolar carcinoma (BAC)
- Carcinoid tumorlets

- Chronic pneumonitis of infancy
- Combined pulmonary fibrosis and emphysema (CPFE)
- Constrictive bronchiolitis
- COVID-19: acute respiratory distress syndrome
- COVID-19: pulmonary fibrosis
- CREST – Restrictive
- Eosinophilic granuloma
- Fibrosing Mediastinitis
- Graft versus host disease (GVHD)
- Hermansky Pudlak syndrome
- Hypersensitivity pneumonitis
- Idiopathic interstitial pneumonia, with at least one of the following disease entities:
  - Acute interstitial pneumonia
  - Cryptogenic organizing pneumonia/Bronchiolitis obliterans with organizing pneumonia (BOOP)
  - Desquamative interstitial pneumonia
  - Idiopathic pulmonary fibrosis (IPF)
  - Nonspecific interstitial pneumonia
  - Lymphocytic interstitial pneumonia (LIP)
  - Respiratory bronchiolitis-associated interstitial lung disease
- Idiopathic pulmonary hemosiderosis
- Lung retransplant or graft failure: acute rejection
- Lung retransplant or graft failure: non-specific
- Lung retransplant or graft failure: obliterative bronchiolitis-obstructive
- Lung retransplant or graft failure: obliterative bronchiolitis-restrictive
- Lung retransplant or graft failure: obstructive
- Lung retransplant or graft failure: other specify
- Lung retransplant or graft failure: primary graft failure
- Lung retransplant or graft failure: restrictive
- Lupus
- Mixed connective tissue disease
- Obliterative bronchiolitis: non-retransplant
- Occupational lung disease: other specify
- Paraneoplastic pemphigus associated Castleman’s disease
- Polymyositis
- Pulmonary fibrosis: other specify cause
- Pulmonary hyalinizing granuloma
- Pulmonary lymphangiectasia (PL)
- Pulmonary telangiectasia – restrictive
- Rheumatoid disease
- Sarcoidosis with PA mean pressure greater than 30 mm Hg
- Scleroderma – restrictive
- Silicosis
- Sjogren’s syndrome
- Surfactant protein B deficiency
- Surfactant protein C deficiency

- Teratoma
- Wegener's granuloma – restrictive

10.2 Lung Composite Score Exceptions

If a candidate's current lung composite allocation score does not appropriately prioritize the candidate for transplant, the candidate's transplant program may submit an exception request to the Lung Review Board. A candidate's lung composite allocation score cannot exceed 100, inclusive of score exceptions.

10.2.A Lung Review Board Composition

For lung exceptions, there is a Lung Review Board.

The Lung Review Board reviews lung medical urgency score, lung post-transplant outcomes score, lung biological disadvantages score, and lung patient access score exceptions.

The Lung Transplantation Committee will develop and approve operational guidelines that detail the administrative details of the Lung Review Board operations. The Lung Transplantation Committee may develop clinical guidance documents for specific clinical scenarios. These guidelines may include appropriate documentation for the Lung Review Board to consider, appropriate clinical values, and suggested (but not automatically accepted) exception requests.

10.2.B Exception Requests

An exception request must include all of the following:
1. Indication of the applicable goal in the composite allocation score
2. A request for a specific score
3. A justification of how the medical criteria supports the higher score for the candidate
4. An explanation of how the candidate's current condition is comparable to that of other candidates with the requested score

Approved exception scores are valid until the candidate is transplanted, is removed from the lung waiting list, or withdraws the exception.

10.2.C Review of Exceptions

The Lung Review Board must review exception requests within five days of the date the request is submitted to the Lung Review Board.

10.2.D Appeals to Lung Review Board

If the Lung Review Board denies an exception request, the candidate's transplant program may appeal to the Lung Review Board within seven days of receiving the denial. The Lung Review Board must review appeals within five days of the date the appeal is submitted to the Lung Review Board.

10.2.E Appeals to Lung Transplantation Committee

If the Lung Review Board denies an exception request on appeal, the candidate's transplant program may appeal to the Lung Transplantation Committee within seven days of receiving the

denial. The Lung Transplantation Committee must review the appeal no later than fourteen days following the request to the Committee.

10.3 Clinical Values and Update Schedule

Transplant programs must report to the OPTN clinical data corresponding with the factors outlined in OPTN *Policies 10.1.A.1: Waitlist Survival Points for Candidates at least 12 Years Old* and *10.1.B.1: Post-Transplant Outcomes Points for Candidates at Least 12 Years Old.*

For any six-minute walk distances reported during the six months preceding a candidate turning 12 years old, and for any initial six-minute walk distances reported for candidates at least 12 years old, transplant programs must perform an oxygen titration test prior to conducting the six-minute walk test for a candidate on the lung waiting list. The final amount of supplemental oxygen from the oxygen titration test must be the amount provided to the candidate at the start of the six-minute walk test and documented in the candidate's medical record.

For six-minute walk distances reported prior to the six months preceding the candidate turning 12 years old, and for any subsequent updates to the six-minute walk distance according to Policy 10.3.B Lung Clinical Values That Must Be Updated Every Six Months, transplant programs may conduct an oxygen titration test prior to the six-minute walk test and may modify the amount of supplemental oxygen provided to the candidate at the start of the six-minute walk test.

The data reported at the time of the candidate's registration on the lung transplant waiting list must be six months old or less from the date of the candidate's registration date, with the exception of the following values:

- Cardiac index (L/min/m2) at rest, prior to any exercise
- PA mean pressure
- Pulmonary artery (PA) systolic pressure (mm Hg) at rest, prior to any exercise

The transplant program must maintain source documentation for all clinical values reported in the candidate's medical chart.

10.3.A Lung Clinical Values That Must Be Updated Every 28 Days

When a transplant program reports that a candidate on the lung waiting list is on continuous mechanical ventilation or ECMO, or requires supplemental oxygen provided via a high flow nasal cannula, the program must report the following values, assessed within the 28 days preceding the report:

- Amount of supplemental oxygen required to maintain adequate oxygen saturation (88% or greater) (L/min)
- Assisted ventilation status

The transplant program must continue to assess and report the amount of supplemental oxygen required to maintain adequate oxygen saturation (88% or greater) and assisted ventilation status every 28 days following the most recent assessment while the candidate remains on continuous mechanical ventilation or ECMO, or continues to require supplemental oxygen provided via a high flow nasal cannula.

10.3.B Lung Clinical Values That Must Be Updated Every Six Months

Transplant hospitals must update *all* of the following clinical values at least once in every six month period following registration for each candidate on the lung waiting list:

- Bilirubin (mg/dL) value with the most recent test date and time
- Weight to determine body mass index (BMI) (kg/m2)
- Creatinine (serum) (mg/dL) value with the most recent test date and time
- Functional Status
- Amount of supplemental oxygen required to maintain adequate oxygen saturation (88% or greater) (L/min)
- PCO_2 (mm Hg)
- Six-minute-walk distance (feet)
- Assisted ventilation status

The transplant program must maintain source documentation for all clinical values reported in the candidate's medical chart.

Candidates who are less than 12 years old and are assigned priority 1 based on evidence of respiratory failure in accordance with OPTN *Policy 10.1.A.2.a Candidates Less than 12 Years Old - Priority 1* will be assigned to priority 2 if the clinical values that qualify the candidates for priority 1 are more than six months old on the six-month anniversary of the candidate's listing date.

10.3.C Lung Clinical Values That Must Be Updated When Performed

Transplant hospitals must report updated values for the following clinical values if they were obtained within any six month period following registration for each candidate at an active or inactive status.

- Cardiac index (L/min/m2) at rest, prior to any exercise
- PA mean pressure, if candidate's diagnosis is Sarcoidosis
- Pulmonary artery (PA) systolic pressure (mm Hg) at rest, prior to any exercise

The transplant program must maintain source documentation for all clinical values reported in the candidate's medical chart.

10.4 Eligibility Criteria

10.4.A Eligibility for Intended Incompatible Blood Type Offers for Deceased Donor Lungs

Incompatible blood types are defined in *Table 10-2: Incompatible Blood Types for Deceased Donor Lungs*.

Table 10-2: Incompatible Offers Blood Types for Deceased Donor Lungs

Deceased Donor's Blood Type	Candidate's Blood Type
A	O and B
B	O and A
AB	O, A, and B

Candidates with incompatible blood types will be screened from lung match runs unless the candidate meets the criteria for eligibility in *Table 10-3: Eligibility for Intended Incompatible Blood Type Offers for Deceased Donor Lungs* below.

Table 10-3: Eligibility for Intended Incompatible Blood Type Offers for Deceased Donor Lungs

If the candidate is registered prior to turning 18 years old and is:	And meets *all* of the following:
Less than one year old at the time of the match run	1. Has reported isohemagglutinin titer information for A or B blood type antigens to the OPTN within the last 30 days
At least one year old at the time of the match run	1. Has reported to the OPTN isohemagglutinin titers less than or equal to 1:16 for A or B blood type antigens from a blood sample collected within the last 30 days. The candidate must not have received treatments that may have reduced isohemagglutinin titers to 1:16 or less within 30 days of when this blood sample was collected

10.4.B Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Group Incompatible Lung

If a laboratory provides more than one isohemagglutinin titer value for a tested blood sample, the transplant program must report the highest titer value to the OPTN.

Accurate isohemagglutinin titers must be reported for candidates eligible for an intended blood type incompatible lung, according to Table 10-4 below, at all of the following times:

1. Upon initially reporting that a candidate is willing to accept an intended blood type incompatible lung.
2. Every 30 days after initially reporting that a candidate is willing to accept an intended blood type incompatible lung.

Table 10-4: Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Type Incompatible Lung

If the candidate's blood type is:	Then the transplant program must report the following isohemagglutinin titers to the OPTN:
A	Anti-B
B	Anti-A
O	Anti-A and Anti-B

Accurate isohemagglutinin titers must be reported for recipients of an intended blood type incompatible lung, according to *Table 10-5*, as follows:

1. At transplant, from a blood sample taken within 24 hours prior to transplant.
2. If graft loss occurs within one year after transplant from the most recent sample, if available.
3. If recipient death occurs within one year after transplant from the most recent blood sample, if available.

Table 10-5: Isohemagglutinin Titer Reporting Requirements for a Recipient of an Intended Blood Type Incompatible Lung

If the deceased donor's blood type is:	And the recipient's blood type is:	Then the transplant program must report the following isohemagglutinin titers to the OPTN:
A	B or O	Anti-A
B	A or O	Anti-B
AB	A	Anti-B
AB	B	Anti-A
AB	O	Anti-A and Anti-B

Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets

11.1 Pancreas Allocation Score

Candidates receive an allocation score according to the total of all points assigned in *Table 11-1*.

Table 11-1: Allocation Points

If the candidate:	Then the candidate receives this many points:
Is registered for pancreas or islet transplant	1/365 points for each day since candidate's registration date
Is registered for kidney-pancreas transplant and meets the qualifying criteria described in OPTN *Policy 11.4: Waiting Time*	1/365 points for each day since meeting the qualifying criteria in OPTN *Policy 11.4: Waiting Time*
Meets the qualifying criteria described in *Table 11-2: Points for Allocation of Pancreas, Kidney-Pancreas, and Islets based on Proximity to Donor Hospital*	See *Table 11-2: Points for Allocation of Pancreas, Kidney-Pancreas, and Islets based on Proximity to Donor Hospital*

Table 11-2: Points for Allocation of Pancreas, Kidney-Pancreas, and Islets based on Proximity to Donor Hospital

For purposes of this section, distance is calculated in nautical miles between candidate's hospital of registration and the donor hospital.

If the candidate is:	Then the candidate receives this many points:
Registered at a transplant program that is 250 nautical miles or less away from the donor hospital	$2 - \left[\left(\frac{2}{250 - 0}\right) \times distance\right]$
Registered at a transplant program that is more than 250 nautical miles but 2,500 nautical miles or less away from the donor hospital	$4 - \left[\left(\left(\frac{4}{2500 - 250}\right) \times distance\right) - \left(4 \times \frac{250}{2500 - 250}\right)\right]$
Registered at a transplant program that is more than 2,500 nautical miles away from the donor hospital	0

11.2 Waiting List Registration

11.2.A Pancreas Registration

Each candidate registered on the pancreas waiting list must meet *one* of the following requirements:

- Be diagnosed with diabetes
- Have pancreatic exocrine insufficiency
- Require the procurement or transplantation of a pancreas as part of a multiple organ transplant for technical reasons

11.2.B Combined Kidney-Pancreas Registration

Each candidate registered on the kidney-pancreas waiting list must be diagnosed with diabetes or have pancreatic exocrine insufficiency with renal insufficiency.

11.2.C Islet Registration Status

A transplant hospital may register an islet candidate on the waiting list with an active status if the candidate meets *either* of the following requirements:

1. Is insulin dependent
2. Has a hemoglobin A1c (HbA1c) value greater than 6.5%

An islet candidate that does not meet either of these requirements above must have an inactive status on the waiting list. If the transplant hospital changes a candidate's status from inactive to active, the transplant hospital must document that the candidate met one of the above requirements.

If a candidate's clinical condition changes and the candidate becomes inactive, the transplant hospital must report this to the OPTN within 72 hours of the transplant hospital's knowledge of this change. The transplant hospital must document in the candidate's medical record when the transplant hospital learned of this change.

If the candidate is active and is insulin independent, then the transplant hospital must document in the candidate's medical record the candidate's insulin status and HbA1c value. The transplant hospital must use the most recent HbA1c test performed within the last six months when determining whether the candidate meets the criteria for active status.

11.3 Waiting Time

Waiting time for pancreas and islet candidates begins on the date the candidate is first registered as a pancreas or islet candidate on the waiting list.

Pancreas, kidney-pancreas, and islet candidates continue to accrue waiting time while registered as active or inactive.

11.3.A Kidney-Pancreas Waiting Time Criteria for Candidates Less than 18 Years Old

To accrue waiting time for a kidney-pancreas transplant, a kidney-pancreas candidate who is less than 18 years old at the time of kidney-pancreas registration does not have to meet the qualifying criteria according to OPTN *Policy 11.4.B* below.

11.3.B Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old

If a kidney-pancreas candidate is 18 years or older on the date the candidate is registered for a kidney-pancreas, then the candidate begins to accrue waiting time once the candidate has met all of the following conditions:

1. The candidate is registered for a kidney-pancreas.
2. The candidate qualifies for kidney waiting time according to OPTN *Policy 8.: Waiting Time*.
3. The candidate is on insulin.

Once a kidney-pancreas candidate begins to accrue waiting time, the candidate will remain qualified for waiting time.

11.3.C Islet Waiting Time Criteria

An islet candidate will retain waiting time through three registrations at the registering transplant hospital, including the waiting time from the previous registrations and any intervening time. After a candidate has received a series of three islet infusions at the registering transplant hospital, waiting time will be reset, and the candidate will retain waiting time through another three infusions.

11.3.D Waiting Time Assignments for Kidney, Kidney-Pancreas, Pancreas, and Islet Candidates

The OPTN may assign multi-organ candidates waiting time from one waiting list to another waiting list according to *Table 11-3* below.

Table 11-3: Waiting Time Assignments for Multi-organ Candidates

From this registration:	To this registration:
Kidney	Kidney-pancreas; if criteria in OPTN *Policy 11.3.B: Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old* are met.
Kidney	Pancreas
Kidney-pancreas	Kidney
Kidney-pancreas	Pancreas
Pancreas	Islet; if criteria in OPTN *Policy 11.3.D.i* below are met.
Islet	Pancreas; if criteria in OPTN *Policy 11.3.D.ii* below are met.

Waiting time accrued by an isolated pancreas candidate or an islet candidate while registered on the waiting list will not be assigned to the listing for a combined kidney-pancreas transplant or an isolated kidney transplant unless the candidate qualifies for a waiting time modification according to OPTN *Policy 3.7: Waiting Time Modifications*.

Waiting time accrued by an islet candidate while registered on the waiting list will not be assigned to the registration for a combined kidney-pancreas transplant or an isolated kidney transplant except as outlined in OPTN *Policy 3.7: Waiting Time Modifications*.

Additionally, a kidney-pancreas candidate who received a kidney transplant and subsequently registered on the pancreas or islet waiting list will be assigned waiting time beginning on the *earliest* of the following dates:

1. The date the candidate registered for a pancreas transplant.
2. The date the candidate registered for a kidney-pancreas transplant.
3. The date the candidate began accruing waiting time for a kidney-pancreas transplant.

11.3.D.i Criteria to assign Pancreas Waiting Time to Islet Waiting Time

Waiting time accrued by an isolated pancreas transplant candidate while registered on the waiting list will be assigned to the registration for an islet transplant after consideration and approval of a request for transfer by the OPTN Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that the transfer is reasonable and is in the candidate's best interest and comply with other application requirements set by the Committee. These requests, along with decisions of the Pancreas Transplantation Committee, will be reported to the Board of Directors retrospectively.

11.3.D.ii Criteria to assign Islet Waiting Time to Pancreas

Waiting time accrued by an islet transplant candidate while registered on the waiting list will be assigned to the registration for an isolated pancreas transplant after consideration and approval of a request for transfer by the OPTN Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that the transfer is reasonable and is in the candidate's best interest, and comply with other application requirements set by the Committee. These requests, along with decisions of the Pancreas Transplantation Committee, will be reported to the Board of Directors retrospectively.

11.4 Pancreas, Kidney-Pancreas, and Islet Allocation Classifications and Rankings

11.4.A Kidney-Pancreas Allocation Order

If a host OPO has both a kidney and a pancreas to offer for allocation, then the host OPO

1. Must offer the kidney and pancreas according to classifications 1–4 in *Tables 11-5: Allocation of Kidneys and Pancreas from Deceased Donors 50 Years Old and Less with a BMI less than or equal to 30 kg/m^2* and *Table 11-6: Allocation of Kidneys and Pancreas from Deceased Donors more than 50 Years Old or with a BMI greater than 30 kg/m^2*.

2. Then, the host OPO may do *either*:
   a. Continue to offer the kidney and pancreas according to the remaining classifications in *Table 11-5 and Table 11-6*.
   b. Offer the pancreas to pancreas and islet candidates, but not kidney-pancreas candidates, according to the remaining classifications *Table 11-5* and *Table 11-6* and offer the kidney to kidney candidates according to OPTN *Policy 8: Allocation of Kidneys*.

The host OPO may switch between options 2.a and 2.b above at any time after completing step 1 above.

This subsection does not apply if the kidney and pancreas have been released according to OPTN *Policy 5.9: Released Organs*.

11.4.B Pancreas Allocation When a Kidney is Unavailable

If a host OPO only has a pancreas, but not a kidney to offer for allocation, then the host OPO must offer the pancreas to pancreas and islet candidates but not kidney-pancreas candidates according to *Tables 11-5: Allocation of Kidneys and Pancreas from Deceased Donors 50 Years Old and Less with a BMI less than or equal to 30 kg/m^2* and *Table 11-6: Allocation of Kidneys and Pancreas from Deceased Donors more than 50 Years Old or with a BMI Greater than 30 kg/m^2*.

OPOs may not allocate a kidney to a potential pancreas recipient who is receiving the pancreas offer due to the match run prioritization of the potential recipient's isolated pancreas registration.

11.4.C Organ Offer Limits

Any pancreas that will be allocated as 0-ABDR mismatches, either alone or in combination with kidneys, must be offered within eight hours after procurement.

If there are at least 10 0-ABDR mismatched potential recipients on the match run, the pancreas must be offered to the first 10 0-ABDR mismatched potential recipients. If there are less than 10 0-ABDR mismatched potential recipients, the pancreas must be offered to all 0-ABDR mismatched potential recipients.

If these offers are not accepted then the host OPO must:

- Allocate the kidney according to the match run under OPTN *Policy 8.5: Kidney Allocation Classifications and Rankings* and allocate the pancreas according to OPTN *Policy 11.4: Pancreas, Kidney-Pancreas, and Islet Allocation Classifications and Rankings*.
- Allocate the organ for the remaining 0-ABDR mismatched potential recipients.

This subsection does not apply if the kidney and pancreas have been released according to OPTN *Policy 5.9: Released Organs*.

11.4.D Blood Type for Kidney-Pancreas Allocation

Within each classification, kidney-pancreas will be allocated to candidates according to the blood type matching requirements in *Table 11-4* below:

11-4: Allocation of Kidney-Pancreas by Blood Type

Kidney-Pancreas from Deceased Donors with:	Are Allocated to Candidates with:
Blood Type O	Blood type O or blood type A, B, or AB if the candidate has a 0-ABDR mismatch with the deceased donor and a CPRA greater than or equal to 80 percent
Blood Type A	Blood type A or AB
Blood Type B	Blood type B
Blood Type AB	Blood type AB

11.4.E Sorting Within Each Classification

Within each allocation classification, pancreas, kidney-pancreas, and islet candidates are sorted in the following order:

1. Total points (highest to lowest)
2. Date and time of the candidate's registration (oldest to most recent)

11.4.F Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m2

Pancreas, kidney-pancreas, and islets from donors 50 years old or less and who have a BMI less than or equal to 30 kg/m^2 will be allocated to candidates according to *Table 11-5*.

Table 11-5: Allocation of Kidneys and Pancreas from Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m^2

Classification	Candidates that are	And registered at a transplant program that is at or within this distance from the donor hospital:
1	Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%	250NM
2	Either pancreas or kidney-pancreas candidates and CPRA greater than or equal to 80%	250NM
3	Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%	Nation
4	Pancreas or kidney-pancreas candidates	250NM

Classification	Candidates that are	And registered at a transplant program that is at or within this distance from the donor hospital:
5	Either pancreas or kidney-pancreas candidates, and CPRA greater than or equal to 80%	Nation
6	Pancreas or kidney-pancreas candidates	Nation
7	Islet candidates	250NM
8	Islet candidates	Nation

11.4.G Deceased Donors More than 50 Years Old or with a BMI Greater Than 30 kg/m^2

Pancreas, kidney-pancreas, and islets from deceased donors more than 50 years old or from deceased donors who have a BMI greater than 30 kg/m^2 are allocated to candidates according to *Table 11-6*.

Table 11-6: Allocation of Kidneys and Pancreas from Deceased Donors More Than 50 Years Old or with a BMI Greater Than 30 kg/m^2

Classification	Candidates that are:	And registered at a transplant program that is at or within this distance from the donor hospital:
1	Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%	250NM
2	Either pancreas or kidney-pancreas candidates and CPRA greater than or equal to 80%	250NM
3	Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%	Nation
4	Pancreas or kidney-pancreas candidates	250NM
5	Islet candidates	250NM
6	Islet candidates	Nation
7	Either pancreas or kidney-pancreas candidates and CPRA greater than or equal to 80%	Nation
8	Pancreas or kidney-pancreas candidates	Nation

11.5 Reallocation of Unsuitable Islets

Islets must be allocated to the most medically suitable candidate based on the transplant program's Investigational New Drug (IND) application, as approved by the United States Food and Drug Administration (FDA). After islet processing is completed, the transplant program must determine and document *both*:

1. Whether the islet preparation meets the transplant program's islet product release criteria contained in the IND.
2. Whether the islets are medically suitable or medically unsuitable for the candidate that accepted the islets.

If the islets are found medically unsuitable for the candidate, the transplant program must document the reason the islets were determined to be medically unsuitable for the candidate.

If the transplant program determines that the islets are medically unsuitable for the candidate, the transplant program will reallocate the islets according to *all* of the following criteria:

1. To a candidate that is medically suitable
2. To a candidate that is registered at a transplant program covered by the same IND
3. The candidate's allocation score according to *Table 11-1: Allocation Points*

The transplant program that reallocates the islets must document that it followed this policy.

11.6 Facilitated Pancreas Allocation

11.6.A Transplant Program Qualifications

A transplant program qualifies to receive facilitated pancreas offers if within the two previous years it has transplanted a minimum of two pancreas recovered from deceased donors located at hospitals more than 250 NM away from the transplant program. This includes pancreas transplanted as part of a multi-organ transplant.

Transplant programs that qualify for facilitated pancreas allocation must notify the OPTN in writing if they do not wish to participate.

11.6.B Facilitated Pancreas Offers

OPOs and the OPTN are permitted to make facilitated pancreas offers if no pancreas offer has been accepted three hours prior to the scheduled donor organ recovery. The OPO or OPTN must offer the pancreas only to potential transplant recipients registered at a transplant program that participates in facilitated pancreas allocation. Facilitated pancreas offers must be made in the order of the match run, and OPOs will only have access to facilitated allocation after all pancreas and kidney-pancreas offers made to candidates registered at transplant programs within 250 nautical miles of the donor hospital have been declined.

11.7 Allocation of Released Kidney-Pancreas, Pancreas or Islets

For kidney-pancreas, pancreas or islets released according to OPTN *Policy 5.9: Released Organs*, the host OPO may

1. Continue allocation according to the original match run
2. Allocate the kidney-pancreas, pancreas or islets to a potential transplant recipient at the transplant program that originally accepted the organ(s). If allocating to a pancreas alone potential transplant recipient at the same program, the kidney must be allocated according to OPTN *Policy 8.7: Allocation of Released Kidneys* or
3. Contact the OPTN for assistance allocating the organ(s)

11.8 Administrative Rules

11.8.A Location of Donor Hospitals

For the purpose of determining the location of the donor hospital for allocation of pancreas, kidney-pancreas, or islets, kidneys and pancreata procured in Alaska will be considered procured from the Sea-Tac Airport, Seattle, Washington.

Policy 12: Allocation of Covered Vascularized Composite Allografts

12.1 Waiting Time

Waiting time for candidates registered for a covered VCA begins when the candidate is registered on the waiting list. Candidates are registered by covered VCA type: upper limb, head and neck, abdominal wall, uterus, external male genitalia, other genitourinary organ, vascularized gland, lower limb, musculoskeletal composite graft segment, or spleen.

12.2 Covered VCA Allocation

A covered VCA from a deceased donor is allocated to candidates registered for that covered VCA according to *Table 12-1* below.

Table 12-1: Allocation of Covered VCAs from Deceased Donors

Classification	Candidates registered for the covered VCA at a transplant hospital that is at or within this distance from a donor hospital:	And are:
1	500 NM	Blood type compatible with the donor
2	Nation	Blood type compatible with the donor

Within each classification, candidates are sorted by waiting time (longest to shortest).

Policy 13: Kidney Paired Donation (KPD)

13.1 Candidate Requirements for Participation

In order to participate in the OPTN Kidney Paired Donation (KPD) program, candidates must be registered on the deceased donor kidney waiting list at the transplant hospital that wishes to enroll the candidate in the OPTN KPD program.

13.2 Potential KPD Donor Requirements for Participation

In order to participate in the OPTN KPD program, potential KPD donors must comply with *both* of the following requirements:

1. Be at least 18 years old
2. Not be currently registered as a potential KPD donor for any other candidate registered in the OPTN KPD program

13.3 Informed Consent for KPD Candidates

The below requirements apply to candidates participating in any KPD program, unless otherwise specified.

