OPTN POLICIES

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Public Comment Draft

About this version of the OPTN Policy Rewrite:

One of the areas of complexity and confusion with this project is which version of policy to rewrite. At any time, there are three possible versions of policy: 1) policy that is Board approved and implemented; 2) policy that is Board approved but not yet implemented; and 3) policy that has gone out for public comment but is not yet Board approved. The 2012 public comment version of this rewrite mixed those three versions.

Consistent with the rest of this project, this proposal is focusing on the long term structure of the policies. Therefore, this proposal contains a plain language rewrite of the most recent version of the policy approved by the Board. This includes language that has not been programmed or may not be implemented yet. When this rewrite is adopted by the Board, the Policies displayed on the OPTN website will contain only those Policies that are programmed and in effect. Where those policies are different than the latest version of the Policies that were Board approved, the Policies will display the current policy language (pre-rewrite).

Headings in this rewrite that are GREEN show the Policies in the rewrite that still require programming and implementation. You can see the language that is currently in effect by using the crosswalk to find the current policy language on the OPTN website with the strikethroughs and underlines.

Public Comment Draft

Policy 1: Administrative Rules and Definitions

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1.1 Rules of Construction (2.4, 2.5.5, 2.5.6, 3.4)

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 Gender

A word used in the masculine includes the feminine.

1.1.C Headings, Notes, and History

The headings, as well as the 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.D Reporting of Information to the OPTN Contractor (7.5)

Members must report information to the OPTN Contractor to fulfill membership requirements and to ensure compliance with OPTN Policies and Bylaws. The OPTN Contractor 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.

1.2 Definitions

(2.2.1, 2.2.3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.1.5, 3.1.6, 3.1.7, 3.1.8, 3.1.9, 3.1.10, 3.1.11, 3.1.12, 3.1.13, 3.2.1.2, 3.5.3.1, 3.5.3.3, 3.5.6.4, 3.5.11.2, 3.6, 3.7.2, 6.1, 6.1.1, 6.1.2, 7.1, 7.1.1, 7.1.4, 7.1.6, 7.1.7, 9.7, 12.1)

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.

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

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.

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

C

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 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.

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 an organ to a specific candidate named by the person who authorized the donation.

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 Contractor.

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 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 the current standards of accepted medical practice and 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 be initially deemed to meet the eligible data definition unless the donor meets *one* 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 be initially deemed to meet the eligible data definition unless the donor meets *one* 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 be initially deemed to meet the eligible data definition unless the donor meets *one* of the following criteria:
    - 60 years old or older
    - 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
    - Acute myocarditis or endocarditis, or both
    - Heart failure due to cardiomyopathy
    - Internal defibrillator or pacemaker
    - Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair
    - Serial echo results showing severe global hypokinesis
    - Myxoma
    - Congenital defects (surgically corrected or not)
  - The lung would be initially deemed to meet the eligible data definition unless the donor meets *one* of the following criteria:
    - Age 65 years or older

- Diagnosed 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 has no suitable organ for transplant (as defined above)
- The donor goes to the operating room with intent to recover organs for transplant and all organs are deemed not medically suitable for transplant
- The donor exhibits *any* of the following:
  - Active infections (with a specific diagnosis)
  - Bacterial: tuberculosis, gangrenous bowel or perforated bowel or intra-abdominal sepsis
  - Viral: HIV infection by serologic or molecular detection, rabies, reactive hepatitis B surface antigen, retroviral infections including viral encephalitis or meningitis, active herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia, acute epstein barr virus (mononucleosis), West Nile virus infection, SARS
  - Fungal: active infection with cryptococcus, aspergillus, histoplasma, coccidioides, active candidemia or invasive yeast infection
  - Parasites: active infection with trypanosoma cruzi (Chagas'), Leishmania, strongyloides, or malaria (*plasmodium sp*.)
  - Prion: Creutzfeldt-Jacob disease
  - General [Exclusions to the Definition of Eligible]: 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, meningitis or encephalitis
  - No discernible cause of death

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

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

Extra vessel
A vessel taken during procurement of deceased or living donor organs with the intent to be used for vasculature reconstruction or modification of a transplanted organ. Vessels directly attached to the transplantable organ are not considered extra vessels. Extra vessels are routinely taken from areas not immediately connected to the transplantable organ.

