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 and Bylaws. The OPTN will determine the required method and format for reporting any information required by OPTN Policies and Bylaws, 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 available to the candidate according to Policy. Allocation MELD or PELD score includes liver-intestine points.

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.

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 who does not have a match identified during the same match run as the donor's paired candidate and continues a chain in a future match run.

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 group and haplotype frequencies for the different ethnic groups 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.

Covered Vascularized Composite Allograft body parts (covered VCAs)

The body parts listed below are covered VCAs. 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, internal and external male and female genitalia, and urinary bladder	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-heartbeating, 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)

o 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):
  - o Bacterial: tuberculosis, gangrenous bowel or perforated bowel or intra-abdominal sepsis
  - o 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 HIV positive organ procured for transplantation into an HIV positive recipient at a transplant hospital that meets the requirements in *Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors* would still meet the requirements of an eligible death, according to the OPTN Final Rule.
  - o Fungal: active infection with cryptococcus, aspergillus, histoplasma, coccidioides, active candidemia or invasive yeast infection
  - o 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.

Graft failure
For all organs except pancreas, 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

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 Bylaws*.

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.

Lung allocation score (LAS)
The scoring system used to measure illness severity in the allocation of lungs to candidates 12 years and older.

M

Match MELD or PELD Score
The MELD or PELD score available to the candidate at the time of the match for a deceased donor liver or liver-intestine.

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 adults.

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 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, and OPTN 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.

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

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.

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.

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 Washington Regional Transplant Community (DCTC) 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

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 and Bylaws.

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 and Bylaws.
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 Application for 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 *Article XI: Adoption of Policies* of the *OPTN Bylaws*.

The application must address *all* of the following:

1. The purpose for the proposed variance and how the variance will further this purpose.
2. 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. Committees will not review a member's variance application unless the applicant receives affirmative support from at least 75% of the members required to join the proposed variance.
3. 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.
4. An evaluation plan with objective criteria to measure the variance's success achieving the variance's stated purpose.
5. Any anticipated difficulties in demonstrating whether the variance is achieving its stated purpose.
6. 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. However, if the application to join an existing open variance does not receive affirmative support from all of the members required to join by the application, the OPTN Contractor may not approve the application and only the sponsoring Committee may approve the application.

1.3.D Reporting Requirements for Variances

Members participating in a variance must submit data and status reports to the sponsoring Committee 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

Participating members must also provide a final report to the sponsoring Committee at least six months before the variance's expiration date. 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. The previous sentence does not apply to covered VCA transplants; instead, members must allocate covered VCAs according to *Policy 12.2: VCA 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* of 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.

2.7.A Exceptions to HIV Screening Requirement

Exceptions to the HIV screening requirement may be made for organs *other than* kidneys, when, in the medical judgment of the host OPO and recipient transplant hospital or OPO, an extreme medical emergency warrants the transplantation of an organ that has not been tested for HIV.

In this case the host OPO must do *both* of the following:

1. Provide all available deceased donor medical and social history to the transplant program.
2. Treat the deceased donor as having any risk criteria for acute HIV, HBV, or HCV infection according to the *U.S. Public Health Service (PHS) Guideline*.

In this case the receiving transplant hospital must:

- Inform the potential transplant recipient or the recipient's authorized agent before transplantation according to *Policy 15.3.B: Donors with Risk Identified Pre-Transplant*
- Obtain HIV screening test results prior to storing, sharing, or using the extra vessels in another recipient, according to *Policy 16.6: Extra Vessels Transplant and Storage*.

2.7.B 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.

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. Height
9. Organ anatomy and recovery information
10. Sex
11. All vital signs, including blood pressure, heart rate, and temperature
12. Weight
13. 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. Biopsy results, if performed
3. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers
4. Injuries to or abnormalities of blood vessels, ureters, or kidney
5. Kidney perfusion information, if performed
6. Kidney laterality

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, 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, 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, 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, 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 *either* of the following:

1. The potential deceased donor's attending physician at the time of death
2. The physician who declares the time of the potential deceased donor's death

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-heartbeating, 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 is authorized to declare death must not be a member of the OPO or the organ recovery team. Circulatory death is death defined as the irreversible cessation of circulatory and respiratory functions. 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 Computer Systems

Only the following categories of members may access the match system:

1. Transplant hospitals
2. Organ procurement organizations (OPO)
3. Histocompatibility laboratories

The waiting list may only be accessed by members, and members may not use the match system for non-members or add candidates to the waiting list on behalf of non-member transplant hospitals.

3.1.A Non-member Access

Members may not use the match system for non-members or allow non-members access to the match system unless *all* of the following requirements are met:

1. The non-member is assisting the member with facilitating organ transplants, placing organs for purposes other than transplantation, or reporting data to the OPTN.
2. The member has a data use agreement (DUA) with the non-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 non-members.

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*:

- The transplant program does not accept candidates with multiple registrations
- 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 Bylaws Section 1.2(D): Registration Fees*.

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 and is at least 12 years old	No time
Lung and is less than 12 years old	Unlimited time
Pancreas	Unlimited time
Pancreas islet	Unlimited time
All other organs	Up to 30 days

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 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.

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:

1. The candidate must be registered at the new transplant program.
2. The candidate must currently be, or have previously been, registered at the earlier transplant program.
3. The candidate must sign a Wait Time Transfer Form, requesting transfer of primary waiting time to the new transplant program.
4. 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.
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

3.8 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 Bylaws. 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, 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

For the purposes of this policy, a human leukocyte antigen (HLA) critical discrepancy is a difference among non-equivalent values, according to *Policy 4.10: Reference Tables of HLA Antigen Values and Split Equivalences*, at one or more loci in a candidate's, donor's, or recipient's HLA typing.

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 Critical Discrepant Donor and Recipient HLA Typing Results

The laboratory director of each laboratory involved in the HLA typing discrepancy, or their designee, must identify the correct HLA typing and report the reason for the discrepancy to the OPTN within 60 days of discovery of the discrepancy.

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 Crossmatching

4.6.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.

4.6.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.

4.7 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.

4.8 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.

4.9 HLA Antigen Values and Split Equivalences

HLA matching of antigens is based on the antigens which are listed in *Policy 4.10: Reference Tables of HLA Antigen Values and Split Equivalences*. The Histocompatibility Committee must review and recommend any changes needed to the tables on an annual basis. Changes to the tables in Policy 4.10 are eligible for future expedited updates pursuant to OPTN Bylaw 11.8: *Expedited Actions*. For matching purposes, split antigens not on this list will be indicated on the waiting list as the parent antigens and will match only with the corresponding parent antigens.

4.10 Reference Tables of HLA Antigen Values and Split Equivalences

Tables 4-2, 4-3, and *4-4* show candidate-donor antigen equivalencies and whether they are mismatches. For each candidate antigen, the donor antigens that are not mismatched are listed below. All other combinations are considered mismatches.

Examples of how "Matching Antigen Equivalences" works:

- If the candidate types as B70: only donors that type as B70 are considered matched. Donors typed as B71 or B72 are considered mismatched.
- If the candidate types as B71: only donors that type as B71, B15:10, or B15:18 are considered matched. Donors typed as B70 are considered mismatched.

Table 4-2: HLA A Matching Antigen Equivalences

Candidate A-Locus Antigen	Equivalent Donor Antigens
1	1, 01:01, 01:02
01:01	01:01, 1
01:02	01:02, 1
2	2, 02:01, 02:02, 02:03, 02:05, 02:06, 02:07, 02:10, 02:18
02:01	02:01, 2
02:02	02:02, 2
02:03	02:03, 2
02:05	02:05, 2

Candidate A-Locus Antigen	Equivalent Donor Antigens
02:06	02:06, 2
02:07	02:07, 2
02:10	02:10, 2
02:18	02:18, 2
3	3, 03:01, 03:02, 32:04
03:01	03:01, 3
03:02	03:02, 3
9	9
10	10
11	11, 11:01, 11:02
11:01	11:01, 11
11:02	11:02, 11
19	19
23	23
24	24, 24:02, 24:03
24:02	24:02, 24
24:03	24:03, 24
25	25
26	26, 26:01, 26:02, 26:03
26:01	26:01, 26
26:02	26:02, 26
26:03	26:03, 26
28	28
29	29, 29:01, 29:02
29:01	29:01, 29
29:02	29:02, 29
30	30, 30:01, 30:02
30:01	30:01, 30
30:02	30:02, 30
31	31
32	32
32:04	32:04, 3
33	33, 33:01, 33:03
33:01	33:01, 33
33:03	33:03, 33
34	34, 34:01, 34:02
34:01	34:01, 34
34:02	34:02, 34

Candidate A-Locus Antigen	Equivalent Donor Antigens
36	36
43	43
66	66, 66:01, 66:02
66:01	66:01, 66
66:02	66:02, 66
68	68, 68:01, 68:02
68:01	68:01, 68
68:02	68:02, 68
69	69
74	74
80	80

Table 4-3: HLA B Matching Antigen Equivalences

Candidate B-Locus Antigen	Equivalent Donor Antigens
5	5
7	7, 07:02, 07:03, 07:14
07:02	07:02, 7
07:03	07:03, 7
07:14	07:14, 7
8	8, 08:01, 08:02, 08:03, 08:04
08:01	08:01, 8
08:02	08:02, 8
08:03	08:03, 8
08:04	08:04, 8
12	12
13	13, 13:01, 13:02
13:01	13:01, 13
13:02	13:02, 13
14	14
14:01	14:01, 64
14:02	14:02, 65
15	15
15:01	15:01, 62
15:02	15:02, 75
15:03	15:03, 72
15:04	15:04, 62
15:06	15:06, 62
15:07	15:07, 62
15:10	15:10, 71
15:11	15:11, 75
15:12	15:12, 76
15:13	15:13, 77
15:16	15:16, 63
15:17	15:17, 63
15:18	15:18, 71
15:20	15:20, 62
15:21	15:21, 75
15:24	15:24
15:27	15:27, 62
16	16
17	17
18	18
21	21
22	22
27	27, 27:03, 27:04, 27:05, 27:06
27:03	27:03, 27
27:04	27:04, 27

Candidate B-Locus Antigen	Equivalent Donor Antigens
27:05	27:05, 27
27:06	27:06, 27
27:08	27:08
35	35, 35:01, 35:02, 35:03 35:08, 35:12
35:01	35:01, 35
35:02	35:02, 35
35:03	35:03, 35
35:08	35:08, 35
35:12	35:12, 35
37	37
38	38, 38:01, 38:02
38:01	38:01, 38
38:02	38:02, 38
39	39, 39:01, 39:02, 39:04, 39:05, 39:06, 39:13
39:01	39:01, 39
39:02	39:02, 39
39:04	39:04, 39
39:05	39:05, 39
39:06	39:06, 39
39:13	39:13, 39
40	40
40:01	40:01, 60
40:02	40:02, 61
40:03	40:03, 61
40:04	40:04, 61
40:05	40:05, 50
40:06	40:06, 61
41	41, 41:01, 41:02
41:01	41:01, 41
41:02	41:02, 41
42	42, 42:01, 42:02
42:01	42:01, 42
42:02	42:02, 42
44	44, 44:02, 44:03
44:02	44:02, 44
44:03	44:03, 44
45	45, 50:02
46	46
47	47
48	48, 48:01, 48:02
48:01	48:01, 48
48:02	48:02, 48
49	49
50	50, 50:01, 40:05
50:01	50:01, 50

Candidate B-Locus Antigen	Equivalent Donor Antigens
50:02	50:02, 45
51	51, 51:01, 51:02
51:01	51:01, 51
51:02	51:02, 51
52	52
53	53
54	54
55	55, 55:01, 55:02, 55:04
55:01	55:01, 55
55:02	55:02, 55
55:04	55:04, 55
56	56, 56:01, 56:03
56:01	56:01, 56
56:03	56:03, 56
57	57, 57:01, 57:03
57:01	57:01, 57
57:03	57:03, 57
58	58
59	59
60	60, 40:01
61	61, 40:02, 40:03, 40:04, 40:06
62	62, 15:01, 15:04, 15:06, 15:07, 15:20, 15:27
63	63, 15:16, 15:17
64	64, 14:01
65	65, 14:02
67	67
70	70
71	71, 15:10, 15:18
72	72, 15:03
73	73
75	75, 15:02, 15:11, 15:21
76	76, 15:12
77	77, 15:13
78	78
81	81
82	82
83:01	83:01

Table 4-4: HLA DR Matching Antigen Equivalences

Candidate DR-Locus Antigen	Equivalent Donor Antigens
1	1, 01:01, 01:02
01:01	01:01, 1
01:02	01:02, 1
01:03	01:03, 103

Candidate DR-Locus Antigen	Equivalent Donor Antigens
2	2
3	3, 03:01, 03:02, 03:03
03:01	03:01, 17
03:02	03:02, 18
03:03	03:03, 18
4	4, 04:01, 04:02, 04:03, 04:04, 04:05, 04:06, 04:07, 04:10, 04:11
04:01	04:01, 4
04:02	04:02, 4
04:03	04:03, 4
04:04	04:04, 4
04:05	04:05, 4
04:06	04:06, 4
04:07	04:07, 4
04:10	04:10, 4
04:11	04:11, 4
5	5
6	6
7	7
8	8, 08:01, 08:02, 08:03, 08:07
08:01	08:01, 8
08:02	08:02, 8
08:03	08:03, 8
08:07	08:07, 8
9	9, 09:01, 09:02
09:01	09:01, 9
09:02	09:02, 9
10	10
11	11, 11:01,11:03, 11:04
11:01	11:01, 11
11:03	11:03, 11
11:04	11:04, 11
12	12, 12:01, 12:02
12:01	12:01, 12
12:02	12:02, 12
13	13, 13:01, 13:02, 13:03, 13:05
13:01	13:01, 13
13:02	13:02, 13
13:03	13:03, 13
13:05	13:05, 13
14	14, 14:01, 14:02, 14:03, 14:04, 14:05, 14:06, 14:54
14:01	14:01, 14, 14:54
14:02	14:02, 14
14:03	14:03, 14
14:04	14:04, 14
14:05	14:05, 14

Candidate DR-Locus Antigen	Equivalent Donor Antigens
14:06	14:06, 14
14:54	14:54, 14, 14:01
15	15, 15:01, 15:02, 15:03
15:01	15:01, 15
15:02	15:02, 15
15:03	15:03, 15
16	16, 16:01, 16:02
16:01	16:01, 16
16:02	16:02, 16
17	17, 03:01
18	18, 03:02, 03:03
103	103, 01:03

- Tables 4-5, 4-6, 4-7, 4-8, 4-9, 4-10, 4-11, 4-12, 4-13, and 4-14 show candidate-donor unacceptable antigen combinations. For each candidate antigen, the donor antigens that are unacceptable are listed below.
- Table 4-15 shows a candidate unacceptable epitopes for DPB1 and their corresponding donor HLA types.
- Table 4-16 shows the values that can be reported as valid DPB1 HLA typing.
- Table 4-17 shows additional unacceptable antigen equivalences to be used in the Calculated Panel Reactive Antibody (CPRA) only.

Examples of how “Unacceptable Antigen Equivalences” works:
If a candidate has B70 listed as an “unacceptable antigen”, donors typed as B70, B71, B72, 15:03, 15:10, or 15:18 are considered unacceptable.