13.3.A Release of Protected Health Information

For any KPD exchange, a paired candidate will not be eligible for a KPD match run until the paired candidate's transplant hospital obtains written consent from the paired candidate to share protected health information (PHI) with all other transplant hospitals in the KPD exchange.

The paired candidate's transplant hospital must maintain documentation of this consent in the paired candidate's medical record.

13.3.B Agreement to Accept a Shipped Kidney

The OPTN KPD program will only match a paired candidate with a donor whose recovery will occur at a transplant hospital that is different than the paired candidate's transplant hospital if the paired candidate's transplant hospital has obtained documentation in the candidate's medical record that the candidate is willing to receive a shipped kidney.

For any KPD exchange, the paired candidate's transplant hospital must document in the candidate's medical record that the candidate has been informed of the potentially negative consequences related to shipping a kidney, including that the donor's kidney could be lost in transport.

13.3.C Additional Requirements for KPD Candidates

For any KPD exchange, the paired candidate's transplant hospital must document in the candidate's medical record that it has informed the paired candidate of all the following elements of the KPD program:

1. The KPD program's matching requirements
2. KPD donors and candidates do not choose their match
3. A KPD donor or a candidate may decline a match
4. The KPD program's rules for when members are allowed to facilitate meetings between matched donors and recipients
5. That even if the candidate's paired donor donates, the paired candidate might not be transplanted.
6. The KPD program's remedy for failed KPD exchanges and that the remedy does not include any additional priority for the paired candidate on the deceased donor waiting list

The paired candidate's transplant hospital must inform the candidate of the right to withdraw from participation in the KPD program at any time, for any reason.

13.4 Informed Consent for KPD Donors

The below requirements apply to candidates participating in any KPD program, unless otherwise specified.

13.4.A Release of Protected Health Information (PHI)

For any KPD exchange, a paired donor will not be eligible for a KPD match run until the paired donor's transplant hospital obtains written consent from the paired donor to share protected health information (PHI) with all other transplant hospitals in the KPD exchange. The paired donor's transplant hospital must maintain documentation of this consent in the paired donor's medical record.

13.4.B General KPD Donor Informed Consent

For any KPD exchange, the paired donor's transplant hospital is responsible for obtaining and documenting informed consent from the paired donor according to OPTN *Policy 14.3: Informed Consent Requirements*. If a different transplant hospital performs the organ recovery, the recovery hospital must also obtain and document informed consent according to OPTN *Policy 14*.

13.4.C Additional Requirements for KPD Donors

For any KPD exchange, the paired donor's transplant hospital must maintain documentation in the paired donor's medical record that it has informed the paired donor of *all* of the following:

1. The KPD program's matching requirements
2. KPD donors and candidates do not choose their match
3. A KPD donor or a candidate may decline a match
4. The possibility of helping more than one candidate receive a transplant
5. The possibility that the paired donor may have to wait to find a match
6. The possibility that the paired donor might have to wait longer to donate after a match has been identified because of logistical issues
7. The possibility that the paired candidate might not receive a transplant because of an unexpected issue with the matched donor's kidney found during or after surgery
8. The possibility that the paired donor's kidney might not be transplanted or the paired donor's matched candidate might not receive a transplant because of unexpected events
9. The KPD program's remedy for failed KPD exchanges and that the remedy does not include any additional priority for the paired candidate on the deceased donor waiting list
10. The possibility that personal expenses of travel, housing, childcare costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation related costs.
11. The possibility that the paired donor's paired recipient and the paired donor's matched recipient might not have equal outcomes
12. The possibility of the paired donor's name appearing on the matched candidate's insurance estimation of benefits
13. That the donor's kidney could be lost in transport, and other potentially negative consequences related to shipping a kidney
14. That the paired donor may require additional testing, including multiple blood draws for crossmatching
15. That the paired donor may require re-evaluation
16. The KPD program's rules for when members are allowed to facilitate meetings between matched donors and recipients

For initial evaluations of all donors, the paired donor's transplant hospital must obtain the paired donor's signature that confirms the donor has been informed that of the paired donor may withdraw from participation in the KPD program at any time, for any reason.

For re-evaluation of OPTN KPD donors, the paired donor's transplant hospital must confirm the donor has been informed that the paired donor may withdraw from participation in the KPD program at any time, for any reason.

13.4.D Additional Requirements for Non-Directed Donor (NDD) Participants in KPD Programs

For any KPD exchange, before a NDD can participate in the KPD program, the NDD's transplant hospital must document in the NDD's medical record that it has informed the NDD of *all* their donation options including:

1. Participating in KPD
2. Donating to a candidate waiting for a deceased donor kidney according to OPTN *Policy 14.6.B: Placement of Non-directed Living Donor Kidneys*
3. Any other options available to the NDD

13.4.E Additional Requirements for Bridge Donors

For any KPD exchange, before a bridge donor is entered into a KPD match run, the bridge donor's transplant hospital is responsible for obtaining and maintaining documentation in the donor's medical record that it has informed the bridge donor of *all* of the following:

1. The bridge donor may need to have another medical evaluation at a future time.
2. The bridge donor may need to be available to provide blood on multiple occasions for crossmatching.
3. How the KPD program determines whether a chain ends with a bridge donor
4. The bridge donor may decline to donate at any time, for any reason
5. All of the bridge donor's options for donation, including:
    a. Continued participation as a bridge donor in the KPD program
    b. Donation to a candidate waiting for a deceased donor kidney
    c. Any other options available to the bridge donor
6. The bridge donor determines the amount of time the donor is willing to be a bridge donor. The bridge donor's transplant hospital will document in the donor's medical record how long the donor is willing to be a bridge donor. If the bridge donor revises the amount of time the donor is willing to be a bridge donor, the bridge donor's transplant hospital must document that revision in the donor's medical record.

The bridge donor's transplant hospital must maintain documentation in the donor's medical record that the donor has verbally consented to remain a bridge donor each time the donor is identified as a bridge donor in an accepted KPD exchange.

13.5 OPTN KPD Histocompatibility Testing

13.5.A HLA Typing Requirements for OPTN KPD Candidates

Before a candidate can appear on an OPTN KPD match run, the paired candidate's transplant hospital is responsible for reporting to the OPTN Contractor serological split level molecular typing results for *all* of the following:

- HLA-A
- HLA-B
- HLA-Bw4
- HLA-Bw6
- HLA-DR

If the candidate has unacceptable antigens listed for any of the following HLA types, then the paired candidate's transplant hospital is responsible for reporting to the OPTN Contractor serological split level molecular typing results for the corresponding HLA type before the candidate can appear on an OPTN KPD match run:

- HLA-C
- HLA-DR51
- HLA-DR52
- HLA-DR53
- HLA-DPA1
- HLA-DPB1
- HLA-DQA1
- HLA-DQB1

13.5.B Antibody Screening Requirements for OPTN KPD Candidates

The paired candidate's transplant hospital must complete antibody screening tests and report to the OPTN Contractor as follows:

1. Use an antibody testing method that is at least as sensitive as the crossmatch method. If antibodies are detected, then identify unacceptable antigens using a solid-phase single phenotype or solid-phase single-antigen test.
2. If no HLA antibodies or unacceptable antigens are detected, then report the paired candidate as unsensitized.

Report donor antigens that are considered absolute contraindications to transplant with the paired candidate as unacceptable antigens.

Before candidates can appear on their first OPTN KPD match run, each paired candidate's physician or surgeon or their designee and the histocompatibility laboratory director or the director's designee must review and sign a written approval of the unacceptable antigens listed for the paired candidate. The paired candidate's transplant hospital must document this review in the paired candidate's medical record.

Retest active candidates for antibodies according to #1 above at all of the following times:

- Within 110 days from the date of the most recent antibody test
- When any potentially sensitizing event occurs
- When a paired candidate who has been inactive for more than 90 days has been reactivated
- When an unacceptable and positive physical crossmatch occurs that precludes transplantation of the matched candidate

If any new unacceptable antigens are identified, then the paired candidate's transplant hospital must report these antigens using the process outlined in #3 and #4 above. If no new unacceptable antigens are identified, the paired candidate's transplant hospital must document the antibody screening results in the paired candidate's medical record.

13.5.C HLA Typing Requirements for OPTN KPD Donors

Before a donor can appear on an OPTN KPD match run, the donor's transplant hospital is responsible for reporting to the OPTN Contractor serological split level molecular typing results for *all* of the following:

- HLA-A
- HLA-B
- HLA-Bw4
- HLA-Bw6
- HLA-C
- HLA-DR
- HLA-DR51
- HLA-DR52
- HLA-DR53
- HLA-DPA1
- HLA-DQA1
- HLA-DQB1
- HLA-DPB1

13.5.D Responding to OPTN KPD Match Offers

1. Before declining an OPTN KPD match offer due to unacceptable antigens, the matched candidate's physician or surgeon or their designee must review the matched donor's antigens and their matched candidate's unacceptable antigens with the histocompatibility laboratory director or the director's designee. This joint review must be documented in the matched candidate's medical record.

When an OPTN KPD match offer is declined due to either a positive crossmatch or unacceptable antigens prior to crossmatch, the transplant hospital declining the offer must submit a written explanation to the OPTN Contractor within 7 days after declining the offer.
The matched candidate's transplant hospital is responsible for performing HLA typing on the matched donor and verifying the HLA information reported prior to transplant.

13.6 Matching within the OPTN KPD Program

13.6.A Requirements for Match Run Eligibility for Candidates

The OPTN KPD program will only match candidates who comply with *all* of the following requirements:

1. The candidate's transplant hospital must comply with OPTN *Policies 5.6.A: Receiving and Reviewing Organ Offers, 5.7: Organ Check-In, and 5.8: Pre-Transplant Verification*

2. The candidate's transplant hospital must complete the informed consent process according to OPTN *Policy 13.3: Informed Consent for KPD Candidates*
3. The candidate's transplant hospital must submit *all* the information for these required fields to the OPTN Contractor:

    a. Candidate details, including *all* of the following:
        - Last name
        - First name
        - SSN
        - Date of birth
        - Gender
        - Ethnicity
        - Race
        - ABO
        - Whether the candidate has signed an agreement to participate in the OPTN KPD program
        - Whether the candidate has signed a release of protected health information
        - Whether the candidate is a prior living donor
        - KPD status: active, inactive or removed. A candidate must have current active status in the OPTN KPD program to be eligible for a match run.

    b. Candidate choices, including *all* of the following
        - Whether the candidate would be willing to travel, and, if so, the transplant hospitals to which a candidate would be willing to travel or the distance the candidate is willing to travel
        - Whether the candidate is willing to accept a shipped kidney, and, if so, from which transplant hospitals the candidate would be willing to accept a shipped kidney
        - Minimum and maximum acceptable donor age
        - Minimum acceptable donor creatinine clearance or glomerular filtration rate (GFR)
        - Maximum acceptable donor BMI
        - Maximum acceptable systolic and diastolic blood pressure
        - Whether the candidate is willing to accept a hepatitis B core antibody positive KPD donor, a CMV positive KPD donor, and an EBV positive KPD donor
        - Whether the candidate would be willing to accept a left kidney, right kidney, or either kidney

    c. Candidate HLA as defined in OPTN *Policy 13.5.A: Histocompatibility Requirements for KPD Candidates*

4. The candidate must have at least one active and eligible potential KPD donor registered in the OPTN KPD program

5. The candidate's transplant hospital must submit a response for all previous match offers for the candidate in the OPTN KPD program, including reasons for refusing offers
6. The candidate must not be in a pending exchange in the OPTN KPD program

13.6.B Requirements for Match Run Eligibility for Potential KPD Donors

The OPTN KPD program will only match potential KPD donors that comply with *all* of the following requirements:

1. The transplant hospital registering the potential KPD donor must perform blood typing and subtyping as required by OPTN *Policy 14.5: Living Donor Blood Type Determination and Reporting* with the following modifications:
    a. The transplant hospital registering the potential KPD donor must report the potential KPD donor's actual blood type to the OPTN Contractor
    b. A qualified health care professional, other than the qualified health care professional who initially reported the potential KPD donor's blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential KPD donor's blood type to the OPTN Contractor
    c. The potential KPD donor is not eligible for a KPD match run until the transplant hospital verifies and reports two identical blood types
2. The transplant hospital registering the potential KPD donor must complete the informed consent process according to OPTN *Policy 13.4: Informed Consent for KPD Donors.*
3. The transplant hospital registering the potential KPD donor must complete the evaluation process according to OPTN *Policy 14: Living Donation*.
4. The transplant hospital registering the potential KPD donor must submit the information for the required fields below to the OPTN Contractor:
    a. Donor details, including *all* of the following:
        - Last name
        - First name
        - SSN
        - Date of birth
        - Gender
        - Ethnicity
        - Race
        - ABO
        - Height and weight
        - Whether the potential KPD donor is a non-directed donor or a paired donor
        - If the potential KPD donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential KPD donor's relationship to the candidate
        - Whether the potential KPD donor has signed an agreement to participate in the OPTN KPD program
        - Whether the potential KPD donor has signed a release of protected health information

- Whether the potential KPD donor has signed an informed consent as required in policy
- Whether the potential KPD donor has undergone all evaluations as required in OPTN *Policy 14: Living Donation*
- Whether the potential KPD donor has had all cancer screenings as required in OPTN *Policy 14: Living Donation*
- KPD status: active, inactive or removed. A donor must have current active status in the OPTN KPD program to be eligible for a match run.

b. Clinical information, including *all* of the following:
- The number of anti-hypertensive medications the potential KPD donor is currently taking
- Systolic and diastolic blood pressure with date (either 24-hour monitoring or two measurements)
- Creatinine clearance or glomerular filtration rate (GFR), date, and method
- Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results

c. Donor choices, including *all* of the following:
- Whether the potential KPD donor would be willing to travel, and, if so, the transplant hospitals to which the potential KPD donor would be willing to travel or the distance the donor is willing to travel
- Whether the potential KPD donor is willing to ship a kidney
- Whether the potential KPD donor is willing to donate a left kidney, right kidney, or either kidney
- Whether the KPD candidate-donor pair and the transplant hospital are willing to participate in a three-way exchange or a donor chain
- Whether the potential KPD donor and the transplant hospital are willing for the potential KPD donor to be a bridge donor

d. Donor HLA as defined in OPTN *Policy 13.5.C: HLA Typing Requirements for OPTN KPD Donors*

5. The potential KPD donor must be paired to an active and eligible candidate registered in the OPTN KPD program or be a non-directed donor
6. The transplant hospital registering the potential KPD donor must submit a response for all previous match offers for the potential KPD donor in the OPTN KPD program, including reason for refusing offers
7. The potential KPD donor must not be in a pending exchange in the OPTN KPD program
8. The transplant program has re-evaluated the potential KDP donor per *Policy 13.7: Re-Evaluation Requirements for KPD Donors* and reported to the OPTN the date of re-evaluation

13.7 Re-Evaluation Requirements for OPTN KPD Donors

Transplant programs must re-evaluate donors in the OPTN KPD Program annually. The donor's re-evaluation deadline is based on donor's date of registration in the OPTN KPD program or the date of the donor's re-evaluation, whichever is most recent.

Transplant programs will have 30 days after the donor's re-evaluation deadline to perform the re-evaluation. The paired donor's transplant hospital must report the date the donor re-evaluation was completed and any changes to the donor information reported per *Policy 13.6.B: Requirements for Match Run Eligibility for Potential Donors*. Failure to report date of completed donor re-evaluation by this time will render the donor ineligible to participate in match runs in the OPTN KPD program until a re-evaluation date is reported.

13.7.A Psychosocial Re-Evaluation Requirements for OPTN KPD Donors

A psychosocial re-evaluation of the OPTN KPD donor must be performed by the paired donor's transplant program per OPTN *Policy 14.1.A: Living Donor Psychosocial Evaluation Requirements.*

13.7.B Medical Re-Evaluation Requirements for OPTN KPD Donors

A medical re-evaluation of the paired donor must be performed by a physician or surgeon experienced in living donation at the paired donor's transplant program. Documentation of the medical re-evaluation must be maintained in the donor medical record.

The medical re-evaluation must include *all* of the components in *Table 13-1* and *Table 13-2* below.

Table 13-1: Requirements for OPTN KPD Donor Medical Re-Evaluation:

This re-evaluation must be completed:	Including evaluation for and assessment of this information:
General Donor History	1. A personal history of significant medical conditions, which include but are not limited to: o Hypertension o Diabetes o Lung disease o Heart disease o Gastrointestinal disease o Autoimmune disease o Neurologic disease o Genitourinary disease o Hematologic disorders o Bleeding or clotting disorders o History of cancer including melanoma 2. History of infections 3. Active and past medications with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medication 4. Allergies 5. Evaluation for coronary artery disease
Kidney-specific Donor History	1. A personal history of significant medical conditions which include, but are not limited to, kidney-specific personal history including: o Kidney disease, proteinuria, hematuria o Kidney injury o Diabetes including gestation diabetes

This re-evaluation must be completed:	Including evaluation for and assessment of this information:
	o Nephrolithiasis o Recurrent urinary tract infections
Social History	1. Occupation 2. Employment status 3. Health insurance status 4. Living arrangements 5. Social support 6. Smoking, alcohol and drug use and abuse 7. Psychiatric illness, depression, suicide attempts 8. Risk criteria for acute HIV, HBV, and HCV infection according to the *U.S. Public Health Services (PHS) Guideline*
Physical Exam	1. Height 2. Weight 3. BMI 4. Vital signs 5. Examination of all major organ systems 6. Blood pressure taken on at least two different occasions or 24-hour or overnight blood pressure monitoring
General laboratory and imaging tests	1. Complete blood count (CBC) with platelet count 2. Prothrombin Time (PT) or International Normalized Ratio (INR) 3. Partial Thromboplastin Time (PTT) 4. Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin) 5. HCG quantitative pregnancy test for premenopausal women without surgical sterilization 6. Chest X-Ray 7. Electrocardiogram (ECG)
Other metabolic testing:	1. Fasting blood glucose 2. Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LCL cholesterol) 3. Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high-risk individuals
Kidney-specific tests	1. Urinalysis or urine microscopy 2. Measurement of urinary protein and albumin excretion 3. The following, if clinically indicated: o Urine culture o Measurement of glomerular filtration rate by isotopic methods or creatinine clearance calculated from a 24-hour urine collection o Patients with a history of nephrolithiasis or nephrolithiasis (>3 mm) identified on radiographic imaging must have a 24-hour urine stone panel measuring calcium, oxalate, uric acid, citric acid, creatinine, and sodium
Cancer Screening:	1. The paired donor's transplant hospital must develop and comply with protocols consistent with the American Cancer Society (ACS) or the U.S. Preventive Services Task Force to screen for:

This re-evaluation must be completed:	Including evaluation for and assessment of this information:
	o Cervical cancer o Breast cancer o Prostate cancer o Colon cancer o Lung cancer
Anatomic assessment	1. The following, if clinically indicated: o Whether the kidneys are of equal size o If the kidneys have masses, cysts, or stones o If the kidneys have other anatomical defects o Which kidney is more anatomically suited for transplant

The paired donor's transplant program must re-evaluate the donor for transmissible diseases per *Table 13-2.*

Table 13-2: Infectious Disease Testing Re-Evaluation Requirements:

This re-evaluation must be completed:	Including evaluation for and assessment of this information:
Transmissible disease screening:	Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using FDA-licensed, approved, or cleared tests. Testing must include all the following: 1. CMV (Cytomegalovirus) antibody 2. EBV (Epstein Barr Virus) antibody 3. HIV antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination 4. HIV ribonucleic acid (RNA) by nucleic acid test (NAT) 5. Hepatitis B surface antigen (HbsAg) 6. Hepatitis B core antibody (total anti-HBc) testing 7. HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT) 8. Hepatitis C antibody (anti-HCV) testing 9. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) 10. Syphilis testing The donor does not need to be retested for the following infectious disease antibodies for which they have previously tested positive: 1. CMV (Cytomegalovirus) antibody 2. EBV (Epstein Barr Virus) antibody 3. Hepatitis B core antibody (total anti-HBc) testing 4. Hepatitis C antibody (anti-HCV) testing For tuberculosis (TB), the paired donor's transplant hospital must retest and follow protocol per *Policy 14.4: Medical Evaluation Requirements for Living Donors*

This re-evaluation must be completed:	Including evaluation for and assessment of this information:
	Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation.

13.7.C Informed Consent Requirements Upon Donor Re-Evaluation

Upon re-evaluation of the OPTN KPD donor, the paired donor's transplant hospital must maintain documentation in the paired donor's medical record that it has informed the paired donor of all of the requirements in *Policy 13.4.C: Informed Consent for KPD Donors*. The paired donor's transplant hospital must also confirm that the donor has been re-informed that they may withdraw from participation in the OPTN KPD program at any time, for any reason.

13.8 OPTN KPD Screening Criteria

13.8.A Blood Type

The OPTN Contractor will only match candidates and potential donors who have identical or compatible blood types as defined in *Table 13-1* below.

Table 13-3: Allocation by Blood Type

Donors with:	Are Matched to Candidates with:
Blood Type O	Blood type O Blood types A, A_1, or A, non-A_1 Blood types B, AB, A_1B, or AB, non- A_1B
Blood Type A or A_1	Blood types A, A_1, or A, non-A_1 Blood types AB, A_1B, or AB, non- A_1B
Blood Type A, non-A_1	Blood types A, A_1, or A, non-A_1 Blood types AB, A_1B, or AB, non-A_1B Blood type O or B if the candidate meets the requirements in *Policy 13.7.B: Blood Type A, non-A_1 and Blood Type AB, non-A_1B Matching*.
Blood Type B	Blood type B Blood types AB, A_1B, or AB, non-A_1B
Blood Type AB	Blood types AB, A_1B, or AB, non-A_1B
Blood Type A_1B	Blood types AB, A_1B, or AB, non-A_1B

Donors with:	Are Matched to Candidates with:
Blood Type AB, non-A_1B	Blood types AB, A_1B, or AB, non-A_1B Blood type B if the candidate meets the requirements in *Policy 13.7.B: Blood Type A, non-A_1 and Blood Type AB, non-A_1B Matching*.

13.8.B Blood Type A, non-A_1 and Blood Type AB, non-A_1B Matching

Kidneys from donors with blood types A, non-A1 may be matched with candidates with blood type B or blood type O, and kidneys from donors with blood types AB, non-A1B may be matched with candidates with blood type B, so long as *all* of the following criteria are met:

1. The paired candidate's transplant program establishes a written policy regarding its programs titer threshold for transplanting blood type A, non-A_1 and blood type AB, non- A_1B kidneys into candidates with blood type B and for transplanting blood type A, non- A_1 into candidates with blood type O.
2. The paired candidate's transplant program obtains written informed consent from the candidate regarding their willingness to accept a blood type A, non-A_1, or blood type AB, non-A_1B blood type kidney
3. The paired candidate's transplant program must confirm the candidate's eligibility every 90 days (+/- 20 days).

13.8.C Unacceptable Antigens

A transplant hospital must specify any unacceptable antigens it will not accept for its paired candidates using the process outlined in OPTN *Policy 13.5.B: Antibody Screening Requirements for OPTN KPD Candidates*. The OPTN Contractor will not match the paired candidate with any potential KPD donor who has one of the candidate's unacceptable antigens entered as a human leukocyte antigen (HLA) value.

13.8.D Candidate and Potential Donor Choices

A transplant hospital may specify criteria it will not accept for any of its KPD candidates as outlined in OPTN *Policy 13.6.A: Requirements for Match Run Eligibility for Candidates* or potential KPD donors as outlined in OPTN *Policy 13.6.B: Requirements for Match Run Eligibility for Potential KPD Donors*. The OPTN Contractor will not match the KPD candidates with potential KPD donors who fall outside the specified criteria or potential KPD donors with KPD candidates who fall outside the specified criteria.

13.8.E Donor Pre-Acceptance and Pre-Refusal

If an OPTN KPD candidate has a CPRA greater than or equal to 90%, then the candidate's transplant hospital must pre-accept or pre-refuse potential donors. The OPTN KPD candidate will only be matched with donors that are pre-accepted. If a donor is not pre-accepted, the donor will automatically be treated as pre-refused and will not be matched with the candidate.

If an OPTN KPD candidate has a CPRA less than 90%, then the candidate's transplant hospital has the option to pre-accept or pre-refuse potential donors. These candidates will automatically be matched with all potential donors, unless the candidate's transplant hospital exercises the option to pre-refuse a potential donor.

13.8.F OPTN KPD Prioritization Points

All OPTN KPD matches receive 100 base points. KPD matches will receive additional points according to *Table 13-2: OPTN KPD Prioritization Points* when the OPTN Contractor identifies all possible matches and exchanges from the list of eligible KPD donors and candidates. The OPTN Contractor will then prioritize the set of exchanges with the highest total point value.

Table 13-4: OPTN KPD Prioritization Points

If the:	Then the match will receive:
Candidate is registered for the OPTN KPD program	.07 points for each day according to Policy 13.7.G: OPTN KPD Waiting Time Reinstatement
Candidate is a 0-ABDR mismatch with the potential donor	10 points
Transplant hospital that registered both the candidate and potential donor in the OPTN KPD program is the same	75 points
Candidate and potential donor had a previous crossmatch that was one of the following: • Negative • Positive and acceptable with desensitization • Positive and acceptable without desensitization	75 points
Candidate was less than 18 years old at the time the candidate was registered in the OPTN KPD program	100 points
Candidate is a prior living organ donor	150 points
Candidate ABO is O	100 points
Candidate ABO is B	50 points
Candidate ABO is A	25 points
Candidate ABO is AB	0 points
Paired donor ABO is O	0 points
Paired donor ABO is B	100 points

If the:	Then the match will receive:
Paired donor ABO is A	250 points
Paired donor ABO is AB	500 points
Candidate CPRA is 0-19	0 points
Candidate CPRA is 20-29	5 points
Candidate CPRA is 30-39	10 points
Candidate CPRA is 40-49	15 points
Candidate CPRA is 50-59	20 points
Candidate CPRA is 60-69	25 points
Candidate CPRA is 70-74	50 points
Candidate CPRA is 75-79	75 points
Candidate CPRA is 80-84	125 points
Candidate CPRA is 85-89	200 points
Candidate CPRA is 90-94	300 points
Candidate CPRA is 95	500 points
Candidate CPRA is 96	700 points
Candidate CPRA is 97	900 points
Candidate CPRA is 98	1250 points
Candidate CPRA is 99	1500 points
Candidate CPRA is 100	2000 points
Candidate is an orphan candidate	1,000,000 points

If a candidate has multiple paired donors with different blood types, then all of the candidate's matches will be awarded the priority point value associated with the paired donor whose ABO receives the fewest amount of points.

13.8.G OPTN KPD Waiting Time Reinstatement

KPD waiting time begins on the day the candidate's transplant hospital registers the candidate in the OPTN KPD program. Candidates accrue 0.07 points per day from the date the candidate is registered in the OPTN KPD program. A candidate will accrue KPD waiting time at both active and inactive status in the OPTN KPD program.