I

Imminent neurological death
Imminent Neurological Death is defined as a 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 in accordance with 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 has an absence of at least two additional brain stem reflexes.

Brain Stem Reflexes:

- 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.

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.

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

Match run
A procedure that filters and ranks waiting list candidates based on deceased 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.

N

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

Native Organ Failure
For living liver donors, native organ failure is defined as registering on the waiting list for a liver. For living kidney donors, native organ failure is defined registering on the waiting list for a kidney, or requiring dialysis.

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-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.

Organ
A human kidney, liver, heart, lung, pancreas, or intestine (including the esophagus, stomach, small or large intestine, or any portion of the gastrointestinal tract). Blood 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 this part 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 .*

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 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
Begins once any initiation of anastomosis has taken place during the intended transplant or the initiation of an islet cell infusion. The transplant procedure is complete when *either* occurs:

- The chest or abdominal cavity is closed and the final skin stitch or staple is applied.
- The islet cell infusion is complete.

Organ transplants include solid organ transplants and islet infusions.

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 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.

Potential donor's transplant hospital
The transplant hospital that enters the potential living donor in a KPD program.

Potential Transplant Recipient (PTR)
A candidate who appears on a match run.

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.

Q

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 donor organ from an OPO.

Recipient
A candidate that has received an organ transplant.

Recipient transplant hospitals
Transplant hospitals that perform living donor transplants.

Recovery hospital
A healthcare facility that recovers living donor organs.

Region
For the administration of organ allocation and appropriate geographic representation within the OPTN policy structure, the 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.

T

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 beginning of organ anastomosis. In the event of a multi-organ transplant procedure, the transplant date for each organ is determined by the beginning of anastomosis of the first transplanted organ.

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 Public Health Service (PHS) Guideline
The current U.S. Public Health Service Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ.

V

Variance
An experimental policy that tests methods of improving allocation.

W

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

Y

Year
Calendar year.

Z

Zero antigen mismatch
A candidate is considered a zero antigen 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 zero-antigen mismatch may also be referred to as a zero mismatch or 0-ABDR mismatch.

Zone
A geographical area used in the allocation of certain organs. The allocation of thoracic organs uses the following five concentric bands:

Zone A Includes all transplant hospitals within 500 nautical miles of the donor hospital but outside of the donor hospital's DSA.
Zone B All transplant hospitals within 1,000 nautical miles of the donor hospital but outside of Zone A and the donor hospital's DSA.
Zone C All transplant hospitals within 1,500 nautical miles of the donor hospital but outside of Zone B and the donor hospital's DSA.
Zone D All transplant hospitals within 2,500 nautical miles of the donor hospital but outside of Zone C.
Zone E All transplant hospitals more than 2,500 nautical miles from the donor hospital.

1.3 Variances (3.4.8, 3.7.1)

1.3.A Acceptable Variances (3.4.8.1)

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. There must be a single waiting list for each organ within each DSA.
5. Where the alternative local unit created by a variance is a subdivision of the OPO's DSA the OPO will allocate organs to the remainder of the DSA after allocating organs to this alternative local unit.
6. 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.
7. The Board of Directors may extend, amend, or terminate a variance at any time.

1.3.B Application for a Variance (3.4.8.2)

Members wishing to create or amend a variance must submit an application to the OPTN Contractor. 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 (3.4.8.2)

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 (3.4.8.3)

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 (3.4.8.4)

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 (3.4.8.5)

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 (3.4.8.6)

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 (3.1.4.1, 3.4.11)

1.4.A Regional and National Emergencies (3.4.11.1)

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

1.4.B Transportation Disruptions (3.4.11.1, 3.4.11.2)

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

1.4.C Internet Outages (3.4.11.2)

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

1.4.D Telecommunications Outage (3.4.11.2)

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

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

1.4.E OPTN Computer Match Program Outages (3.4.11.3)

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

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

1.5 Department of Defense Directive (3.4.4)

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*.