Table 4-5: HLA A Unacceptable Antigen Equivalences

Candidate Unacceptable A-Locus Antigen	Donor Equivalent Antigens
1	1, 01:01, 01:02
01:01	01:01
01:02	01:02
2	2, 02:01, 02:02, 02:03, 02:05, 02:06, 02:07, 02:10, 02:18
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, 03:01, 03:02, 32:04
03:01	03:01

Candidate Unacceptable A-Locus Antigen	Donor Equivalent Antigens
03:02	03:02
9	9, 23, 24, 24:02, 24:03
10	10, 25, 26, 26:01, 26:02, 26:03, 34, 34:01, 34:02, 66, 66:01, 66:02, 43
11	11, 11:01, 11:02
11:01	11:01
11:02	11:02
19	19, 29, 29:01, 29:02, 30, 30:01, 30:02, 31, 32, 33, 33:01, 33:03, 74
23	23
24	24, 24:02, 24:03
24:02	24:02
24:03	24:03
25	25
26	26, 26:01, 26:02, 26:03
26:01	26:01
26:02	26:02
26:03	26:03
28	28, 68, 69, 68:01, 68:02
29	29, 29:01, 29:02
29:01	29:01
29:02	29:02
30	30, 30:01, 30:02
30:01	30:01
30:02	30:02
31	31
32	32
32:04	32:04
33	33, 33:01, 33:03
33:01	33:01
33:03	33:03
34	34, 34:01, 34:02
34:01	34:01
34:02	34:02
36	36
43	43
66	66, 66:01, 66:02
66:01	66:01
66:02	66:02

Candidate Unacceptable A-Locus Antigen	Donor Equivalent Antigens
68	68, 68:01, 68:02
68:01	68:01
68:02	68:02
69	69
74	74
80	80

Table 4-6 HLA B Unacceptable Antigen Equivalences

Candidate Unacceptable B-Locus Antigen	Donor Equivalent Antigens
5	5, 51, 51:01, 51:02, 52
7	7, 07:02, 07:03, 07:14
07:02	07:02
07:03	07:03
07:14	07:14
8	8, 08:01, 08:02, 08:03, 08:04
08:01	08:01
08:02	08:02
08:03	08:03
08:04	08:04
12	12, 44, 44:02, 44:03, 45, 50:02
13	13, 13:01, 13:02
13:01	13:01
13:02	13:02
14	14, 64, 65, 14:01, 14:02
14:01	14:01, 64
14:02	14:02, 65
15	15, 62, 63, 70, 71, 72, 75, 76, 77, 15:01, 15:02, 15:03, 15:04, 15:06, 15:07, 15:10, 15:11, 15:12, 15:13, 15:16, 15:17, 15:18, 15:20, 15:21, 15:24, 15:27
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

Candidate Unacceptable B-Locus Antigen	Donor Equivalent Antigens
15:20	15:20
15:21	15:21
15:24	15:24
15:27	15:27
16	16, 38, 38:01, 38:02, 39, 39:01, 39:02, 39:04, 39:05, 39:06, 39:13
17	17, 57, 57:01, 57:03, 58
18	18
21	21, 49, 50, 40:05, 50:01
22	22, 54, 55, 55:01, 55:02, 55:04, 56, 56:01, 56:03
27	27, 27:03, 27:04, 27:05, 27:06
27:03	27:03
27:04	27:04
27:05	27:05
27:06	27:06
27:08	27:08
35	35, 35:01, 35:02, 35:03, 35:08, 35:12
35:01	35:01
35:02	35:02
35:03	35:03
35:08	35:08
35:12	35:12
37	37
38	38, 38:01, 38:02
38:01	38:01
38:02	38:02
39	39, 39:01, 39:02, 39:04, 39:05, 39:06,39:13
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, 40:01, 40:02, 40:03, 40:04, 40:06
40:01	40:01, 60
40:02	40:02
40:03	40:03
40:04	40:04
40:05	40:05, 50
40:06	40:06
41	41, 41:01, 41:02
41:01	41:01
41:02	41:02
42	42, 42:01, 42:02
42:01	42:01

Candidate Unacceptable B-Locus Antigen	Donor Equivalent Antigens
42:02	42:02
44	44, 44:02, 44:03
44:02	44:02
44:03	44:03
45	45, 50:02
46	46
47	47
48	48, 48:01, 48:02
48:01	48:01
48:02	48:02
49	49
50	50, 40:05, 50:01
50:01	50:01
50:02	50:02, 45
51	51, 51:01, 51:02
51:01	51:01
51:02	51:02
52	52
53	53
54	54
55	55, 55:01, 55:02, 55:04
55:01	55:01
55:02	55:02
55:04	55:04
56	56, 56:01, 56:03
56:01	56:01
56:03	56:03
57	57, 57:01, 57:03
57:01	57:01
57:03	57:03
58	58
59	59
60	60, 40:01
61	61, 40:02, 40:03, 40:04, 40:06
62	62, 15:01, 15:04, 15:06, 15:07, 15:20, 15:27
63	63, 15:16, 15:17
64	64, 14:01
65	65, 14:02
67	67
70	70, 71, 72, 15:03, 15:10, 15:18
71	71, 15:10, 15:18
72	72, 15:03
73	73
75	75, 15:02, 15:11, 15:21

Candidate Unacceptable B-Locus Antigen	Donor Equivalent Antigens
76	76, 15:12
77	77, 15:13
78	78
81	81
82	82
83:01	83:01
Bw4	Bw4, 08:02, 08:03, 5, 13, 13:01, 13:02, 15:13, 15:16, 15:17, 15:24,17, 27, 27:03, 27:04, 27:05, 27:06, 37, 38, 38:01, 38:02, 44, 44:02, 44:03, 47, 49, 51, 51:01, 51:02, 52, 53, 57, 57:01, 57:03, 58, 59, 63, 77
Bw6	Bw6, 7, 07:02, 07:03, 07:14, 8, 08:01, 08:04, 14, 14:01, 14:02,15:01, 15:02, 15:03, 15:04, 15:06, 15:07, 15:10, 15:11,15:12, 15:18, 15:20, 15:21, 15:27, 18, 22, 27:08, 35, 35:01, 35:02, 35:03, 35:08, 35:12, 39, 39:01, 39:02, 39:04, 39:05, 39:06, 39:13, 40, 40:01, 40:02, 40:03, 40:04, 40:05, 40:06, 41, 41:01, 41:02, 42, 42:01, 42:02, 45, 48, 48:01 48:02, 50, 50:01, 50:02, 54, 55, 55:01, 55:02, 55:04, 56, 56:01, 56:03, 60, 61, 62, 64, 65, 67, 70, 71, 72, 75, 76, 78, 81, 82

Table 4-7: HLA C Unacceptable Antigen Equivalences

Candidate Unacceptable C-Locus Antigen	Donor Equivalent Antigens
01	01, 01:02, 01:03
01:02	01:02
01:03	01:03
02	02, 02:02, 02:10
02:02	02:02
02:10	02:10
03	03, 03:02, 03:03, 03:04, 03:05, 03:06, 09, 10
03:02	03:02
03:03	03:03
03:04	03:04
03:05	03:05
03:06	03:06
04	04, 04:01, 04:03, 04:04, 04:07
04:01	04:01
04:03	04:03
04:04	04:04
04:07	04:07
05	05, 05:01
05:01	05:01
06	06, 06:02
06:02	06:02
07	07, 07:01, 07:02, 07:04, 07:06, 07:18
07:01	07:01
07:02	07:02

Candidate Unacceptable C-Locus Antigen	Donor Equivalent Antigens
07:04	07:04
07:06	07:06
07:18	07:18
08	08, 08:01, 08:02, 08:03, 08:04
08:01	08:01
08:02	08:02
08:03	08:03
08:04	08:04
09	09, 03:03
10	10, 03:02, 03:04, 03:06
12	12, 12:02, 12:03, 12:04
12:02	12:02
12:03	12:03
12:04	12:04
14	14, 14:02, 14:03
14:02	14:02
14:03	14:03
15	15, 15:02, 15:04, 15:05, 15:06, 15:09
15:02	15:02
15:04	15:04
15:05	15:05
15:06	15:06
15:09	15:09
16	16, 16:01, 16:02, 16:04
16:01	16:01
16:02	16:02
16:04	16:04
17	17, 17:01, 17:03
17:01	17:01
17:03	17:03
18	18, 18:01, 18:02
18:01	18:01
18:02	18:02

Table 4-8: HLA DR Unacceptable Antigen Equivalences

Candidate Unacceptable DR Locus Antigen	Donor Equivalent Antigens
1	1, 01:01, 01:02
01:01	01:01
01:02	01:02
01:03	01:03, 103
2	2, 15, 15:01, 15:02, 15:03, 16, 16:01, 16:02
3	3, 17, 18, 03:01, 03:02, 03:03
03:01	03:01, 17
03:02	03:02, 18
03:03	03:03, 18
4	4, 04:01, 04:02, 04:03, 04:04, 04:05, 04:06, 04:07, 04:10, 04:11
04:01	04:01

Candidate Unacceptable DR Locus Antigen	Donor Equivalent Antigens
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, 11:01, 11:04, 12, 12:01, 12:02
6	6, 13, 13:01, 13:02, 13:03, 13:05, 14, 14:01, 14:02, 14:03, 14:04, 14:05, 14:06, 14:54
7	7
8	8, 08:01, 08:02, 08:03, 08:07
08:01	08:01
08:02	08:02
08:03	08:03
08:07	08:07
9	9, 09:01, 09:02
09:01	09:01
09:02	09:02
10	10
11	11, 11:01, 11:03, 11:04
11:01	11:01
11:03	11:03
11:04	11:04
12	12, 12:01, 12:02
12:01	12:01
12:02	12:02
13	13, 13:01, 13:02,13:03, 13:05
13:01	13:01
13:02	13:02
13:03	13:03
13:05	13:05
14	14, 14:01, 14:02, 14:03, 14:04, 14:05, 14:06, 14:54
14:01	14:01, 14:54
14:02	14:02
14:03	14:03
14:04	14:04
14:05	14:05
14:06	14:06
14:54	14:54, 14:01
15	15, 15:01, 15:02, 15:03
15:01	15:01
15:02	15:02
15:03	15:03
16	16, 16:01, 16:02
16:01	16:01
16:02	16:02
17	17, 03:01

Candidate Unacceptable DR Locus Antigen	Donor Equivalent Antigens
18	18, 03:02, 03:03
103	103, 01:03

Table 4-9: HLA DR51 Unacceptable Antigen Equivalences

Candidate Unacceptable DR51-Locus Antigen	Donor Equivalent Antigens
5*01	5*01, 5*01:01, 5*01:02
5*01:01	5*01:01
5*01:02	5*01:02
5*02	5*02, 5*02:02
5*02:02	5*02:02
51	51, 5*01:01, 5*01:02, 5*02:02, 5*01, 5*02

Table 4-10: HLA DR52 Unacceptable Antigen Equivalences

Candidate Unacceptable DR52-Locus Antigen	Donor Equivalent Antigens
3*01	3*01, 3*01:01
3*01:01	3*01:01
3*02	3*02, 3*02:01, 3*02:02
3*02:01	3*02:01
3*02:02	3*02:02
3*03	3*03, 3*03:01
3*03:01	3*03:01
52	52, 3*01:01, 3*02:01, 3*02:02, 3*03:01, 3*01, 3*02, 3*03

Table 4-11: HLA DR53 Unacceptable Antigen Equivalences

Candidate Unacceptable DR-53 Locus Antigen	Donor Equivalent Antigens
4*01	4*01, 4*01:01, 4*01:03
4*01:01	4*01:01
4*01:03	4*01:03
53	53, 4*01:01, 4*01:03, 4*01

Table 4-12: HLA DQA1 Unacceptable Antigen Equivalences

Candidate Unacceptable DQA1 Locus Antigen	Donor Equivalent Antigens
01	01, 01:01, 01:02, 01:03, 01:04, 01:05, 01:06, 01:07, 01:08, 01:09, 01:10, 01:11, 01:12
01:01	01:01
01:02	01:02

Candidate Unacceptable DQA1 Locus Antigen	Donor Equivalent Antigens
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, 02:01
02:01	02:01
03	03, 03:01, 03:02, 03:03
03:01	03:01
03:02	03:02
03:03	03:03
04	04, 04:01, 04:02, 04:04
04:01	04:01
04:02	04:02
04:04	04:04
05	05, 05:01, 05:02, 05:03, 05:04, 05:05, 05:06, 05:07, 05:08, 05:09, 05:10, 05:11
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, 06:01, 06:02

Candidate Unacceptable DQA1 Locus Antigen	Donor Equivalent Antigens
06:01	06:01
06:02	06:02

Table 4-13: HLA DQB1 Unacceptable Antigen Equivalences

Candidate Unacceptable DQB1 Locus Antigen	Donor Equivalent Antigens
2	2, 02:01, 02:02
02:01	02:01
02:02	02:02
3	3, 7, 8, 9, 03:01, 03:02, 03:03, 03:19
03:01	03:01, 7
03:02	03:02, 8
03:03	03:03, 9
03:19	03:19, 7
4	4, 04:01, 04:02
04:01	04:01
04:02	04:02
5	5, 05:01, 05:02, 05:03
05:01	05:01
05:02	05:02
05:03	05:03
6	6, 06:01, 06:02, 06:03, 06:04, 06:09
06:01	06:01
06:02	06:02
06:03	06:03
06:04	06:04
06:09	06:09
7	7, 3, 03:01, 03:19
8	8, 3, 03:02
9	9, 3, 03:03

Table 4-14: HLA DPB1 Unacceptable Antigen Equivalences

Candidate Unacceptable DPB1 Locus Antigen	Donor Equivalent Antigen
01:01	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
02:01	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
02:02	02:02, 547:01,721:01, 766:01
03:01	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

Candidate Unacceptable DPB1 Locus Antigen	Donor Equivalent Antigen
04:01	04:01, 126:01, 350:01, 415:01, 459:01, 464:01, 534:01, 615:01, 618:01, 670:01, 699:01, 702:01, 755:01, 757:01, 765:01, 767:01, 784:01, 804:01, 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
04:02	04:02, 105:01, 463:01, 571:01, 647:01, 665:01, 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
05:01	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
06:01	06:01,737:01, 906:01, 914:01, 1022:01
08:01	08:01
09:01	09:01, 797:01, 899:01
10:01	10:01, 650:01, 673:01, 902:01
11:01	11:01, 649:01, 654:01, 672:01, 707:01, 907:01, 937:01
13:01	13:01, 107:01, 133:01, 518:01, 519:01, 888:01, 924:01, 947:01, 996:01
14:01	14:01, 498:01, 572:01, 651:01, 671:01, 705:01, 834:01, 854:01, 949:01
15:01	15:01, 585:01, 896:01, 910:01
16:01	16:01, 652:01, 653:01, 864:01, 886:01, 940:01, 968:01
17:01	17:01, 131:01, 168:01, 460:01, 846:01, 956:01, 1032:01
18:01	18:01, 897:01, 942:01
19:01	19:01, 106:01, 533:01, 535:01, 785:01, 965:01
20:01	20:01, 905:01
21:01	21:01, 1019:01
22:01	22:01, 1026:01
23:01	23:01, 138:01
24:01	24:01
25:01	25:01
26:01	26:01
27:01	27:01
28:01	28:01, 296:01
29:01	29:01, 909:01
30:01	30:01
31:01	31:01, 945:01
34:01	34:01, 835:01, 913:01
35:01	35:01
39:01	39:01, 584:01

Candidate Unacceptable DPB1 Locus Antigen	Donor Equivalent Antigen
40:01	40:01, 745:01
45:01	45:01, 832:01
51:01	51:01, 736:01
57:01	57:01, 648:01
59:01	59:01,782:01
80:01	80:01, 762:01
85:01	85:01, 713:01, 901:01, 1034:01
90:01	90:01, 1012:01
104:01	104:01
105:01	105:01
106:01	106:01
107:01	107:01
124:01	124:01
126:01	126:01
131:01	131:01
132:01	132:01, 1027:01
135:01	135:01
137:01	137:01, 791:01
152:01	152:01, 944:01
398:01	398:01, 922:01

Table 4-15: Epitope based Unacceptable Antigen Assignment for DPB1

Candidate Unacceptable Epitope	Donor Equivalent Antigens								
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

Candidate Unacceptable Epitope	Donor Equivalent Antigens								
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	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
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	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
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	1001:01	1002:01	1003:01	1004:01	1010:01	1011:01	1012:01	1016:01	1023:01
	1024:01	1033:01	1034:01						
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
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	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	508:01	509:01	530:01	536:01	540:01

Candidate Unacceptable Epitope	Donor Equivalent Antigens								
	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	
	02:01	04:02	08:01	10:01	16:01	18:01	25:01	28:01	37:01
55DEE	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
55DEE	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
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	515:01	525:01	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

Candidate Unacceptable Epitope	Donor Equivalent Antigens								
	1028:01	1031:01	1035:01	1036:01					
55EAE	02:02	05:01	19:01	21:01	22:01	24:01	30:01	36:01	38:01
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	140:01	170:01	171:01	223:01	226:01	233:01	284:01	291:01	300:01
	301:01	302:01	317:01	330:01	331:01	337:01	358:01	390:01	395:01
	400:01	406:01	408:01	473:01	478:01	495:01	496:01	527:01	533:01
	535:01	547:01	550:01	558:01	560:01	573:01	587:01	588:01	589:01
	590:01	611:01	619:01	638:01	668:01	697:01	715:01	717:01	718:01
	720:01	721:01	729:01	744:01	746:01	764:01	766:01	778:01	779:01
	785:01	790:01	798:01	802:01	847:01	848:01	851:01	860:01	923:01
	928:01	929:01	951:01	961:01	962:01	965:01	971:01	980:01	982:01
	1008:01	1015:01	1018:01	1019:01	1026:01				
84DEAV	01:01	03:01	05:01	06:01	08:01	09:01	10:01	11:01	13:01
	14:01	16:01	17:01	19:01	20:01	21:01	22:01	25:01	26:01
	27:01	29:01	30:01	31:01	35:01	36:01	37:01	38:01	44:01
	45:01	50:01	52:01	54:01	55:01	56:01	57:01	58:01	63:01
	65:01	67:01	68:01	69:01	70:01	76:01	78:01	79:01	84:01
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	530:01	532:01	533:01	535:01	536:01	538:01	541:01	542:01	543:01
	545:01	548:01	550:01	552:01	558:01	560:01	562:01	563:01	564:01
	565:01	566:01	567:01	568:01	572:01	573:01	587:01	588:01	597:01
	599:01	600:01	608:01	609:01	610:01	611:01	612:01	613:01	616:01