The OPTN Contractor will reinstate OPTN KPD waiting time to recipients, without interruption, if the OPTN KPD candidate experiences immediate and permanent non-function of any transplanted kidney and the KPD candidate is re-registered in the OPTN KPD program with

another living donor. Immediate and permanent non-function of a transplanted kidney is defined as *either*:

1. Kidney graft removal within the first 90 days of transplant documented by a report of the removal of the transplanted kidney.

2. Kidney graft failure within the first 90 days of transplant with documentation that the candidate is either on dialysis or has measured creatinine clearance (CrCl) or calculated glomerular filtration rate (GFR) less than or equal to 20 mL/min within 90 days after the candidate's kidney transplant.

KPD waiting time will be reinstated when the OPTN Contractor receives a request for reinstatement of KPD waiting time and the required supporting documentation from the KPD candidate's transplant hospital.

13.8.H Priority for Orphan Candidates

A candidate will be eligible for orphan candidate priority *only* if the candidate qualified for orphan status through participation in the OPTN KPD program. An orphan candidate will receive priority according to *Table 13-2: OPTN KPD Prioritization Points*, even if the candidate has another willing living donor. The orphan candidate will retain this priority until the orphan candidate receives a kidney transplant. The orphan candidate can always refuse a match offer and retain orphan candidate priority.

13.9 Two- and Three-Way Matches

13.9.A Match Size

The OPTN Contractor will match KPD donor-candidate pairs only in two-way or three-way exchanges unless the exchange includes a non-directed donor (NDD) according to OPTN *Policy 13.9: Donor Chains.*

13.8.B Logistical Requirements

In two-way or three-way exchanges in the OPTN KPD program, each matched donor recovery must be scheduled to begin within 24 hours of the start of the previous matched donor recovery. The donor surgeries in the exchange will begin only after all transplant programs agree to proceed.

13.10 Donor Chains

13.10.A Chain Size

In the OPTN KPD program, there is no limit on the length of the KPD donor chains.

13.10.B Logistical Requirements for Donor Chains

In OPTN KPD chains, each matched donor recovery must be scheduled to begin within 21 days from the date the matched donor's paired candidate receives a transplant. However, a KPD

candidate-donor pair has the option to either have their surgeries begin within 24 hours of one another or refuse the match. Surgeries occurring within 24 hours would follow the same requirements as the two-way or three-way exchange according to OPTN *Policy 13.8.B: Logistical Requirements for Two- and Three-Way Matches.*

13.10.C Ending Chains

Transplant hospitals participating in OPTN KPD must follow the requirements for ending a chain according to *Table 13-3* below.

Table 13-5: Logistical Requirements for Ending Chains

If a chain begins that:	Then:
Does not include a match for an orphan candidate	The transplant hospital that entered the non-directed donor (NDD) can choose to *either*: Allow the chain to continue through bridge donation, if the last paired donor in the chain is willing to be a bridge donor. End the chain with a donation from the last paired donor in the chain to a candidate on the deceased donor waiting list at the transplant hospital that entered the NDD that started the chain.
Includes a match for an orphan candidate	The chain must end with a donation to the orphan candidate.

If the transplant hospital that entered the non-directed donor initially chooses to allow the chain to continue through bridge donation, the chain will extend until the transplant hospital reports to the OPTN Contractor that *one* of the following events has occurred:

- The bridge donor declines to donate
- The bridge donor donates to an orphan candidate
- The bridge donor donates to the deceased donor waitlist
- The transplant hospital that registered the bridge donor in the OPTN KPD program refuses to allow the donor to serve as a bridge donor

A transplant hospital that entered the non-directed donor can also request to end the chain with a donation to the deceased donor waiting list.

13.10.D What to Do When a Chain Breaks

In the OPTN KPD program, a donor chain will proceed until a KPD candidate or matched donor refuses a match offer.

If a KPD candidate or matched donor in a chain refuses a match offer, then the matched donor at the end of the chain may donate to an orphan candidate, the deceased donor waiting list, or may be a bridge donor as outlined in OPTN *Policy 13.9.B: Logistical Requirements for Donor Chains* and *Policy 13.9.C: Ending Chains*.

13.11 OPTN KPD Crossmatching Requirements

The matched candidate's transplant hospital must do *all* of the following:

1. Perform a physical crossmatch between the matched candidate and the matched donor before the matched donor's recovery is scheduled.
2. Perform a final crossmatch prior to transplant.
3. Report all crossmatching results to the OPTN Contractor and the matched donor's transplant hospital.

If, at any time, the matched candidate's transplant hospital refuses a match offer due to an unacceptable positive crossmatch between the candidate and the matched donor, then the matched candidate is ineligible for subsequent match runs. The candidate will remain ineligible until *all* of the following are completed:

1. The matched candidate's physician or surgeon or their designee and the histocompatibility laboratory director or the director's designee review the unacceptable antigens reported for the candidate.
2. The matched candidate's transplant hospital reports to the OPTN Contractor that the review has occurred.

13.12 KPD Match Offer and Transplant Timing Requirements

Each OPTN KPD program must designate a KPD contact to receive notification of match offers.

Table 13-6: Deadlines for Performing Responsibilities upon Receiving a KPD Match Offer

The following members:	Must:	Within:
Each transplant hospital receiving a match offer	Report to the OPTN Contractor a preliminary response	2 business days of receiving the match offer.
The matched candidate's transplant hospital and the matched donor's transplant hospital	Agree in writing upon all of the following: • Contents required in the crossmatch kit • Instructions for the donor • Address at which to send the completed blood samples	3 business days of receiving the match offer.
The matched donor's transplant hospital	Report to the OPTN Contractor the agreed upon date of the crossmatch	3 business days of receiving the match offer.

The following members:	Must:	Within:
The matched donor's transplant hospital	Make all of the following matched donor's records accessible to the matched candidate's transplant hospital: • Any serologic and nucleic acid testing (NAT) results that have not already been shared with the matched candidate's transplant hospital • Whether the matched donor has any risk criteria for acute HIV, HBV, or HCV infection according to the *U.S. Public Health Service (PHS) Guideline* • Additional records requested by the matched candidate's transplant hospital	3 business days of receiving the match offer.
The matched candidate's transplant hospital	Report to the OPTN Contractor the results of the crossmatch	10 business days of receiving the match offer.
The matched candidate's transplant hospital	Review the matched donor's records and confirm acceptance or report a refusal of the match offer to the OPTN Contractor	10 business days of receiving the match offer.
The matched candidate's transplant hospital and the matched donor's transplant hospital	Agree upon a date and time for the recovery of the matched kidney(s)	15 business days of receiving the match offer
The matched donor's transplant hospital and matched candidate's transplant hospital	Schedule both the recovery of the kidney from one of the matched donors in the exchange *and* the subsequent transplant of their matched candidate to occur	60 days of receiving the match offer

If the matched candidate's and matched donor's transplant hospitals do not meet any of the deadlines above, then the exchange will be terminated unless a transplant hospital requests an extension. If a transplant hospital submits an extension request before the deadline, the exchange will not terminate until the resolution of the extension request or the deadline is reached, whichever comes last.

13.12.A Requesting a Deadline Extension for a KPD Exchange

The transplant hospital may request an extension for any of the deadlines in *Table 13-4* by submitting a request in writing to the OPTN Contractor. This written request must include the reason for the request and the new requested deadline date. Upon receipt of the request for extension, the OPTN Contractor will notify all of the transplant hospitals in the exchange. Upon notification, the transplant hospitals in the exchange must respond to the request for extension

within 2 business days. If all other transplant hospitals in the exchange agree to the extension, it will be granted. If any of the transplant hospitals in the exchange refuse the extension request, the extension will not be granted.

The transplant hospitals will have two business days to respond to the extension request. At the end of the first business day, the OPTN will send a second notification to any transplant hospital that has not yet responded. If any of the transplant hospitals fail to respond to the extension request at the end of the second business day, the extension will be granted.

13.13 Transportation of Kidneys

For any KPD exchange, the recovery hospital is responsible for packaging, labeling, and transporting kidneys from donors according to OPTN *Policy 16.1: Organs Recovered by Living Donor Recovery Hospitals*.

In the OPTN KPD program, the recovery hospital must specify *both* of the following:

1. The location where the recovered kidney must be picked up for transport to the recipient's transplant hospital.
2. The name and telephone number of the person or company who will package and label the kidney.

The recipient's transplant hospital must document *both* of the following:

1. The location where the recovered kidney must be delivered.
2. The name and telephone number of the person or company who will be transporting the kidney from the time that the kidney is recovered until the kidney is delivered to the location specified by the KPD recipient's transplant hospital.

The recovery and recipient hospitals must complete this documentation, along with the date and time it was documented, before the potential KPD donor enters the operating room for the kidney recovery surgery and must maintain this documentation in the donor's medical record.

13.14 Communication between KPD Donors and Recipients

The following rules apply to communication between KPD donors and matched KPD recipients that participated in an OPTN KPD program exchange. These rules do not apply to meetings between potential KPD donors and paired KPD candidates.

Members can facilitate communication such as meetings or other correspondence between KPD donors and their matched recipients that participated in an OPTN KPD program exchange only if *all* of the follow conditions are met:

1. All the KPD donors and recipients participating in the communication agree on conditions of the meeting or correspondence.
2. The meeting or communication occurs after the donor kidney recovery and transplant surgeries have been completed.

3. The transplant hospital establishes and complies with a written protocol for when KPD donors and their matched recipients can communicate. This protocol must include, at a minimum, the timing of the meeting or correspondence and what staff must be involved.
4. The transplant hospital complies with the written protocol for when KPD donors and recipients can communicate. The transplant hospital must maintain documentation of compliance in the KPD donor's or matched recipient's medical record.

Policy 14: Living Donation

14.1 Psychosocial Evaluation Requirements for Living Donors

14.1.A Living Donor Psychosocial Evaluation Requirements

The living donor psychosocial evaluation must be performed by a psychiatrist, psychologist, masters prepared social worker, or licensed clinical social worker prior to organ recovery. Documentation of the psychosocial evaluation must be maintained in the living donor medical record and include *all* of the following components:

1. An evaluation for any psychosocial issues, including mental health issues, that might complicate the living donor's recovery and could be identified as risks for poor psychosocial outcome.
2. An assessment of risk criteria for acute HIV, HBV, and HCV infection according to the *U.S. Public Health Service (PHS) Guideline.*
3. A review of the living donor's history of smoking, alcohol, and drug use, including past or present substance abuse disorder.
4. The identification of factors that warrant educational or therapeutic intervention prior to the final donation decision.
5. The determination that the living donor understands the short and long-term medical and psychosocial risks for both the living donor and recipient associated with living donation.
6. An assessment of whether the decision to donate is free of inducement, coercion, and other undue pressure by exploring the reasons for donating and the nature of the relationship, if any, to the transplant candidate.
7. An assessment of the living donor's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes evaluating whether the donor has a realistic plan for donation and recovery, with social, emotional and financial support available as recommended.

8. A review of the living donor's occupation, employment status, health insurance status, living arrangements, and social support.
9. The determination that the living donor understands the potential financial implications of living donation.

14.2 Independent Living Donor Advocate (ILDA) Requirements

14.2.A ILDA Requirements for Living Donor Recovery Hospitals

For any living donor who is undergoing evaluation for donation, the living donor recovery hospital must designate and provide each living donor with an ILDA who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient. The ILDA may be one person or an ILDA team with multiple members. An ILDA team must designate one person from the team as the key contact for each living donor. All ILDA requirements must be completed prior to organ recovery.

The ILDA must:

1. Function independently from the transplant candidate's team.
2. Advocate for the rights of the living donor.
3. Fulfill the qualification and training requirements specified in the recovery hospital's protocols regarding knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressure on the living donor's decision about whether to donate.
4. Review and document whether the living donor has received information on each of the following areas and assist the donor in obtaining additional information from other professionals as needed about the:
    a. Informed consent process as described in OPTN *Policy 14.3: Informed Consent Requirements*
    b. Evaluation process according to OPTN *Policies 14.1.A: Living Donor Psychosocial Evaluation Requirements* and *14.4.A: Living Donor Medical Evaluation Requirements*
    c. Surgical procedure
    d. Follow-up requirements, and the benefit and need for participating in recovery hospital's requirements according to OPTN *Policies 18.1: Data Submission Requirements, 18.4: Living Donor Data Submission Requirements,* and *18.5.B: Reporting of Living Donor Events by Recovery Hospitals*

14.2.B ILDA Protocols for Living Donor Recovery Hospitals

The living donor recovery hospital must develop, and once developed must comply with, written protocols for:

1. The composition of the ILDA team, if the hospital uses a team.
2. The qualifications and training (both initial and ongoing) required for the ILDA. Minimum qualifications must include knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressures on the potential living donor's donation decision. Document that each requirement has been met.
3. The duties and responsibilities of the ILDA, which must include at least the functions and

duties according to OPTN *Policy 14.2.A: ILDA Requirements for Living Donor Recovery Hospitals.*

4. The process the living donor recovery hospital will provide for the ILDA to file a grievance when necessary to protect the rights or best interests of the living donor.
5. The process the living donor recovery hospital will use to address any grievance raised by the ILDA concerning the rights or best interests of the living donor.

14.3 Informed Consent Requirements

The living donor recovery hospital is responsible for obtaining and documenting informed consent prior to organ recovery. Informed consent requirements must include *all* of the components in *Tables 14-1* through *14-5*. Documentation of informed consent must be maintained in the living donor medical record.

Table 14-1: Requirements for Living Donor Informed Consent

The recovery hospital must:	These elements of informed consent :
Obtain from living donors	The living donor's signature on a document that confirms that the donor: 1. Is willing to donate 2. Is free from inducement and coercion 3. Has been informed that he or she may decline to donate at any time
Provide to living donors	1. An opportunity to discontinue the living donor consent or evaluation process in a way that is protected and confidential. 2. The ILDA must be available to assist the living donor during the consent process, according to OPTN *Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements.* 3. Instruction about all phases of the living donation process, which includes: • Consent • Medical and psychosocial evaluations • Pre- and post-operative care • Required post-operative follow-up according to OPTN *Policy 18.4: Living Donor Data Submission Requirements.* Teaching or instructional material can include any media, one-on-one or small group interaction. Teaching or instruction must be provided in a language in which the living donor is able to engage in meaningful dialogue with recovery hospital's staff.
Disclose to living donors	1. It is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for anything of value including, but not limited, to cash, property, and vacations. 2. The recovery hospital must provide an ILDA. 3. Alternate procedures or courses of treatment for the recipient, including deceased donor transplantation. 4. A deceased donor organ may become available for the candidate before the recovery hospital completes the living donor's evaluation or the living donor transplant occurs.

The recovery hospital must:	These elements of informed consent :
	5. Transplant hospitals determine candidacy for transplantation based on existing hospital specific guidelines or practices and clinical judgment. 6. The recovery hospital will take all reasonable precautions to provide confidentiality for the living donor and recipient. 7. Any transplant candidate may have an increased likelihood of adverse outcomes (including but not limited to graft failure, complications, and mortality) that: • Exceed local or national averages • Do not necessarily prohibit transplantation • Are not disclosed to the living donor 8. The recovery hospital can disclose to the living donor certain information about candidates only with permission of the candidate, including: • The reasons for a transplant candidate's increased likelihood of adverse outcomes • Personal health information collected during the transplant candidate's evaluation, which is confidential and protected under privacy law 9. Health information obtained during the living donor evaluation is subject to the same regulations as all medical records and could reveal conditions that must be reported to local, state, or federal public health authorities. 10. The recovery hospital is required to: a. Report living donor follow-up information, at the time intervals specified in OPTN *Policy 18.4: Living Donor Data Submission Requirements* b. Have the donor commit to post donation follow-up testing coordinated by the recovery hospital. c. Obtain and store a living donor blood specimen for ten years, only to be used for investigation of potential donor-derived disease. 11. Any infectious disease or malignancy that is pertinent to acute recipient care discovered during the donor's first two years of follow-up care: a. May need to be reported to local, state or federal public health authorities b. Will be disclosed to their recipient's transplant hospital c. Will be reported through the OPTN Improving Patient Safety Portal 12. A living donor must undergo a medical evaluation according to OPTN *Policy 14.4: Medical Evaluation Requirements for Living Donors* and a psychosocial evaluation as required by OPTN *Policy 14.1: Psychosocial Evaluation Requirements for Living Donors*. 13. The hospital may refuse the living donor. In such cases, the recovery hospital must inform the living donor that a different recovery hospital may evaluate the living donor using different selection criteria 14. The following are inherent risks associated with evaluation for living donation: a. Allergic reactions to contrast b. Discovery of reportable infections c. Discovery of serious medical conditions d. Discovery of adverse genetic findings unknown to the living donor

The recovery hospital must:	These elements of informed consent :
	e. Discovery of certain abnormalities that will require more testing at the living donor's expense or create the need for unexpected decisions on the part of the transplant team 15. There are surgical, medical, psychosocial, and financial risks associated with living donation, which may be temporary or permanent and include, but are not limited to, *all* of the following: a. Potential medical or surgical risks: i. Death ii. Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure iii. Abdominal symptoms such as bloating, nausea, and developing bowel obstruction iv. That the morbidity and mortality of the living donor may be impacted by age, obesity, hypertension, or other donor-specific pre-existing conditions b. Potential psychosocial risks: i. Problems with body image ii. Post-surgery depression or anxiety iii. Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies iv. Changes to the living donor's lifestyle from donation c. Potential financial impacts: i. Personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation-related costs ii. Need for life-long follow up at the living donor's expense iii. Loss of employment or income iv. Negative impact on the ability to obtain future employment v. Negative impact on the ability to obtain, maintain, or afford health insurance, disability insurance, and life insurance vi. Future health problems experienced by living donors following donation may not be covered by the recipient's insurance

Table 14-2: Additional Requirements for the Informed Consent of Living Kidney Donors

The recovery hospital must:	These additional elements as components of informed consent for living kidney donors:
Provide to all living kidney donors	Education about expected post-donation kidney function, and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the living donor in the future, to include: a. On average, living donors will have a 25-35% permanent loss of kidney function after donation.

The recovery hospital must:	These additional elements as components of informed consent for living kidney donors:
	b. Although risk of ESRD for living kidney donors does not exceed that of the general population with the same demographic profile, risk of ESRD for living kidney donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors. c. Living donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occurs, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young living donor cannot predict lifetime risk of CKD or ESRD. d. Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD may be faster with only one kidney. e. Dialysis is required if the living donor develops ESRD. f. Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to OPTN *Policy 8.2: Kidney Allocation Score*.
Disclose to all living kidney donors	Surgical risks may be transient or permanent and include but are not limited to: • Decreased kidney function • Acute kidney failure and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period
Disclose to all female living kidney donors	Risks of preeclampsia or gestational hypertension are increased in pregnancies after donation
Disclose to all living kidney donors with HIV	The potential impact on their health and the long-term outcomes associated with donating an organ while living with HIV is unknown

Table 14-3: Additional Requirements for the Informed Consent of Living Liver Donors

The recovery hospital must:	These additional elements as components of informed consent for living liver donors:
Disclose to all living liver donors	Surgical risks may be transient or permanent and include but are not limited to: • Acute liver failure with need for liver transplant. • Transient liver dysfunction with recovery. The potential for transient liver dysfunction depends upon the amount of the total liver removed for donation. • Risk of red cell transfusions or other blood products. • Biliary complications, including leak or stricture that may require additional intervention. • Post-donation laboratory tests may result in abnormal or false positive results that may trigger additional tests that have associated risks.
Disclose to all living liver donors with HIV	The potential impact on their health and the long-term outcomes associated with donating an organ while living with HIV is unknown

Table 14-4: Additional Requirements for the Informed Consent of Living Donors of Covered VCAs

The recovery hospital must:	These additional elements as components of informed consent for living VCA donors:

Disclose to all living donors of covered VCAs other than covered genitourinary organ VCAs	There are surgical, psychosocial, and financial risks associated with living donation of covered non-genitourinary VCAs, which may be temporary or permanent and include, but are not limited to, *all* of the following:
	• Potential surgical risks:
	  • Loss of function
	  • Physical disability
	  • Physical disfigurement
	• Potential psychosocial risk: Feelings of emotional distress or grief if the transplant recipient does not experience a successful functional or cosmetic outcome
	• Potential financial impacts: Procedure may not be covered by health insurance

Disclose to all living donors of covered genitourinary organ VCAs	There are surgical, psychosocial, and financial risks associated with living donation of covered genitourinary VCAs, which may be temporary or permanent and include, but are not limited to, *all* of the following:
	• Potential surgical risks:
	  • Bowel injury
	  • Need for hormonal replacement therapy
	  • Pain or discomfort with intercourse
	  • Partial or complete loss of organ-specific function including reproductive function
	  • Physical disfigurement
	  • Urinary tract injury or dysfunction
	• Potential psychosocial risk: Feelings of emotional distress or grief if the transplant recipient does not experience a successful functional, cosmetic, or reproductive outcome
	• Potential financial impacts: Procedure may not be covered by health insurance

As part of the informed consent process, recovery hospitals must also provide transplant recipient outcome and transplanted organ survival data to living donors according to *Table 14-5*. The requirements in Table 14-5 do not apply to donors of covered VCAs.

Table 14-5: Required Recipient Outcome and Transplanted Organ Survival Data

If the recovery hospital and the recipient hospital:	Then the recovery hospital must provide the living donor with:	Including *all* the following information:
Are the same	Both national and that hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) program-specific reports.	• National 1-year patient and transplanted organ survival • The hospital's 1-year patient and transplanted organ survival • Notification about all Centers for Medicare and Medicaid Services (CMS) outcome requirements not being met by the transplant hospital
Will not be the same and the recipient hospital is known	Both national and the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR program-specific reports.	• National 1-year patient and transplanted organ survival • The recipient hospital's 1-year patient and transplanted organ survival • Notification about all CMS outcome requirements not being met by the recipient hospital
Will not be the same and the recipient hospital is not known	National transplant recipient outcomes from the most recent SRTR reports.	• National 1-year patient and transplanted organ survival

14.4 Medical Evaluation Requirements for Living Donors

14.4.A Living Donor Medical Evaluation Requirements

A medical evaluation of the living donor must be performed by the recovery hospital and by a physician or surgeon experienced in living donation. Documentation of the medical evaluation must be maintained in the donor medical record.

The medical evaluation must include *all* of the components in *Tables 14-6* through *14-10* below.

Table 14-6: Requirements for Living Donor Medical Evaluations

This evaluation must be completed:	Including evaluation for and assessment of this information:
General donor history	1. A personal history of significant medical conditions which include but are not limited to: a. Hypertension b. Diabetes c. Lung disease d. Heart disease e. Gastrointestinal disease f. Autoimmune disease g. Neurologic disease h. Genitourinary disease i. Hematologic disorders j. Bleeding or clotting disorders k. History of cancer including melanoma 2. History of infections 3. Active and past medications with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medication 4. Allergies 5. An evaluation for coronary artery disease
General family history	• Coronary artery disease • Cancer
Social history	• Occupation • Employment status • Health insurance status • Living arrangements • Social support • Smoking, alcohol and drug use and abuse • Psychiatric illness, depression, suicide attempts • Risk criteria for acute HIV, HBV, and HCV infection according to the *U.S. Public Health Services (PHS) Guideline*
Physical Exam	• Height • Weight • BMI • Vital signs • Examination of all major organ systems

This evaluation must be completed:	Including evaluation for and assessment of this information:
General laboratory and imaging tests	• Complete blood count (CBC) with platelet count • Blood type and subtype as specified in OPTN *Policy 14.5: Living Donor Blood Type Determination and Reporting* and its subsections • Prothrombin Time (PT) or International Normalized Ratio (INR) • Partial Thromboplastin Time (PTT) • Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin) • HCG quantitative pregnancy test for premenopausal women without surgical sterilization • Chest X-Ray • Electrocardiogram (ECG)
Transmissible disease screening	Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using FDA-licensed, approved, or cleared tests. Testing must include *all* the following: 1. CMV (Cytomegalovirus) antibody 2. EBV (Epstein Barr Virus) antibody 3. HIV antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination test as close as possible, but within 28 days prior to organ recovery 4. HIV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 5. Hepatitis B surface antigen (HBsAg) testing as close as possible, but within 28 days prior to organ recovery 6. Hepatitis B core antibody (total anti-HBc) testing as close as possible, but within 28 days prior to organ recovery 7. HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 8. Hepatitis C antibody (anti-HCV) testing as close as possible, but within 28 days prior to organ recovery 9. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 10. Syphilis testing For tuberculosis (TB), living donor recovery hospitals must determine if the donor is at increased risk for this infection. If TB risk is suspected, testing must include screening for latent infection using *either*: • Intradermal PPD • Interferon Gamma Release Assay (IGRA)

This evaluation must be completed:	Including evaluation for and assessment of this information:
Endemic transmissible diseases	Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation.
Cancer screening	Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) or the U.S. Preventive Services Task Force to screen for: • Cervical cancer • Breast cancer • Prostate cancer • Colon cancer • Lung cancer

14.4.B Additional Requirements for the Medical Evaluation of Living Kidney Donors

Table 14-7: Additional Requirements for the Medical Evaluation of Living Kidney Donors

This evaluation must be completed:	Including evaluation for and assessment of this information:
Kidney - specific donor history	A personal history of significant medical conditions which include, but are not limited to, kidney-specific personal history including: a. Genetic renal diseases b. Kidney disease, proteinuria, hematuria c. Kidney injury d. Diabetes including gestational diabetes e. Nephrolithiasis f. Recurrent urinary tract infections
Kidney-specific family history	• Kidney disease • Diabetes • Hypertension • Kidney Cancer
Physical Exam	• Blood pressure taken on at least two different occasions or 24-hour or overnight blood pressure monitoring

This evaluation must be completed:	Including evaluation for and assessment of this information:
Other metabolic testing	• Fasting blood glucose • Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol) • Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high risk individuals
Kidney-specific tests	• Urinalysis or urine microscopy • Urine culture if clinically indicated • Measurement of urinary protein and albumin excretion • Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection • Hospitals must develop and comply with a written protocol for polycystic kidney disease or other inherited renal disease as indicated by family history • Patients with a history of nephrolithiasis or nephrolithiasis (>3 mm) identified on radiographic imaging must have a 24-hour urine stone panel measuring: o Calcium o Oxalate o Uric acid o Citric acid o Creatinine o Sodium
Anatomic assessment	Determine: • Whether the kidneys are of equal size • If the kidneys have masses, cysts, or stones • If the kidneys have other anatomical defects • Which kidney is more anatomically suited for transplant

14.4.C Additional Requirements for the Medical Evaluation of Living Liver Donors

Table 14-8: Additional Requirements for the Medical Evaluation of Living Liver Donors

This evaluation must be completed:	Including evaluation for and assessment of this information:
Liver- specific family history	• Liver diseases • Bleeding or clotting disorders

This evaluation must be completed:	Including evaluation for and assessment of this information:
General laboratory and imaging tests	• Hospitals must develop and follow a written protocol for hypercoagulable state evaluation
Liver-specific tests	• Hepatic function panel • Ceruloplasmin in a donor with a family history of Wilson's Disease • Iron, iron binding capacity, ferritin • Alpha-1-antitrypsin level: those with a low alpha-1-antitrypsin levels should have a phenotype • must develop and follow a written protocol for testing for genetic diseases • Hospitals must develop and follow a written protocol for screening for autoimmune disease • Hospitals must develop and follow a written protocol for pre-donation liver biopsy
Anatomic assessment	A radiological assessment must be performed to determine if the liver is anatomically suitable for transplantation, and to assess safety of resection for the donor. The evaluation must include at least all of the following: • Assessment of projected graft volume • Donor's remnant volume, • Vascular anatomy • Presence of steatosis

14.4.D Additional Requirements for the Medical Evaluation of Living Donors of Covered VCAs

Table 14-9: Additional Requirements for the Medical Evaluation of Living Donors of Covered VCAs

This evaluation must be completed:	For living donors of these organs:	Including evaluation for and assessment of this information:
Transmissible disease screening	All covered VCAs	Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by CMS using FDA-licensed, approved, or cleared tests. Testing must include *all* of the following: • Toxoplasma Immunoglobulin G (IgG) antibody test
Additional specific medical history	Uterus	• Gynecological and obstetric history including prior childbirth

This evaluation must be completed:	For living donors of these organs:	Including evaluation for and assessment of this information:
Additional specific tests	Uterus	• Pap smear
Additional anatomic assessment	Uterus	• Pelvic exam • A radiological assessment must be performed to determine if the uterus is anatomically suitable for transplantation
Additional transmissible disease screening	Uterus	Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by CMS using FDA-licensed, approved, or cleared tests. Testing must include *all* of the following: • Bacterial Vaginosis (Gardnerella Vaginalis) • Chlamydia by nucleic acid test (NAT) • Gonorrhea by nucleic acid test (NAT) • Herpes Simplex Virus (HSV) 1/2 Immunoglobulin G (IgG) antibody test • Human Papilloma Virus (HPV) cervical specimen only by DNA or mRNA • Trichomoniasis • Fungal screening to include Vaginal Candidiasis (at evaluation and time of donation)

14.4.E Living Donor Exclusion Criteria

Table 14-10: Living Donor Exclusion Criteria

Exclusion criteria for all Living Donors	Living donor recovery hospitals may exclude a donor with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation.
	