History

Policy 3.1: *Definitions*: 6/25/2007; 2/21/2008; 3/3/2009; 11/15/2011; 6/26/2012
Policy 3.4: Organ Procurement, Distribution, and Allocation: 11/17/2009; 6/22/2010; 6/26/2012
Policy 1: Administrative Rules and Definitions:

Notes

- For patient notification requirements for inactive programs due to natural disasters, see OPTN *Bylaws*, *K.1: Transplant Program Inactivity*.
- For the policy development process, see *OPTN Bylaws Article XI*.
- For Department of Defense rules regarding organ and tissue donation, see *DOD Directive 6465.*3.
- For terms defined in the Final Rule, see *42 CFR 121.*2.
- For terms defined in NOTA, see *42 USC §§ 274b(d), 274e(c),* and *274f(e).*
- For terms defined by *OPTN Bylaws*, see *OPTN Bylaws, Appendix M*.
- Guidance documents *will go here*.

Policy 2: Deceased Donor Organ Procurement

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2.1 OPO Organ Acceptance Criteria (3.3.1)

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 (2.1, 2.2, 2.2.1, 2.4, 2.5.1, 2.5.6, 2.5.7, 2.9, 7.1.7, 7.5)

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. Managing the deceased donor.
8. Assuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, packaging, and transporting the organs.
11. Reporting to the OPTN Contractor all deceased donor information required for organ placement, including the donor's human leukocyte antigen (HLA) type.
12. Executing the match run and using the resulting match for each deceased donor organ allocation.
13. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
14. Ensuring that written documentation of the deceased donor evaluation, donor management,

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authorization for donation, death pronouncement, and organ procurement quality accompanies the organ as described in *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage.*

15. Maintaining a serum sample for each deceased donor for at least 10 years after the date of organ transplant and ensuring the serum sample is available for retrospective testing. 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

(2.1, 2.2, 2.2.2, 2.2.2.1, 2.2.2.2, 2.2.2.3)

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*.
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 (2.2.2.1)

The host OPO will attempt to obtain a history on each potential deceased donor to screen for medical conditions that may affect the decision to use the donated organ.

The medical and behavioral history for each potential deceased donor should 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 factors associated with an increased risk for disease transmission, including blood-borne pathogens HIV, Hepatitis B, and Hepatitis C. If the deceased donor meets the criteria set forth in the current U.S. Public Health Service (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 receipt of 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 (2.2.3.1)

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

If serological testing occurs on a hemodiluted blood sample, the host OPO must treat the deceased donor as presenting an increased risk for disease transmission as specified in the current U.S. PHS Guideline.

Prior to screening, the host OPO must assess all potential deceased donor blood samples that were obtained for serological screening tests for hemodilution using a U.S. Food and Drug Administration (FDA)

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approved 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 (3.2.4)

The host OPO must ensure that each deceased donor's blood type is accurately determined, report the blood type to the OPTN Contractor, and then verify that the correct blood type was reported.

2.6.A Deceased Donor Blood Type Determination

The host OPO must ensure that each deceased donor's blood type is accurately determined by testing two donor blood samples prior to incision. If the two samples are from the same blood draw, then the samples must be tested by two different laboratories.

The host OPO must document that two separate tests to determine the deceased donor's blood type were performed.

2.6.B Deceased Donor Blood Subtype Determination

When a deceased donor is determined to be blood type A, then subtype testing must be completed. All subtype testing must be completed using pre-transfusion blood samples. The host OPO may choose whether to perform subtype testing on deceased donors with blood type AB.

When deceased donor blood type A or AB is sub-typed and found to be non-A1 or non-A1B, the host OPO must complete a second subtype test. If the sample used for the second subtype test is from the same blood draw as the sample used for the first subtype test, the second sample must be tested by a different laboratory.

The host OPO must document that blood subtype determination tests have been completed to determine the deceased donor's blood subtype.

2.6C Primary Reporting of Deceased Donor Blood Type and Subtype

The host OPO must report the deceased donor's blood type to the OPTN Contractor. The OPO must only report the deceased donor's blood subtype to the OPTN Contractor if two pre-transfusion samples were tested and the test results agree. If there are conflicting subtype test results, the deceased donor must be allocated based on the primary blood type.

All blood types and subtypes reported to the OPTN Contractor must be entered by a person consulting the source documents from the blood samples used for testing.