Candidate Unacceptable Epitope	Donor Equivalent Antigens								
84DEAV	619:01	621:01	623:01	629:01	630:01	631:01	632:01	633:01	634:01
	635:01	636:01	638:01	645:01	648:01	649:01	650:01	651:01	652:01
	653:01	654:01	662:01	664:01	667:01	668:01	669:01	671:01	672:01
	673:01	675:01	676:01	684:01	688:01	689:01	698:01	703:01	704:01
	705:01	706:01	707:01	708:01	709:01	710:01	711:01	713:01	714:01
	715:01	716:01	717:01	718:01	720:01	727:01	728:01	729:01	733:01
	737:01	744:01	746:01	749:01	760:01	764:01	778:01	785:01	789:01
	790:01	791:01	797:01	798:01	801:01	802:01	807:01	810:01	815:01
	822:01	825:01	829:01	832:01	833:01	834:01	839:01	846:01	847:01
	848:01	851:01	853:01	854:01	855:01	856:01	860:01	864:01	879:01
	883:01	886:01	888:01	891:01	892:01	893:01	898:01	899:01	901:01
	902:01	904:01	905:01	906:01	907:01	908:01	909:01	912:01	914:01
	920:01	922:01	923:01	924:01	929:01	930:01	931:01	935:01	937:01
	938:01	940:01	944:01	945:01	946:01	947:01	948:01	949:01	951:01
	952:01	953:01	956:01	965:01	968:01	969:01	970:01	971:01	976:01
	977:01	979:01	980:01	982:01	983:01	990:01	991:01	994:01	996:01
	998:01	999:01	1000:01	1006:01	1007:01	1008:01	1009:01	1012:01	1014:01
	1015:01	1017:01	1018:01	1019:01	1021:01	1022:01	1024:01	1026:01	1027:01
	1030:01	1032:01	1034:01						
84GGPM	02:01	02:02	04:01	04:02	23:01	24:01	32:01	33:01	39:01
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	399:01	402:01	406:01	414:01	415:01	416:01	418:01	419:01	420:01
	421:01	423:01	424:01	425:01	426:01	427:01	428:01	429:01	430:01

Candidate Unacceptable Epitope	Donor Equivalent Antigens								
84GGPM	432:01	433:01	434:01	435:01	440:01	441:01	443:01	444:01	451:01
	452:01	453:01	456:01	457:01	459:01	461:01	463:01	464:01	465:01
	468:01	469:01	474:01	475:01	476:01	477:01	478:01	479:01	480:01
	485:01	486:01	487:01	488:01	494:01	496:01	497:01	500:01	501:01
	502:01	508:01	510:01	511:01	520:01	521:01	522:01	523:01	524:01
	525:01	528:01	529:01	531:01	534:01	537:01	539:01	540:01	547:01
	549:01	553:01	554:01	555:01	556:01	557:01	559:01	561:01	569:01
	571:01	574:01	575:01	576:01	577:01	578:01	579:01	581:01	582:01
	583:01	584:01	586:01	591:01	593:01	594:01	595:01	596:01	601:01
	602:01	603:01	604:01	605:01	606:01	607:01	614:01	615:01	617:01
	618:01	620:01	622:01	624:01	625:01	626:01	627:01	628:01	637:01
	639:01	640:01	641:01	642:01	643:01	646:01	647:01	655:01	656:01
	658:01	659:01	660:01	663:01	665:01	666:01	670:01	674:01	677:01
	678:01	679:01	680:01	681:01	682:01	683:01	685:01	686:01	687:01
	690:01	692:01	694:01	699:01	701:01	702:01	721:01	722:01	723:01
	725:01	726:01	730:01	731:01	734:01	735:01	736:01	739:01	741:01
	742:01	747:01	750:01	751:01	753:01	755:01	757:01	758:01	759:01
	761:01	762:01	763:01	765:01	766:01	767:01	769:01	770:01	771:01
	772:01	773:01	774:01	775:01	776:01	779:01	780:01	781:01	782:01
	783:01	784:01	787:01	788:01	795:01	796:01	799:01	803:01	804:01
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	830:01	836:01	837:01	840:01	841:01	842:01	843:01	845:01	849:01
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	882:01	884:01	885:01	887:01	889:01	890:01	895:01	915:01	916:01
	921:01	926:01	927:01	928:01	932:01	933:01	934:01	936:01	943:01
	954:01	955:01	957:01	958:01	961:01	962:01	963:01	964:01	966:01
	967:01	972:01	973:01	975:01	978:01	981:01	987:01	988:01	989:01
	992:01	993:01	997:01	1001:01	1002:01	1003:01	1004:01	1005:01	1010:01
	1011:01	1013:01	1016:01	1020:01	1023:01	1025:01	1028:01	1031:01	1033:01
	1035:01	1036:01							
84VGPM	15:01	18:01	28:01	34:01	40:01	53:01	62:01	74:01	139:01
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	471:01	482:01	484:01	493:01	499:01	512:01	526:01	580:01	585:01
	644:01	695:01	745:01	752:01	768:01	835:01	896:01	897:01	900:01
	903:01	910:01	913:01	918:01	942:01				

Table 4-16: Reportable OPTN DPB1 HLA Allele Values

01:01	02:01	02:02	03:01	04:01	04:02	05:01	06:01	08:01	09:01
10:01	11:01	13:01	14:01	15:01	16:01	17:01	18:01	19:01	20:01
21:01	22:01	23:01	24:01	25:01	26:01	27:01	28:01	29:01	30:01
31:01	32:01	33:01	34:01	35:01	36:01	37:01	38:01	39:01	40:01
41:01	44:01	45:01	46:01	47:01	48:01	49:01	50:01	51:01	52:01
53:01	54:01	55:01	56:01	57:01	58:01	59:01	60:01	62:01	63:01
65:01	66:01	67:01	68:01	69:01	70:01	71:01	72:01	73:01	74:01
75:01	76:01	77:01	78:01	79:01	80:01	81:01	82:01	83:01	84:01
85:01	86:01	87:01	88:01	89:01	90:01	91:01	92:01	93:01	94:01
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1015:01	1016:01	1017:01	1018:01	1019:01	1020:01	1021:01	1022:01	1023:01	1024:01
1025:01	1026:01	1027:01	1028:01	1030:01	1031:01	1032:01	1033:01	1034:01	1035:01
1036:01									

Table 4-17: Additional Unacceptable Antigen Equivalences to be used in the Calculated Panel Reactive Antibody (CPRA) Only

Locus	Patient Unacceptable Antigen	Unacceptable DR antigen equivalences used for CPRA calculation
DR51	51	2, 15, 16
DR52	52	3, 5, 6, 11, 12, 13, 14, 17, 18
DR53	53	4, 7, 9

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 highly sensitized candidates according to *Policy 8.5.F: Highly Sensitized Candidates*.

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. CPRA will be derived from HLA antigen/allele group and haplotype frequencies for the different racial and ethnic groups in proportion to their representation in the national deceased donor population. CPRA values will be rounded to the nearest one hundredth percentage.

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
Hepatitis B Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis C (HCV) Antibody	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis C Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Human Immunodeficiency Virus (HIV); Organs from HIV positive donors may only be recovered and transplanted according to the requirements in the Final Rule	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas

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 *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 is willing to accept an HIV positive liver as part of an institutional review board approved research protocol that meets the requirement in the OPTN Final Rule

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

A transplant hospital may specify whether a candidate registered before two years of age is willing to accept a heart from an intended blood group incompatible 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.

5.4 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, 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 *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.

This policy does not apply to covered VCA transplants; instead, members must allocate covered VCAs according to *Policy 12.2: Covered VCA Allocation*.

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 *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 HIV positive deceased donors, the OPO and transplant hospital must also do *both* of the following:

        a. Verify that the potential recipient is registered as a HIV positive candidate at a transplant hospital that meets the requirements in *Policy 15.7.C Transplant Hospital Requirements for Transplantation of HIV Positive Organs*
        b. Meet the requirements in *Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors*

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.

5.5 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 Results

If a donor is found to be positive for HIV after any match run has been executed, the host OPO must report the updated information 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* HIV-positive candidates participating in an institutional review board approved research protocol that meets the requirements in the Final Rule regarding the recovery of organs from individuals known to be infected with HIV according to *Policy 15.7.A: Requirements for Allocating HIV Positive Deceased Donor Organs*
3. Withdraw any pending offers to candidates who are not HIV positive *and* also participating in an institutional review board approved research protocol that meets the requirements in the OPTN Final Rule according to *Policy 15.7.C: Transplant Hospital Requirements for Transplantation of HIV Positive Organs*
4. 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 previous sentence does not apply to covered VCA transplants.

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 *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 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.

This policy does not apply to covered VCA transplants.

5.6.C Organ Offer Acceptance Limit

For any one candidate, the transplant hospital can only have two organ offer acceptances 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.

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 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

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

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 *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 *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 *Policy 6.6.F: Allocation of Heart-Lungs*.

5.10.B Allocation of Liver-Kidneys

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

5.10.C Other Multi-Organ Combinations

When multi-organ candidates are registered on the heart, lung, or liver waiting list, the second required organ will be allocated to the multi-organ candidate from the same donor according to *Table 5-4*.

Table 5-4

Organ	Candidate is registered at a transplant hospital that is at or within the following this distance of the donor hospital
Heart	250NM
Liver	150NM
Lung	250NM

If the multi-organ candidate is on a waiting list outside the geographical areas listed above, it is permissible to allocate the second organ to the multi-organ candidate receiving the first organ.

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 *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 *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 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*. This status can be extended by the transplant program every 7 days by submission of 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 14 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 14 days from submission of *the Heart Status 1 Justification Form*. This status can be extended by the transplant program every 14 days by submission of another *Heart Status 1 Justification Form* if the candidate remains hospitalized on continuous intravenous antiarrhythmic therapy.

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 *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 *Policy 6.1.B.ii* below.
- Is supported by a mechanical circulatory support device (MCSD) that is malfunctioning, according to *Policy 6.1.B.iii* below.
- Is supported by a percutaneous endovascular mechanical circulatory support device, according to *Policy 6.1.B.iv* below.
- Is supported by an intra-aortic balloon pump (IABP), according to *Policy 6.1.B.v* below.
- Is experiencing recurrent or sustained ventricular tachycardia or ventricular fibrillation according to *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, *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 inotropes
  c. Pulmonary capillary wedge pressure greater than 15 mmHg

- If hemodynamic measurements could not be obtained within 7 days prior to percutaneous endovascular mechanical circulatory support, at least *one* of the following is 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
2. Within 48 hours prior to the status expiring, the transplant program failed at weaning the candidate from the percutaneous endovascular mechanical circulatory support device 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 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 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, *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 inotropes
  c. Pulmonary capillary wedge pressure greater than 15 mmHg

- If hemodynamic measurements could not be obtained within 7 days prior to IABP support, at least *one* of the following is 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
2. Within 48 hours prior to the status expiring, the transplant program failed to wean the candidate from the IABP 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/m2
   - 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 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 *Policy 6.1.C.i* below.
- Is supported by multiple inotropes or a single high dose inotrope and has hemodynamic monitoring, according to *Policy 6.1.C.ii* below.
- Is supported by a mechanical circulatory support device (MCSD) with hemolysis, according to *Policy 6.1.C.iii* below.
- Is supported by an MCSD with pump thrombosis, according to *Policy 6.1.C.iv* below.
- Is supported by an MCSD and has right heart failure, according to *Policy 6.1.C.v* below.
- Is supported by an MCSD and has a device infection, according to *Policy 6.1.C.vi* below.
- Is supported by an MCSD and has bleeding, according to *Policy 6.1.C.vii* below.
- Is supported by an MCSD and has aortic insufficiency, according to *Policy 6.1.C.viii* below.
- Is supported by veno-arterial extracorporeal membrane oxygenation (VA ECMO) after 7 days, according to *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 *Policy 6.1.C.x* below.
- Is supported by a percutaneous endovascular mechanical circulatory support device after 14 days, according to *Policy 6.1.C.xi* below.
- Is supported by an intra-aortic balloon pump (IABP) after 14 days, according to *Policy 6.1.C.xii* 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 supported by an MCSD and is experiencing pump thrombosis as evidenced by at least *one* of the following:

- Visually detected thrombus in a paracorporeal ventricular assist device (VAD)
- Transient ischemic attack, stroke, or peripheral thromboembolic event, with non-invasive testing to exclude *both*:
  1. Intracardiac thrombus in all candidates
  2. Significant carotid artery disease in candidates with a neurological event

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.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, this status can be extended by the transplant program every 14 days by submission of 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, with either leukocytosis or a 50 percent increase in white blood cell count from the last recorded white blood cell count, 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	14 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 of completing antibiotic treatment to which the bacteria is susceptible	90 days from submission of *the Heart Status 3 Justification Form*.

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.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 *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 *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 *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 *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.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 *Policy 6.1.D.i* below.
- Is supported by inotropes without continuous hemodynamic monitoring, according to *Policy 6.1.D.ii* below.
- Is diagnosed with congenital heart disease, according to *Policy 6.1.D.iii* below.
- Is diagnosed with ischemic heart disease with intractable angina, according to *Policy 6.1.D.iv* below.
- Is diagnosed with amyloidosis, hypertrophic cardiomyopathy or restrictive cardiomyopathy, according to *Policy 6.1.D.v* below.
- Is a re-transplant, according to *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
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 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
Pediatric status 1A	• Candidate is admitted to the transplant hospital that registered the candidate on the waiting list • 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 Bylaws.

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 Allocation of Hearts by Blood Type

Within each classification, hearts are first allocated to primary blood type candidates then to secondary blood type candidates according to the blood type matching requirements in *Table 6-4* below.

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

Pediatric candidates that are less than one year old at the time of the match run, including candidates eligible to receive a heart from an intended blood group incompatible deceased donor, will be classified as a primary blood type match candidate.

Pediatric candidates that are at least one year of age at the time of the match run but registered before their second birthday and are eligible to receive a heart from an intended blood group incompatible deceased donor will be 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 Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Hearts

The candidate will be eligible for intended blood group incompatible heart offers if the candidate meets at least *one* of the following conditions:

1. Candidate is less than one year old at the time of the match run, and meets *both* of the following:
   a. Is registered as status 1A or 1B.
   b. Has reported isohemagglutinin titer information for A or B blood type antigens to the OPTN within the last 30 days.
2. Candidate is at least one year old at the time of the match run, and meets all of the following:
   a. Is registered prior to turning two years old.
   b. Is registered as status 1A or 1B.
   c. 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.

Accurate isohemagglutinin titers must be reported for candidates eligible to accept an intended blood group incompatible heart according to *Table 6-5* below, at all of the following times:

1. Upon initially reporting that a candidate is willing to accept an intended blood group incompatible heart.
2. Every 30 days after initially reporting that a candidate is willing to accept an intended blood group incompatible heart.

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

Accurate 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 Blood Group Incompatible 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 *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
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

Classification	Candidates that are within the	And registered at a transplant hospital that is at or within this distance from the donor hospital
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
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

Classification	Candidates that are within the	And registered at a transplant hospital that is at or within this distance from the donor hospital
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
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

Classification	Candidates that are within the	And registered at a transplant hospital that is at or within this distance from the donor hospital
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
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

Classification	Candidates that are within the	And registered at a transplant hospital that is at or within this distance from the donor hospital
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

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
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
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

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
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
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

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
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
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

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
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
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

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
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
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

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
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
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

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
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

If a host OPO is offering a heart and a lung from the same deceased donor, then the host OPO must offer the heart and the lung according to *Policy 6.6.F.i: Allocation of Heart-Lungs from Deceased Donors at Least 18 Years Old* or *Policy 6.6.F.ii: Allocation of Heart-Lungs from Deceased Donors Less Than 18 Years Old.*

The blood type matching requirements described in *Policy 6.6.A: Allocation of Hearts by Blood Type* apply to heart-lung candidates when the candidates appear on the heart match run. The blood type matching requirements in *Policy 10.4.B: Allocation of Lungs by Blood Type* apply to heart-lung candidates when the candidates appear on the lung match run.