	Living donor recovery hospitals must exclude all donors who meet any of the following exclusion criteria:
	• Is both less than 18 years old and mentally incapable of making an informed decision
	• Living with HIV, and
	  o the living donor is donating a non-kidney or non-liver organ and
	  o the requirements for a variance are not met, according to *Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from Donors with HIV*
	• Active malignancy, or incompletely treated malignancy that either
	  o requires treatment other than surveillance or
	  o has more than minimal known risk of transmission
	• High suspicion of donor inducement, coercion, or other undue pressure
	• High suspicion of knowingly and unlawfully acquiring, receiving, or otherwise transferring anything of value in exchange for any human organ
	• Evidence of acute symptomatic infection (until resolved)
	• Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality

Additional Exclusion Criteria for Living Kidney Donors	Kidney recovery hospitals must exclude all donors who meet *any* of the following additional exclusion criteria:
	• Uncontrollable hypertension or history of hypertension with evidence of end organ damage
	• Type 1 diabetes
	• Type 2 diabetes where an individualized assessment of donor demographics or comorbidities reveals either
	  o evidence of end organ damage or
	  o unacceptable lifetime risk of complications

Additional Exclusion Criteria for Living Liver Donors	Liver recovery hospitals must exclude all donors who meet *any* of the following additional exclusion criteria: • HCV RNA positive • HBsAg positive • Donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes • Expected donor remnant volume less than 30% of native liver volume • Prior living liver donor

14.5 Living Donor Blood Type Determination and Reporting

Recovery hospitals must develop and comply with a written protocol for blood type determination and reporting that includes all of the requirements below.

14.5.A Living Donor Blood Type Determination

The recovery hospital must ensure that each living donor's blood type is determined by testing at least two donor blood samples prior to generation of the living donor ID.

Living donor blood samples must:

1. Be drawn on two separate occasions
2. Have different collection times
3. Be submitted as separate samples

The recovery hospital must include a process to address conflicting or indeterminate primary blood type results in their written protocol.

The recovery hospital must document that blood type determination was conducted according to the hospital's protocol and the above requirements.

14.5.B Living Donor Blood Subtype Determination

Subtyping is optional for living donors.

If the recovery hospital chooses to subtype *and* pre-red blood cell transfusion samples are available, then subtyping must be completed according to *Table 14-11.*

Table 14-11: Subtyping Requirements by First Subtype Result

If the donor's primary blood type is:	A second subtyping must be completed if the first subtype result is:
A	Blood type A, non-A_1
AB	Blood type AB, non-A_1B

Living donor blood samples for subtyping must:

1. Be tested using pre-red blood cell transfusion samples
2. Be drawn on two separate occasions
3. Have different collection times
4. Be submitted as separate samples

All subtype results reported to the OPTN must be from two separate tests indicating the same result. If there are conflicting or indeterminate subtype results, the subtype results must not be reported to the OPTN and living donor transplant compatibility or allocation must be based on the primary blood type.

If subtype is determined and reported, the recovery hospital must document that subtyping was conducted according to the above requirements.

14.5.C Reporting of Living Donor Blood Type and Subtype

The recovery hospital must report and verify the living donor blood type prior to registration with the OPTN using the *Living Donor Feedback Form* as required below:

1. Two different qualified health care professionals, as defined in the recovery hospital's protocol, must each make an independent report to the OPTN for blood type.
2. If blood subtype is used for ensuring transplant compatibility or allocation, a qualified health care professional must report blood subtype to the OPTN. This report must be verified by a different qualified health care professional according to the recovery hospital's protocol.
3. Both qualified health care professionals must use all known available blood type and subtype determination source documents to verify they:
    a. Contain blood type and subtype (if used for ensuring transplant compatibility or allocation) results for the donor
    b. Indicate the same blood type and subtype (if used for ensuring transplant compatibility or allocation) on the test results. If the results are conflicting or indeterminate, the recovery hospital must refer to their written protocol as outlined in OPTN *Policy 14.5.A: Living Donor Blood Type Determination*.
    c. Match the result reported to the OPTN

The recovery hospital must document that reporting was completed according to the hospital's protocol and the above requirements.

14.6 Placement of Living Donor Organs

14.6.A Prospective Crossmatching prior to Kidney Placement

A prospective crossmatch is mandatory for all potential kidney living donor recipients. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are outlined in *Policy 4: Histocompatibility*.

14.6.B Placement of Non-directed Living Donor Organs

Prior to determining the placement of a non-directed living donor organ, including non-directed organs from domino donors and non-domino therapeutic organ donors, the recovery hospital must obtain the match run of its waiting list candidates from its local OPO or the Organ Center. When a non-directed living donor organ is placed, the recovery hospital must document how the organ is placed and the rationale for placement.

This requirement does not apply to non-directed living kidney donors who donate a kidney through a Kidney Paired Donation (KPD) arrangement.

14.6.C Transplant Hospital Acceptance of Living Donor Organs

A transplant hospital must only accept and transplant living donor organs according to *Table 14-12* below.

Table 14-12: Transplant Hospital Requirements for Accepting and Transplanting Living Donor Organs

If this type of living donor organ is being recovered:	Then the recovery hospital must:
Kidney	Meet the requirements according to the *OPTN Management and Membership Policy E.6: Kidney Transplant Programs that Perform Living Donor Recovery*
Liver	Meet the requirements according to the *OPTN Management and Membership Policy F.8: Liver Transplant Programs that Perform Living Donor Recovery*
Other organ types, excluding kidney or liver	Have current designated transplant program approval for that organ type

14.7 Living Donor Pre-Recovery Verification

Recovery hospitals must develop and comply with a written protocol to perform pre-recovery verifications as required below.

The recovery hospital must conduct a pre-recovery verification that meets *all* of the following requirements:

1. The verification must occur prior to the induction of general anesthesia on the day of the living donor recovery.
2. Recovery hospitals must use at least one of the acceptable sources during the pre-recovery verification to verify all of the following information according to *Table 14-13* below. Recovery hospitals may use the OPTN organ tracking system for assistance in completing these verifications.

Table 14-13: Pre-Recovery Verification Requirements

The recovery hospital must verify *all* of the following information:	Using at least *one* of the following:	By *both* of the following individuals:
Donor ID	• Donor identification band containing the donor ID • Donor identification band and OPTN computer system	1. Recovery surgeon 2. Licensed health care professional
Organ type and laterality (if applicable)	• OPTN computer system	1. Recovery surgeon 2. Licensed health care professional
Donor blood type and subtype (if used for ensuring transplant compatibility or allocation)	• Donor blood type and subtype source documents	1. Recovery surgeon 2. Licensed health care professional
Intended recipient unique identifier	• Recipient medical record • OPTN computer system	1. Recovery surgeon 2. Licensed health care professional
Intended recipient blood type	• Recipient medical record • OPTN computer system	1. Recovery surgeon 2. Licensed health care professional
Donor and intended recipient are blood type compatible (or intended incompatible).	• OPTN computer system • Recipient medical record • Attestation following verification of donor and recipient blood types	1. Recovery surgeon 2. Licensed health care professional
Correct donor organ has been identified for the correct intended recipient	• Donor medical record • OPTN computer system • Attestation following verification of donor ID, organ, and recipient unique identifier	1. Recovery surgeon 2. Licensed health care professional

The recovery hospital must document that the verification was completed according to the hospital's protocol and the above requirements.

14.8 Packaging, Labeling, and Transporting of Living Donor Organs, Extra Vessels, and Tissue Typing Materials

Recovery hospitals are responsible for packaging and labeling any living donor organs or tissue typing specimens that are recovered from living donors according to OPTN *Policy 16: Organ and Extra Vessels Packaging, Labeling, Shipping, and Storage* when *either* of the following occurs:

- Living donor organs or tissue typing specimens are recovered and must be transported outside the recovery hospital
- Living donor organs or tissue typing specimens require repackaging by a transplant hospital for transport outside the transplant hospital

14.8.A Living Donor Extra Vessels Recovery and Storage

A recovery hospital must only recover extra vessels for transplant if the living donor consents to the removal of extra vessels for transplant. The extra vessels from a living donor must only be used for the implantation or modification of a solid organ transplant for the original intended recipient.

Any extra vessels recovered from living donors must be stored according to OPTN *Policy 16.6.B: Extra Vessels Storage*.

14.8.B Living Donor Specimen Collection and Storage

The recovery hospital must obtain specimens appropriate for serological and NAT testing within 24 hours prior to organ recovery. The recovery hospital is responsible for arranging storage of these specimens for at least 10 years after the date of transplant and ensuring these samples are available for retrospective testing. The recovery hospital must document the type of sample in the living donor medical record.

14.9 Requirements for Domino Donors and Non-Domino Therapeutic Donors

Although domino donors and non-domino therapeutic donors are considered living donors, the requirements in OPTN *Policy 14: Living Donation* are limited only to Policies 14.9 A through 14.9 E below for domino donors and non-domino therapeutic donors.

14.9.A Informed Consent Requirements for Domino Donors and Non-Domino Therapeutic Donors

Recovery hospitals must obtain the donor's signature on a document that confirms that the donor:

1. Is willing to donate
1. Is free from inducement and coercion
2. Has been informed that the donor may decline to donate at any time
3. Has received information on treatment options that would not involve organ donation

Recovery hospitals must also provide *all* of the following to domino donors and non-domino therapeutic donors:

1. The disclosure that the recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient
2. The disclosure that it is a federal crime for any person to knowingly acquire, obtain, or otherwise transfer any human organ for anything of value including, but not limited to, cash, property, and vacations.
3. The disclosure that health information obtained during the evaluation for donation is subject to the same regulations as all health records and could reveal conditions that must be reported to local, state, or federal public health authorities.
4. The disclosure that any new information discovered during the domino donor's or non-domino therapeutic donor's first two years of post-donation care that indicates risk of potential transmission of infectious disease or malignancy to the recipient of the domino donor's or non-domino therapeutic donor's native organ:
    a. May need to be reported to local, state, or federal public health authorities
    b. Will be disclosed to the recipient's transplant hospital
    c. Will be reported through the OPTN Improving Patient Safety Portal
5. Information on treatment options that would not involve organ donation.
6. An opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential.

Documentation of the informed consent must be maintained in the donor medical record.

14.9.B Psychosocial and Medical Evaluation Requirements for Domino and Non-Domino Therapeutic Donors

Recovery hospitals must evaluate domino donors and non-domino therapeutic donors according to *all* of the following requirements:

1. Perform an assessment for risk criteria for acute HIV, HBV, and HCV infection according to the *U.S. Public Health Service (PHS) Guideline*
2. Screen the domino donor or non-domino therapeutic donor for all of the following according to OPTN *Policy 14.4: Medical Evaluation Requirements for Living Donors*, *Table 14-6: Requirements for Living Donor Medical Evaluations*:
    a. Transmissible diseases screening
    b. Endemic transmissible diseases
    c. Cancer screening
3. Develop and comply with written protocols for the domino donor and non-domino therapeutic donor exclusion criteria considering incorporating as appropriate the elements of *Table 14-10: Living Donor Exclusion Criteria*

4. Register and verify the blood type of the domino donor or non-domino therapeutic donor according to OPTN *Policy 14.5: Living Donor Blood Type Determination and Reporting*

Documentation of the psychosocial and medical evaluation must be maintained in the donor medical record.

14.9.C Recovery of Domino Donor and Non-Domino Therapeutic Donor Organs

Transplant hospitals can recover domino donor and non-domino therapeutic donor organs if the hospital has current designated transplant program approval for that organ type.

14.9.D Acceptance of Domino Donor and Non-Domino Therapeutic Donor Organs

Transplant hospitals must only accept domino donor and non-domino therapeutic donor organs recovered at transplant hospitals that have a current designated transplant program approval for that organ type.

14.9.E Reporting and Data Submission Requirements for Domino Donors and Non-Domino Therapeutic Donors

Recovery hospitals must submit the living donor feedback and living donor registration (LDR) forms for the domino donor and non-domino therapeutic donor according to OPTN *Policy 18.1: Data Submission Requirements*.

14.10 Living Donor Organ Check-In

Transplant hospitals must perform organ check-ins as required by OPTN *Policy 5.7: Organ Check-In*.

14.11 Living Donor Pre-Transplant Verification

Transplant hospitals must perform pre-transplant verifications as required by OPTN *Policy 5.8: Pre-Transplant Verification.*

14.12 Reporting Requirements

Members are responsible for submitting living donor forms according to OPTN *Policy 18.4: Living Donor Data Submission Requirements.*

Policy 15: Identification of Transmissible Diseases

15.1 Patient Safety Contact

Each OPO and transplant program must identify a primary and secondary Patient Safety Contact and develop and comply with a written protocol for the patient safety contact to fulfill all the following responsibilities:

1. Be available 24 hours a day.
2. Receive notifications of potential disease transmission and related communication from the OPTN.
3. Receive relevant medical information that may affect or change recipient care.
4. Communicate any information regarding potential disease transmissions to the medical staff responsible for the recipient's clinical care at the transplant program as soon as possible, but no later than 24 hours after becoming aware of the potential disease transmission.
5. Facilitate communication about the current clinical status of any recipient when the transplant program is notified of a potential or proven disease transmission that may affect the recipient.

15.2 Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements

Transplant candidates must be tested for:
1. HIV using a CDC recommended laboratory HIV testing algorithm
2. Hepatitis B surface antigen (HBsAg)
3. Hepatitis B core antibody (total anti-HBc)
4. Hepatitis B surface antibody (HBsAb)
5. Hepatitis C antibody (anti-HCV)
6. Hepatitis C ribonucleic acid (RNA) by nucleic acid test (NAT)

unless the testing would violate state or federal laws.
Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by CMS using FDA-licensed, approved, or cleared tests.

For all candidates 12 years or older, candidate samples must be drawn during the hospital admission for transplant but prior to anastomosis of the first organ.

If the candidate is known to be living with HIV, HBV, or HCV, then testing for the known viral infection or infections is not required, however the other tests required according to this policy must still be performed.

Candidates who test positive for HIV, hepatitis B, or hepatitis C must be offered appropriate counseling.

As part of the candidate's medical evaluation, an assessment for the need to provide HBV vaccination must occur. The transplant program must report the candidate's HBV vaccination status to the OPTN. If the transplant program determines that vaccination cannot be initiated or completed due to timing related to transplant, medical contraindication, or other reasons in the transplant program's medical judgement, the reason for not initiating or completing HBV vaccination must be documented in the candidate's medical records and reported to the OPTN.

15.3 Informed Consent of Transmissible Disease Risk

15.3.A General Risks of Potential Malignancy or Disease Transmission

Transplant programs must inform candidates of the general risks of potential transmission of malignancies and disease from organ donors, including *all* of the following information:

1. Deceased donors are evaluated and screened according to OPTN *Policy 2.3: Evaluating and Screening Potential Deceased Donors*.
2. Living donors are required to undergo screening for diseases according to OPTN *Policy 14.4: Medical Evaluation Requirements for Living Donor*.
3. There is no comprehensive way to screen deceased and living donors for all transmissible diseases.
4. Malignancies and diseases may be identified and transmitted after transplant.
5. Donor evaluation and screening results may impact post-transplant evaluation, screening, and management of the candidate.

The transplant program must do *both* of the following:

1. Explain these risks and obtain informed consent from the candidate or candidate's agent any time prior to transplant.
2. Document consent in the candidate's medical record.

15.3.B Donors with Risk Identified Pre-Transplant

Transplant programs must meet the requirements according to *Table 15-1* below when the deceased or living donor has risk of disease transmission identified pre-transplant.

Table 15-1: Requirements for Donors with Risk Identified Pre-Transplant

Each time any of the following occurs:	Then transplant programs must do *all* of the following:
• The donor tests positive for *any* of the following: a. Hepatitis B surface antigen (HBsAg) b. Hepatitis B nucleic acid test (NAT) c. Hepatitis C NAT	1. Explain the risks and obtain informed consent from the intended recipient or the intended recipient's agent after the organ offer but before transplant 2. Document this consent in the intended recipient's medical record 3. Follow the recipient for the development of potential donor-derived disease after transplant
• The donor tests positive for HIV antibody (anti-HIV), HIV antigen/antibody (Ag/Ab), or HIV NAT, and the organ offered is a kidney, liver, or liver-kidney	1. A transplant physician must confirm that the candidate is living with HIV. 2. A transplant physician must explain the risks and obtain informed consent from the intended recipient or the intended recipient's agent after the organ offer but before transplant. 3. Document this consent in the intended recipient's medical record
• The donor tests positive for HIV antibody (anti-HIV), HIV antigen/antibody (Ag/Ab), or HIV NAT, and the transplant program participates in an approved variance according to *Policy 15.7.D: Open Variance for the Recovery and Transplantation of Non-Kidney and Non-Liver Organs from Donors with HIV*	1. Confirm that the candidate is living with HIV. 2. Explain the risks and obtain informed consent from the intended recipient or the intended recipient's agent after the organ offer but before transplant. 3. Document this consent in the intended recipient's medical record
• The donor has any risk criteria for acute HIV, HBV, or HCV infection according to the *U.S. Public Health Service (PHS) Guideline*	1. Inform the intended recipient or the intended recipient's agent after the organ offer but before transplant that risk criteria are present in the donor 2. Document that this information was provided in the intended recipient's medical record

If in the medical judgment of the transplanting physician, extra vessels are required for use in an emergency transplant procedure for an organ other than the organ with which they were recovered, then the transplant hospital must do *both* of the following post-transplant:

1. Inform the recipient of the use of the extra vessels and if the donor had any risk criteria for acute HIV, HBV, or HCV infection according to the *U.S. Public Health Service (PHS) Guideline*
2. Provide follow up to the recipient according to OPTN *Policy 15.3.C: Required Post-Transplant Infectious Disease Testing*

15.3.C Required Post-Transplant Infectious Disease Testing

1. Transplant programs must test all recipients post-transplant for:
   a. HIV ribonucleic acid (RNA) by nucleic acid test (NAT)
   b. HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT)
   c. HCV ribonucleic acid (RNA) by nucleic acid test (NAT)
2. Testing must be performed on the recipient at least 28 days but no later than 56 days post-transplant.
3. If the candidate is known to be infected with HIV, HBV, or HCV, then testing for the known viral infection or infections is not required, however the other tests required according to this policy must still be performed.
4. The transplant program must offer recipients treatment of or prophylaxis for HIV, HBV, or HCV, when medically appropriate.
5. Transplant programs must conduct HBV NAT testing on liver recipients at least 335 days but no later than 395 days post-transplant.

15.4 Host OPO Requirements for Reporting Post-Procurement Test Results and Discovery of Potential Disease Transmissions

Host OPOs must report any test results or information received post-procurement that indicate there may be a possibility for donor-derived disease as follows.

15.4.A Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

The host OPO must report all positive test results and other relevant information received post-procurement for each donor as soon as possible but no later than 24 hours after receipt as follows:

1. All results indicating Pathogens of Special Interest must be reported to the receiving transplant program's patient safety contact and the OPTN Improving Patient Safety Portal. The OPTN Contractor provides a list of Pathogens of Special Interest, including any results that can be excluded from reporting. The OPTN Contractor reviews and updates this list at least annually.
2. All other positive test results and relevant information must be reported according to *Table*

15-2 below.

Table 15-2: Host OPO Reporting Requirements for Positive Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

The host following	OPO must report *all* of the *positive* results:	To:
Samples relevant to all recipients	Serologic, NAT, or antigen results indicating presence of parasites, virus, or fungi	The receiving transplant program's patient safety contact
	Cultures from the following specimens: • Ascites • Blood • Cerebrospinal fluid (CSF) • Deep wound • Genital • Pericardial • Pleural fluid	The receiving transplant program's patient safety contact
	Mycobacterial smears and cultures	The receiving transplant program's patient safety contact
	Fungal smears and cultures with the exception of *Candida* species	The receiving transplant program's patient safety contact
Relevant information	Respiratory samples (bacterial or *Candida species*) *only* to transplant programs receiving lungs or covered head and neck VCAs	The receiving transplant program's patient safety contact
	Urine cultures *(*bacterial or *Candida species) only* to transplant programs receiving kidneys or covered genitourinary organ VCAs	The receiving transplant program's patient safety contact
	Malignancy or other findings highly suggestive of malignancy recognized after procurement	1. The receiving transplant program's patient safety contact 2. The OPTN Improving Patient Safety Portal
	Histopathology results reported post-procurement	The receiving transplant program's patient safety contact
	All *final* culture information for any culture results that were reported according to these requirements	The receiving transplant program's patient safety contact

The host following	OPO must report *all* of the *positive* results:	To:
Relevant information	Other psycho-social history, medical history, autopsy, testing, and laboratory findings identifying infectious conditions that may adversely affect a potential transplant recipient	The receiving transplant program's patient safety contact

15.4.B Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy

If the host OPO is notified that an organ recipient is suspected to have, is confirmed positive for, or dies from a potential transmissible disease, infection, or malignancy and there is substantial concern that it could be from the transplanted organ, then the host OPO must do *all* the following:

1. Communicate the suspected donor's and affected organ recipient's test results and diagnosis that may be relevant to acute patient care, as soon as possible but no more than 24 hours after receipt, to any transplant program patient safety contacts and tissue banks that received organs or tissue from the donor. This includes any test results that were not available at the time of procurement or that were performed after procurement. The host OPO must document that this information is shared with all receiving transplant programs and tissue banks.
2. Report the event to the OPTN Improving Patient Safety Portal as soon as possible but no more than 24 hours after notification or receipt of recipient test results or diagnosis.

15.4.C Host OPO Requirements for Post-Reporting Follow Up

If the host OPO reports test results or other relevant information to the OPTN through the OPTN Improving Patient Safety Portal, then the host OPO must also do *all* the following:

1. Complete and submit the *Potential Disease Transmission Report Form* no later than 24 hours after reporting the event through the OPTN Improving Patient Safety Portal.
2. Contribute to a follow up review of the event, in partnership with OPTN patient safety staff.
3. Provide additional information or specimens related to the deceased donor if requested.

15.5 Transplant Program Requirements for Communicating Discovery of Potential Transmission of Unexpected Pathogen, Disease or Malignancy

A potential transmission of a pathogen, disease, or malignancy is unexpected if the pathogen, disease, or malignancy was not known to the transplant program by the time of donor cross-clamp.

Transplant programs must communicate any test results or information that indicates unexpected donor-derived disease is possible as follows.

15.5.A Transplant Program Requirements for Discovery of Potential Transmission of Unexpected Donor Pathogen, Disease or Malignancy

If the transplant program identifies any results indicative of unexpected pathogen, disease or malignancy from donor specimen testing collected pre-transplant, then the transplant program must do *all* of the following:

1. Notify the host OPO or living donor recovery hospital of the findings within 24 hours of discovery.
2. Notify the recipients under care at the transplant program, or the recipient's agents, of the risk or confirmation of unexpected transmissible disease or malignancy.
3. Document the new information about the donor and potential risk or confirmation of unexpected transmissible disease or malignancy in the recipient's medical records.
4. Follow the notified recipients for the potential development of the disease or malignancy after transplant.
5. Offer the recipients additional testing, monitoring, and treatment as appropriate, in addition to routine follow up care.

15.5.B Transplant Program Requirements for Reporting Discovery of Potential Transmission of Unexpected Recipient Pathogen, Disease or Malignancy

Transplant programs are required to report the discovery of a potential transmission for the following recipients:

- A non-lung organ recipient who:
  1. Is suspected to have, is confirmed positive for, or has died from any unexpected potential transmissible pathogen, disease, or malignancy, and
  2. There is substantial concern that the suspected or confirmed pathogen, disease, or malignancy could be from the transplant organ
- A lung recipient who:
  1. Is suspected to have, is confirmed positive for, or has died from an unexpected potential transmissible pathogen, disease, or malignancy, and
  2. There is substantial concern that the suspected or confirmed disease, malignancy, or infection could be from the transplanted organ and
  3. There is clinical evidence of infection. A lung recipient is considered to have clinical evidence of infection based on the clinical judgment of the treating physician or team if:
     1. An organism is isolated from the respiratory tract or other site and
     2. There is substantial concern that the organism is donor-derived and contributes to the lung recipient's illness
- A lung recipient who:
  1. Shows evidence of colonization but not clinical evidence of infection and
  2. Respiratory tract testing reveals an unexpected positive result identifying a Pathogen of Special Interest or malignancy, and

3. There is substantial concern that the unexpected positive result is from the transplanted organ.

Transplant programs are required to report the discovery of a potential transmission of an unexpected recipient pathogen, disease, or malignancy meeting the criteria above by doing all of the following:

1. Notify the primary Patient Safety Contact at the host OPO of the deceased donor or transplant program at which the living donor was recovered and provide available documentation within 24 hours of learning of the event. If the primary Patient Safety Contact of the host OPO of the deceased donor or transplant program at which the living donor was recovered does not acknowledge receipt of the information within 24 hours, then the transplant program must notify the secondary Patient Safety Contact.
2. Report as a disease transmission event through the OPTN Improving Patient Safety Portal as soon as possible but no more than 24 hours after learning of the event.
3. Provide additional related information or specimens if requested.
4. Update the host OPO and the OPTN disease transmission report in the OPTN Patient Safety Reporting Portal with any new information related to the event, including death of the recipient.