2.6.D Secondary Reporting of Deceased Donor Blood Type and Subtype

In order to verify that the correct blood type and subtype is reported to the OPTN Contractor,

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each OPO must establish and then implement a protocol for secondary reporting of blood type that is completed by someone:

1. Other than the individual who completed the primary reporting of the donor's blood type to the OPTN Contractor.
2. Consulting source documents from the blood samples used for blood type testing.

If sub-typing of A or AB blood types is reported and used for allocation, the subtype determination must also be verified. Each OPO must establish and then implement a protocol for secondary reporting of blood subtype that is completed by someone:

1. Other than the individual who completed the primary reporting of the blood subtype determination to the OPTN Contractor.
2. Consulting both source documents from the two samples used for the blood subtype testing

The OPO must maintain documentation that secondary reporting was completed using both sub-typing source documents.

2.7 HIV Screening of Potential Deceased Donors (2.2.3.2, 2.2.3.3)

The host OPO must screen all potential deceased donors for anti-HIV-1 and anti-HIV-2 using an FDA-licensed, serological screening test. Members may not participate in the recovery or transplantation of organs from deceased donors known to be infected with HIV. Members may only recover organs if the laboratory data, medical history, and behavioral history indicate that the donor is not HIV infected.

Retesting the potential deceased donor for HIV is not necessary if *all* the following are true:

1. The sample is qualified.
2. The HIV screening test is negative.
3. Blood for subsequent transfusions has been tested and found to be HIV negative.

If the host OPO performs multiple HIV tests, it must report the results of all HIV tests directly to all receiving OPOs and transplant programs.

2.7.A Exceptions to HIV Screening Requirement (2.2.3.4)

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 an increased risk for disease transmission based on current U.S. PHS Guideline.

In this case the receiving transplant hospital must:

- Obtain and document informed authorization from the potential transplant recipient or the recipient's authorized agent before transplantation.

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2.7.B Informing Personnel (2.2.3.5)

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

2.8 Required Deceased Donor Information (2.2.4, 2.2.4.1, 2.2.4.2, 2.2.4.3, 2.2.4.4, 2.2.4.5, 2.2.4.6, 3.7.12.1, 3.8.2)

The host OPO is responsible for evaluating all deceased donors.

Laboratory testing must occur in an appropriately accredited laboratory using FDA licensed, approved, or cleared serological screening tests. If a required screening test is not commercially available before transplant, then the host OPO may use an FDA-licensed, approved, or cleared diagnostic test for all tests except Anti-HIV.

The host OPO must document in the deceased donor record the tests that were used and must report the results of all tests performed to all receiving transplant programs and OPOs.

All the following information is required for each potential deceased donor:

1. Blood type determination and reporting as outlined in *Policy 2.6 above*, including sub-typing for blood type A donors
2. FDA licensed anti-HIV-1 and anti-HIV-2 serological testing as outlined in *Policy 2.7* above
3. Hepatitis serological testing; including hepatitis B surface antigen, hepatitis B core antibody, and Anti-HCV
4. Venereal disease research laboratory (VDRL) or rapid plasma regain (RPR) testing. (FDA-approved diagnostic tests are acceptable.)
5. Anti-cytomegalovirus (CMV) assay
6. Epstein-barr virus (EBV) serological testing
7. Age
8. Arterial blood gas results
9. Blood and urine cultures
10. Chest x-ray
11. Complete blood count (CBC)
12. Diagnosis
13. Electrolytes
14. Serum glucose
15. Sex
16. Urinalysis within 24 hours prior to cross clamp

2.8.A Required Information for Deceased Kidney Donors (3.5.7.4)

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. Assurance that final blood and urine cultures are pending
3. Current history of abdominal injuries and operations
4. Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria

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5. Current medication and transfusion history
6. Date of admission for the current hospitalization
7. Donor ID
8. Donor name
9. Final urinalysis
10. Final blood urea nitrogen (BUN) and creatinine
11. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR51, DR52, DR53 and DQB antigens. The lab is encouraged to report splits for all loci as outlined in *Policy 4: Histocompatibility*.
12. Indications of sepsis
13. Injuries to or abnormalities of the blood
14. Race
15. Recovery blood pressure and urine output information
16. Recovery medications
17. Relevant past medical or social history
18. Type of recovery procedure, flush solution and method, and flush storage solution
19. Warm ischemia time and organ flush characteristics