6.6.F.i Allocation of Heart-Lungs from Deceased Donors at Least 18 Years Old

If a heart or heart-lung potential transplant recipient (PTR) requires a lung, the OPO must offer the lungs from the same deceased donor to the heart or heart-lung PTR according to *Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old.*

If a lung or heart-lung PTR in allocation classifications 1 through 12 according to *Policy 10.4.C: Allocation of Lungs From Deceased Donors at Least 18 Years Old* requires a heart, the OPO cannot allocate the heart from the same deceased donor to the lung or heart-lung PTR until after the heart has been offered to all heart and heart-lung PTRs in allocation classifications 1 through 4 according to *Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old.*

6.6.F.ii Allocation of Heart-Lungs from Deceased Donors Less Than 18 Years Old

If a heart or heart-lung potential transplant recipient (PTR) requires a lung, the OPO must offer the lungs from the same deceased donor to the heart or heart-lung PTR according to *Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old*.

If a lung or heart-lung PTR in allocation classifications 1 through 10 according to *Policy 10.4.D: Allocation of Lungs From Deceased Donors Less Than 18 Years Old* requires a heart, the OPO cannot allocate the heart from the same deceased donor to the lung or heart-lung PTR until after the heart has been offered to all heart and heart-lung PTRs in allocation classifications 1 through 12 according to *Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old*.

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 Calculated Panel Reactive Antibody (CPRA)

CPRA is the percentage of donors expected to have one or more of a candidate's indicated unacceptable antigens. CPRA will be calculated automatically when a transplant hospital reports unacceptable antigens to the OPTN according to *Policy 5.3.A: Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA)*.

8.2 Exceptions

8.2.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 *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.

8.3 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 8.4: Waiting Time*	8.5.H, 8.5.I, 8.5.J, or 8.5.K	1/365 points for each day since the qualifying criteria in *Policy 8.4: Waiting Time*
Aged 0-10 at time of match and a 0-ABDR mismatch with the donor	8.5.H, 8.5.I, or 8.5.J	4 points
Aged 11-17 at time of match and a 0-ABDR mismatch with the donor	8.5.H, 8.5.I, or 8.5.J	3 points
Aged 0-10 at time of match and donor has a KDPI score <35%	8.5.H, 8.5.I	1 point
A prior living donor	8.5.H, 8.5.I, or 8.5.J	4 points
Sensitized (CPRA at least 20%)	8.5.H, 8.5.I, or 8.5.J	*See Table 8-2: Points for CPRA*
A single HLA-DR mismatch with the donor*	8.5.H, 8.5.I, or 8.5.J	1 point
A zero HLA-DR mismatch with the donor*	8.5.H, 8.5.I, or 8.5.J	2 points
Meets the qualifying criteria described in *Table 8-3: Points for Allocation of Kidneys based on Proximity to Donor Hospital*	8.5.H, 8.5.I, 8.5.J, or 8.5.K	*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

If the candidate's CPRA score is:	Then the candidate receives this many points:
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

8.4 Waiting Time

8.4.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 measured or calculated creatinine clearance or glomerular filtration rate (GFR) less than or equal to 20 mL/min.
2. The date after registration that a candidate's measured or calculated creatinine clearance or GFR 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.

8.4.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.

8.4.C Time at Medically Urgent Status

For registered kidney candidates that also qualify for medically urgent status according to *Policy 8.5.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.

8.4.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 *Policy 3.6.B.i: Non-function of a Transplanted Kidney*.

8.5 Kidney Allocation Classifications and Rankings

8.5.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 *Policy 8.4: 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.

8.5.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 *Policy 8.4: 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 Bylaws.

8.5.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	0.0128*(age-40)
	Donors with age < 18	-0.0194*(age-18)
	Donors with age > 50	0.0107*(age-50)
Ethnicity	African American donors	0.1790
Creatinine (mg/dL)	All donors	0.2200*(creatinine - 1)
	Donors with creatinine > 1.5	-0.2090*(creatinine -1.5)
History of Hypertension	Hypertensive donors	0.1260
History of Diabetes	Diabetic donors	0.1300
Cause of Death	Donors with cerebrovascular accident as cause of death	0.0881
Height (cm)	All donors	-0.0464*(height -170) / 10
Weight (kg)	All donors with weight < 80 kg	-0.0199*(weight - 80) / 5
Donor type	DCD donors	0.1330
HCV status	HCV positive donors	0.2400

To calculate KDRI, follow these steps:

1. Sum each of the applicable KDRI score components in *Table 8-3*
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.

8.5.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)

8.5.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.

Kidneys from Donors with:	Are Allocated to Candidates with:
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 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).

8.5.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

8.5.F Highly Sensitized Candidates

Before a candidate with a CPRA score of 99% or 100% can receive offers in classifications 1 through 4, 8 or 9 according to *Table 8-7* and *8-8*; classifications 1 through 4, 7 or 8 according to *Table 8-9*; and classifications 1 through 4, 6 or 7 in *Table 8-10*, the transplant program's HLA laboratory director and the candidate's transplant physician or surgeon must review and sign a written approval of the unacceptable antigens listed for the candidate. The transplant hospital must document this approval in the candidate's medical record.

8.5.G 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 measured or calculated 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 *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 *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 *Policy 3.6.B.i: Non-function of a Transplanted Kidney*

8.5.H 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 *Policy 8.8: 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

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, 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

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, top 20% EPTS, and blood type B	250NM	O
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

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, 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
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

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:
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
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

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:
43	All remaining candidates, blood type identical or permissible	Nation	Any

8.5.I 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 *Policy 8.8: 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

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	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
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

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 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
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

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:
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
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 recipients that meet the qualifying criteria according to *Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List*, blood type identical or permissible	250NM	Any
28	Blood type B	250NM	A2 or A2B
29	All remaining candidates, 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:
30	Registered prior to 18 years old, blood type identical or permissible	Nation	Any
31	Blood type B	Nation	A2 or A2B
32	All remaining candidates, blood type identical or permissible	Nation	Any

8.5.J 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 *Policy 8.8: 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
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

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	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
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

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	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
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 recipients that meet the qualifying criteria according to *Policy 8.5.G*: *Prioritization for Liver Recipients on the Kidney Waiting List*, 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:
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
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

8.5.K 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 *Policy 8.8:*

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

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, blood type identical or permissible	250NM	Any
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 recipients that meet the qualifying criteria according to *Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List*, blood type identical or permissible	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

8.6 Allocation of Both Kidneys from a Single Deceased Donor to a Single Candidate

8.6.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 *Policy 8.5.J: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%* or *Policy 8.5.K: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 85%*.

8.6.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 *Policy 8.5.H: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%.*

8.6.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 *Policy 5.9: Released Organs*.
- Release both kidneys to be allocated according to the KDPI score of the deceased donor, pursuant to *Policy 5.9: Released Organs*. Kidneys originally allocated en bloc and then split can no longer be allocated as en bloc.

8.7 Administrative Rules

8.7.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.

8.7.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

8.7.C 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 *Policy 5.9: Released Organs*.

8.7.D 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.

8.8 Allocation of Released Kidneys

For kidneys allocated according to *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:

- *Policy 9.8.F: Allocation of Livers from Non- DCD Deceased Donors 11 to 17 Years Old*
- *Policy 9.8.G: Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old*
- *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. Primary 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, 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 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 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 with a calculated MELD or PELD greater than 25, and has at least *one* of the following criteria:
        i. Is on a mechanical ventilator
        ii. Has gastrointestinal bleeding requiring at least 30 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)
        iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension.

d. Chronic liver disease and is a combined liver-intestine candidate with an adjusted MELD or PELD score greater than 25 according to *Policy 9.1.F: Liver-Intestine Candidates* and has at least *one* of the following criteria:
   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)
   iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension.

9.1.D MELD Score

Candidates who are at least 12 years old receive an initial $MELD_{(i)}$ score equal to: *0.957 x Loge(creatinine mg/dL) + 0. 378 x* Log_e*(bilirubin mg/dL) + 1.120 x* Log_e *(INR) + 0.643*

Laboratory 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 4.0 mg/dL:

- Candidates with a creatinine value greater than 4.0 mg/dL
- Candidates who received two or more dialysis treatments within the prior 7 days
- Candidates who received 24 hours of continuous veno-venous hemodialysis (CVVHD) within the prior 7 days

The maximum MELD score is 40. The MELD score derived from this calculation will be rounded to the tenth decimal place and then multiplied by 10.

For candidates with an initial MELD score greater than 11, the MELD score is then re-calculated as follows:

$MELD = MELD_{(i)} + 1.32*(137-Na) – [0.033*MELD_{(i)}*(137-Na)]$

Sodium values less than 125 mmol/L will be set to 125, and values greater than 137 mmol/L will be set to 137.

9.1.E PELD Score

Candidates who are less than 12 years old receive a PELD score equal to:

0.436 (Age (<1 YR.)) – 0.687 x Loge (albumin g/dL) + 0.480 x Loge (total bilirubin mg/dL) + 1.857 x Loge (INR) +0.667 (Growth failure (<- 2 Std. Deviations present))

The PELD score derived from this calculation will be rounded to the tenth decimal place and then multiplied by 10.

Scores for candidates registered for liver transplantation before the candidate's first birthday continue to include the value of 0.436 until the candidate is 24 months old.

Laboratory values less than 1.0 will be set to 1.0 when calculating a candidate's PELD score.

A candidate has growth failure if the candidate is more than two standard deviations below the candidate's expected growth based on age and gender using the most recent Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics pediatric clinical growth chart.

9.1.F Liver-Intestine Candidates

Adult liver candidates who 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. Candidates less than 18 years old will receive 23 additional points to their calculated MELD or PELD score instead of the 10 percentage point increase. 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 9-1*.

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 9-1: 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 9-1*, 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, or will remain at the uncertified PELD score if it is less than 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 *Policy 9.1.C: Pediatric Status 1B Requirements* or a metabolic disease in *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 Bylaws.

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 *all* of the following:

1. A request for a specific MELD or PELD score
2. A justification of how the medical criteria supports that the candidate has a higher MELD or PELD score
3. An explanation of how the candidate's current condition is comparable to that of other candidates with that MELD or PELD score

Approved MELD or PELD exception scores are valid for 90 days from the date the exception is approved.

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 *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 exception will be maintained if the transplant hospital 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 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

Median MELD at transplant (MMaT) is calculated by using the median of the MELD scores at the time of transplant of all recipients at least 12 years old who were transplanted at hospitals within 250 nautical miles of the candidate's listing hospital ina prior 365 day period.

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 in the nation.

The MMaT and MPaT calculations exclude recipients who are either of the following:
1. Transplanted with livers from living donors, DCD donors, and donors from donor hospitals more than 500 nautical miles away from the transplant hospital
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. If there have been fewer than 10 qualifying transplants within 250 nautical miles of a transplant hospital in the cohort, the MMaT will be calculated based on a total of a 730 day period.

Exceptions scores will be updated to reflect changes in MMaT or MPaT each time the MMaT or MPaT is recalculated. The following exception scores are not awarded relative to MMaT or MPaT and will not be updated:

1. Exception scores of 40 or higher awarded by the NLRB according to *Policy 9.4.A: MELD or PELD Score Exception Requests*
2. Any exception awarded according to *Policy 9.5.D: Requirements for Hepatic Artery Thrombosis (HAT) MELD Score Exceptions*

3. Exceptions awarded to candidates less than 18 years old at time of registration according to *Policy 9.5.I: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions*
4. Initial and first exceptions awarded to candidates at least 18 at time of registration according to *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:

- Cholangiocarcinoma (CCA), according to *Policy 9.5.A: Requirements for Cholangiocarcinoma MELD or PELD Score Exceptions*
- Cystic fibrosis, according to *Policy 9.5.B: Requirements for Cystic Fibrosis MELD or PELD Score Exceptions*
- Familial amyloid polyneuropathy, according to *Policy 9.5.C: Requirements for Familial Amyloid Polyneuropathy (FAP) MELD or PELD Score Exceptions*
- Hepatic artery thrombosis, according to *Policy 9.5.D: Requirements for Hepatic Artery Thrombosis (HAT) MELD Score Exceptions*
- Hepatopulmonary syndrome, according to *Policy 9.5.E: Requirements for Hepatopulmonary Syndrome (HPS) MELD or PELD Score Exceptions*
- Metabolic disease, according to *Policy 9.5.F: Requirements for Metabolic Disease MELD or PELD Score Exceptions*
- Portopulmonary hypertension, according to *Policy 9.5.G: Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions*
- Primary hyperoxaluria, according to *Policy 9.5.H: Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions*
- Hepatocellular carcinoma, according to *Policy 9.5.I: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exception*

If a candidate's exception score based on the score assignments relative to MMaT or MPaT in this section would be lower than 15, the candidate's exception score will be 15.

9.5.A Requirements for Cholangiocarcinoma (CCA) MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for CCA, if the candidate's transplant hospital meets *all* the following qualifications:

1. Submits a written protocol for patient care to the Liver and Intestinal Organ Transplantation Committee that must include *all* of the following:
   - Candidate selection criteria
   - Administration of neoadjuvant therapy before transplantation
   - Operative staging to exclude any patient with regional hepatic lymph node metastases, intrahepatic metastases, or extrahepatic disease
   - 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 be assigned a score according to *Table 9-2*.

Table 9-2: 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 hospitals must submit an exception extension request according to *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 be assigned 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 hospitals must submit an exception extension request according to *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 hospital 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 be assigned 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 hospitals must submit an exception extension request according to *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 *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 hospitals must submit an exception extension request according to *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 hospital 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 be assigned 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 hospitals must submit an exception extension request according to *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 hospital submits evidence of urea cycle disorder or organic acidemia.

A candidate who meets the requirements for a standardized MELD or PELD score exception will be assigned 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 hospitals must submit an exception extension request according to *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 hospital 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 be assigned 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 hospitals must submit an exception extension request according to *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 hospital 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. Estimated glomerular filtration rate (eGFR) by six variable Modification of Diet in Renal Disease formula (MDRD6), or glomerular filtration rate (GFR) measured by iothalamate or iohexol, is 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 be assigned 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 hospitals must submit an exception extension request according to *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 be provided a score according to *Policy 9.5.I.vii: Extensions of HCC Exceptions* if the candidate meets the criteria according to *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 before local-regional therapy that meet Class 5 criteria using a dynamic contrast enhanced computed tomography (CT) or magnetic resonance imaging (MRI)
2. A CT of the chest to rule out metastatic disease
3. A CT or MRI to rule out any other sites of extrahepatic spread or macrovascular involvement
4. An indication that the candidate is not eligible for resection
5. An indication whether the candidate has undergone local-regional therapy
6. 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 pathology report does not show evidence of HCC, the transplant hospital must also submit documentation or imaging studies confirming HCC at the time of assignment. The Liver and Intestinal Organ Transplantation Committee will review a transplant hospital when more than 10 percent of the HCC cases in a one-year period are not supported by the required pathologic confirmation or submission of clinical information.

9.5.I.ii Eligible Candidates Definition of T2 Lesions

Candidates with T2 HCC lesions 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 and *either* of the following:

- One lesion greater than or equal to 2 cm and less than or equal to 5 cm in size.
- Two or three 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 *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 local-regional therapy, they have lesions that meet *one* of the following criteria:

- One lesion greater than 5 cm and less than or equal to 8 cm
- Two or three 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 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 local-regional therapy, their residual lesions must subsequently meet the requirements for T2 lesions according to *Policy 9.5.I.ii: Eligible Candidates Definition of T2 Lesions* to be eligible for a standardized MELD or PELD exception. Downstaging to meet eligibility requirements for T2 lesions must be demonstrated by CT or MRI performed after local-regional therapy. Candidates with lesions that do not initially meet the downstaging protocol inclusion criteria who are later downstaged and then meet eligibility for T2 lesions 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 criteria according to *Policy 9.5.I.ii Eligible Candidates Definition of T2 Lesions* but with an alpha-fetoprotein (AFP) level greater than 1000 ng/mL may be treated with local-regional 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 local-regional therapy at any time must be referred to the NLRB for consideration of a MELD or PELD exception.

9.5.I.v Requirements for Dynamic Contrast-enhanced CT or MRI of the Liver

CT scans and MRIs performed for a Hepatocellular Carcinoma (HCC) MELD or PELD score exception request must be interpreted by a radiologist at a transplant hospital. If the scan is inadequate or incomplete then the lesion will be classified as OPTN Class 0 and imaging must be repeated or completed to receive an HCC MELD or PELD exception.

9.5.I.vi Imaging Requirements for Class 5 Lesions

Lesions found on images of cirrhotic livers are classified according to *Table 9-9*.

Table 9-9: Classification System for Lesions Seen on Imaging of Cirrhotic Livers

Class	Description
0	Incomplete or technically inadequate study

5A	• Maximum diameter of at least 1 cm and less than 2 cm, as measured on late arterial or portal phase images.
	• Increased contrast enhancement, relative to hepatic parenchyma, on late arterial phase.
	• *Either* of the following:
	  • Washout during the later contrast phases and peripheral rim enhancement on delayed phase
	  • Biopsy

5A-g	Must meet *all* of the following: 1. Maximum diameter of at least 1 cm and less than 2 cm, as measured on late arterial or portal phase images. 2. Increased contrast enhancement, relative to hepatic parenchyma, on late arterial phase. 3. Maximum diameter increase of at least 50% documented on serial MRI or CT obtained at least 6 months apart.