15.5.C Transplant Program Requirements for Post-Reporting Follow-Up

If the transplant program has a recipient that is involved in an OPTN Improving Patient Safety Portal report, then the transplant program must also do *all* of the following:

1. Submit any relevant test results including cultures, infectious disease testing results, imaging studies, or autopsy results to OPTN patient safety staff.
2. Respond to host OPO, living donor recovery hospital, and OPTN patient safety staff requests for information regarding the recipient and communicate updated information regarding recipient condition, test results, diagnosis, and plans for treatment and follow up.
3. Contribute to a follow up review of the event in partnership with OPTN patient safety staff.
4. Provide additional related information or specimens if requested.

15.6 Living Donor Recovery Hospital Requirements for Reporting Post-Donation Discovery of Disease or Malignancy

Living donor recovery hospitals must report any post donation test results or information that indicate there may be a possibility for donor-derived disease.

15.6.A Living Donor Recovery Hospital Requirements for Reporting Post-Donation Discovery of Living Donor Disease or Malignancy

If a living donor recovery hospital learns new information about a living donor during the first two years post donation that indicates risk of potential transmission of disease or malignancy, then the living donor recovery hospital must do *all* of the following:

1. Disclose to the living donor that the potential disease transmission or malignancy will be reported to the receiving transplant program and the OPTN Improving Patient Safety Portal.
2. Notify the receiving transplant program.
3. Report the potential transmission through the OPTN Improving Patient Safety Portal as soon as possible but no more than seven days after receipt of the new information.

15.6.B Living Donor Program Requirements for Post Reporting Follow-Up

If the living donor recovery hospital reports test results or other information to the OPTN through the Improving Patient Safety Portal, then the recovery hospital must also do *all* of the following:

1. Contribute to a follow up review of the event in partnership with OPTN patient safety staff.
2. Provide additional information or specimens related to the living donor if requested.

15.7 Recovery and Transplantation of Organs from Donors with HIV

15.7.A Requirements for Allocating Organs from Deceased Donors with HIV

The OPO may allocate organs from deceased donors with HIV only after determining the following:

1. That the potential deceased donor has been tested according to *Policy 2.9: Required Deceased Donor Infectious Testing* and has HIV and
2. That the candidate is living with HIV and willing to accept an organ from a donor with HIV
3. For non-kidney and non-liver candidates living with HIV, that the candidate must be willing to accept the organ as part of an IRB-approved research protocol that meets the requirements in the National Institutes of Health (NIH) Final Notice regarding the recovery and transplantation of organs from donors with HIV and the requirements outlined in *Policy 15.7.D: Open Variance for the Recovery and Transplantation of Non-Kidney and Non-Liver Organs from Donors with HIV*.

The OPO must only allocate organs from donors with HIV to candidates living with HIV appearing on the match run, except in cases of directed donation. The OPO must verify that the potential recipient is a candidate living with HIV who is registered at a transplant program that meets the requirements in OPTN *Policy 15.7.B: Transplant Program Requirements for Transplantation of Organs from Donors with HIV*.

15.7.B Transplant Program Requirements for Transplantation of Organs from Donors with HIV

The transplant program must meet the informed consent requirements according to *Policy 15.3: Informed Consent of Transmissible Disease Risk*.

In order for a candidate living with HIV to appear on a deceased donor match run for an organ from a donor with HIV, the transplant hospital must complete a two-person reporting and verification process. This process must include two different individuals who each make an

independent report to the OPTN that the candidate is living with HIV and willing to accept an organ from a donor with HIV.

For kidney, liver, and liver-kidney candidates, a transplant physician must verify and document in the medical record that the candidate is living with HIV and willing to accept an organ from a donor with HIV. This must occur prior to the two-person reporting and verification process.

For non-kidney and non-liver candidates, the candidate must be willing to accept an organ from a donor with HIV as part of an IRB-approved research protocol that meets the requirements in the NIH Final Notice and the requirements outlined in *Policy 15.7: Open Variance for the Recovery and Transplantation of Non-Kidney and Non-Liver Organs from Donors with HIV*.

15.7.C Recovery Hospital Requirements for Transplantation of Organs from Living Donors with HIV

The recovery hospital must confirm that the potential living donor is living with HIV and the candidate is living with HIV and willing to accept an organ from a living donor with HIV.

For non-kidney and non-liver living donors with HIV, the recovery hospital must confirm that the candidate is willing to accept an organ from a living donor with HIV as part of an IRB-approved research protocol that meets the requirements in the NIH Final Notice and the requirements outlined in *Policy 15.7.D: Open Variance for the Recovery and Transplantation of Non-Kidney and Non-Liver Organs from Donors with HIV*.

15.7.D Open Variance for the Recovery and Transplantation of Non-Kidney and Non-Liver Organs from Donors with HIV

This variance applies to transplant programs participating in an institutional review board (IRB) approved research protocol regarding the recovery of non-kidney and non-liver organs from donors that test positive for human immunodeficiency virus (HIV) and the transplantation of these organs into candidates living with HIV.

Transplant programs may transplant non-kidney and non-liver organs from donors with HIV only if *all* of the following are true:

1. The transplant program notifies and provides documentation to the OPTN that it is participating in an IRB-approved research protocol that meets the requirements in the NIH Final Notice regarding the research criteria for recovery and transplantation of non-kidney and non-liver organs from donors with HIV.
2. The transplant program obtains informed consent from the potential transplant recipient to participate in the IRB-approved protocol that meets research criteria requirements described in the NIH Final Notice.
3. The transplant program meets the informed consent requirements according to *Policy: 15.3 Informed Consent of Transmissible Disease Risk*.

The OPTN has the authority to collect data safety monitoring reports from transplant programs participating in this variance upon request.

Transplant programs must notify the OPTN of when protocols will be renewed and if they will no longer be participating in an IRB-approved research protocol that meets the requirements in the NIH Final Notice regarding the recovery and transplantation of non-kidney and non-liver organs from donors with HIV.

The OPTN may release to the public the names of transplant programs participating in this variance.

Policy 16: Organ and Extra Vessel Packaging, Labeling, Shipping, and Storage

16.1 Packaging and Labeling Requirements for Living Donor Organs and Extra Vessels

Living donor recovery hospitals are responsible for packaging, labeling, and transporting living donor organs and tissue typing samples according to OPTN *Policy 16*, with these differences:

1. Members are not required to use the OPTN organ tracking system for labeling and packaging living donor organs and tissue typing samples.
2. When a member repackages a living donor organ, the member is not required to notify the member that originally packaged the organ.
3. In addition to the list of documents in OPTN *Policy 16.4: Documentation Accompanying the Organ or Extra Vessels*, living donor organs must contain the blood type source documents, donor informed consent form, and the complete medical record of the living donor. Extra vessels that are shipped separately from living donor organs must include the same documents as are required for shipping living donor organs.
4. Blood samples and tissue typing materials must contain the donor ID and *one* of the following identifiers: donor date of birth, donor initials, or a locally assigned unique ID. Each sample must contain the donor's blood type and subtype, the type of tissue, and the date and time when the sample was obtained. The recovery hospital must document in the donor record all unique identifiers used to label blood samples and tissue typing materials.
5. The recovery hospital will provide specimens for tissue typing if requested. The minimum typing materials for living donor kidneys are: two ACD (yellow top) tubes per kidney.

16.2 Packaging and Labeling Responsibilities

The host OPO or recovery hospital is responsible for packaging and labeling organs and tissue typing materials that travel outside the recovery facilities.

The host OPO must complete labeling and packaging using the OPTN organ tracking system. The OPO

must develop and comply with a written protocol for an alternative labeling and packaging process if, for any temporary reason, the OPTN organ tracking system is not used. This written protocol must fulfill all the requirements according to OPTN *Policy 16: Organ and Extra Vessels Packaging, Labeling, Shipping, and Storage* and the host OPO must document the reasons the OPTN organ tracking system was not used.

Transplant hospital staff may not leave the operating room without allowing the host OPO to package and label deceased donor organs and tissue typing specimens as required. OPOs are required to report these events according to OPTN *Policy 18.5: Reporting of Patient Safety Events*.

If a transplant hospital repackages an organ for transport, it must package, label, and transport the organ according to OPTN *Policy 16: Organ and Extra Vessels Packaging, Labeling, Shipping, and Storage,* except that the use of the OPTN organ tracking system is not required. The transplant hospital must immediately notify the host OPO of the repackaging.

16.3 Packaging and Labeling

The host OPO must package all organs and tissue typing materials in a sterile environment using universal precautions.

The packaged organs from the deceased or living donor's surgical back table are to be placed directly into the wet iced shipping container. Proper insulation and temperature controlled packaging including adequate ice or refrigeration must be used to protect the organs during transport. The host OPO may either package extra vessels in the same external transport container with the organ or separate from the organs.

The transplant hospital or OPO must use both internal and external transport containers to package a deceased or living donor organ that travels outside of the facility where the organ is recovered.

16.3.A Internal Packaging

A triple sterile barrier must protect organs. A rigid container must be used as one of these layers when packaging kidneys, pancreas, or extra vessels that are packaged separately from the organs. If the rigid container is sterile, it can serve as one layer of the required triple sterile barrier. The use of a rigid container is optional for all other organs.

16.3.B Internal Labeling of Organs

The host OPO must securely attach the completed OPTN internal label, identifying the specific contents, to the outer-most layer of the triple sterile barrier or cassette of mechanical preservation machine holding each organ. The OPTN Contractor distributes a standardized label that must be used for this purpose. The internal label must be completed using the OPTN organ tracking system. The label must include a description of the contents of the package, the donor ID, and donor blood type and blood subtype, if used for allocation.

16.3.C Internal Labeling of Blood and Tissue Typing Materials

Each separate specimen container of blood or tissue typing material must have a label that will

remain secured to the container under normal conditions of transport. If the blood and tissue typing materials will be accompanying the organ, the internal label must be completed using the OPTN organ tracking system. The label must include the donor ID and at least *one* of the following identifiers:

1. Locally assigned unique ID
2. Donor date of birth
3. Donor initials

Additionally each specimen should be labeled with *both* of the following:

1. The date and time the sample was procured
2. The type of tissue

The donor blood type and subtype, if used for allocation, should be included on tissue typing material and blood samples if known. If the donor ID or blood type is not available during the preliminary evaluation of a donor, a locally assigned unique ID and one other identifier for the transportation of initial screening specimens may be used. The OPO must document in the OPO donor record all unique identifiers used to label tissue typing specimens.

16.3.D Internal Labeling of Extra Vessels

The rigid container holding the extra vessels and the outermost layer of the triple sterile barrier must each have a completed OPTN extra vessels label. The OPTN Contractor distributes standardized labels that must be used for this purpose. The internal label on the outermost layer of the triple sterile barrier must be completed using the OPTN organ tracking system. The labels must include *all* of the following information according to *Table 16-1* below.

Table 16-1: Required Information on Internal Labels for Vessels

This information must be included:	On the rigid container:	On the outermost layer of the triple sterile barrier:
1. Donor ID	●	●
2. Donor blood type	●	●
3. Donor blood subtype, if used for allocation	●	●
4. Recovery date	●	●
5. Description of the container contents	●	●
6. That the extra vessels are for use in organ transplantation only	●	●

This information must be included:	On the rigid container:	On the outermost layer of the triple sterile barrier:
7. Infectious disease donor screening test results for *all* of the following: a. anti-HIV I/II b. HIV Ag/Ab combo c. HIV NAT d. total anti-HBc e. HBsAg f. HBV NAT g. anti-HCV h. HCV NAT		●
8. Whether the extra vessels are from a donor with a positive result (NAT included) for any of the following: • HIV, HBV, or HCV • total anti-HBc	●	
9. Whether the extra vessels are from a donor that has any risk criteria for acute HIV, HBV, or HCV infection, according to the *U.S. Public Health Service (PHS) Guideline*	●	●

16.3.E External Packaging

Only disposable shipping boxes, coolers, or mechanical preservation machines must be used as external transport containers.

16.3.E.i Disposable Shipping Box

If organs or tissue typing materials are shipped commercially, they must be transported in a new disposable shipping box. Disposable shipping boxes may not be reused and each box must contain *all* of the following:

1. A closed plastic liner inside the insulated container to encase the cooling material. The liner must be secured and leak-proof.
2. An inner insulated container, 1.5 inches thick, or a container with an equivalent thermal resistance. The container must have proper insulation and enough cooling material to protect the organs during normal conditions of transport.
3. A water-tight, secured, colored, opaque plastic liner between the outer and inner containers. The liner must be secured and leak-proof.
4. An outer container of corrugated plastic or corrugated cardboard, with at least 200 pounds burst strength, that is coated with a water resistant substance.

16.3.E.ii Mechanical Preservation Machine

Members may use a mechanical preservation machine to transport organs. A mechanical preservation machine may be reused only if it is properly cleaned and sanitized and all labels from previous donor organs are removed.

16.3.E.iii Cooler

If a member of the organ recovery team is accompanying the organ to the potential transplant recipient's transplant hospital, the organs and tissue typing material may be transported in a cooler. A cooler may be reused only if it is properly cleaned and sanitized and all labels from previous donor organs are removed.

16.3.F External Labeling

A label, that under normal conditions of transport will remain secured, must be attached to the outside of the external transport container. Disposable shipping boxes, coolers, and mechanical preservation machines must have the OPTN external label. The OPTN Contractor distributes a standardized label that must be used for this purpose.

The OPTN External label must be completed using the OPTN organ tracking system. The label must include *all* of the following:

1. The donor ID
2. The sender's name and telephone number
3. The donor's blood type
4. The donor's subtype, if used for allocation
5. A description of the specific contents of the box
6. The Organ Center's telephone number

16.4 Documentation Accompanying the Organ or Extra Vessels

16.4.A Organ Documentation

Each external deceased and living donor transport container holding an organ must be sent with *all* of the following source documentation:

1. Blood type
2. Blood subtype, if used for allocation
3. Infectious disease testing results available at the time of organ packaging

The source documentation must be placed in a watertight container in *either* of the following:

1. A location specifically designed for documentation
2. Between the inner and external transport containers

For deceased donor organs, the host OPO must label the watertight container. This label must be completed using the OPTN organ tracking system. The label must include the donor ID, blood type, and blood subtype if used for allocation.

If extra vessels are not shipped in the same external transport container as other organs, then the separate extra vessels external transport container must include the same complete donor documentation.

16.5 Verification and Recording of Information before Shipping

Each OPO or recovery hospital must establish and then implement a protocol for verifying the accuracy of organ packaging labels by an individual other than the individual initially performing the labeling and documentation.

This verification must occur after completing the required labels and documentation for organs and the host OPO or recovery hospital must document that verification.

The host OPO must use the OPTN organ tracking system to:

1. Record each item placed into the external organ package
2. Report to the OPTN that the package is ready for tracking

16.6 Extra Vessels Transplant and Storage

16.6.A Extra Vessels Use and Sharing

Extra vessels must only be used for organ transplantation or modification of an organ transplant.

Transplant hospitals may share deceased donor extra vessels with other transplant hospitals, unless storage is prohibited by OPTN *Policy 16.6.B: Extra Vessels Storage*. Extra vessels from a living donor must only be used for transplant or modification of an organ transplant for the original intended recipient and must not be shared. Extra vessels from a donor with HIV must only be used for transplant for the original intended recipient.

16.6.B Extra Vessels Storage

Transplant hospitals must not store a donor's extra vessels if the donor has tested positive for *any* of the following:

- HIV by antibody, antigen, or nucleic acid test (NAT)
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B (HBV) by NAT
- Hepatitis C (HCV) by antibody or NAT

Extra vessels from donors that do not test positive for HIV, HBV, or HCV as above may be stored. When a transplant hospital stores extra vessels it must do *all* of the following:

1. Use stored extra vessels *only* for organ transplantation

2. Designate at least one person to monitor extra vessels storage, use, destruction, and reporting
3. Package and label extra vessels as required by OPTN *Policy 16.3: Packaging and Labeling* and OPTN *Policy 16.4: Documentation Accompanying the Organ or Extra Vessels*
4. Store extra vessels in a Food and Drug Administration (FDA) approved preservation solution
5. Store extra vessels in a secured refrigerator with a temperature monitor and maintain the temperature no colder than 2 degrees Celsius and no warmer than 8 degrees Celsius
6. Maintain a log of stored extra vessels
7. Maintain all records relating to the monitoring and use of extra vessels
8. Monitor extra vessels daily and log security and refrigerator temperature checks
9. Destroy unused extra vessels within 14 days after the recovery date

16.6.C Reporting Requirements for Extra Vessels

Transplant hospitals must report to the OPTN the disposition of all extra vessels, including their use, sharing, or destruction, within seven days of their use, sharing, or destruction.

16.7 Transportation Responsibilities

16.7.A Transportation Arrangements

The host OPO is responsible for determining that non-local procurement teams have transportation to and from the local airport.

16.7.B Transportation Costs for Deceased Donor Kidneys

If deceased donor kidneys, and associated tissue typing materials are shipped without any other organs, then the host OPO is responsible for all transportation costs.

16.7.C Transportation Costs for Living Donor Kidneys

The organ recipient's transplant hospital is responsible for transportation costs for living donor kidneys and associated tissue typing material according to CMS regulations.

16.7.D Transportation Costs for all other Organs

For all non-renal organs and tissue typing materials from deceased or living donors, including kidney-pancreas, transportation costs are the responsibility of the member receiving the organ. If an organ or tissue typing material is forwarded to another member for any reason the member that finally receives the organ or tissue typing material is responsible for transportation costs; unless otherwise agreed upon by the parties involved.

16.7.E Transportation Costs for Tissue Typing Material

The organ recipient's transplant hospital is responsible for payment of transportation costs for tissue typing material sent to crossmatch potential recipients of a living donor kidney. When an organ recipient's transplant hospital requests tissue typing material to crossmatch potential recipients for a non-renal organ, it must pay transportation costs for the tissue typing material.

Policy 17: International Organ Transplantation

17.1 Registration and Transplants of Non-US Citizens/Non-US Residents

17.1.A Referrals

Members may not enter into contracts with foreign agencies or governments for the transplant of non-US residents/non-US citizens. Members may negotiate the terms and conditions under which any individual candidate would be treated with the understanding that each candidate must be referred on a case-by-case and physician-to-physician basis.

17.1.B Review of Non-US Citizens/Non-US Resident Registrations and Transplants

The Ad Hoc International Relations Committee will review all citizenship data reported to the OPTN. The Ad Hoc International Relations Committee may request that transplant hospitals voluntarily provide additional information about registrations or transplants of non-US citizens/non-US residents.

17.1.C Report of Activities Related to The Transplantation of Non-US Citizens/Non-US Residents

The Ad Hoc International Relations Committee will prepare and provide public access to an annual report of transplant hospital activities related to the registration and transplantation of non-US citizens/non-US residents.

17.2 Importation of Deceased Donor Organs from Foreign Sources

Members may import deceased donor organs from foreign sources according to the requirements in the Policies outlined below.

17.2.A Formal Deceased Donor Import Agreement

A member that wishes to enter into a formal, deceased donor organ import agreement with a foreign entity must

1. Submit a proposal to the Ad Hoc International Relations Committee for review
2. Have approval of the agreement by the OPTN Board of Directors

Each formal agreement cannot exceed two years in duration and must include *all* of the following:

1. The basis for the agreement.
2. The expected benefits to the foreign and domestic participants.

3. Credentials of the foreign entity.
4. The number and type of deceased donor organs anticipated for import.
5. An outline of a plan for reporting the results of the agreement.
6. A requirement for the donor organization to submit documentation certifying the authorization of the deceased donor or the deceased donor's agent.
7. A requirement for the donor organization to submit documentation certifying that the deceased donor has met the brain death or donation after circulatory death (DCD) protocols that are in compliance with recognized US standards for domestic organ procurement.
8. A requirement for the donor organization to submit documentation of the deceased donor's ABO.

The Ad Hoc International Relations Committee will review each formal agreement every two years.

17.2.B Requirements for Importing Deceased Donor Organs through a Formal Agreement

The member importing any deceased donor organ from a foreign entity must fulfill *all* the following requirements:

1. Report the event within 72 hours to the Organ Center.
2. Allocate the organ according to the organ allocation policies.
3. Provide the minimum required information about the foreign deceased donor organ, as specified in OPTN *Policy 2: Deceased Donor Organ Procurement* and *Policy 5: Organ Offers, Acceptance, and* Verification.
4. Comply with the blood type verification requirements in OPTN *Policy 2.6: Deceased Donor Blood Type Determination and Reporting* and OPTN *Policy 3.3: Candidate Blood Type Determination and Reporting before Waiting List Registration*.
5. Evaluate the organ for transmissible diseases as specified *in* OPTN *Policy 15: Identification of Transmissible Diseases*.
6. Verify that the foreign entity is authorized as a transplant hospital or organ procurement program by an appropriate agency of its national government.
7. Obtain official documentation from the exporting party that it is a medical center authorized to export organs for transplantation.

17.2.C Deceased Donor Organs Imported from Outside of the United States without a Formal Agreement

A member may import a deceased donor organ recovered outside of the United States without a formal agreement. An imported deceased donor organ must meet all the requirements in OPTN *Policy 17.2.B: Requirements for Importing Deceased Donor Organ through a Formal Agreement*. The member must notify the Organ Center immediately so that the OPTN Contractor can allocate the organ according to the match run for that organ.

The member importing the organ must provide *all* of the following to the OPTN:

1. Documentation certifying that the donor has met brain death or DCD protocols that are in compliance with recognized standards for domestic organ procurement.
2. Documentation from the donor organization certifying the authorization of the donor or the donor's agent.
3. Documentation from the donor organization verifying the donor's ABO.

The Ad Hoc International Relations Committee will review the circumstances of each deceased donor organ imported without a formal agreement.

Policy 18: Data Submission Requirements

18.1 Data Submission Requirements

18.1.A Accurate Submission of Data

OPTN members must submit accurate data to the OPTN. Members must maintain documentation demonstrating the accuracy of all data submitted to the OPTN.

18.1.B Timely Submission of Certain Data

Members must submit data to the OPTN according to Table 18-1.

Table 18-1: Data Submission Requirements

The following member:	Must submit the following instruments to the OPTN:	Within:	For:
Histocompatibility Laboratory	*Donor Histocompatibility* (DHS)	60 days after the DHS record is generated	Each living and deceased donor

The following member:	Must submit the following instruments to the OPTN:	Within:	For:
Histocompatibility Laboratory	*Recipient Histocompatibility* (RHS)	60 days after the transplant hospital removes the candidate from the waiting list because of transplant	Each heart, intestine, kidney, liver, lung, or pancreas, or covered VCA transplant recipient typed by the laboratory
OPOs	*Death Notification Registration* (DNR)	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	All imminent neurological deaths and eligible deaths in its DSA
OPOs	*Monthly Donation Data Report: Reported Deaths*	30 days after the end of the month in which a donor hospital reports a death to the OPO	All deaths reported by a hospital to the OPO
Allocating OPO	*Potential Transplant Recipient* (PTR)	30 days after the match run date by the OPO or the OPTN	Each deceased donor heart, intestine, kidney, liver, lung, pancreas, or covered VCA that is offered to a potential recipient

The following member:	Must submit the following instruments to the OPTN:	Within:	For:
Host OPO	*Donor Organ Disposition (Feedback)*	5 business days after the procurement date	Individuals, except living donors, from whom at least one organ is recovered
Host OPO	*Deceased Donor Registration* (DDR)	60 days after the *donor organ disposition (feedback)* form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	*Living Donor Feedback*	The time prior to donation surgery	Each potential living donor organ recovered at the hospital
Recovery Hospitals	*Living Donor Feedback*	72 hours after the donor organ recovery procedure	Any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient
Recovery Hospitals	*Living Donor Registration* (LDR)	90 days after the recovery hospital submits the *living donor feedback* form	Each living donor organ recovered at the hospital
Recovery Hospitals	*Living Donor Follow-up* (LDF)	90 days after the six-month, 1-year, and 2-year anniversary of the donation date	Each living donor organ recovered at the hospital This does not apply to domino donor and non-domino therapeutic donor organs.

The following member:	Must submit the following instruments to the OPTN:	Within:	For:
Transplant hospitals	*Organ Specific Transplant Recipient Follow-up* (TRF)	*Either* of the following: • 90 days after the six-month and annual anniversary of the transplant date until the recipient's death, graft failure, or planned graft removal of a uterus • 14 days from notification of the recipient's death or graft failure	Each recipient followed by the hospital
Transplant hospitals	*Organ Specific Transplant Recipient Registration* (TRR)	90 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60 days after transplant hospital removes candidate from waiting list	Each liver recipient transplanted by the hospital
Transplant hospitals	*Waiting List Removal for Transplant*	1 day after the transplant	Each heart, intestine, kidney, liver, lung, pancreas, or covered VCA recipient transplanted by the hospital
Transplant hospitals	*Recipient Malignancy* (PTM)	30 days after the transplant hospital reports the malignancy on the *transplant recipient follow-up* form	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital.
Transplant hospitals	*Transplant Candidate Registration* (TCR)	90 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, pancreas or covered VCA candidate on the waiting list or recipient transplanted by the hospital

18.1.C Retrospective Data Collection during COVID-19 Emergency

The following member	Must submit the following instruments to the OPTN	For the following	By
Recovery Hospitals	*Living Donor Follow-up* (LDF)	Living donors with forms due during the period of March 13, 2020 through March 31, 2021.	July 1, 2021
Transplant hospitals	*Organ Specific Transplant Recipient Follow-up (TRF)*	Recipients with forms due during the period of March 13, 2020 through March 31, 2021.	July 1, 2021
Transplant hospitals	*Recipient Malignancy* (PTM)	Recipients with forms due during the period of March 13, 2020 through March 31, 2021.	July 1, 2021

18.1.D Changes to Submitted Data

Upon expiration of the corresponding timeframe listed in Table 18-1, data submitted using the following instruments are considered final:

- Deceased Donor Registration (DDR)
- Donor Histocompatibility (DHS)
- Recipient Histocompatibility (RHS)
- Transplant Candidate Registration (TCR)
- Transplant Recipient Registration (TRR)
- Living Donor Registration (LDR)
- Transplant Recipient Follow-up (TRF)
- Living Donor Follow-up (LDF)

Changes to final data will not be permitted unless the member reports, within the data collection system prior to making the changes, both the approval of the member's official OPTN Representative (or designee) and the reason for the changes.