5B	Must meet *all* of the following:
	1. Maximum diameter of at least 2 cm and less than or equal to 5 cm, as measured on late arterial or portal phase images.
	2. Increased contrast enhancement, relative to hepatic parenchyma, on late hepatic arterial images.
	3. *One* of the following:
	  1. Washout on portal venous/delayed phase.
	  2. Peripheral rim enhancement.
	  3. Maximum diameter increase, in the absence of ablation, by 50% or more and documented on serial MRI or CT obtained at least 6 months apart. Serial imaging and measurements must be performed on corresponding contrast phases.
	  4. Biopsy.

5T	Any Class 5A, 5A-g, 5B lesion that was automatically approved upon initial request or extension and has subsequently been ablated.

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 using a 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

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 *9.5.I.ii: Eligible Candidates Definition of T2 Lesions*
- 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 liver candidate at least 18 years old at the time of registration submits an initial request or the first extension request that meets the requirements for a standardized MELD score exception, the candidate will receive a MELD score of 6, and appear on the match according to that exception score or the calculated MELD score, whichever is higher.

A candidate who meets these requirements for a MELD or PELD score exception for HCC will be assigned 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	6
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 assigned MELD or PELD score.

A candidate's waiting time at a MELD or PELD score equals the sum of *all* the following:

1. Waiting time at current MELD or PELD score
2. Previous waiting time accrued during an earlier period at current MELD or PELD score

3. Previous total waiting time accrued at any MELD or PELD score higher than the current MELD or PELD score
4. Previous total waiting time accrued at status 1A and status 1B

Status 1A or 1B candidates will receive waiting time points based on their waiting time in that status, according to *Policy 9.7.A: Points for Waiting Time*.

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 *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.

9.8 Liver Allocation, Classifications, and Rankings

Unless otherwise stated, all mentions of MELD or PELD in this section reference a candidate's match 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 *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. Total waiting time and blood type compatibility points (highest to lowest), according to *Policy 9.7: Liver Allocation Points*
2. Total waiting time at status 1A (highest to lowest)

Within each status 1B allocation classification, candidates are sorted in the following order:

1. Total waiting time and blood type compatibility points (highest to lowest), according to *Policy 9.7: Liver Allocation Points*
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. MELD or PELD score (highest to lowest)
2. Identical blood types, compatible blood types, then incompatible blood types
3. Waiting time at the current or higher MELD or PELD score (highest to lowest)
4. Time since submission of initial approved MELD or PELD exception request (highest to lowest)
5. 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

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
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
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

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
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	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

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	Any	Nation	O	O
46	Any	Nation	Non-O	Any
47	29	150NM	O	B
48	29	250NM	O	B
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

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	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
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
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
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

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
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
18	MELD of at least 30 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
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
30	MELD of at least 30 and candidate is at least 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
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
39	Any MELD and candidate is less than 18 years old at registration	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
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
48	Adult or Pediatric Status 1A, 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
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

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
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
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

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	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

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
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
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

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
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
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

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
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
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

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
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
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

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
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
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 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

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 *Policy 8*: *Allocation of Kidneys*:

- *Policy 5.10.C: Other Multi-Organ Combinations*
- *Policy 9.9: Liver-Kidney Allocation*
- *Policy 11.4.A: Kidney-Pancreas Allocation Order*

If a host OPO is offering a kidney and a liver from the same deceased donor, then before allocating the kidney to kidney alone candidates, the host OPO must offer the kidney with the liver to candidates who meet eligibility according to *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation* and are one of the following:

1. Within 150 nautical miles of the donor hospital and have a MELD or PELD of 15 or higher
2. Within 250 nautical miles of the donor hospital and have a MELD or PELD of at least 29
3. Within 250 nautical miles of the donor hospital and status 1A or 1B.

The host OPO may then do *either* of the following:

1. Offer the kidney and liver to any candidates who meet eligibility in *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*.
2. Offer the liver to liver alone candidates according to *Policy 9: Allocation of Livers and Liver-Intestines* and offer the kidney to kidney alone candidates according to *Policy 8: Allocation of Kidneys*.

9.9.A Liver-Kidney Candidate Eligibility for Candidates Less than 18 Years Old

Candidates who are less than 18 years old when registered on the liver waiting list are eligible to receive a liver and kidney from the same deceased donor when the candidate is registered on the waiting list for both organs. Before allocating the kidney to kidney alone candidates, the host OPO must offer the kidney with the liver to all local, regional, and national candidates less than 18 years old at the time of registration.

9.9.B Liver-Kidney Candidate Eligibility for Candidates 18 Years or Older

Candidates who are 18 years or older when registered on the liver waiting list are eligible to receive both a liver and a kidney from the same deceased donor when the candidate is registered on the waiting list for both organs and meets at least *one* of the criteria according to *Table 9-17.*

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 measured or calculated 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 calculated 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 calculated 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 calculated 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 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 *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 *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 *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 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 Priorities and Score Assignments for Lung Candidates

Lung candidates:

- Less than 12 years old are assigned a priority for lung allocation that is based on medical urgency.
- At least 12 years old use a Lung Allocation Score (LAS) to determine lung allocation, as well as geography and blood type.

10.1.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. 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

The OPTN will maintain examples of accepted medical therapy for pulmonary hypertension. Transplant programs must indicate which of these medical therapies the candidate has received. If the candidate has not received any of the listed therapies, the transplant program must submit an exception request to the lung review board (LRB).

10.1.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 level 1, then the candidate is priority 2.

10.1.C Priority and Clinical Data Update Schedule for Candidates Less than 12 Years Old

A transplant program may update the reported clinical data to justify a candidate's priority at any time. When a candidate meets the requirements for priority 1 the candidate will remain at priority 1 for six months from the date first registered as priority 1 on the lung transplant waiting list.

To remain as priority 1, the transplant program must then update the required clinical data, except data that requires a heart catheterization, every six months following the first six months as a priority 1 candidate. The updates must occur in each six month period following the initial six months at priority 1 to remain at priority 1. The transplant program may determine the frequency of performing the heart catheterization.

If the data used to justify the priority 1 criteria are more than 6 months old at the 6-month anniversary date, other than data requiring a heart catheterization, the candidate will automatically be assigned priority 2.

Lung candidates registered on the waiting list at inactive status are subject to these same requirements for updating clinical data.

10.1.D Candidates at Least 12 Years Old - LAS

Candidates who are at least 12 years old or who have an approved adolescent classification exception receive offers for deceased donor lungs based on their calculated LAS. Candidates with a higher LAS receive higher waiting list priority within geography and blood type classifications.

10.1.E LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old

When registering a candidate who is at least 12 years old for a lung transplant, or when registering a candidate with an approved adolescent classification exception according to *Policy 10.2.B: Lung Candidates with Exceptional Cases*, transplant programs must report to the OPTN clinical data corresponding with to the covariates shown in *Table 10-3: Waiting List Mortality Calculation: Covariates and Their Coefficients* and *Table 10-4: Post-Transplant Survival Calculation, Covariates, and Their Coefficients*.

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. The transplant program must maintain source documentation for all laboratory values reported in the candidate's medical chart.

Except as noted in *Policy 10.1.G: Reporting Additional Data for Candidates with an LAS of 50 or Higher*, transplant programs must report to the OPTN LAS covariate clinical data for every covariate in *Table 10-3* and *Table 10-4* for each candidate at least once in every six month period after the date of the candidate's initial registration or the LRB's approval of an adolescent classification exception. The first six-month period begins six months from the date of the candidate's initial registration, or, in the case of adolescent classification exceptions, six months from the date of LRB approval, with a new six-month period occurring every six months thereafter.

A covariate's value expires if the covariate's test date is six-months older than the most recent six-month anniversary date. The LAS system considers actual values and approved estimated values for pulmonary pressures to be valid until the transplant program updates them with new actual values or new approved estimated values as described in Policy *10.2.B.iii: Estimated Values Approved by the LRB*.

Transplant programs may report a medically reasonable estimated value if a test needed to obtain an actual value for a variable covariate cannot be performed due to the candidate's medical condition. Before entering estimated values, programs must receive approval from the LRB, which will determine whether the estimated values are appropriate according to *Policy 10.2.B.iii: Estimated Values Approved by the LRB.* Approved estimated values remain valid until an updated actual value is reported for the covariate, or until the transplant program reports a new, approved estimated value.

LAS covariate data obtained by heart catheterization does not need to be reported to the OPTN every six months. For LAS covariate data that requires a heart catheterization, the transplant program may determine the frequency of updating the data. However, if a transplant program performs a heart catheterization test on the candidate during the six month interval, then it must report the data to the OPTN.

If values for certain covariates are missing, expired, or below the threshold as defined by *Table 10-1*, then the LAS calculation will substitute normal or least beneficial values to calculate the candidate's LAS. A normal value is one that a healthy individual is likely to exhibit. A least beneficial value is one that will calculate the lowest LAS for a candidate. *Table 10-1* lists the normal and least beneficial values that will be substituted.

Table 10-1: Values Substituted for Missing or Expired Actual Values in Calculating the LAS

If this covariate's value:	Is:	Then the LAS 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/m2
Cardiac index	Missing	3.0 $L/min/m^2$

If this covariate's value:	Is:	Then the LAS calculation will use this substituted value:
Continuous mechanical ventilation	Missing or expired	No mechanical ventilation in the waiting list model Continuous mechanical ventilation while hospitalized in the post-transplant survival measure
Creatinine: serum	Missing or expired	0.1 mg/dL in the waiting list model 40 mg/dL in the post-transplant survival measure for candidates at least 18 years old 0 mg/dL in the post-transplant survival measure for candidates less than 18 years old
Functional status	Missing or expired	No assistance needed in the waiting list model
Oxygen needed at rest	Missing or expired	No supplemental oxygen needed in the waiting list model 26.33 L/min in the post-transplant survival measure
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 in the waiting list urgency measure 0 feet in the post-transplant survival measure

10.1.F The LAS Calculation

The LAS calculation uses *all* of the following measures:

- Waiting List Urgency Measure, which is the expected number of days a candidate will live without a transplant during an additional year on the waiting list.
- Post-transplant Survival Measure, which is the expected number of days a candidate will live during the first year post-transplant.
- Transplant Benefit Measure, which is the difference between the Post-transplant Survival Measure and the Waiting List Urgency Measure.
- Raw Allocation Score, which is the difference between Transplant Benefit Measure and Waiting List Urgency Measure.

To determine a candidate's LAS, the Raw Allocation Score is normalized to a continuous scale of zero to 100.

The equation for the LAS calculation is:

$$\mathrm{LAS} = \frac{100 * [\mathrm{PTAUC} - 2 * \mathrm{WLAUC} + 730]}{1095}$$

Table 10-2: LAS Calculation Values

Where…	Includes…
$PTAUC = \sum_{k=0}^{364} S_{TX}(k)$	PTAUC = the area under the post-transplant survival probability curve during the first post-transplant year. β_I = the coefficient for characteristic i from the waiting list measure, according to *Table 10-3: Waiting List Mortality Calculation: Covariates and their Coefficients.*
$S_{TX}(t) = S_{TX,0}(t)^{e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \ldots + \alpha_q Y_q}}$	$S_{TX}(t)$ = the expected post-transplant survival probability at time t for an individual candidate. Y_i = the value of the j^{th} characteristic for an individual candidate $\propto_j$ = the coefficient for characteristic j from the post-transplant survival measure, according to *Table 10-4: Post-Transplant Survival Calculation, Covariates, and Their Coefficients*.
$WLAUC = \sum_{k=0}^{364} S_{WL}(k)$	WLAUC = the area under the waiting list survival probability curve during the next year.
$S_{WL}(t) = S_{WL,0}(t)^{e^{\beta_1 X_1 + \beta_2 X_2 + \ldots + \beta_p X_p}}$	$S_{WL,0}(t)$ = the baseline waiting list survival probability at time t, according to *Table 10-11: Baseline Waiting List Survival (SWL(t)) Probability*. $S_{TX,0}(t)$ = the baseline post-transplant survival probability at time t, according to *Table 10-12: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability*. $S_{WL}(t)$ = the expected waiting list survival probability at time t for an individual candidate X_i = the value of the i^{th} characteristic for an individual candidate.

Table 10-3 provides the covariates and their coefficients for the waiting list mortality calculation. See *Policy 10.1.F.i: Lung Disease Diagnosis Groups* for specific information on each diagnosis group.

Table 10-3: Waiting List Mortality Calculation: Covariates and their Coefficients

For this covariate:	The following coefficient is used in the LAS calculation:
Age (year)	0.0281444188123287*age
Bilirubin (mg/dL) value with the most recent test date and time	0.15572123729572*(bilirubin – 1) if bilirubin is more than 1.0 mg/dL 0 when bilirubin is 1.0 mg/dL or less
Body mass index (BMI) (kg/m^2)	0.10744133677215*(20 – BMI) for BMI less than 20 kg/m^2 0 if BMI is at least 20 kg/m^2
Ventilation status if candidate is hospitalized	1.57618530736936 if continuous mechanical ventilation needed 0 if no continuous mechanical ventilation needed
Creatinine (serum) (mg/dL) with the most recent test date and time	0.0996197163645* creatinine if candidate is at least 18 years old 0 if candidate is less than 18 years old
Diagnosis Group A	0
Diagnosis Group B	1.26319338239175
Diagnosis Group C	1.78024171092307
Diagnosis Group D	1.51440083414275
Detailed diagnosis: Bronchiectasis (Diagnosis Group A only)	0.40107198445555
Detailed Diagnosis: Pulmonary fibrosis: other specify cause (Diagnosis Group D only)	0.2088684500011
Detailed Diagnosis: COVID-19: pulmonary fibrosis (Diagnosis Group D only)	0.2088684500011
Detailed Diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Diagnosis Group D only)	-0.64590852776042
1. Detailed Diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Diagnosis Group A only)	1.39885489102977

For this covariate:	The following coefficient is used in the LAS calculation:
Detailed Diagnosis: Sarcoidosis with PA mean pressure missing (Diagnosis Group A only)	1.39885489102977
Functional Status	-0.59790409246653 if no assistance needed with activities of daily living 0 if some or total assistance needed with activities of daily living
Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)	0.0340531822566417*O_2 for Diagnosis Group B 0.08232292818591*O_2 for Diagnosis Groups A, C, and D
PCO_2 (mm Hg): current	0.12639905519026*PCO_2/10 if PCO_2 is at least 40 mm Hg
PCO_2 increase of at least 15%	0.15556911866376 if PCO_2 increase is at least 15% 0 if PCO_2 increase is less than 15%
Pulmonary artery (PA) systolic pressure (10 mm Hg) at rest, prior to any exercise	0.55767046368853*(PA systolic – 40)/10 for Diagnosis Group A if the PA systolic pressure is greater than 40 mm Hg 0 for Diagnosis Group A if the PA systolic pressure is 40 mm Hg or less 0.1230478043299*PA systolic/10 for Diagnosis Groups B, C, and D
Six-minute-walk distance (feet) obtained while the candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.	-0.09937981549564*Six-minute-walk distance/100

Table 10-4 lists the covariates and corresponding coefficients in the waiting list and post-transplant survival measures. See *Policy 10.1.F.i: Lung Disease Diagnosis Groups* for specific information on each diagnosis group.

Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients

For this variable:	The following is used in the LAS calculation:
Age (years)	0.0208895939056676*(age–45) if candidate is greater than 45 years old 0 if candidate is 45 years old or younger
Creatinine (serum) at transplant (mg/dL) with the most recent date and time	0.25451764981323*creatinine if candidate is at least 18 years old 0 if candidate is less than 18 years old
Cardiac index (L/min/m^2) at rest, prior to any exercise	0.1448727551614 if less than 2 L/min/m^2 0 if at least 2 L/min/m^2
Ventilation status if candidate is hospitalized	0.33161555489537 if continuous mechanical ventilation needed 0 if no continuous mechanical ventilation needed
Diagnosis Group A	0
Diagnosis Group B	0.51341349576197
Diagnosis Group C	0.23187885123342
Diagnosis Group D	0.12527366545917
Detailed diagnosis: Bronchiectasis (Diagnosis Group A only)	0.12048575705296
Detailed diagnosis: Obliterative bronchiolitis (non-retransplant, Diagnosis Group D only)	-0.33402539276216
Detailed diagnosis: Constrictive bronchiolitis (Diagnosis Group D only)	-0.33402539276216
Detailed diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Diagnosis Group D only)	0.43537371336129
Detailed diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Diagnosis Group A only)	0.98051166673574
Detailed diagnosis: Sarcoidosis with PA mean pressure missing (Diagnosis Group A only)	0.98051166673574

For this variable:	The following is used in the LAS calculation:
Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)	0.0100383613234584*O_2 for Diagnosis Group A 0.0093694370076423*O_2 for Diagnosis Groups B, C, and D
Six-minute-walk-distance (feet) obtained while candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.	0.0001943695814883*(1200-Six-minute-walk distance) 0 if six-minute-distance-walked is at least 1,200 feet

See *Policy 10.5: Probability Data Used in the LAS Calculation* for *Tables 10-11* and *10-12* that provide data used in the LAS calculation.