18.1.E Reporting

The Data Advisory Committee must report to the Board of Directors at least annually all of the following

- Data submission compliance rates;
- The frequencies of data change following submission and reasons reported; and
- Other relevant information identified by the Committee

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN. Timely data on recipients and living donors is based on recipient or living donor status at a time as close as possible to the specified transplant event anniversary. *Table 18-2: Timely Data Collection* sets standards for when the member must collect the data from the patient.

Table 18-2: Timely Data Collection

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Transplant hospital	*Organ specific transplant recipient registration* (TRR)	When the transplant recipient is discharged from the hospital or 42 days following the transplant date, whichever is first
Recovery hospital	*Living donor registration* (LDR)	When the living donor is discharged from the hospital or 42 days following the transplant date, whichever is first
Recovery hospital	*Living donor follow-up* (LDF)	60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date

18.3 Recording and Reporting the Outcomes of Organ Offers

The allocating OPO and the transplant hospitals that received organ offers share responsibility for reporting the outcomes of all organ offers. OPOs are responsible for reporting the outcomes of organ offers to the OPTN within 30 days of the match run date. OPOs, transplant hospitals, and the OPTN may report this information. The OPO or the OPTN must obtain PTR refusal codes directly from the physician, surgeon, or their designee involved with the potential recipient and not from other personnel.

If the OPO reports the refusal code, then the transplant hospital has 45 days from the match run date, to validate the refusal code by either confirming or amending the refusal code. If the OPO and transplant hospital report different refusal codes, then the OPTN will use the transplant hospital's refusal code for data analysis purposes.

If the OPTN reports the refusal code, then the transplant hospital will not be required to validate the refusal code.

18.4 Living Donor Data Submission Requirements

The follow up period for living donors will be a minimum of two years.

The OPTN will calculate follow-up rates separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.

Living donor follow-up reporting requirements do not apply to any transplant recipient whose replaced or explanted organ is donated to another candidate.

18.4.A Reporting Requirements after Living Kidney Donation

LDF forms due between March 13, 2020 and March 31, 2021 are exempt from the requirements in this section.

The recovery hospital must report accurate, complete, and timely follow up data for donor status and clinical information using the LDF form for at least:

- 60% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 70% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 80% of their living kidney donors who donate after December 31, 2014

The recovery hospital must report accurate, complete, and timely follow up kidney laboratory data using the LDF form for at least:

- 50% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 60% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 70% of their living kidney donors who donate after December 31, 2014

Required kidney donor status and clinical information includes *all* of the following:

1. Patient status
2. Working for income, and if not working, reason for not working
3. Loss of medical (health, life) insurance due to donation
4. Has the donor been readmitted since last LDR or LDF form was submitted?
5. Kidney complications
6. Regularly administered dialysis as an ESRD patient
7. Donor developed hypertension requiring medication
8. Diabetes
9. Cause of death, if applicable and known

Required kidney laboratory data includes *all* of the following:

1. Serum creatinine
2. Urine protein

18.4.B Reporting Requirements after Living Liver Donation

LDF forms due between March 13, 2020 and March 31, 2021 are exempt from the requirements in this section.

The recovery hospital must report accurate, complete, and timely follow-up data using the LDF form for living liver donors who donate after September 1, 2014, as follows:

1. Donor status and clinical information for 80% of their living liver donors.
2. Liver laboratory data for at least:
    - 75% of their living liver donors on the 6 month LDF
    - 70% of their living liver donors on the one year LDF

Required liver donor status and clinical information includes *all* of the following:

1. Patient status
2. Cause of death, if applicable and known
3. Working for income, and if not working, reason for not working
4. Loss of medical (health, life) insurance due to donation
5. Hospital readmission since last LDR or LDF was submitted
6. Liver complications, including the specific complications
    - Abscess
    - Bile leak
    - Hepatic resection
    - Incisional hernias due to donation surgery
    - Liver failure
    - Registered on the liver candidate waiting list

Required liver laboratory data includes *all* of the following:

1. Alanine aminotransferase
2. Alkaline phosphatase
3. Platelet count
4. Total bilirubin

18.5 Reporting of Patient Safety Events

18.5.A Required Reporting by Transplant Hospitals

Transplant hospitals must report the following events to the OPTN according to *Table 18-3* below.

Table 18-3: Required Reporting by Transplant Hospitals

Transplant hospitals must report if:	To the:	Within 72 hours after:
A transplant of the incorrect organ into an organ recipient occurs	OPTN Patient Safety Reporting Portal	The transplant hospital becomes aware
A transplant of an organ into the incorrect organ recipient occurs	OPTN Patient Safety Reporting Portal	The transplant hospital becomes aware
A donor organ is identified as incorrect during pre-transplant processes conducted according to either OPTN *Policy 5.8.*A: *Pre-Transplant Verification Prior to Organ Receipt* or OPTN *Policy 5.8.B*: *Pre-Transplant Verification Upon Organ Receipt*	OPTN Patient Safety Reporting Portal	The transplant hospital becomes aware
The potential transplant recipient is identified as incorrect during pre-transplant processes conducted according to either OPTN *Policy 5.8.A: Pre-Transplant Verification Prior to Organ Receipt* or OPTN *Policy 5.8.B: Pre-Transplant Verification Upon Organ Receipt*	OPTN Patient Safety Reporting Portal	The transplant hospital becomes aware
An organ was delivered to the incorrect transplant hospital and resulted in non-use of the organ	OPTN Patient Safety Reporting Portal	The transplant hospital becomes aware
The incorrect organ was delivered to the transplant hospital and resulted in non-use of the organ	OPTN Patient Safety Reporting Portal	The transplant hospital becomes aware

Transplant hospitals must report if:	To the:	Within 72 hours after:
An ABO typing error or discrepancy is caught before or during pre-transplant processes conducted according to either OPTN *Policy 5.8.A*: *Pre-Transplant Verification Prior to Organ Receipt* or OPTN *Policy 5.8.B: Pre-Transplant Verification Upon Organ Receipt*	OPTN Patient Safety Reporting Portal	The transplant hospital becomes aware

18.5.B Required Reporting of Living Donor Events by Recovery Hospitals

Recovery hospitals must report living donor events through the OPTN Patient Safety Reporting Portal or the OPTN according to *Table 18-4* below.

Table 18-4: Living Donor Event Reporting

Recovery hospitals must report if:	To the:	Within 72 hours after:
A living donor organ recovery procedure is aborted after the donor has begun to receive general anesthesia.	OPTN Patient Safety Reporting Portal and the OPTN	The aborted organ recovery procedure
A living donor dies within 2 years after organ donation	OPTN Patient Safety Reporting Portal	The hospital becomes aware
A living donor is listed on the wait list within 2 years after organ donation	OPTN Patient Safety Reporting Portal	The hospital becomes aware
A living kidney donor begins regularly administered dialysis as an ESRD patient within 2 years after organ donation	OPTN Patient Safety Reporting Portal	The hospital becomes aware
A living donor organ is recovered but not transplanted into any recipient	OPTN Patient Safety Reporting Portal and the OPTN	Organ recovery
A living donor organ is recovered and transplanted into someone other than the intended recipient	OPTN Patient Safety Reporting Portal	Organ recovery

18.5.C Required Reporting by OPOs

OPOs must report the following events to the OPTN according to *Table 18-5* below.

Table 18-5: Required Reporting by OPOs

Host OPOs must report if:	To the:	Within 72 hours after:
Transplant hospital procurement staff leave the operating room without allowing the host OPO to package and label deceased donor organs and tissue typing specimens as required	OPTN Patient Safety Reporting Portal	The OPO becomes aware
An ABO typing error or discrepancy is caught after the OPO's deceased donor blood type and subtype verification process, as outlined in Policy 2.6.C: *Reporting of Deceased Donor Blood Type and Subtype*, and after the OPO has executed a match run	OPTN Patient Safety Reporting Portal	The OPO becomes aware

18.5.D Required Reporting by Histocompatibility Laboratories

Histocompatibility laboratories must report the following events to the OPTN according to *Table 18-6* below.

Table 18-6: Required Reporting by Histocompatibility Laboratories

Discovering laboratories must report if:	To the:	Within 72 hours after:
A donor, candidate, or recipient HLA typing critical discrepancy occurs, as defined by the OPTN *Policy 4.4: Critical HLA Discrepancies in Candidate, Donor, and Recipient HLA Typing Results*	OPTN Patient Safety Reporting Portal	The laboratory becomes aware
An incorrect donor or candidate sample was used for a physical crossmatch	OPTN Patient Safety Reporting Portal	The laboratory becomes aware
An incorrect candidate HLA antibody sample was analyzed for a virtual crossmatch per program testing agreement	OPTN Patient Safety Reporting Portal	The laboratory becomes aware

Policy 19: Data Release

The OPTN will release OPTN data according to the Final Rule and other applicable federal and state laws and regulations. The OPTN will release all OPTN data requested by the Secretary of the Department of Health and Human Services (HHS).

Policy 20: Travel Expense and Reimbursement

20.1 Eligibility for Reimbursement

20.1.A General Eligibility Requirements

The OPTN will reimburse approved travel costs for members, contractors, invited guests, and OPTN Contractor staff who are traveling for OPTN business. OPTN Contractor employees and contractors must receive authorization from their director or person who approves travel before confirming travel arrangements. OPTN Contractor staff will approve a member's travel to OPTN sponsored events.

20.1.B Multiple Meetings in the Same City

If the OPTN holds a meeting in a city where the traveler will attend another organization's meeting, the OPTN will pay only for the traveler's additional expenses incurred as a direct result of attending the OPTN meeting.

20.2 Airfare and Rail Reimbursement

20.2.A Booking Travel

OPTN Contractor staff and members must use the approved OPTN Contractor travel agency to arrange all OPTN related travel and obtain a low-cost coach fare that will accommodate the traveler's needs. If the traveler chooses not to accept those flight arrangements, the OPTN will reimburse only up to the amount the approved OPTN travel agency would have paid.

20.2.B Air Travel

If the traveler has an unused airline ticket, the OPTN Contractor will attempt to use the ticket credit on a flight that meets the needs of the traveler.

The OPTN will pay for additional fees resulting from airline ticket changes if the changes result from OPTN business. Travelers who request ticket changes for reasons unrelated to OPTN business will be responsible for all fees incurred. Changes in airline ticketing due to emergencies will be handled on a case-by-case basis.

If a traveler requests to leave an OPTN event early and "standby" is available, then the traveler should go "standby." If the traveler chooses to book a confirmed seat on an earlier flight, the traveler will be responsible for all fees incurred. Leaving early due to emergencies will be handled on a case by case basis.

The approved OPTN Contractor travel agency will not book back-to-back tickets or round-trip airfares for a one-way trip.

The OPTN will not reimburse first class airfare unless it is the same price as the low-cost coach fare. If the traveler chooses to fly first class, the traveler must pay the entire cost of the first class ticket and the OPTN would only reimburse the amount of the low cost coach fare.

20.2.C International Travel

The OPTN will approve international travel on a case-by-case basis.

20.3 Hotel Reimbursement

The OPTN will reimburse overnight accommodations for the number of nights necessary to conduct OPTN business. When making this decision, the OPTN Contractor will take into account the distance between the departing and destination cities, time zones crossed, and the flights available to and from those cities.

20.4 Other Transportation

20.4.A Mileage

The OPTN will reimburse mileage at the applicable IRS rate based on the dates travelled.

20.4.B Transportation To and From the Airport

The OPTN will reimburse *all* of the following costs:

1. Transportation between the airport and the traveler's home.
2. Transportation between the airport and the meeting location.
3. Parking fees at the airport from which the traveler departs.

Travelers must use the least expensive, convenient option to travel to and from airports. The OPTN will not reimburse limousines unless the cost is shared with another traveler and the total cost to the OPTN is no more expensive than cab fare.

20.4.C Rental Cars

The OPTN will not reimburse rental cars if less expensive modes of travel are available. The traveler must elect rental car insurance coverage and must minimize additional rental car fees. If the traveler elects to rent a car when less expensive modes of travel are available, the OPTN will reimburse up to the amount of the estimated cab fare needed for the duration of the stay.

20.4.D Provided Ground Transportation

The OPTN will not reimburse the cost of any other ground transportation if the OPTN provides ground transportation between an airport and a meeting site and the person traveling could reasonably take advantage of this transportation.

20.5 Meals

20.5.A Meal Cost

The OPTN will reimburse individual meal costs during travel except when the traveler is present at the meeting location and a group breakfast, luncheon, or dinner is available at the same time as the individual meal. Individual breakfast and lunch costs must be reasonable.

20.5.B Evening Meal Limitations

The OPTN will reimburse evening meal costs up to $45. This limit includes the cost of the meal and gratuities. The OPTN will not reimburse costs exceeding this limit unless approved by the Assistant Executive Director level or above.

20.5.C Alcoholic Beverages

The OPTN will not reimburse any charges for alcoholic beverages. However, nothing in this Policy prohibits the OPTN Contractor from using private resources to pay for alcohol.

20.6 Miscellaneous Expenses

20.6.A Telecommunication Charges

The OPTN will reimburse OPTN business and personal phone calls of a reasonable length. The OPTN will reimburse Internet connection charges if the traveler is conducting OPTN business.

20.6.B Other Reasonable Expenses

The OPTN will reimburse reasonable, out-of-pocket expenses incurred as a direct result of traveling for OPTN business.

20.7 Non-Reimbursable Expenses

The OPTN will not reimburse costs for in-room movies, valet parking, fitness center, dry cleaning, laundering, or any other personal charges. The OPTN will not reimburse charges incurred for personal travel days.

20.8 Filing Expense Reports

20.8.A Expense Reimbursement Form

To request reimbursement from the OPTN, the traveler must complete and submit an OPTN expense reimbursement form with original receipts. Off-site OPTN members may submit scanned copies of the original receipts. The traveler must sign the expense reimbursement form and must include *all* of the following information:

1. Dates of travel
2. Reason for travel
3. Meeting location and name of event
4. To whom the reimbursement check will be made payable
5. The address to which the reimbursement will be sent
6. The traveler's phone number

20.8.B Receipts

The expense report must have original receipts for expenses attached. Off-site OPTN members may submit scanned copies of the original receipts. If one traveler has a meal receipt that includes other OPTN Contractor travelers, the receipt must include the names of all travelers.

Policy 21: Composite Allocation Score Reference

21.1 Formulas

21.1.A Waiting List Survival Formulas

21.1.A.1 Lung Waitlist Area Under the Curve (WLAUC)

The area under the lung waiting list survival probability curve within one year (WLAUC) is calculated using the formula

$$WL_i = \sum_{k=1}^{365} S_{WL,i}(k-1)$$

The calculation for $S_{WL,i}$ is in OPTN *Policy 21.1.A.2 Expected Lung Waiting List Survival Probability Within One Year*.

21.1.A.2 Expected Lung Waiting List Survival Probability Within One Year

The formula used to calculate expected lung waiting list survival probability within one year is

$$S_{WL,i}(t) = S_{WL,0}(t)^{e^{\beta_1 X_{1i} + \beta_2 X_{2i} + \ldots + \beta_p X_{pi}}}$$

Table 21-1: Expected Lung Waiting List Survival Probability Within One Year Variables lists what each variable in the formula represents.

Table 21-1 Expected Lung Waiting List Survival Probability Within One Year Variables

The variable	Represents
$S_{WL,i}(t)$	the expected waiting list survival probability at time t for candidate i
$S_{WL,0}(t)$	the baseline waiting list survival probability at time t
$\beta_1, \beta_2, \ldots \beta_p$	the parameter estimates from the waiting list model (Table 21-5)
X_{ji}	the value of characteristic j for candidate i
I	1, 2, …, N is the candidate identifier

21.1.A.3 Converting Lung WLAUC to Lung Waiting List Survival Points

Waiting list Survival Points are equal to

$$((25^{(1\text{-WLAUC}/365)} - 1)/24)*25$$

21.1.B Post-Transplant Outcomes Formulas

21.1.B.1 Expected Lung Five Years Post-Transplant Area Under the Curve (PTAUC)

The area under the post-transplant survival probability curve during the first five years post-transplant (PTAUC) is calculated using the formula

$$PT_i = \sum_{k=1}^{1826} S_{TX,i}(k)$$

21.1.B.2 Expected Lung Post-Transplant Survival Probability Within Five Years

The formula used to calculate expected lung post-transplant survival probability within five years is

$$S_{TX,i}(t) = S_{TX,0}(t)^{e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \ldots + \alpha_q Y_q}}$$

Table 21-2: Expected Lung Post-Transplant Survival Probability Within Five Years Variables lists what each variable in the formula represents.

Table 21-2 Expected Lung Post-Transplant Survival Probability Within Five Years Variables

The variable	Represents
$S_{TX,i}(t)$	expected post-transplant survival probability at time t for candidate i
$S_{TX,0}(t)$	the baseline post-transplant survival probability at time t
$\alpha_1, \alpha_2, \ldots \alpha_q$	the parameter estimates from the post-transplant model (Table 21-8)
Y_{ji}	the value of characteristic j for candidate i
I	1, 2, …, N is the candidate identifier

21.1.B.3 Converting Lung PTAUC to Lung Post-Transplant Outcomes Points

Post-Transplant Outcomes Points are equal to

(PTAUC/1826)*25

21.1.C Biological Disadvantages Formulas

21.1.C.1 Lung CPRA Points

The Lung CPRA points are equal to

$((100^{CPRA}-1)/99)*5$

The variable CPRA represents the probability of incompatibility based on the candidate's CPRA.

21.1.C.2 Lung Height Points

The Lung Height points are equal to

$$((100^{HTIN}-1)/99)*5$$

The variable HTIN represents the probability of incompatibility based on the candidate's height found in OPTN *Policy 21.2.C.1: Probability of Incompatible Lung Donors Based on Height*.

21.1.D Efficient Management Formulas

21.1.D.1 Lung Travel Efficiency Points

The Lung travel efficiency points are equal to

$$(1 - [6.3*NM + 247.63 * (NM - 43.44) * I\{NM > 43.44\} - 104.44 * (NM - 67.17) * I\{NM > 67.17\} - 128.34 * (NM - 86.9) * I\{NM > 86.9\}] / 116989.1)*5$$

The variable NM represents straight-line distance between donor hospital and candidate hospital in nautical miles.

21.1.D.2 Lung Proximity Efficiency Points

The Lung proximity efficiency points are equal to

$$(I\{NM \leq 45\} + I\{NM \in (45,90)\}*(1 - 0.15 / 45 * (NM - 45)) + I\{NM \geq 90\}*0.875 / [1 + \exp(0.0025 * (NM - 1500))])*5$$

The variable NM represents straight-line distance between donor hospital and candidate hospital in nautical miles.

21.2 Reference Values

21.2.A Values Used in the Calculation of Lung Waiting List Survival

Table 21-3 provides the covariates and their coefficients for the waiting list mortality calculation. See OPTN *Policy 10.1.F.i: Lung Disease Diagnosis Groups* for specific information on each diagnosis group.

Table 21-3: Waiting List Survival Calculation: Covariates and their Coefficients

For this covariate:	When	The following coefficient is used in the lung waiting list survival calculation:
Age at the time of the match run (fractional calendar year)	Candidates are at least 12 years old	0.0281444188123287*age
Bilirubin (mg/dL) value with the most recent test date and time	Bilirubin is more than 1.0 mg/dL	0.15572123729572*(bilirubin – 1)
	1.0 mg/dL or less	0
Body mass index (BMI) (kg/m^2)	BMI less than 20 kg/m^2	0.10744133677215*(20 – BMI)
	BMI is at least 20 kg/m^2	0
Assisted ventilation	ECMO or continuous mechanical-hospitalized	1.57618530736936
	Not ECMO or continuous mechanical-hospitalized	0
Creatinine (serum) (mg/dL) with the most recent test date and time	Candidate is at least 18 years old	0.0996197163645* creatinine
	Candidate is less than 18 years old	0
Diagnosis Group	A	0
Diagnosis Group	B	1.26319338239175
Diagnosis Group	C	1.78024171092307
Diagnosis Group	D	1.51440083414275
Detailed diagnosis within group A	Bronchiectasis	0.40107198445555
	Sarcoidosis with PA mean pressure of 30 mm Hg or less	1.39885489102977
	Sarcoidosis with PA mean pressure missing	1.39885489102977

For this covariate:	When	The following coefficient is used in the lung waiting list survival calculation:
Detailed Diagnosis within group D	COVID-19: pulmonary fibrosis	0.2088684500011
	Pulmonary fibrosis, other	0.2088684500011
	Sarcoidosis with PA mean pressure greater than 30 mm Hg	-0.64590852776042
Functional Status	No assistance needed with activities of daily living	-0.59790409246653
	Some or total assistance needed with activities of daily living	0
Amount of supplemental oxygen required to maintain adequate oxygen saturation (88% or greater) (L/min)	At rest, Diagnosis Group B	$0.0340531822566417*O_2$
	At rest, Diagnosis Groups A, C, and D	$0.08232292818591*O_2$
	Not needed at rest	0
PCO_2 (mm Hg): current	PCO_2 is at least 40 mm Hg	$0.12639905519026*PCO_2/10$
PCO_2 threshold change	PCO_2 increase is at least 15%	0.15556911866376
	PCO_2 increase is less than 15%	0
Pulmonary artery (PA) systolic pressure (mm Hg) at rest, prior to any exercise	Diagnosis Group A and the PA systolic pressure is greater than 40 mm Hg	0.55767046368853*(PA systolic – 40)/10

For this covariate:	When	The following coefficient is used in the lung waiting list survival calculation:
	Diagnosis Group A and the PA systolic pressure is 40 mm Hg or less	0
	Diagnosis Groups B, C, and D	0.1230478043299*PA systolic/10
Six-minute-walk distance (feet)	Candidates are at least 12 years old	-0.09937981549564*Six-minute-walk distance/100

If values for certain covariates are missing, expired, or outside the threshold as defined by *Table 21-4*, then the composite allocation score calculation will substitute values to calculate the candidate's waiting list survival score. *Table 21-4: Substituted Values in Calculating Waiting List Survival Score* lists the values that will be substituted.

Table 21-4: Substituted Values in Calculating Waiting List Survival Score

If this covariate's value:	Is:	Then the waiting list survival calculation will use this substituted value:
Bilirubin	Missing, expired, or less than 0.7 mg/dL	0.7 mg/dL
Height or weight to determine body mass index (BMI)	Missing	100 kg/m^2
Weight to determine BMI	Expired	100 kg/m^2

If this covariate's value:	Is:	Then the waiting list survival calculation will use this substituted value:
Assisted ventilation	ECMO, and not expired	26.33L/min needed at rest for the "amount of supplemental oxygen required to maintain adequate oxygen saturation (88% or greater) (L/min)" covariate
Assisted ventilation	Missing or expired	No mechanical ventilation
Creatinine (serum) (mg/dL)	Missing or expired	0.1 mg/dL
Functional status	Missing or expired	No assistance needed
Amount of supplemental oxygen required to maintain adequate oxygen saturation (88% or greater) (L/min)	Greater than 26.33 L/min at rest, and not expired	26.33L/min needed at rest
Amount of supplemental oxygen required to maintain adequate oxygen saturation (88% or greater) (L/min)	Missing or expired	No supplemental oxygen needed at rest
PCO_2	Missing, expired, or less than 40 mm Hg	40 mm Hg
Pulmonary artery (PA) systolic pressure	Missing or less than 20 mm Hg	20 mm Hg
Six-minute-walk distance	Missing or expired	4,000 feet

21.2.A.1 PCO_2 Threshold Change in the Waiting List Survival Calculation

The CAS calculation uses two measures of PCO_2:

1. Current PCO_2
2. PCO_2 Threshold Change

Current PCO2

Current PCO_2 is the PCO_2 value reported to the OPTN with the most recent test date and time. A program may report a PCO_2 value from an arterial, venous, or capillary blood gas test. All blood gas values will be converted to an arterial value as follows:

- A capillary value will equal an arterial value.
- A venous value minus 6 mmHg equals an arterial value.

PCO_2 Threshold Change

There are two PCO_2 threshold change calculations:

- The PCO_2 Threshold Change Calculation
- The Threshold Change Maintenance Calculation

The PCO_2 Threshold Change Calculation

An increase in PCO_2 that is at least 15% will impact a candidate's CAS. If a value is less than 40 mmHg, the system will substitute the normal clinical value of 40 mmHg before calculating change. The PCO_2 threshold change calculation uses the highest and lowest values of PCO_2 as follows:

- The test date and time of the lowest value reported to the OPTN used in the PCO_2 threshold change calculation must be earlier than the test date and time of the highest value used in the PCO_2 threshold change calculation.
- Test dates of these highest and lowest values cannot be more than six months apart.
- The PCO_2 threshold change calculation can use an expired lowest value but cannot use an expired highest value.

If a current PCO_2 value expires according *to Policy 10.3 Clinical Update Schedule,* the candidate's CAS will lose the impact from the PCO_2 threshold change calculation. The equation for the PCO_2 threshold change calculation is:

$$\frac{\text{Highest } PCO_2 - \text{Lowest } PCO_2}{\text{Lowest } PCO_2}$$

The Threshold Change Maintenance Calculation

When a 15% or greater PCO_2 threshold change calculation impacts a candidate's CAS, the CAS threshold change maintenance calculation assesses whether to maintain that impact. To maintain the impact of the PCO_2 increase, the candidate's current PCO_2 value must be at least 15% higher than the lowest value used in the PCO_2 threshold change calculation. The equation for this threshold change maintenance calculation is:

$$\frac{\text{Current } PCO_2 - \text{Lowest } PCO_2}{\text{Lowest } PCO_2}$$

The threshold change maintenance calculation occurs either when the current PCO_2 value expires, according to OPTN *Policy 10.3 Clinical Update Schedule,* or a new current PCO_2 value is entered. For this calculation, the lowest and highest values that were used in the PCO_2 threshold change calculation can be expired. The current PCO_2 value can be the highest one that was used in the PCO_2 threshold change calculation. If a current PCO_2 value expires, the candidate's CAS will no longer be affected by the PCO_2 threshold change.

If a transplant hospital reports a new current PCO_2 value for a candidate who has lost the impact from the PCO_2 threshold change calculation, the CAS will perform the threshold change maintenance calculation. If the new current PCO_2 value is at least 15% higher than the lowest value used in the PCO_2 threshold change calculation, the candidate's CAS will again be affected by the PCO_2 threshold change calculation.

Normal PCO_2 Value

The normal clinical PCO_2 value is 40mmHg. If a current PCO_2 value is below 40 mmHg, or if the current PCO_2 value is missing or expired, the CAS calculation will use the normal clinical PCO_2 value.

21.2.A.2 Probabilities Used in Calculating Lung Waiting List Survival

Table 21-5: Baseline Waiting List Survival (SWL(t)) Probability Where t=Time in Days

T	$S_{TX}(t)$	T	$S_{TX}(t)$	T	$S_{TX}(t)$	T	$S_{TX}(t)$
0	1.000000	41	0.999060	82	0.998347	123	0.997734
1	0.999998	42	0.999048	83	0.998314	124	0.997656
2	0.999983	43	0.999048	84	0.998306	125	0.997656
3	0.999956	44	0.999036	85	0.998295	126	0.997650
4	0.999928	45	0.999036	86	0.998257	127	0.997637
5	0.999902	46	0.999002	87	0.998244	128	0.997610
6	0.999878	47	0.998978	88	0.998244	129	0.997610
7	0.999856	48	0.998967	89	0.998244	130	0.997610
8	0.999814	49	0.998949	90	0.998226	131	0.997599
9	0.999786	50	0.998922	91	0.998179	132	0.997584
10	0.999770	51	0.998886	92	0.998179	133	0.997577
11	0.999740	52	0.998852	93	0.998171	134	0.997570
12	0.999705	53	0.998843	94	0.998144	135	0.997570
13	0.999682	54	0.998843	95	0.998131	136	0.997561
14	0.999650	55	0.998821	96	0.998115	137	0.997552
15	0.999635	56	0.998815	97	0.998115	138	0.997540
16	0.999629	57	0.998772	98	0.998076	139	0.997540
17	0.999615	58	0.998734	99	0.998046	140	0.997540
18	0.999597	59	0.998725	100	0.998046	141	0.997540
19	0.999565	60	0.998703	101	0.998036	142	0.997540
20	0.999527	61	0.998703	102	0.998036	143	0.997534
21	0.999508	62	0.998665	103	0.998026	144	0.997534
22	0.999493	63	0.998665	104	0.997991	145	0.997534
23	0.999460	64	0.998660	105	0.997980	146	0.997530
24	0.999430	65	0.998630	106	0.997980	147	0.997515
25	0.999406	66	0.998617	107	0.997976	148	0.997504
26	0.999382	67	0.998575	108	0.997965	149	0.997499
27	0.999361	68	0.998570	109	0.997944	150	0.997492
28	0.999335	69	0.998567	110	0.997877	151	0.997477
29	0.999302	70	0.998556	111	0.997872	152	0.997477
30	0.999294	71	0.998510	112	0.997828	153	0.997455
31	0.999272	72	0.998494	113	0.997824	154	0.997410
32	0.999262	73	0.998490	114	0.997824	155	0.997335
33	0.999243	74	0.998431	115	0.997824	156	0.997335
34	0.999201	75	0.998413	116	0.997824	157	0.997327
35	0.999178	76	0.998403	117	0.997824	158	0.997321
36	0.999155	77	0.998391	118	0.997824	159	0.997315
37	0.999130	78	0.998391	119	0.997783	160	0.997294
38	0.999128	79	0.998379	120	0.997777	161	0.997294
39	0.999103	80	0.998370	121	0.997767	162	0.997294
40	0.999080	81	0.998363	122	0.997761	163	0.997273

T	$S_{TX}(t)$	T	$S_{TX}(t)$	T	$S_{TX}(t)$	T	$S_{TX}(t)$
164	0.997273	**207**	0.996819	**250**	0.995974	**293**	0.995548
165	0.997273	**208**	0.996819	**251**	0.995974	**294**	0.995505
166	0.997269	**209**	0.996819	**252**	0.995955	**295**	0.995498
167	0.997223	**210**	0.996810	**253**	0.995955	**296**	0.995479
168	0.997223	**211**	0.996796	**254**	0.995938	**297**	0.995464
169	0.997218	**212**	0.996717	**255**	0.995938	**298**	0.995439
170	0.997209	**213**	0.996636	**256**	0.995938	**299**	0.995439
171	0.997209	**214**	0.996621	**257**	0.995938	**300**	0.995414
172	0.997209	**215**	0.996621	**258**	0.995927	**301**	0.995414
173	0.997209	**216**	0.996614	**259**	0.995927	**302**	0.995385
174	0.997209	**217**	0.996602	**260**	0.995923	**303**	0.995358
175	0.997183	**218**	0.996579	**261**	0.995923	**304**	0.995345
176	0.997169	**219**	0.996579	**262**	0.995923	**305**	0.995345
177	0.997169	**220**	0.996574	**263**	0.995923	**306**	0.995345
178	0.997169	**221**	0.996524	**264**	0.995923	**307**	0.995309
179	0.997169	**222**	0.996511	**265**	0.995923	**308**	0.995296
180	0.997160	**223**	0.996439	**266**	0.995895	**309**	0.995296
181	0.997160	**224**	0.996439	**267**	0.995794	**310**	0.995274
182	0.997132	**225**	0.996423	**268**	0.995794	**311**	0.995274
183	0.997113	**226**	0.996423	**269**	0.995778	**312**	0.995251
184	0.997113	**227**	0.996412	**270**	0.995778	**313**	0.995251
185	0.997109	**228**	0.996388	**271**	0.995778	**314**	0.995251
186	0.997099	**229**	0.996388	**272**	0.995778	**315**	0.995228
187	0.997099	**230**	0.996368	**273**	0.995778	**316**	0.995228
188	0.997099	**231**	0.996368	**274**	0.995770	**317**	0.995228
189	0.997099	**232**	0.996368	**275**	0.995764	**318**	0.995167
190	0.997099	**233**	0.996368	**276**	0.995741	**319**	0.995131
191	0.997099	**234**	0.996368	**277**	0.995726	**320**	0.995131
192	0.997099	**235**	0.996368	**278**	0.995726	**321**	0.995131
193	0.997099	**236**	0.996368	**279**	0.995726	**322**	0.995131
194	0.997091	**237**	0.996368	**280**	0.995726	**323**	0.995131
195	0.997067	**238**	0.996368	**281**	0.995691	**324**	0.995080
196	0.996968	**239**	0.996368	**282**	0.995691	**325**	0.995080
197	0.996968	**240**	0.996368	**283**	0.995691	**326**	0.995080
198	0.996968	**241**	0.996258	**284**	0.995691	**327**	0.995080
199	0.996959	**242**	0.996258	**285**	0.995680	**328**	0.995080
200	0.996959	**243**	0.996195	**286**	0.995680	**329**	0.995080
201	0.996945	**244**	0.996195	**287**	0.995680	**330**	0.995080
202	0.996861	**245**	0.996195	**288**	0.995661	**331**	0.995080
203	0.996838	**246**	0.996096	**289**	0.995661	**332**	0.995067
204	0.996838	**247**	0.996044	**290**	0.995639	**333**	0.994986
205	0.996825	**248**	0.996025	**291**	0.995639	**334**	0.994951
206	0.996819	**249**	0.995988	**292**	0.995548	**335**	0.994951

T	$S_{TX}(t)$
336	0.994951
337	0.994937
338	0.994937
339	0.994937
340	0.994937
341	0.994937
342	0.994937
343	0.994937

T	$S_{TX}(t)$
344	0.994842
345	0.994842
346	0.994842
347	0.994738
348	0.994695
349	0.994685
350	0.994685
351	0.994685

T	$S_{TX}(t)$
352	0.994685
353	0.994685
354	0.994585
355	0.994585
356	0.994572
357	0.994527
358	0.994527
359	0.994527

T	$S_{TX}(t)$
360	0.994477
361	0.994477
362	0.994477
363	0.994477
364	0.994390

21.2.B Values Used in the Calculation of Post-Transplant Outcomes

21.2.B.1 Coefficients Used in Calculating Lung Post-Transplant Outcomes

Table 21-6: Post-Transplant Outcomes Calculation: Covariates and Their Coefficients lists the covariates and corresponding coefficients in the waiting list and post-transplant survival measures. See OPTN *Policy 10.1.F: Lung Disease Diagnosis Groups* for specific information on each diagnosis group.

Table 21-6: Post-Transplant Outcomes Calculation: Covariates and Their Coefficients

For this covariate	When	The following coefficient is used in the lung post-transplant outcomes score calculation
Age at the time of the match run (fractional calendar year)	age is less than 20	0.0676308559079852 x (20 - age) + 0.78241832
	age is at least 20 and less than 30	-0.0782418319259552 x (age - 20) + 0.78241832
	age is at least 30 and less than 40	0
	age is at least 40 and less than 50	0.0025908121347866 x (age - 40)
	age is at least 50 and less than 60	0.0167463361760962 x (age - 50) + 0.02590812
	age is at least 60 and less than 70	0.0227144625797883 x (age - 60) + 0.19337148
	age is at least 70	0.0612288624399672 x (age - 70) + 0.42051611
Creatinine (serum) (mg/dL) with the most recent test date and time	creatinine is less than 0.4 and candidate is at least 18 years old	-7.4016726145812200 x (0.4 - creatinine) + 0.41872820
	creatinine is at least 0.4 and less than 0.6 and candidate is at least 18 years old	-1.2584103289549000 x (creatinine - 0.4) + 0.41872820

For this covariate	When	The following coefficient is used in the lung post-transplant outcomes score calculation
	creatinine is at least 0.6 and less than 0.8 and candidate is at least 18 years old	0.3712348866558860 x (creatinine - 0.6) + 0.16704614
	creatinine is at least 0.8 and less than 1.4 and candidate is at least 18 years old	0.6844301806854400 x (creatinine - 0.8) + 0.24129311
	creatinine is at least 1.4 and candidate is at least 18 years old	0.6881894154264970 x (creatinine - 1.4) + 0.65195122
	Candidate is less than 18 years old	0
Cardiac index (L/min/m^2) at rest, prior to any exercise	Less than 2 L/min/m^2	-0.4837491139906200 x (2 – cardiac index) + 0.04030226
	At least 2 and less than 2.5 L/min/m^2	-0.0806045255202868 x (cardiac index - 2) + 0.04030226
	At least 2.5 and less than 3.5 L/min/m^2	0.0136169358319050 x (cardiac index - 2.5)
	At least 3.5 and less than 4.5 L/min/m^2	0.0808432592591954 x (cardiac index - 3.5) + 0.01361694
	At least 4.5 and less than 5 L/min/m^2	0.0696938839239190 x (cardiac index - 4.5) + 0.09446020
	At least 5 L/min/m^2	-0.0023264599609358 x (cardiac index - 5) + 0.12930714
Assisted ventilation	ECMO or continuous mechanical-hospitalized	0.267537018672253
	not ECMO or continuous mechanical-hospitalized	0
Diagnosis Group	A	-0.098901796
	B	0
	C	-0.167126401
	D	0
Detailed diagnosis within Group A	Bronchiectasis	-0.026706663
	Lymphangioleiomyomatosis	-0.271420386
	Sarcoidosis with PA mean pressure of 30 mm Hg or less	0.501743373724746

For this covariate	When	The following coefficient is used in the lung post-transplant outcomes score calculation
	Sarcoidosis with PA mean pressure missing	0.501743373724746
Detailed diagnosis within Group D	COVID-19: pulmonary fibrosis	0.046504644
	Obliterative bronchiolitis (non-retransplant)	-0.132634978
	Constrictive bronchiolitis	-0.132634978
	Sarcoidosis with PA mean pressure greater than 30 mm Hg	0.0561853179859775
	Pulmonary fibrosis, other	0.046504644
Functional Status	No assistance needed with activities of daily living	-0.005304128
	Some assistance needed with activities of daily living	0
	Total assistance needed with activities of daily living	0.074378407
Six-minute-walk distance (feet)	Less than 200 feet	-0.0002535116049789 x (200 - Six-minute-walk distance) + 0.11168755
	At least 200 feet and less than 600 feet	-0.0002841805913329 x (Six-minute-walk distance - 200) + 0.11168755
	At least 600 feet and less than 800 feet	-0.0000049617083362 x (Six-minute-walk distance - 600) - 0.00198468
	At least 800 feet and less than 1,200 feet	-0.0001950464256370 x (Six-minute-walk distance - 800) - 0.00297703
	At least 1,200 feet and less than 1,600 feet	-0.0007428583659073 x (Six-minute-walk distance - 1200) - 0.08099560
	At least 1,600 feet	0.0035374143842919 x (Six-minute-walk distance - 1600) - 0.37813894

If values for certain covariates are missing, expired, or outside the threshold as defined by *Table 21-7*, then the composite allocation score calculation will substitute values to calculate the candidate's post-transplant outcomes score. *Table 21-7: Substituted Values in Calculating Post-Transplant Outcomes Score* lists the values that will be substituted.

ENACTMENT CLAUSE: For lung candidates registered prior to September 3, 2024, who are at least 11 years 6 months old on September 3, 2024, transplant programs must perform an oxygen titration test prior to conducting the six-minute walk test for reporting a six-minute walk distance by March 3, 2025.

Table 21-7: Substituted Values in Calculating Post-Transplant Outcomes Score

If this covariate's value:	Is:	Then the post-transplant outcomes score calculation will use this substituted value:
Cardiac index	Missing, or greater than 5	5.0 L/min/m^2
Assisted ventilation	Missing or expired	Continuous mechanical ventilation while hospitalized
Creatinine (serum) (mg/dL)	Missing, expired or greater than 1.6	1.6 mg/dL
Functional status	Missing or expired	Total assistance needed
Six-minute-walk distance	Missing or expired	200 feet
	Greater than 1,600	1,600 feet

21.2.B.2 Probabilities Used in Calculating Lung Post-Transplant Survival

Table 21-8: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability Where t=Time in Days

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
0	1	14	0.990802	28	0.985917	42	0.980957
1	0.999154	15	0.99025	29	0.985463	43	0.980652
2	0.998058	16	0.989747	30	0.984907	44	0.980297
3	0.997111	17	0.989294	31	0.984705	45	0.980144
4	0.996312	18	0.988942	32	0.984048	46	0.980043
5	0.995562	19	0.98864	33	0.983592	47	0.97989
6	0.995162	20	0.988287	34	0.98344	48	0.979687
7	0.994562	21	0.988086	35	0.983238	49	0.979484
8	0.994011	22	0.987633	36	0.982731	50	0.979484
9	0.99336	23	0.98738	37	0.982478	51	0.979179
10	0.992859	24	0.986977	38	0.982225	52	0.978772
11	0.992107	25	0.986574	39	0.981616	53	0.978772
12	0.991806	26	0.986473	40	0.981363	54	0.978467
13	0.991154	27	0.986069	41	0.981007	55	0.978162

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
56	0.977857	98	0.971474	140	0.965615	182	0.959876
57	0.977653	99	0.971423	141	0.965461	183	0.959565
58	0.977347	100	0.971064	142	0.965358	184	0.959513
59	0.977195	101	0.970808	143	0.965254	185	0.959358
60	0.977042	102	0.970757	144	0.965151	186	0.95915
61	0.976634	103	0.970552	145	0.964842	187	0.958994
62	0.976431	104	0.970398	146	0.96479	188	0.958943
63	0.976125	105	0.970398	147	0.964481	189	0.958839
64	0.976074	106	0.970346	148	0.964377	190	0.958579
65	0.975921	107	0.970193	149	0.964223	191	0.958475
66	0.975717	108	0.969987	150	0.964068	192	0.958164
67	0.975666	109	0.969885	151	0.963913	193	0.958008
68	0.975513	110	0.969731	152	0.963913	194	0.957852
69	0.975411	111	0.969474	153	0.963655	195	0.9578
70	0.975156	112	0.969423	154	0.963345	196	0.9578
71	0.974748	113	0.969269	155	0.963241	197	0.957644
72	0.974645	114	0.969115	156	0.963138	198	0.957384
73	0.974441	115	0.968755	157	0.963035	199	0.957176
74	0.974339	116	0.968652	158	0.96288	200	0.957072
75	0.974339	117	0.968395	159	0.962724	201	0.956864
76	0.974339	118	0.968292	160	0.962621	202	0.956604
77	0.974288	119	0.967984	161	0.962518	203	0.956396
78	0.974186	120	0.967932	162	0.962414	204	0.95624
79	0.974083	121	0.967675	163	0.962311	205	0.955928
80	0.973981	122	0.967572	164	0.962207	206	0.955824
81	0.973879	123	0.967469	165	0.962052	207	0.955772
82	0.973828	124	0.967315	166	0.961845	208	0.955511
83	0.973726	125	0.967161	167	0.961741	209	0.955303
84	0.973675	126	0.967161	168	0.961638	210	0.955147
85	0.973572	127	0.966955	169	0.961586	211	0.954886
86	0.97347	128	0.966903	170	0.961483	212	0.95473
87	0.973214	129	0.966852	171	0.961275	213	0.954678
88	0.972908	130	0.966749	172	0.961224	214	0.954469
89	0.972703	131	0.966697	173	0.961017	215	0.954313
90	0.972549	132	0.966646	174	0.960913	216	0.954156
91	0.972549	133	0.966543	175	0.960706	217	0.954052
92	0.972396	134	0.966543	176	0.96055	218	0.954
93	0.972396	135	0.96644	177	0.960447	219	0.953843
94	0.972242	136	0.966388	178	0.960239	220	0.953739
95	0.971884	137	0.966131	179	0.960187	221	0.953634
96	0.971884	138	0.965925	180	0.960032	222	0.953478
97	0.971782	139	0.965925	181	0.959928	223	0.953269

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
224	0.95306	266	0.946881	308	0.941193	350	0.935259
225	0.952956	267	0.946724	309	0.940982	351	0.935259
226	0.952799	268	0.946566	310	0.940876	352	0.935047
227	0.952642	269	0.946461	311	0.940771	353	0.934887
228	0.952329	270	0.946198	312	0.940559	354	0.934728
229	0.952277	271	0.945935	313	0.9404	355	0.934728
230	0.952016	272	0.945935	314	0.940295	356	0.934675
231	0.951963	273	0.94583	315	0.940189	357	0.934462
232	0.951702	274	0.945778	316	0.94003	358	0.934196
233	0.95165	275	0.945567	317	0.939925	359	0.934037
234	0.95144	276	0.945462	318	0.939766	360	0.933877
235	0.951074	277	0.94541	319	0.939713	361	0.933664
236	0.950813	278	0.945199	320	0.93966	362	0.933664
237	0.950603	279	0.945147	321	0.939607	363	0.933664
238	0.950446	280	0.944989	322	0.939501	364	0.933664
239	0.950342	281	0.944936	323	0.939342	365	0.933664
240	0.950342	282	0.944831	324	0.939342	366	0.933505
241	0.950289	283	0.94462	325	0.939078	367	0.933239
242	0.950185	284	0.94462	326	0.938972	368	0.932866
243	0.950028	285	0.944515	327	0.938919	369	0.932653
244	0.949923	286	0.944357	328	0.938707	370	0.932546
245	0.949713	287	0.944094	329	0.938495	371	0.93228
246	0.949713	288	0.943936	330	0.938389	372	0.931854
247	0.949556	289	0.943831	331	0.938177	373	0.931801
248	0.949556	290	0.943673	332	0.938124	374	0.931747
249	0.949399	291	0.943356	333	0.937913	375	0.931641
250	0.949137	292	0.943198	334	0.937701	376	0.931481
251	0.949085	293	0.942987	335	0.937435	377	0.931374
252	0.949032	294	0.942882	336	0.93717	378	0.931267
253	0.94898	295	0.942777	337	0.936905	379	0.930947
254	0.94877	296	0.942777	338	0.93664	380	0.930947
255	0.948613	297	0.942513	339	0.936534	381	0.930787
256	0.948193	298	0.94246	340	0.936428	382	0.930627
257	0.947931	299	0.942302	341	0.936162	383	0.930147
258	0.947826	300	0.942196	342	0.936056	384	0.929987
259	0.947774	301	0.941985	343	0.936003	385	0.929666
260	0.947616	302	0.941985	344	0.93595	386	0.929506
261	0.947459	303	0.941827	345	0.935897	387	0.929453
262	0.947406	304	0.941774	346	0.935737	388	0.929292
263	0.947301	305	0.94151	347	0.935631	389	0.929079
264	0.947196	306	0.941405	348	0.935578	390	0.928865
265	0.946986	307	0.941352	349	0.935472	391	0.928811

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
392	0.928704	434	0.922646	476	0.916442	518	0.910797
393	0.928277	435	0.922485	477	0.916388	519	0.910688
394	0.92817	436	0.922377	478	0.91628	520	0.910525
395	0.927956	437	0.922108	479	0.916172	521	0.910525
396	0.927849	438	0.922001	480	0.916117	522	0.910471
397	0.927421	439	0.921839	481	0.916009	523	0.910362
398	0.927368	440	0.92157	482	0.915955	524	0.910253
399	0.927207	441	0.921409	483	0.915793	525	0.910144
400	0.926993	442	0.921355	484	0.915522	526	0.909926
401	0.926886	443	0.921301	485	0.915413	527	0.909872
402	0.926725	444	0.921247	486	0.915413	528	0.909817
403	0.926725	445	0.921193	487	0.915142	529	0.909817
404	0.926618	446	0.921139	488	0.915088	530	0.909599
405	0.926457	447	0.920816	489	0.91498	531	0.90949
406	0.926189	448	0.920708	490	0.91498	532	0.909436
407	0.926136	449	0.920493	491	0.91498	533	0.909381
408	0.925975	450	0.920277	492	0.91498	534	0.909381
409	0.925921	451	0.920223	493	0.914926	535	0.909272
410	0.925868	452	0.920062	494	0.914709	536	0.909163
411	0.925707	453	0.9199	495	0.914655	537	0.908945
412	0.925439	454	0.919846	496	0.914492	538	0.908836
413	0.925439	455	0.919576	497	0.914221	539	0.908618
414	0.925332	456	0.919361	498	0.914112	540	0.908618
415	0.925332	457	0.919199	499	0.914058	541	0.908455
416	0.925117	458	0.919091	500	0.913949	542	0.908291
417	0.925063	459	0.918983	501	0.913841	543	0.908073
418	0.924956	460	0.918821	502	0.913732	544	0.908018
419	0.924634	461	0.918821	503	0.913461	545	0.9078
420	0.924634	462	0.918659	504	0.913352	546	0.907745
421	0.924581	463	0.918389	505	0.913243	547	0.907636
422	0.92442	464	0.918173	506	0.913026	548	0.907527
423	0.924312	465	0.918119	507	0.912972	549	0.907472
424	0.924205	466	0.917795	508	0.912809	550	0.907254
425	0.923829	467	0.917632	509	0.912592	551	0.907144
426	0.92356	468	0.917416	510	0.912429	552	0.906926
427	0.923507	469	0.917308	511	0.912265	553	0.906871
428	0.923292	470	0.917254	512	0.912157	554	0.906817
429	0.923184	471	0.917092	513	0.911939	555	0.906598
430	0.923184	472	0.916875	514	0.911776	556	0.90627
431	0.92313	473	0.916821	515	0.911613	557	0.906161
432	0.922969	474	0.916659	516	0.911232	558	0.906161
433	0.922915	475	0.916442	517	0.911069	559	0.906051

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
560	0.905723	602	0.901051	644	0.896247	686	0.890805
561	0.905559	603	0.900829	645	0.896075	687	0.890567
562	0.90534	604	0.900773	646	0.895845	688	0.890507
563	0.905231	605	0.900662	647	0.895729	689	0.890448
564	0.905121	606	0.90055	648	0.895556	690	0.890448
565	0.905121	607	0.900438	649	0.895441	691	0.890328
566	0.905121	608	0.900326	650	0.895268	692	0.890268
567	0.904902	609	0.90027	651	0.89521	693	0.890149
568	0.904738	610	0.900103	652	0.895152	694	0.890089
569	0.904574	611	0.900103	653	0.895152	695	0.890089
570	0.90441	612	0.899934	654	0.894978	696	0.889669
571	0.904355	613	0.89971	655	0.894746	697	0.889548
572	0.904245	614	0.899654	656	0.894688	698	0.889368
573	0.904136	615	0.899485	657	0.894688	699	0.889187
574	0.903971	616	0.899317	658	0.894572	700	0.889067
575	0.903862	617	0.899204	659	0.894514	701	0.888946
576	0.903643	618	0.899148	660	0.894455	702	0.888946
577	0.903533	619	0.899035	661	0.894222	703	0.888825
578	0.903259	620	0.898979	662	0.893988	704	0.888705
579	0.903149	621	0.898866	663	0.893872	705	0.888584
580	0.903094	622	0.898866	664	0.893638	706	0.888341
581	0.902875	623	0.89864	665	0.893579	707	0.88816
582	0.902875	624	0.898527	666	0.893404	708	0.888038
583	0.902765	625	0.898414	667	0.893345	709	0.887856
584	0.902655	626	0.898414	668	0.893287	710	0.887735
585	0.90249	627	0.898187	669	0.893228	711	0.887613
586	0.902269	628	0.898017	670	0.893052	712	0.887309
587	0.902159	629	0.897903	671	0.892935	713	0.887188
588	0.902104	630	0.89779	672	0.892641	714	0.887188
589	0.902049	631	0.897562	673	0.892641	715	0.887005
590	0.901938	632	0.897505	674	0.892523	716	0.886883
591	0.901883	633	0.897448	675	0.892405	717	0.886883
592	0.901773	634	0.897277	676	0.892346	718	0.886883
593	0.901662	635	0.897163	677	0.89211	719	0.886821
594	0.901607	636	0.896992	678	0.892051	720	0.886821
595	0.901551	637	0.896935	679	0.891874	721	0.886821
596	0.901496	638	0.896878	680	0.891756	722	0.886637
597	0.901496	639	0.89682	681	0.891519	723	0.886515
598	0.90133	640	0.89682	682	0.89146	724	0.886453
599	0.90133	641	0.896591	683	0.89146	725	0.886207
600	0.901274	642	0.896534	684	0.891341	726	0.886146
601	0.901274	643	0.896477	685	0.891162	727	0.886084

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
728	0.886084	770	0.88006	812	0.87453	854	0.868112
729	0.886022	771	0.879932	813	0.874398	855	0.868112
730	0.885961	772	0.879676	814	0.874332	856	0.867768
731	0.885899	773	0.87942	815	0.874265	857	0.867768
732	0.885775	774	0.879356	816	0.874265	858	0.867768
733	0.885528	775	0.879292	817	0.874133	859	0.867561
734	0.885528	776	0.8791	818	0.873933	860	0.867422
735	0.885404	777	0.878971	819	0.873866	861	0.867353
736	0.885404	778	0.878779	820	0.8736	862	0.867215
737	0.885032	779	0.878586	821	0.8734	863	0.867215
738	0.884845	780	0.878457	822	0.8734	864	0.867215
739	0.884721	781	0.878264	823	0.873199	865	0.867006
740	0.884597	782	0.878199	824	0.873066	866	0.866937
741	0.884597	783	0.878199	825	0.872865	867	0.866867
742	0.884285	784	0.87807	826	0.872664	868	0.866797
743	0.884035	785	0.87794	827	0.872462	869	0.866728
744	0.88366	786	0.877811	828	0.872395	870	0.866588
745	0.883472	787	0.877811	829	0.872261	871	0.866518
746	0.88316	788	0.877681	830	0.872193	872	0.866518
747	0.883097	789	0.877616	831	0.872059	873	0.866379
748	0.882721	790	0.877551	832	0.871856	874	0.866169
749	0.882532	791	0.877551	833	0.871519	875	0.865889
750	0.88247	792	0.877291	834	0.871384	876	0.865748
751	0.882407	793	0.877226	835	0.871249	877	0.865608
752	0.882344	794	0.877161	836	0.871046	878	0.865467
753	0.882092	795	0.877031	837	0.870775	879	0.865397
754	0.882029	796	0.876835	838	0.870707	880	0.865397
755	0.881902	797	0.876639	839	0.870435	881	0.865186
756	0.881839	798	0.876443	840	0.870367	882	0.865044
757	0.881713	799	0.876443	841	0.870231	883	0.865044
758	0.88165	800	0.876312	842	0.869755	884	0.864974
759	0.881586	801	0.876312	843	0.869619	885	0.864903
760	0.881333	802	0.876246	844	0.869482	886	0.864832
761	0.881142	803	0.876115	845	0.869414	887	0.86469
762	0.881015	804	0.876049	846	0.869209	888	0.864619
763	0.880888	805	0.875918	847	0.869141	889	0.864619
764	0.880825	806	0.875786	848	0.868936	890	0.864477
765	0.880761	807	0.875654	849	0.868799	891	0.864335
766	0.880634	808	0.875522	850	0.868593	892	0.864335
767	0.880315	809	0.87539	851	0.868456	893	0.864192
768	0.880187	810	0.875192	852	0.868319	894	0.864121
769	0.880187	811	0.874795	853	0.86825	895	0.864049