10.1.F.i Lung Disease Diagnosis Groups

The LAS calculation uses diagnosis Groups A, B, C, and D as listed below.

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:
    - mean pulmonary artery pressure of 30 mm Hg or less
    - missing mean pulmonary artery pressure
- 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
- 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 or more 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 mean pulmonary artery 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

10.1.F.ii PCO2 in the LAS

The LAS 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 LAS. 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 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old,* the candidate's LAS 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 LAS, the LAS 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 *Policy 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old*, 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 LAS 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 LAS 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 LAS 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 LAS calculation will use the normal clinical PCO_2 value.

10.1.G Reporting Additional Data for Candidates with an LAS of 50 or Higher

Within 14 days of the date a candidate's LAS becomes 50 or higher, the candidate's transplant program must assess and report to the OPTN the following variables:

1. Assisted ventilation
2. Supplemental oxygen
3. Current PCO_2

While the candidate's LAS remains 50 or higher, the transplant program must continue to assess and report assisted ventilation and supplemental oxygen data every 14 days. The transplant program is only required to report updated PCO_2 data if the assessment was performed during the previous 14 day interval.

The transplant program must maintain documentation of each assessment in the candidate's medical chart.

10.2 Priority and Score Exceptions

10.2.A Allocation Exception for Highly Sensitized Patients

A lung candidate's transplant physician may use medical judgment to determine that a lung candidate is highly sensitized.

If there is one or more lung transplant programs that have potential transplant recipients (PTRs) who appear on the match run above the highly sensitized candidate, then the highly sensitized candidate's transplant program may request that those transplant programs refuse the offer so that the transplant program can accept the offer for the highly sensitized candidate.

If the only PTRs on the match run are registered at the same transplant program as the highly sensitized candidate, the transplant physician may use medical judgment to accept the offer for the highly sensitized candidate out of sequence.

10.2.B Lung Candidates with Exceptional Cases

The Lung Transplantation Committee establishes guidelines for special case review by the LRB.

If a candidate's transplant program believes that a candidate's current priority or LAS does not appropriately reflect the candidate's medical urgency for transplant, the transplant program may request approval of a specific priority or LAS by the LRB. The transplant program can also ask the LRB to approve specific estimated values or diagnoses.

For lung candidates less than 12 years old, transplant programs may request classification as an adolescent candidate for the purposes of *Policy 10.4.C: Allocation of Lungs from Deceased Donors at Least 18 Years Old* and *Policy 10.4.D: Allocation of Lungs from Deceased Donors Less than 18 Years Old*. Candidates receiving this exception will also maintain their pediatric classification for the purposes of *Policy 10.4.D: Allocation of Lungs from Deceased Donors Less than 18 Years Old*.

10.2.B.i LRB Review Process

Requests for approval of estimated values, diagnoses, specific LAS, or adolescent classification exceptions require prospective review by the LRB. The transplant hospital must submit requests for LRB review to the OPTN, and accompany each request for special review with a supporting narrative. The LRB will have seven days to reach a decision regarding the request, starting from the date that the OPTN sends the request to the LRB.

If the LRB denies a request upon initial review, then the transplant program may choose to appeal the decision and request reconsideration by the LRB. The transplant program has seven days from the date of the initial denial of the initial request to appeal. The LRB has seven days to reach a decision on the appeal, starting from the date that the OPTN sends the appealed request to the LRB. If the LRB does not complete its review of an initial request or appeal within seven days of receiving it, then the candidate will not receive the requested LAS, diagnosis,

estimated value, or adolescent classification, and the OPTN will send the request or appeal to the Lung Transplantation Committee for further review.

Requests to register a candidate less than 12 years old as priority 1 require retrospective LRB review by the LRB.

10.2.B.ii LRB Decision Overrides

If the LRB denies a transplant hospital's initial request or appeal for an estimated value, adolescent classification, or specific LAS on appeal, the transplant hospital has the option to override the decision of the LRB. If the transplant hospital elects to override the decision of the LRB, then the OPTN will send the request or appeal to the Lung Transplantation Committee for review. This review by the Lung Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee (MPSC). If the MPSC agrees with the Lung Transplantation Committee's decision, a member who has registered a candidate with an unapproved estimated value, adolescent classification, or LAS will be subject to action according to *Appendix L: Reviews, Actions, and Due Process* of the *OPTN Bylaws*.

10.2.B.iii Estimated Values Approved by the LRB

Approved estimated values approved by the LRB or Lung Transplantation Committee are valid until an actual value is reported to the OPTN or a new estimated value is reported to the OPTN.

10.2.B.iv LAS Diagnoses Approved by the LRB

A diagnosis that has been approved by the LRB or the Lung Transplantation Committee is valid indefinitely, or until an adjustment is requested and, if necessary, approved by the LRB.

10.2.B.v LAS Approved by the LRB

An LAS approved by the LRB or the Lung Transplantation Committee will remain valid for six months from the date the candidate's LAS is updated, (or from the candidate's twelfth birthday, whichever occurs later). If the candidate is still on the waiting list six months after the date the LAS is updated, then the candidate's LAS will be computed as described in Policy *10.1: Priorities and Score Assignments for Lung Candidates* unless a new LAS or priority request is submitted to the OPTN.

10.3 Waiting Time

Waiting time for lung candidates begins when the candidate is registered on the waiting list. Candidates at least 12 years old awaiting a lung transplant on the waiting list at inactive status will not accrue any waiting time while at inactive status. Lung candidates less than 12 years old accrue waiting time when registered at inactive status.

When waiting time is used for lung allocation, a candidate will receive a preference over other candidates who have accumulated less waiting time within the same priority or LAS.

10.3.A Lung Candidates at Least 12 Years Old

If multiple candidates have identical computed LASs greater than zero, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by the earliest date and time of each candidate's most recent data used in the calculation of the LAS reported to the OPTN.

If multiple candidates have identical assigned LASs due to an exceptional case request as defined by *Policy 10.2.B*, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by the earliest date and time that each candidate's most recent LRB approval of that LAS was reported to the OPTN.

10.3.B Lung Candidates Less than 12 Years Old

Allocation ranking for a priority 1 lung candidate is based on the candidate's most recent priority 1 waiting time, which only includes the candidate's current time as priority 1 and does not include any previous time spent as priority 1.

If there is ever a tie among priority 1 candidates within the same classification due to identical priority 1 waiting times, then the lung will be allocated to the priority 1 candidate with the most total waiting time. Total waiting time includes time spent waiting as priority 1, priority 2, and at inactive status. Allocation ranking will also consider this total waiting time.

Among priority 2 candidates, allocation ranking considers total waiting time for receiving deceased donor lung offers. Total waiting time includes the time a candidate spent waiting as priority 1, priority 2, and inactive. A priority 2 lung candidate's waiting time is the same as total waiting time.

10.4 Lung Allocation Classifications and Rankings

10.4.A Sorting Within Each Classification

Lung candidates at least 12 years old are sorted in the following order:

1. LAS (highest to lowest)
2. Total active waiting time (longest to shortest)
3. LAS variable update date and time (earliest to most recent approval)
4. LAS exception date (earliest to most recent approval)

Lung candidates less than 12 years old are sorted in the following order:

1. Pediatric priority waiting time (longest to shortest)
2. Total waiting time (longest to shortest)

10.4.B Allocation of Lungs by Blood Type

A deceased donor's blood type compatibility with a lung candidate is defined in *Table 10-5* below.

Table 10-5: Deceased Donor Blood Type Compatibility with a Lung Candidate

Deceased Donor's	Candidate's Blood Type			
Blood Type	O	A	B	AB
O	Identical	Compatible	Compatible	Compatible
A	Screened*	Identical	Screened*	Compatible
B	Screened*	Screened*	Identical	Compatible
AB	Screened*	Screened*	Screened*	Identical

*Screened from match run, unless eligible for intended blood group incompatible offers according to *Policy 10.4.B.i*.

10.4.B.i Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Lungs

Candidates will be eligible for intended blood group incompatible deceased donor lungs if they meet the requirements according to *Table 10-6* below.

Table 10-6: Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Lungs

If the candidate is:	And meets *all* of the following:
Less than one year old at the time of the match run	1. Is priority 1. 2. 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. Is registered prior to turning two years old. 2. Is priority 1. 3. 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.ii 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 group incompatible lung, according to *Table 10-7* below, at *all* of the following times:

1. Upon initially reporting that a candidate is willing to accept an intended blood group incompatible lung.
2. Every 30 days after initially reporting that a candidate is willing to accept an intended blood group incompatible lung.

Table 10-7: Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Group 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 group incompatible lung, according to *Table 10-8*, 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 10-8: Isohemagglutinin Titer Reporting Requirements for a Recipient of an Intended Blood Group 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

10.4.C Allocation of Lungs from Deceased Donors at Least 18 Years Old

Single and double lungs from deceased donors at least 18 years old are allocated according to *Table 10-9* below.

Table 10-9: Allocation of Lungs from Deceased Donors at Least 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	At least 12 years old, blood type identical to the donor	250NM
2	At least 12 years old, blood type compatible with the donor	250NM
3	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers	250NM
4	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers	250NM
5	Priority 2, blood type identical to the donor	250NM
6	Priority 2, blood type compatible with the donor	250NM
7	At least 12 years old, blood type identical to the donor	500NM
8	At least 12 years old, blood type compatible with the donor	500NM

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
9	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers	500NM
10	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers	500NM
11	Priority 2, blood type identical to the donor	500NM
12	Priority 2, blood type compatible with the donor	500NM
13	At least 12 years old, blood type identical to the donor	1000NM
14	At least 12 years old, blood type compatible with the donor	1000NM
15	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers	1000NM

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
16	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers	1000NM
17	Priority 2, blood type identical to the donor	1000NM
18	Priority 2, blood type compatible with the donor	1000NM
19	At least 12 years old, blood type identical to the donor	1500NM
20	At least 12 years old, blood type compatible with the donor	1500NM
21	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers	1500NM
22	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers	1500NM
23	Priority 2, blood type identical to the donor	1500NM
24	Priority 2, blood type compatible 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
25	At least 12 years old, blood type identical to the donor	2500NM
26	At least 12 years old, blood type compatible with the donor	2500NM
27	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers	2500NM
28	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers	2500NM
29	Priority 2, blood type identical to the donor	2500NM
30	Priority 2, blood type compatible with the donor	2500NM
31	At least 12 years old, blood type identical to the donor	Nation
32	At least 12 years old, blood type compatible 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
33	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers	Nation
34	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers	Nation
35	Priority 2, blood type identical to the donor	Nation
36	Priority 2, blood type compatible with the donor	Nation

10.4.D Allocation of Lungs from Deceased Donors Less than 18 Years Old

Single and double lungs from deceased donors less than 18 years old are allocated according to *Table 10-10* below.

Table 10-10: Allocation of Lungs from Deceased 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	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor Less than 1 year old and eligible for intended blood group incompatible offers	1000NM
2	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers	1000NM
3	Priority 2, blood type identical to the donor	1000NM
4	Priority 2, blood type compatible with the donor	1000NM
5	12 to less than 18 years old, blood type identical to the donor	1000NM
6	12 to less than 18 years old, blood type compatible with the donor	1000NM
7	At least 18 years old, blood type identical to the donor	250NM
8	At least 18 years old, blood type compatible with the donor	250NM
9	At least 18 years old, blood type identical to the donor	500NM
10	At least 18 years old, blood type compatible with the donor	500NM
11	At least 18 years old, blood type identical to the donor	1000NM
12	At least 18 years old, blood type compatible 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
13	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor Less than 1 year old and eligible for intended blood group incompatible offers	1500NM
14	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers	1500NM
15	Priority 2, blood type identical to the donor	1500NM
16	Priority 2, blood type compatible with the donor	1500NM
17	12 to less than 18 years old, blood type identical to the donor	1500NM
18	12 to less than 18 years old, blood type compatible with the donor	1500NM
19	At least 18 years old, blood type identical to the donor	1500NM
20	At least 18 years old, blood type compatible 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
21	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor Less than 1 year old and eligible for intended blood group incompatible offers	2500NM
22	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers	2500NM
23	Priority 2, blood type identical to the donor	2500NM
24	Priority 2, blood type compatible with the donor	2500NM
25	12 to less than 18 years old, blood type identical to the donor	2500NM
26	12 to less than 18 years old, blood type compatible with the donor	2500NM
27	At least 18 years old, blood type identical to the donor	2500NM
28	At least 18 years old, blood type compatible with the donor	2500NM
29	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers	Nation

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
30	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers	Nation
31	Priority 2, blood type identical to the donor	Nation
32	Priority 2, blood type compatible with the donor	Nation
33	12 to less than 18 years old, blood type identical to the donor	Nation
34	12 to less than 18 years old, blood type compatible with the donor	Nation
35	At least 18 years old, blood type identical to the donor	Nation
36	At least 18 years old, blood type compatible with the donor	Nation

10.5 Probability Data Used in the LAS Calculation

Table 10-11: Baseline Waiting List Survival (SWL(t)) Probability Where t=Time in Days