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
896	0.863978	938	0.859012	980	0.854082	1022	0.849815
897	0.863978	939	0.858863	981	0.854005	1023	0.849492
898	0.863978	940	0.858863	982	0.853927	1024	0.849492
899	0.863978	941	0.858714	983	0.853694	1025	0.849492
900	0.863691	942	0.85849	984	0.853616	1026	0.849492
901	0.863691	943	0.85849	985	0.853539	1027	0.84933
902	0.863691	944	0.858266	986	0.853539	1028	0.84933
903	0.863619	945	0.858191	987	0.853383	1029	0.84933
904	0.863474	946	0.857966	988	0.853305	1030	0.849249
905	0.863402	947	0.857891	989	0.853149	1031	0.849086
906	0.86333	948	0.857665	990	0.853071	1032	0.848842
907	0.863186	949	0.85759	991	0.852914	1033	0.848679
908	0.862896	950	0.85759	992	0.852836	1034	0.848598
909	0.862607	951	0.85744	993	0.852836	1035	0.848353
910	0.862317	952	0.85744	994	0.852758	1036	0.848109
911	0.8621	953	0.857364	995	0.852679	1037	0.848109
912	0.862027	954	0.857063	996	0.852601	1038	0.847782
913	0.862027	955	0.856987	997	0.852601	1039	0.847619
914	0.861881	956	0.85676	998	0.852286	1040	0.847619
915	0.861809	957	0.856685	999	0.852049	1041	0.847455
916	0.86159	958	0.856305	1000	0.852049	1042	0.847373
917	0.861517	959	0.856229	1001	0.852049	1043	0.84729
918	0.861444	960	0.856229	1002	0.851812	1044	0.847126
919	0.861078	961	0.856153	1003	0.851495	1045	0.846961
920	0.861078	962	0.856077	1004	0.851336	1046	0.846879
921	0.860785	963	0.855772	1005	0.851336	1047	0.846714
922	0.860712	964	0.855619	1006	0.851257	1048	0.846549
923	0.860712	965	0.855619	1007	0.851257	1049	0.846301
924	0.860492	966	0.855543	1008	0.851098	1050	0.84597
925	0.860345	967	0.855313	1009	0.851018	1051	0.845804
926	0.860197	968	0.855313	1010	0.851018	1052	0.845638
927	0.860124	969	0.85516	1011	0.851018	1053	0.845389
928	0.859976	970	0.855083	1012	0.850858	1054	0.845389
929	0.859828	971	0.85493	1013	0.850778	1055	0.845389
930	0.859828	972	0.854699	1014	0.850778	1056	0.845222
931	0.85968	973	0.854622	1015	0.850778	1057	0.845138
932	0.859606	974	0.854622	1016	0.850618	1058	0.845138
933	0.859458	975	0.854545	1017	0.850538	1059	0.845138
934	0.859384	976	0.854468	1018	0.850217	1060	0.844971
935	0.859384	977	0.854237	1019	0.849895	1061	0.844971
936	0.859235	978	0.854159	1020	0.849895	1062	0.844887
937	0.859012	979	0.854159	1021	0.849895	1063	0.844887

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
1064	0.844719	1106	0.839473	1148	0.834256	1190	0.82861
1065	0.844635	1107	0.839385	1149	0.834256	1191	0.828417
1066	0.844635	1108	0.839122	1150	0.834072	1192	0.828224
1067	0.84455	1109	0.839034	1151	0.834072	1193	0.827837
1068	0.844466	1110	0.838946	1152	0.834072	1194	0.827643
1069	0.844466	1111	0.838946	1153	0.833795	1195	0.827546
1070	0.844128	1112	0.838858	1154	0.83361	1196	0.827546
1071	0.844044	1113	0.838858	1155	0.833518	1197	0.827449
1072	0.844044	1114	0.838682	1156	0.833147	1198	0.827449
1073	0.843959	1115	0.838505	1157	0.833147	1199	0.827254
1074	0.843959	1116	0.838417	1158	0.833055	1200	0.827059
1075	0.843789	1117	0.838328	1159	0.832869	1201	0.826961
1076	0.84362	1118	0.838151	1160	0.832683	1202	0.826863
1077	0.84362	1119	0.838151	1161	0.832683	1203	0.826765
1078	0.843535	1120	0.837973	1162	0.83231	1204	0.826569
1079	0.843364	1121	0.837795	1163	0.832217	1205	0.826373
1080	0.843194	1122	0.837795	1164	0.832124	1206	0.826373
1081	0.843023	1123	0.837706	1165	0.832124	1207	0.826373
1082	0.843023	1124	0.837706	1166	0.831843	1208	0.826373
1083	0.843023	1125	0.837706	1167	0.831655	1209	0.826373
1084	0.842851	1126	0.837527	1168	0.831561	1210	0.826275
1085	0.842508	1127	0.837437	1169	0.831186	1211	0.826078
1086	0.842337	1128	0.837437	1170	0.831092	1212	0.825782
1087	0.842251	1129	0.837257	1171	0.830997	1213	0.825585
1088	0.841993	1130	0.836987	1172	0.830997	1214	0.825487
1089	0.841907	1131	0.836896	1173	0.830997	1215	0.825487
1090	0.841907	1132	0.836806	1174	0.830997	1216	0.825487
1091	0.841821	1133	0.836806	1175	0.830808	1217	0.825487
1092	0.841734	1134	0.836535	1176	0.830524	1218	0.825387
1093	0.841561	1135	0.836263	1177	0.830524	1219	0.825288
1094	0.841389	1136	0.835901	1178	0.830429	1220	0.824991
1095	0.841129	1137	0.835719	1179	0.830144	1221	0.824891
1096	0.841042	1138	0.835719	1180	0.830049	1222	0.824891
1097	0.840956	1139	0.835628	1181	0.830049	1223	0.824891
1098	0.840869	1140	0.835537	1182	0.829858	1224	0.824692
1099	0.840695	1141	0.835446	1183	0.829763	1225	0.824392
1100	0.840695	1142	0.835082	1184	0.829763	1226	0.824392
1101	0.840608	1143	0.835082	1185	0.829667	1227	0.824292
1102	0.840434	1144	0.834899	1186	0.829571	1228	0.823992
1103	0.840259	1145	0.834899	1187	0.829379	1229	0.823791
1104	0.839735	1146	0.834532	1188	0.829187	1230	0.823791
1105	0.839648	1147	0.834532	1189	0.82861	1231	0.823791

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
1232	0.823791	1274	0.818021	1316	0.813698	1358	0.808793
1233	0.82369	1275	0.817809	1317	0.813587	1359	0.808676
1234	0.823489	1276	0.817598	1318	0.813365	1360	0.808676
1235	0.823187	1277	0.817492	1319	0.813365	1361	0.808676
1236	0.822884	1278	0.817386	1320	0.813142	1362	0.808442
1237	0.822884	1279	0.817173	1321	0.813142	1363	0.80809
1238	0.822884	1280	0.817067	1322	0.813142	1364	0.80809
1239	0.822884	1281	0.817067	1323	0.813142	1365	0.807972
1240	0.822681	1282	0.817067	1324	0.812918	1366	0.807855
1241	0.822579	1283	0.817067	1325	0.812918	1367	0.807855
1242	0.822274	1284	0.816854	1326	0.812806	1368	0.807737
1243	0.822172	1285	0.81664	1327	0.812806	1369	0.807737
1244	0.82207	1286	0.81664	1328	0.812581	1370	0.807737
1245	0.82207	1287	0.81664	1329	0.812468	1371	0.807618
1246	0.821968	1288	0.816426	1330	0.812468	1372	0.807618
1247	0.821968	1289	0.816426	1331	0.812356	1373	0.807618
1248	0.821456	1290	0.816211	1332	0.812356	1374	0.8075
1249	0.821149	1291	0.816103	1333	0.812356	1375	0.807143
1250	0.821149	1292	0.816103	1334	0.812243	1376	0.807024
1251	0.821149	1293	0.815887	1335	0.812243	1377	0.806905
1252	0.821149	1294	0.81567	1336	0.81213	1378	0.806905
1253	0.82084	1295	0.815562	1337	0.811903	1379	0.806905
1254	0.820634	1296	0.815562	1338	0.811903	1380	0.806905
1255	0.82053	1297	0.815562	1339	0.811561	1381	0.806786
1256	0.82022	1298	0.815453	1340	0.811446	1382	0.806786
1257	0.82022	1299	0.815236	1341	0.811332	1383	0.806546
1258	0.82022	1300	0.815236	1342	0.811217	1384	0.806427
1259	0.820116	1301	0.815236	1343	0.810988	1385	0.806187
1260	0.819804	1302	0.815236	1344	0.810873	1386	0.806067
1261	0.819804	1303	0.815236	1345	0.810528	1387	0.805826
1262	0.8197	1304	0.815236	1346	0.810298	1388	0.805586
1263	0.819595	1305	0.814798	1347	0.810183	1389	0.805586
1264	0.819387	1306	0.814798	1348	0.810068	1390	0.805344
1265	0.819387	1307	0.814579	1349	0.809953	1391	0.805223
1266	0.819177	1308	0.814359	1350	0.809722	1392	0.805223
1267	0.818968	1309	0.814359	1351	0.809722	1393	0.805102
1268	0.818863	1310	0.814029	1352	0.809722	1394	0.805102
1269	0.818653	1311	0.814029	1353	0.809374	1395	0.805102
1270	0.818548	1312	0.813809	1354	0.809258	1396	0.804981
1271	0.818442	1313	0.813809	1355	0.809142	1397	0.804737
1272	0.818126	1314	0.813809	1356	0.809025	1398	0.804615
1273	0.818126	1315	0.813809	1357	0.808909	1399	0.804494

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
1400	0.804494	1442	0.799108	1484	0.792737	1526	0.788947
1401	0.804371	1443	0.799108	1485	0.792737	1527	0.788947
1402	0.804249	1444	0.799108	1486	0.792737	1528	0.788947
1403	0.804249	1445	0.798849	1487	0.792464	1529	0.788654
1404	0.804126	1446	0.79872	1488	0.792464	1530	0.788654
1405	0.803635	1447	0.79872	1489	0.792464	1531	0.788361
1406	0.803635	1448	0.798332	1490	0.792189	1532	0.788215
1407	0.803635	1449	0.798332	1491	0.792052	1533	0.787921
1408	0.803512	1450	0.798072	1492	0.791776	1534	0.787921
1409	0.803265	1451	0.797942	1493	0.791776	1535	0.787627
1410	0.803265	1452	0.797682	1494	0.791362	1536	0.787479
1411	0.803141	1453	0.797682	1495	0.791223	1537	0.787479
1412	0.803141	1454	0.79729	1496	0.791223	1538	0.787479
1413	0.803017	1455	0.79729	1497	0.791084	1539	0.787479
1414	0.802893	1456	0.796897	1498	0.791084	1540	0.787035
1415	0.802395	1457	0.796765	1499	0.791084	1541	0.787035
1416	0.802395	1458	0.796634	1500	0.791084	1542	0.787035
1417	0.802145	1459	0.796502	1501	0.790945	1543	0.787035
1418	0.801895	1460	0.796502	1502	0.790805	1544	0.787035
1419	0.801895	1461	0.796238	1503	0.790665	1545	0.786736
1420	0.801895	1462	0.796238	1504	0.790665	1546	0.786287
1421	0.801644	1463	0.796105	1505	0.790524	1547	0.786137
1422	0.801519	1464	0.795708	1506	0.790524	1548	0.786137
1423	0.801141	1465	0.795708	1507	0.790524	1549	0.785986
1424	0.801141	1466	0.795441	1508	0.790524	1550	0.785835
1425	0.801141	1467	0.795174	1509	0.790524	1551	0.785684
1426	0.801015	1468	0.795174	1510	0.790383	1552	0.785533
1427	0.800636	1469	0.795174	1511	0.790241	1553	0.785533
1428	0.800256	1470	0.79504	1512	0.790241	1554	0.785381
1429	0.800003	1471	0.794638	1513	0.790098	1555	0.785381
1430	0.800003	1472	0.794503	1514	0.790098	1556	0.785076
1431	0.800003	1473	0.794503	1515	0.790098	1557	0.785076
1432	0.800003	1474	0.794368	1516	0.789813	1558	0.784923
1433	0.800003	1475	0.794368	1517	0.789813	1559	0.784769
1434	0.799875	1476	0.794233	1518	0.789813	1560	0.784769
1435	0.79962	1477	0.793827	1519	0.789813	1561	0.784769
1436	0.799493	1478	0.793691	1520	0.789669	1562	0.784462
1437	0.799365	1479	0.793419	1521	0.789525	1563	0.784308
1438	0.799365	1480	0.793419	1522	0.789237	1564	0.784308
1439	0.799365	1481	0.793147	1523	0.789237	1565	0.784153
1440	0.799365	1482	0.79301	1524	0.789237	1566	0.784153
1441	0.799365	1483	0.792737	1525	0.789092	1567	0.784153

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
1568	0.784153	1610	0.782559	1652	0.778475	1694	0.77443
1569	0.784153	1611	0.782228	1653	0.778298	1695	0.774048
1570	0.784153	1612	0.782228	1654	0.777943	1696	0.774048
1571	0.784153	1613	0.782228	1655	0.777943	1697	0.773856
1572	0.783997	1614	0.782228	1656	0.777943	1698	0.773664
1573	0.783997	1615	0.781895	1657	0.777943	1699	0.773471
1574	0.783997	1616	0.781895	1658	0.777765	1700	0.773471
1575	0.783997	1617	0.781895	1659	0.777765	1701	0.773471
1576	0.783839	1618	0.781895	1660	0.777765	1702	0.773471
1577	0.783682	1619	0.781895	1661	0.777765	1703	0.773277
1578	0.783524	1620	0.781895	1662	0.777765	1704	0.773277
1579	0.783524	1621	0.781895	1663	0.777765	1705	0.773083
1580	0.783366	1622	0.781726	1664	0.777765	1706	0.773083
1581	0.783366	1623	0.781726	1665	0.777584	1707	0.772692
1582	0.783366	1624	0.781558	1666	0.777584	1708	0.772497
1583	0.783207	1625	0.781221	1667	0.777584	1709	0.772497
1584	0.783207	1626	0.781052	1668	0.777584	1710	0.772497
1585	0.783047	1627	0.781052	1669	0.777584	1711	0.772497
1586	0.783047	1628	0.780544	1670	0.777402	1712	0.772497
1587	0.783047	1629	0.780205	1671	0.777402	1713	0.772497
1588	0.783047	1630	0.780035	1672	0.777402	1714	0.7723
1589	0.782887	1631	0.780035	1673	0.777219	1715	0.7723
1590	0.782887	1632	0.780035	1674	0.777219	1716	0.7723
1591	0.782887	1633	0.780035	1675	0.776668	1717	0.772101
1592	0.782887	1634	0.780035	1676	0.776668	1718	0.771505
1593	0.782887	1635	0.780035	1677	0.776301	1719	0.771505
1594	0.782887	1636	0.780035	1678	0.776116	1720	0.770906
1595	0.782887	1637	0.779691	1679	0.776116	1721	0.770906
1596	0.782887	1638	0.779691	1680	0.775931	1722	0.770505
1597	0.782887	1639	0.779691	1681	0.775931	1723	0.770304
1598	0.782887	1640	0.779345	1682	0.77556	1724	0.770103
1599	0.782887	1641	0.779172	1683	0.77556	1725	0.769699
1600	0.782887	1642	0.778825	1684	0.77556	1726	0.769699
1601	0.782887	1643	0.778825	1685	0.775373	1727	0.769699
1602	0.782887	1644	0.778652	1686	0.774998	1728	0.769699
1603	0.782723	1645	0.778652	1687	0.774998	1729	0.769699
1604	0.782723	1646	0.778652	1688	0.774809	1730	0.769496
1605	0.782723	1647	0.778652	1689	0.774809	1731	0.769293
1606	0.782559	1648	0.778652	1690	0.77462	1732	0.769293
1607	0.782559	1649	0.778652	1691	0.77462	1733	0.769293
1608	0.782559	1650	0.778652	1692	0.77462	1734	0.769293
1609	0.782559	1651	0.778475	1693	0.77462	1735	0.769088

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
1736	0.768883	1759	0.764701	1782	0.760782	1805	0.758303
1737	0.768883	1760	0.764487	1783	0.760337	1806	0.758303
1738	0.768678	1761	0.764487	1784	0.760337	1807	0.758303
1739	0.768472	1762	0.764487	1785	0.760337	1808	0.75807
1740	0.768472	1763	0.764487	1786	0.760337	1809	0.757837
1741	0.768472	1764	0.764057	1787	0.760337	1810	0.757837
1742	0.768265	1765	0.763412	1788	0.759442	1811	0.757837
1743	0.768265	1766	0.763196	1789	0.759217	1812	0.757602
1744	0.76785	1767	0.763196	1790	0.759217	1813	0.757602
1745	0.76785	1768	0.763196	1791	0.759217	1814	0.757602
1746	0.767434	1769	0.763196	1792	0.759217	1815	0.757602
1747	0.766599	1770	0.763196	1793	0.759217	1816	0.757602
1748	0.766599	1771	0.763196	1794	0.759217	1817	0.757602
1749	0.766389	1772	0.76276	1795	0.758991	1818	0.757365
1750	0.765758	1773	0.762542	1796	0.758991	1819	0.757365
1751	0.765758	1774	0.762542	1797	0.758991	1820	0.757365
1752	0.765547	1775	0.762323	1798	0.758991	1821	0.756888
1753	0.765125	1776	0.761884	1799	0.758762	1822	0.756888
1754	0.764913	1777	0.761664	1800	0.758533	1823	0.756888
1755	0.764913	1778	0.761224	1801	0.758533	1824	0.756409
1756	0.764701	1779	0.761003	1802	0.758303	1825	0.756169
1757	0.764701	1780	0.760782	1803	0.758303		
1758	0.764701	1781	0.760782	1804	0.758303		

21.2.C Values Used in the Calculation of Biological Disadvantages

21.2.C.1 Probability of Incompatible Lung Donors Based on Height

Table 21-9 lists the proportion of incompatible donors based on the candidate's height and diagnosis group.

Table 21-9 Proportion of Incompatible Donors Based on Lung Height

Candidate height (cm)	Proportion for Candidates in Diagnosis Groups A and C	Proportion for Candidates in Diagnosis Group B	Proportion for Candidates in Diagnosis Group D
63 or less	0.9989	0.9989	0.9989
64	0.9982	0.9989	0.9989
65	0.9982	0.9989	0.9989
66	0.9978	0.9989	0.9989
67	0.9975	0.9989	0.9989
68	0.9975	0.9989	0.9989
69	0.9975	0.9982	0.9989
70	0.9975	0.9982	0.9989

Candidate height (cm)	Proportion for Candidates in Diagnosis Groups A and C	Proportion for Candidates in Diagnosis Group B	Proportion for Candidates in Diagnosis Group D
71	0.9971	0.9975	0.9982
72	0.9971	0.9975	0.9982
73	0.9967	0.9975	0.9978
74	0.9967	0.9975	0.9975
75	0.9967	0.9975	0.9975
76	0.9971	0.9971	0.9975
77	0.9967	0.9971	0.9975
78	0.9967	0.9967	0.9971
79	0.9967	0.9967	0.9971
80	0.9967	0.9971	0.9967
81	0.9967	0.9971	0.9967
82	0.9971	0.9967	0.9967
83	0.9971	0.9967	0.9967
84	0.9975	0.9967	0.9964
85	0.9975	0.9967	0.9967
86	0.9975	0.9971	0.9967
87	0.9967	0.9971	0.9967
88	0.9967	0.9975	0.9967
89	0.9967	0.9975	0.9967
90	0.9967	0.9975	0.9967
91	0.9967	0.9975	0.9971
92	0.9964	0.9967	0.9971
93	0.9964	0.9967	0.9975
94	0.9960	0.9967	0.9967
95	0.9960	0.9967	0.9967
96	0.9960	0.9967	0.9967
97	0.9960	0.9964	0.9967
98	0.9960	0.9964	0.9967
99	0.9956	0.9960	0.9964
100	0.9964	0.9960	0.9964
101	0.9964	0.9960	0.9960
102	0.9971	0.9960	0.9960
103	0.9971	0.9960	0.9960
104	0.9971	0.9964	0.9960
105	0.9971	0.9964	0.9960
106	0.9971	0.9967	0.9956
107	0.9971	0.9971	0.9956
108	0.9975	0.9971	0.9956
109	0.9975	0.9971	0.9964
110	0.9967	0.9971	0.9964
111	0.9967	0.9975	0.9967
112	0.9964	0.9971	0.9971
113	0.9964	0.9975	0.9971

Candidate height (cm)	Proportion for Candidates in Diagnosis Groups A and C	Proportion for Candidates in Diagnosis Group B	Proportion for Candidates in Diagnosis Group D
114	0.9964	0.9975	0.9967
115	0.9956	0.9967	0.9967
116	0.9949	0.9967	0.9971
117	0.9935	0.9964	0.9964
118	0.9917	0.9964	0.9967
119	0.9913	0.9964	0.9964
120	0.9877	0.9956	0.9960
121	0.9866	0.9949	0.9960
122	0.9837	0.9924	0.9956
123	0.9822	0.9913	0.9949
124	0.9815	0.9913	0.9935
125	0.9731	0.9877	0.9917
126	0.9728	0.9866	0.9913
127	0.9586	0.9822	0.9877
128	0.9503	0.9822	0.9866
129	0.9488	0.9815	0.9837
130	0.9274	0.9731	0.9815
131	0.9270	0.9728	0.9808
132	0.8987	0.9517	0.9731
133	0.8824	0.9503	0.9728
134	0.8795	0.9492	0.9586
135	0.8410	0.9274	0.9499
136	0.8225	0.9267	0.9485
137	0.8156	0.8987	0.9270
138	0.7586	0.8824	0.9267
139	0.7525	0.8799	0.8987
140	0.6947	0.8261	0.8824
141	0.6697	0.8218	0.8795
142	0.6639	0.8156	0.8407
143	0.5800	0.7586	0.8221
144	0.5735	0.7525	0.8156
145	0.5183	0.6762	0.7586
146	0.4973	0.6682	0.7525
147	0.4904	0.6642	0.6947
148	0.4174	0.5800	0.6697
149	0.4131	0.5735	0.6639
150	0.3673	0.5002	0.5797
151	0.3426	0.4973	0.5731
152	0.3372	0.4911	0.5183
153	0.2548	0.4174	0.4966
154	0.2526	0.4131	0.4897
155	0.2069	0.3481	0.4167
156	0.1902	0.3434	0.4123

Candidate height (cm)	Proportion for Candidates in Diagnosis Groups A and C	Proportion for Candidates in Diagnosis Group B	Proportion for Candidates in Diagnosis Group D
157	0.1837	0.3387	0.3673
158	0.1165	0.2555	0.3419
159	0.1143	0.2519	0.3358
160	0.0947	0.1917	0.2515
161	0.0889	0.1909	0.2490
162	0.0857	0.1866	0.2040
163	0.0806	0.1165	0.1858
164	0.0820	0.1140	0.1789
165	0.0809	0.1027	0.1103
166	0.0897	0.0893	0.1089
167	0.0904	0.0998	0.0918
168	0.1267	0.0820	0.0799
169	0.1285	0.0824	0.0770
170	0.1310	0.1027	0.0588
171	0.1822	0.0900	0.0584
172	0.1862	0.1183	0.0708
173	0.2083	0.1296	0.0664
174	0.2479	0.1310	0.0679
175	0.2541	0.1848	0.0857
176	0.3307	0.1855	0.0838
177	0.3379	0.1924	0.1118
178	0.3637	0.2479	0.1252
179	0.4258	0.2541	0.1281
180	0.4327	0.3303	0.1815
181	0.5064	0.3368	0.1840
182	0.5096	0.3423	0.1909
183	0.5358	0.4258	0.2479
184	0.5898	0.4323	0.2537
185	0.5942	0.5064	0.3292
186	0.6599	0.5093	0.3358
187	0.6675	0.5162	0.3416
188	0.6719	0.5898	0.4258
189	0.7564	0.5942	0.4323
190	0.7608	0.6399	0.5064
191	0.8243	0.6653	0.5093
192	0.8279	0.6715	0.5162
193	0.8334	0.7564	0.5898
194	0.9056	0.7604	0.5942
195	0.9089	0.8062	0.6399
196	0.9408	0.8261	0.6653
197	0.9430	0.8334	0.6715
198	0.9459	0.9056	0.7564
199	0.9724	0.9089	0.7604

Candidate height (cm)	Proportion for Candidates in Diagnosis Groups A and C	Proportion for Candidates in Diagnosis Group B	Proportion for Candidates in Diagnosis Group D
200	0.9735	0.9281	0.8062
201	0.9779	0.9423	0.8261
202	0.9880	0.9459	0.8334
203	0.9880	0.9724	0.9056
204	0.9931	0.9731	0.9089
205	0.9946	0.9750	0.9281
206	0.9953	0.9880	0.9423
207	0.9975	0.9880	0.9459
208	0.9975	0.9931	0.9724
209	0.9989	0.9942	0.9731
210	0.9989	0.9946	0.9750
211	0.9989	0.9975	0.9880
212	0.9989	0.9975	0.9880
213	0.9993	0.9989	0.9931
214	1.0000	0.9989	0.9942
215	1.0000	0.9989	0.9946
216	1.0000	0.9989	0.9975
217	1.0000	0.9993	0.9975
218	1.0000	1.0000	0.9989
219	1.0000	1.0000	0.9989
220	1.0000	1.0000	0.9989
221	1.0000	1.0000	0.9989
222	1.0000	1.0000	0.9993
223 or more	1.0000	1.0000	1.0000