t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$
0	1.0000000000	**49**	0.9989492645	**98**	0.9980759414	**147**	0.9975146609	**196**	0.9969683767
1	0.9999975489	**50**	0.9989218966	**99**	0.9980462038	**148**	0.9975044749	**197**	0.9969683767
2	0.9999827070	**51**	0.9988856853	**100**	0.9980462038	**149**	0.9974993058	**198**	0.9969683767
3	0.9999561442	**52**	0.9988518113	**101**	0.9980357746	**150**	0.9974923101	**199**	0.9969587577
4	0.9999275553	**53**	0.9988426443	**102**	0.9980357746	**151**	0.9974768114	**200**	0.9969587577
5	0.9999018223	**54**	0.9988426443	**103**	0.9980261747	**152**	0.9974768114	**201**	0.9969454938
6	0.9998777824	**55**	0.9988209613	**104**	0.9979909233	**153**	0.9974554527	**202**	0.9968612819
7	0.9998561463	**56**	0.9988149888	**105**	0.9979796304	**154**	0.9974097005	**203**	0.9968383024
8	0.9998143795	**57**	0.9987715012	**106**	0.9979796304	**155**	0.9973345023	**204**	0.9968383024
9	0.9997863737	**58**	0.9987338578	**107**	0.9979760272	**156**	0.9973345023	**205**	0.9968247526
10	0.9997696882	**59**	0.9987247079	**108**	0.9979646981	**157**	0.9973270637	**206**	0.9968185781
11	0.9997397377	**60**	0.9987034482	**109**	0.9979440109	**158**	0.9973208018	**207**	0.9968185781
12	0.9997045384	**61**	0.9987034482	**110**	0.9978768653	**159**	0.9973148013	**208**	0.9968185781
13	0.9996823002	**62**	0.9986649209	**111**	0.9978718005	**160**	0.9972940898	**209**	0.9968185781
14	0.9996498264	**63**	0.9986649209	**112**	0.9978279771	**161**	0.9972940898	**210**	0.9968097445
15	0.9996353431	**64**	0.9986596474	**113**	0.9978239640	**162**	0.9972940898	**211**	0.9967964069
16	0.9996288212	**65**	0.9986301115	**114**	0.9978239640	**163**	0.9972727684	**212**	0.9967166260
17	0.9996154867	**66**	0.9986166941	**115**	0.9978239640	**164**	0.9972727684	**213**	0.9966358744
18	0.9995970948	**67**	0.9985746371	**116**	0.9978239640	**165**	0.9972727684	**214**	0.9966212192
19	0.9995652300	**68**	0.9985695968	**117**	0.9978239640	**166**	0.9972688422	**215**	0.9966212192
20	0.9995271489	**69**	0.9985667636	**118**	0.9978239640	**167**	0.9972234233	**216**	0.9966144147
21	0.9995080982	**70**	0.9985563118	**119**	0.9977825323	**168**	0.9972234233	**217**	0.9966016656
22	0.9994934457	**71**	0.9985101367	**120**	0.9977771080	**169**	0.9972179105	**218**	0.9965791846
23	0.9994602264	**72**	0.9984938912	**121**	0.9977674724	**170**	0.9972086398	**219**	0.9965791846
24	0.9994302540	**73**	0.9984903590	**122**	0.9977606316	**171**	0.9972086398	**220**	0.9965744007
25	0.9994060375	**74**	0.9984305838	**123**	0.9977340449	**172**	0.9972086398	**221**	0.9965236975
26	0.9993816059	**75**	0.9984129085	**124**	0.9976558111	**173**	0.9972086398	**222**	0.9965110962
27	0.9993613122	**76**	0.9984027696	**125**	0.9976558111	**174**	0.9972086398	**223**	0.9964387358
28	0.9993350553	**77**	0.9983908074	**126**	0.9976504510	**175**	0.9971827158	**224**	0.9964387358
29	0.9993022038	**78**	0.9983908074	**127**	0.9976370243	**176**	0.9971692174	**225**	0.9964227617
30	0.9992938892	**79**	0.9983787271	**128**	0.9976101536	**177**	0.9971692174	**226**	0.9964227617
31	0.9992721423	**80**	0.9983696472	**129**	0.9976101536	**178**	0.9971692174	**227**	0.9964120372
32	0.9992622566	**81**	0.9983630336	**130**	0.9976101536	**179**	0.9971692174	**228**	0.9963875823
33	0.9992427448	**82**	0.9983467929	**131**	0.9975990034	**180**	0.9971603270	**229**	0.9963875823
34	0.9992005080	**83**	0.9983136954	**132**	0.9975835550	**181**	0.9971603270	**230**	0.9963684607
35	0.9991776739	**84**	0.9983064970	**133**	0.9975766810	**182**	0.9971320838	**231**	0.9963684607
36	0.9991551715	**85**	0.9982951177	**134**	0.9975701094	**183**	0.9971131145	**232**	0.9963684607
37	0.9991302006	**86**	0.9982565537	**135**	0.9975701094	**184**	0.9971131145	**233**	0.9963684607
38	0.9991278479	**87**	0.9982441865	**136**	0.9975607830	**185**	0.9971091508	**234**	0.9963684607
39	0.9991028378	**88**	0.9982441865	**137**	0.9975520103	**186**	0.9970985061	**235**	0.9963684607
40	0.9990801777	**89**	0.9982441865	**138**	0.9975404803	**187**	0.9970985061	**236**	0.9963684607
41	0.9990600363	**90**	0.9982257230	**139**	0.9975404803	**188**	0.9970985061	**237**	0.9963684607
42	0.9990482109	**91**	0.9981791418	**140**	0.9975404803	**189**	0.9970985061	**238**	0.9963684607
43	0.9990482109	**92**	0.9981791418	**141**	0.9975404803	**190**	0.9970985061	**239**	0.9963684607
44	0.9990358743	**93**	0.9981714154	**142**	0.9975404803	**191**	0.9970985061	**240**	0.9963684607
45	0.9990358743	**94**	0.9981444359	**143**	0.9975344179	**192**	0.9970985061	**241**	0.9962582929
46	0.9990016655	**95**	0.9981313503	**144**	0.9975344179	**193**	0.9970985061	**242**	0.9962582929
47	0.9989778087	**96**	0.9981154417	**145**	0.9975344179	**194**	0.9970911735	**243**	0.9961947546
48	0.9989665684	**97**	0.9981154417	**146**	0.9975298313	**195**	0.9970671621	**244**	0.9961947546

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Table 10-11: Baseline Waiting List Survival ($S_{WL}(t)$) Probability Where t=Time in Days (Continued)

t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$
245	0.9961947546	**269**	0.9957784566	**293**	0.9955475237	**317**	0.9952281619	**341**	0.9949369873
246	0.9960956354	**270**	0.9957784566	**294**	0.9955054645	**318**	0.9951666810	**342**	0.9949369873
247	0.9960437794	**271**	0.9957784566	**295**	0.9954978576	**319**	0.9951314001	**343**	0.9949369873
248	0.9960247257	**272**	0.9957784566	**296**	0.9954793243	**320**	0.9951314001	**344**	0.9948416999
249	0.9959880763	**273**	0.9957784566	**297**	0.9954639104	**321**	0.9951314001	**345**	0.9948416999
250	0.9959742895	**274**	0.9957702527	**298**	0.9954392804	**322**	0.9951314001	**346**	0.9948416999
251	0.9959742895	**275**	0.9957639142	**299**	0.9954392804	**323**	0.9951314001	**347**	0.9947378061
252	0.9959552359	**276**	0.9957410244	**300**	0.9954137179	**324**	0.9950798577	**348**	0.9946948263
253	0.9959552359	**277**	0.9957255372	**301**	0.9954137179	**325**	0.9950798577	**349**	0.9946845005
254	0.9959380587	**278**	0.9957255372	**302**	0.9953849510	**326**	0.9950798577	**350**	0.9946845005
255	0.9959380587	**279**	0.9957255372	**303**	0.9953581531	**327**	0.9950798577	**351**	0.9946845005
256	0.9959380587	**280**	0.9957255372	**304**	0.9953445180	**328**	0.9950798577	**352**	0.9946845005
257	0.9959380587	**281**	0.9956914479	**305**	0.9953445180	**329**	0.9950798577	**353**	0.9946845005
258	0.9959272229	**282**	0.9956914479	**306**	0.9953445180	**330**	0.9950798577	**354**	0.9945854823
259	0.9959272229	**283**	0.9956914479	**307**	0.9953093054	**331**	0.9950798577	**355**	0.9945854823
260	0.9959225083	**284**	0.9956914479	**308**	0.9952957037	**332**	0.9950670017	**356**	0.9945720480
261	0.9959225083	**285**	0.9956797646	**309**	0.9952957037	**333**	0.9949858453	**357**	0.9945265776
262	0.9959225083	**286**	0.9956797646	**310**	0.9952741113	**334**	0.9949512121	**358**	0.9945265776
263	0.9959225083	**287**	0.9956797646	**311**	0.9952741113	**335**	0.9949512121	**359**	0.9945265776
264	0.9959225083	**288**	0.9956605860	**312**	0.9952514686	**336**	0.9949512121	**360**	0.9944766010
265	0.9959225083	**289**	0.9956605860	**313**	0.9952514686	**337**	0.9949369873	**361**	0.9944766010
266	0.9958954164	**290**	0.9956391439	**314**	0.9952514686	**338**	0.9949369873	**362**	0.9944766010
267	0.9957938685	**291**	0.9956391439	**315**	0.9952281619	**339**	0.9949369873	**363**	0.9944766010
268	0.9957938685	**292**	0.9955475237	**316**	0.9952281619	**340**	0.9949369873	**364**	0.9943896539

Table 10-12: 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	$S_{TX}(t)$	t	$S_{TX}(t)$
0	1.0000000000	**49**	0.9859396692	**98**	0.9804349392	**147**	0.9760079584	**196**	0.9711061937
1	0.9989168684	**50**	0.9858164949	**99**	0.9801864682	**148**	0.9759453602	**197**	0.9708538746
2	0.9984346294	**51**	0.9855701194	**100**	0.9800000394	**149**	0.9758201487	**198**	0.9706645555
3	0.9977712423	**52**	0.9855701194	**101**	0.9799378767	**150**	0.9757575320	**199**	0.9705383076
4	0.9973484709	**53**	0.9853236329	**102**	0.9798135405	**151**	0.9757575320	**200**	0.9703489195
5	0.9970462337	**54**	0.9850154170	**103**	0.9796891562	**152**	0.9754444350	**201**	0.9702226203
6	0.9965625190	**55**	0.9847070827	**104**	0.9796891562	**153**	0.9753817621	**202**	0.9700962568
7	0.9961993881	**56**	0.9846453556	**105**	0.9796891562	**154**	0.9752564117	**203**	0.9699066925
8	0.9958966278	**57**	0.9844601577	**106**	0.9796269487	**155**	0.9751937214	**204**	0.9698434819
9	0.9954724846	**58**	0.9842749162	**107**	0.9794403086	**156**	0.9751310267	**205**	0.9698434819
10	0.9951086930	**59**	0.9841513879	**108**	0.9793780730	**157**	0.9750683237	**206**	0.9697802663
11	0.9948053130	**60**	0.9838425267	**109**	0.9793158337	**158**	0.9748802003	**207**	0.9694642073
12	0.9942589911	**61**	0.9837807200	**110**	0.9792535831	**159**	0.9748174678	**208**	0.9693376951
13	0.9941374518	**62**	0.9835952969	**111**	0.9792535831	**160**	0.9747547321	**209**	0.9692111628
14	0.9938943616	**63**	0.9835334714	**112**	0.9791290692	**161**	0.9746919892	**210**	0.9691478845
15	0.9936511061	**64**	0.9834716335	**113**	0.9790668010	**162**	0.9746292392	**211**	0.9691478845
16	0.9932859829	**65**	0.9832242857	**114**	0.9788176541	**163**	0.9745037272	**212**	0.9691478845
17	0.9931032767	**66**	0.9831624223	**115**	0.9787553419	**164**	0.9744409567	**213**	0.9690213151
18	0.9927987155	**67**	0.9831624223	**116**	0.9786930245	**165**	0.9743154118	**214**	0.9688947255
19	0.9925549731	**68**	0.9830386904	**117**	0.9786307023	**166**	0.9741898451	**215**	0.9687681067
20	0.9924330443	**69**	0.9827292921	**118**	0.9785060459	**167**	0.9741270468	**216**	0.9687681067
21	0.9921891249	**70**	0.9824197258	**119**	0.9785060459	**168**	0.9741270468	**217**	0.9687681067
22	0.9920061484	**71**	0.9823577717	**120**	0.9783190327	**169**	0.9740014458	**218**	0.9686414652
23	0.9916401290	**72**	0.9822338558	**121**	0.9782566683	**170**	0.9738758131	**219**	0.9685147964
24	0.9914570116	**73**	0.9821718893	**122**	0.9781942967	**171**	0.9738758131	**220**	0.9684514491

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Table 10-12: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability Where t=Time in Days (Continued)

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
25	0.9913959504	**74**	0.9821718893	**123**	0.9781319182	**172**	0.9736245232	**221**	0.9683880937
26	0.9910906393	**75**	0.9821718893	**124**	0.9779447835	**173**	0.9735616621	**222**	0.9682613699
27	0.9909073743	**76**	0.9821099189	**125**	0.9779447835	**174**	0.9734359312	**223**	0.9681979935
28	0.9904797245	**77**	0.9820479459	**126**	0.9778200018	**175**	0.9733101762	**224**	0.9681346105
29	0.9899294478	**78**	0.9819859697	**127**	0.9777575984	**176**	0.9732472868	**225**	0.9681346105
30	0.9898070359	**79**	0.9819239837	**128**	0.9777575984	**177**	0.9729957417	**226**	0.9681346105
31	0.9891950158	**80**	0.9818000096	**129**	0.9777575984	**178**	0.9729957417	**227**	0.9678810937
32	0.9887660579	**81**	0.9818000096	**130**	0.9777575984	**179**	0.9729328284	**228**	0.9678810937
33	0.9886434002	**82**	0.9817380113	**131**	0.9776951904	**180**	0.9728069960	**229**	0.9676274650
34	0.9884593786	**83**	0.9816760095	**132**	0.9775703575	**181**	0.9728069960	**230**	0.9675640123
35	0.9880912671	**84**	0.9816760095	**133**	0.9775703575	**182**	0.9724923862	**231**	0.9675005516
36	0.9879070815	**85**	0.9816140030	**134**	0.9775703575	**183**	0.9724923862	**232**	0.9675005516
37	0.9877842742	**86**	0.9814899878	**135**	0.9775079236	**184**	0.9723664833	**233**	0.9675005516
38	0.9873544476	**87**	0.9813659495	**136**	0.9772581879	**185**	0.9723035158	**234**	0.9672466908
39	0.9871700789	**88**	0.9812418882	**137**	0.9771332758	**186**	0.9721146241	**235**	0.9669292385
40	0.9869242045	**89**	0.9811178010	**138**	0.9771332758	**187**	0.9720516381	**236**	0.9667386173
41	0.9869242045	**90**	0.9811178010	**139**	0.9769458756	**188**	0.9719256562	**237**	0.9666114980
42	0.9868627089	**91**	0.9809936908	**140**	0.9767584228	**189**	0.9716736755	**238**	0.9664843455
43	0.9866167108	**92**	0.9809936908	**141**	0.9766959165	**190**	0.9715476030	**239**	0.9664843455
44	0.9865551891	**93**	0.9809936908	**142**	0.9766959165	**191**	0.9712954163	**240**	0.9664207511
45	0.9864321394	**94**	0.9808074944	**143**	0.9765708928	**192**	0.9712323468	**241**	0.9663571531
46	0.9863705962	**95**	0.9808074944	**144**	0.9763207692	**193**	0.9711692727	**242**	0.9661663551
47	0.9861243805	**96**	0.9806833301	**145**	0.9763207692	**194**	0.9711061937	**243**	0.9660391221
48	0.9859396692	**97**	0.9804970537	**146**	0.9760705488	**195**	0.9711061937	**244**	0.9659118728
245	0.9659118728	**269**	0.9632965280	**293**	0.9611192441	**317**	0.9586128181	**341**	0.9555806338
246	0.9657209456	**270**	0.9631686533	**294**	0.9609908927	**318**	0.9585484383	**342**	0.9555806338
247	0.9657209456	**271**	0.9631686533	**295**	0.9609908927	**319**	0.9585484383	**343**	0.9555159535
248	0.9655936296	**272**	0.9631686533	**296**	0.9607341600	**320**	0.9584840545	**344**	0.9554512674
249	0.9655299608	**273**	0.9631686533	**297**	0.9606699547	**321**	0.9584196607	**345**	0.9553865754
250	0.9655299608	**274**	0.9629768044	**298**	0.9605415356	**322**	0.9582908711	**346**	0.9553865754
251	0.9654662741	**275**	0.9629128396	**299**	0.9604130979	**323**	0.9582908711	**347**	0.9553218775
252	0.9654662741	**276**	0.9628488713	**300**	0.9604130979	**324**	0.9580976632	**348**	0.9552571738
253	0.9652115383	**277**	0.9627209262	**301**	0.9604130979	**325**	0.9579688088	**349**	0.9550630638
254	0.9650840942	**278**	0.9627209262	**302**	0.9602846512	**326**	0.9579688088	**350**	0.9550630638
255	0.9648928664	**279**	0.9625929760	**303**	0.9602204141	**327**	0.9579043700	**351**	0.9548041910
256	0.9647015529	**280**	0.9625929760	**304**	0.9600277027	**328**	0.9577754767	**352**	0.9546099416
257	0.9646377632	**281**	0.9625289763	**305**	0.9599634408	**329**	0.9577754767	**353**	0.9544803563
258	0.9645739650	**282**	0.9623369773	**306**	0.9599634408	**330**	0.9577110163	**354**	0.9544803563
259	0.9645101605	**283**	0.9623369773	**307**	0.9598349128	**331**	0.9576465538	**355**	0.9544155483
260	0.9643187339	**284**	0.9623369773	**308**	0.9596420886	**332**	0.9574531426	**356**	0.9542211322
261	0.9642548867	**285**	0.9621448872	**309**	0.9595777902	**333**	0.9572596959	**357**	0.9539618458
262	0.9641910389	**286**	0.9618886886	**310**	0.9594491836	**334**	0.9569371935	**358**	0.9538321500
263	0.9640633401	**287**	0.9617605348	**311**	0.9593205637	**335**	0.9566145449	**359**	0.9537024130
264	0.9638717349	**288**	0.9617605348	**312**	0.9591919322	**336**	0.9564208317	**360**	0.9535077925
265	0.9638078451	**289**	0.9616964401	**313**	0.9590632846	**337**	0.9561624675	**361**	0.9535077925
266	0.9636800525	**290**	0.9614400217	**314**	0.9589346060	**338**	0.9560332045	**362**	0.9535077925
267	0.9635522259	**291**	0.9614400217	**315**	0.9588059096	**339**	0.9559039159	**363**	0.9535077925
268	0.9634883010	**292**	0.9612475822	**316**	0.9587415497	**340**	0.9556453115	**364**	0.9535077925

Policy 11:Allocation of Pancreas, Kidney-Pancreas, and Islets

11.1 Calculated Panel Reactive Antibody (CPRA)

Pancreas and kidney-pancreas candidates will receive a calculated panel reactive antibody (CPRA) value according to *Policy 8.1 Calculated Panel Reactive Antibody (CPRA)*.

11.2 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 *Policy 11.4: Waiting Time*	1/365 points for each day since meeting the qualifying criteria in *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

11.3 Waiting List Registration

11.3.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

11.3.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.

11.3.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.

11.4 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.

11.4.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 *Policy 11.4.B* below.

11.4.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 *Policy 8.4: 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.

11.4.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.

11.4.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 *Policy 11.4.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 *Policy 11.4.D.i* below are met.
Islet	Pancreas; if criteria in *Policy 11.4.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 *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 *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.

11.4.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.

11.4.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.

11.5 Pancreas, Kidney-Pancreas, and Islet Allocation Classifications and Rankings

11.5.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 *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 Policy 5.9: Released Organs.

11.5.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.

11.5.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 *Policy 8.5: Kidney Allocation Classifications and Rankings* and allocate the pancreas according to *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 Policy 5.9: Released Organs.

11.5.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

11.5.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)

11.5.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
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

11.5.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

11.6 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.

11.7 Facilitated Pancreas Allocation

11.7.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.

11.7.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.

11.8 Allocation of Released Kidney-Pancreas, Pancreas or Islets

For kidney-pancreas, pancreas or islets released according to *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 *Policy 8.8: Allocation of Released Kidneys* or
3. Contact the OPTN for assistance allocating the organ(s)

11.9 Administrative Rules

11.9.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, 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 that are 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).

When a covered VCA is allocated, the host OPO must document *both* of the following:

1. How the organ is allocated and the rationale for allocation.
2. Any reason for organ offer refusals.

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

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

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 *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 *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 the matched candidate's insurance might not cover travel costs if the paired donor travels to the matched recipient transplant hospital
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. The KPD program's rules for when members are allowed to facilitate meetings between matched donors and recipients

The paired donor's transplant hospital must inform the paired donor of the right to withdraw from participation in the KPD program at any time, for any reason.

13.4.D Additional Requirements for Non-Directed Donors (NDD)

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 *Policy 14.6.B: Placement of Non-directed Living Donor Kidneys*
3. Any other options available in the NDD's donation service area

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. Approximately how long the bridge donor can expect to wait before undergoing surgery to recover the bridge donor's kidney, based on the experience of the bridge donor's transplant hospital. The bridge donor will have the option to revise the estimated amount of time the donor is willing be a bridge donor based on this information. 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.

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-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.
3. Report donor antigens that are considered absolute contraindications to transplant with the paired candidate as unacceptable antigens.
4. 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.
5. 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-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.
2. 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.
3. 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 *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 *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
        - 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 *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 *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 *Policy 13.4: Informed Consent for KPD Donors.*
3. The transplant hospital registering the potential KPD donor must complete the evaluation process according to *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
        - 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 *Policy 14: Living Donation*
        - Whether the potential KPD donor has had all cancer screenings as required in *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 *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

13.7 OPTN KPD Screening Criteria

13.7.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 13-1: 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

Donors with:	Are Matched to Candidates with:
	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
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*.

13.7.B Blood Type A, non-A_1 and Blood Type AB, non-A_1B Matching

In order for a blood type B candidate to be eligible to be matched to a blood type A, non-A_1 or blood type AB, non-A_1B potential donor, or for a blood type O candidate to be eligible to match to a blood type A, non-A_1 potential donor in the OPTN KPD Program, the candidate must meet *both* of these conditions:

1. The candidate must have an IgG antibody titer value less than 1:8
2. The candidate's transplant hospital must report to the OPTN Contractor the candidate's titer value and date of the test.

13.7.C Unacceptable Antigens

A transplant hospital must specify any unacceptable antigens it will not accept for its paired candidates using the process outlined in 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.

13.7.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 *Policy 13.6.A: Requirements for Match Run Eligibility for Candidates* or potential KPD donors as outlined in *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.

13.7.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.

13.7.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 13-2: 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.

13.7.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 of the 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.

13.7.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.

13.8 Two- and Three-Way Matches

13.8.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 *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.

13.9 Donor Chains

13.9.A Chain Size

In the OPTN KPD program, there is no limit on the length of the KPD donor chains.

13.9.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 *Policy 13.8.B: Logistical Requirements for Two- and Three-Way Matches.*

13.9.C Ending Chains

Transplant hospitals participating in OPTN KPD must follow the requirements for ending a chain according to *Table 13-3* below.

Table 13-3: 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.

13.9.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 *Policy 13.9.B: Logistical Requirements for Donor Chains* and *Policy 13.9.C: Ending Chains*.

13.10 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.

13.11 Receiving and Accepting KPD Match Offers

Each OPTN KPD program must designate a KPD contact to receive notification of match offers.

Table 13-4: 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	4 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	4 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	4 business days of receiving the match offer.
The matched candidate's transplant hospital	Report to the OPTN Contractor the results of the crossmatch	15 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	15 business days of 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.

13.11.A Requesting a Deadline Extension for a KPD Exchange

The transplant hospital may request an extension for any of the deadlines in *Table 13-3* 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 Contractor 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 not be granted and the exchange will be terminated.

13.12 Transportation of Kidneys

For any KPD exchange, the recovery hospital is responsible for packaging, labeling, and transporting kidneys from donors according to *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.

13.13 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 *Policy 14.3: Informed Consent Requirements*
    b. Evaluation process according to *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 *Policies 18.1: Data Submission Requirements, 18.5: Living Donor Data Submission Requirements,* and *18.6: Reporting of Living Donor Adverse Events*

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 *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 *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 *Policy 18.5: 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.
	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 :
Disclose to living donors **Disclose to living donors**	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 *Policy 18.5: 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 Policy 14.4: Medical Evaluation Requirements for Living Donors and a psychosocial evaluation as required by *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. 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 *Policy 8.3: Kidney Allocation Points*.
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

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.

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

The recovery hospital must:	These additional elements as components of informed consent for living VCA donors:

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

If the recovery hospital and the recipient hospital:	Then the recovery hospital must provide the living donor with:	Including *all* the following information:
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

This evaluation must be completed:	Including evaluation for and assessment of this information:
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
General laboratory and imaging tests	• Complete blood count (CBC) with platelet count • Blood type and subtype as specified in *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)

This 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 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)
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.

This evaluation must be completed:	Including evaluation for and assessment of this information:
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
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

This evaluation must be completed:	Including evaluation for and assessment of this information:
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
General laboratory and imaging tests	• Hospitals must develop and follow a written protocol for hypercoagulable state evaluation

This evaluation must be completed:	Including evaluation for and assessment of this information:
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
Additional specific tests	Uterus	• Pap smear

This evaluation must be completed:	For living donors of these organs:	Including evaluation for and assessment of this information:
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 • HIV, unless the requirements for a variance are met, according *to Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors* • Active malignancy, or incompletely treated malignancy • High suspicion of donor coercion • High suspicion of illegal financial exchange between donor and recipient • 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 • Diabetes
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. For covered VCA recoveries, the blood type verification and reporting must be recorded in the living donor's medical record.
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. For covered VCA recoveries, the blood subtype verification and reporting must be recorded in the living donor's medical record.
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 *Policy 14.5.A: Living Donor Blood Type Determination*.
    c. Match the result reported to the OPTN or VCA donor medical record

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 Bylaws E.6: Kidney Transplant Programs that Perform Living Donor Recovery*
Liver	Meet the requirements according to the *OPTN Bylaws 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 *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 *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 *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
2. Is free from inducement and coercion
3. Has been informed that the donor may decline to donate at any time
4. 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 *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 *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 *Policy 18.1: Data Submission Requirements*.

14.10 Living Donor Organ Check-In

Transplant hospitals must perform organ check-ins as required by Policy *5.7: Organ Check-In*.

14.11 Living Donor Pre-Transplant Verification

Transplant hospitals must perform pre-transplant verifications as required by Policy 5.8: Pre-Transplant Verification.

14.12 Reporting Requirements

Members are responsible for submitting living donor forms according to *Policy 18.5: Living Donor Data Submission Requirements.*

Policy 15:Identification of Transmissible Diseases

15.1 Patient Safety Contact

Each OPO and transplant program must identify a 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

To be eligible for an organ transplant, 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.

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 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.

Candidates who test positive for HIV, hepatitis B, or hepatitis C must be offered appropriate counseling.

The OPTN permits HIV test positive individuals as organ candidates if permitted by the transplant hospital. Care of HIV test positive organ candidate and recipients must not deviate from general medical practice.

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 *Policy 2.3: Evaluating and Screening Potential Deceased Donors*.
2. Living donors are required to undergo screening for diseases according to *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 • The donor tests positive for HIV antibody (anti-HIV), HIV antigen/antibody (Ag/Ab), or HIV NAT, and the transplant hospital participates in an approved variance according to *Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors*	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 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 *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 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

The host following	OPO must report *all* of the *positive* results:	To:
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
Relevant information	All *final* culture information for any culture results that were reported according to these requirements	The receiving transplant program's patient safety contact
	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 Post-Transplant Discovery of Disease or Malignancy

Transplant programs must communicate any test results or information received post-transplant that indicate donor-derived disease is possible as follows.

15.5.A Transplant Program Requirements for Post-Transplant Discovery of Donor Disease or Malignancy

1. If the findings are from transplant program testing of the donor, then the transplant program must notify the host OPO or living donor recovery hospital of the findings.
2. Notify the recipients under care at the transplant program, or the recipient's agents, of the risk or confirmation of transmissible disease or malignancy.
3. Document the new information about the donor and potential risk or confirmation of transmissible disease or malignancy in the recipients' medical records.
4. Follow the notified recipients for the 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 Post-Transplant Discovery of Recipient Disease or Malignancy

When an organ recipient is suspected to have, is confirmed positive for, or has died from a potential transmissible disease, infection, or malignancy and there is substantial concern that it could be from the transplanted organ, then the transplant program must do *all* of the following:

1. Notify host OPO or living donor recovery hospital that procured the organ without waiting for all medical documentation that may eventually become available. The transplant program must notify the host OPO or living donor recovery hospital by phone and provide documentation as soon as possible but no more than 24 hours after learning of the event.
2. Report the 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.

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 Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors

This variance applies to transplant hospitals participating in an institutional review board (IRB) approved research protocol that meets the requirements in the OPTN Final Rule regarding the recovery of organs

from donors that test positive for human immunodeficiency virus (HIV) and the transplantation of these organs into HIV positive recipients, including Health and Human Services (HHS) research criteria pertaining to transplantation of organs from HIV positive donors, as applicable.

Transplant hospitals participating in this variance must submit *all* of the following to the OPTN:

1. A detailed schedule of required deadlines for IRB data safety monitoring reports that addresses the requirements in the HHS research criteria.
2. IRB data safety monitoring reports at each deadline in the schedule.

15.7.A Requirements for Allocating HIV Positive Deceased Donor Organs

In addition to the requirements of the OPTN Final Rule, the OPO may allocate HIV positive organs only after determining the potential deceased donor is HIV positive and the HIV positive candidate is willing to accept an HIV positive organ as part of a research protocol. The OPO must only allocate HIV positive organs to HIV positive candidates appearing on the match run, except in cases of directed donation. The OPO must verify that the potential recipient is registered as a HIV positive candidate at a transplant hospital that meets the requirements in *Policy 15.7.C: Transplant Hospital Requirements for Transplantation of HIV Positive Organs*.

15.7.B Requirements for Allocating HIV Positive Living Donor Organs

In addition to the requirements of the OPTN Final Rule, the recovery hospital must confirm that the potential living donor is HIV positive and the potential recipient is willing to accept an HIV positive organ as part of a research protocol.

15.7.C Transplant Hospital Requirements for Transplantation of HIV Positive Organs

In addition to the requirements of the OPTN Final Rule, transplant hospitals may transplant HIV positive organs only if *all* of the following conditions are true:

1. The transplant hospital notifies and provides documentation to the OPTN that it is participating in an institutional review board approved research protocol that meets the requirements in the OPTN Final Rule regarding the recovery and transplantation of organs from HIV positive individuals.
2. The transplant hospital obtains informed consent from the potential transplant recipient to participate in the institutional review board protocol that meets requirements in the OPTN Final Rule.
3. The transplant hospital meets the informed consent requirements according to *Policy 15.3 Informed Consent of Transmissible Disease Risk.*

In order for an HIV positive candidate to appear on a match run for an organ from a HIV positive donor, 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 willing to accept an HIV positive organ as part of a research protocol.

Transplant hospitals must notify the OPTN if it is no longer participating in an IRB approved research protocol that meets the requirements in the OPTN Final Rule regarding the recovery and transplantation of organs from HIV positive individuals.

The OPTN may release to the public the names of transplant hospitals 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 *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 *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 *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, or the host OPO will be required to submit a report about the event through the OPTN Improving Patient Safety Portal.

If a transplant hospital repackages an organ for transport, it must package, label, and transport the organ according to *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:

- Locally assigned unique ID
- Donor date of birth
- 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:

- A location specifically designed for documentation
- 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 *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 HIV positive donor 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 *Policy 16.3: Packaging and Labeling* and

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 *Policy 2: Deceased Donor Organ Procurement* and *Policy 5: Organ Offers, Acceptance, and* Verification.
4. Comply with the blood type verification requirements in *Policy 2.6: Deceased Donor Blood Type Determination and Reporting* and *Policy 3.3: Candidate Blood Type Determination and Reporting before Waiting List Registration*.
5. Evaluate the organ for transmissible diseases as specified *in 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 *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

Members must report accurate data to the OPTN using standardized forms according to *Table 18-1* below. Members are responsible for providing documentation upon request to verify the accuracy of all data that is submitted to the OPTN through the use of standardized forms.

Table 18-1: Data Submission Requirements

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Histocompatibility Laboratory	*Donor histocompatibility* (DHS)	30 days after the OPO submits the deceased donor registration	Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Histocompatibility Laboratory	*Recipient histocompatibility* (RHS)	*Either* of the following: • 30 days after the transplant hospital removes the candidate from the waiting list because of transplant • 30 days after the transplant hospital submits the *recipient feedback*	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory
OPOs, all	*Death notification records* (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, all	*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, or pancreas that is offered to a potential recipient

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Allocating OPO	*VCA Candidate List*	30 days after the procurement date	Each covered deceased donor VCA organ that is offered to a potential covered VCA recipient
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)	30 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 This does not apply to covered VCA donor organs
Recovery Hospitals	*Living donor feedback* Members must amend the form or contact the OPTN Contractor to amend this form according to *Policy 18.6: Reporting of Living Donor Adverse Events*	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)	60 days after the recovery hospital submits the *living donor feedback* form	Each living donor organ recovered at the hospital This does not apply to covered VCA donor organs

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Recovery Hospitals	*Living donor follow-up* (LDF)	60 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 covered VCA, domino donor, and non-domino therapeutic donor organs.
Transplant hospitals	*Organ specific transplant recipient follow-up* (TRF)	*Either* of the following: • 30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure • 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)	60 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 submits the *recipient feedback* form	Each liver recipient transplanted by the hospital
Transplant hospitals	*Recipient feedback*	1 day after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Transplant hospitals	*Candidate Removal Worksheet*	1 day after the transplant	Each 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)	30 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, or pancreas candidate on the waiting list or recipient transplanted by the hospital

18.1.A 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

18.2 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 This does not apply to covered VCA transplants.
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 or This does not apply to covered VCA transplants.

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.

This policy does not apply to covered VCA organ offers; instead, members must document covered VCA offers according to *Policy 18.1: Data Submission Requirements*.

18.4 Data Submission Standard

18.4.A Timely Data Submission

Table 18-3 below sets standards for Members' data submission.

Table 18-3: Data Submission Standard

The following members:	Must submit:	Of their:	Within:
OPOs, transplant hospitals and Histocompatibility Laboratories	95%	Required forms	Three months of the form due date
OPOs, transplant hospitals and Histocompatibility Laboratories	100%	Required forms	Six months of the form due date
OPOs	100%	PTR refusal code forms	30 days of the match run date
OPOs and transplant hospitals	100%	Donor and recipient feedback forms	30 days of the transplant date

If a member fails to submit forms by the standards above, then the OPTN Contractor will attempt to assist the member. However, if this is unsuccessful, the Membership and Professional Standards Committee (MPSC) may review the members' actions. If the MPSC determines that the member continues to be non-compliant with data submission requirements, then the MPSC may recommend an onsite audit to retrieve the missing data at the members' expense.

18.5 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.

18.5.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

18.5.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

18.6 Reporting of Living Donor Events

Recovery hospitals must report living donor events through the Improving Patient Safety 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.	Improving Patient Safety Portal and the OPTN	The aborted organ recovery procedure
A living donor dies within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware
A living liver donor is listed on the liver wait list within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware

Recovery hospitals must report if:	To the:	Within 72 hours after:
A living kidney donor is listed on the kidney wait list or begins regularly administered dialysis as an ESRD patient within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware
A living donor organ is recovered but not transplanted into any recipient	Improving Patient Safety Portal and the OPTN	Organ recovery
A living donor organ is recovered and transplanted into someone other than the intended recipient	Improving Patient Safety Portal	Organ recovery

The Membership and Professional Standards Committee will review all cases reported according to *Table 18-4* above and report to the OPTN Board of Directors.

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.