2.8.B Required Information for Deceased Liver Donors (3.6.9.1)

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

1. Aspartate aminotransferase (AST)
2. Bilirubin (direct)
3. Current history of hypotensive episodes, urine output, and oliguria
4. Donor ID
5. Donor name
6. Height
7. History of treatment in hospital including current medications, vasopressors, and hydration
8. Indications of sepsis
9. Race
10. Social history, including drug use
11. Vital signs, including blood pressure, heart rate and temperature
12. Weight
13. Other laboratory tests within the past 12 hours including:
    a. Alanine aminotransferase (ALT)
    b. Alkaline phosphatase
    c. Total bilirubin
    d. Creatinine
    e. Hemoglobin (hgb) and hemocrit (hct)
    f. International normalized ration (INR) or Prothrombin (PT) if INR is not available, and partial thromboplastin time (PTT)
    g. White blood cell count (WBC)

2.8.C Required Information for Deceased Heart Donors (3.7.12.1)

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

1. 12-lead interpreted electrocardiogram
2. Arterial blood gas results and ventilator settings
3. Cardiology consult or echocardiogram, if the hospital has the facilities
4. Cardiopulmonary, social, and drug activity histories
5. Details of any documented cardiac arrest or hypotensive episodes
6. History of treatment in hospital including vasopressors and hydration

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7. Height
8. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, and DQB antigens
9. Vital signs, including blood pressure, heart rate, and temperature
10. Weight

For heart deceased donors, if a transplant hospital requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and the transplant hospital must provide the HLA information required in the table above and document this request. The transplant hospital may request HLA-DPB typing, but the OPO need only provide it if its affiliated laboratory performs related testing. The OPO must document HLA typing provided to the requesting transplant hospital.

The heart recovery team must have the opportunity to speak directly with the responsible ICU personnel or the onsite donor coordinator in order to obtain current information about the deceased donor's physiology.

2.8.D Required Information for Deceased Lung Donors (3.7.12.3)

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

1. Arterial blood gases and ventilator settings on 5 cm/$H_2$0/PEEP including PO_2/FiO_2 ratio and preferably 100% FiO_2, within 2 hours prior to the offer
2. Bronchoscopy results
3. Cardiopulmonary, social, and drug activity histories
4. Chest x-ray interpreted by a radiologist or qualified physician within 3 hours prior to the offer
5. Details of any documented cardiac arrest or hypotensive episodes
6. Echocardiogram, if the OPO has the facilities
7. Electrocardiogram
8. History of treatment in hospital including vasopressors and hydration
9. Height
10. HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, and DQB antigens
11. Smoking history
12. Sputum gram stain, with description of sputum
13. Vital signs, including blood pressure, heart rate, and temperature
14. Weight

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 5.5.B: Time Limit for Acceptance* are maintained.

For lung deceased donors, if a transplant hospital requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and the transplant hospital must provide the HLA information required in the table above and document this request. The transplant hospital may request HLA-DPB typing, but the OPO need only provide it if its affiliated laboratory performs related testing. The OPO must document HLA typing provided to the requesting transplant hospital.

The lung recovery team must have the opportunity to speak directly with the responsible ICU personnel or the onsite donor coordinator in order to obtain current information about the deceased donor's physiology.

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2.8.E Required Information for Deceased Pancreas Donors (3.8.2.1, 3.8.2.2)

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

1. Alcohol use (if known)
2. Current history of abdominal injuries and operations including pancreatic trauma
3. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria
4. Current medication and transfusion history
5. Date of admission for the current hospitalization
6. Donor ID
7. Donor name
8. Familial history of diabetes
9. HLA information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, and DQB antigens. The lab is encouraged to report splits for all loci as outlined in *Policy 4: Histocompatibility*.
10. Insulin protocol
11. Indications of sepsis
12. Pertinent past medical or social history including pancreatitis
13. Race
14. Serum amylase
15. Weight

2.9 Requested Deceased Donor Information

2.9.A Kidney (3.5.9.2)

With each kidney offer, the host OPO should provide the recipient transplant hospital with the following biopsy information for all kidneys with a Kidney Donor Profile Index (KDPI) score greater than 85%, and for all other kidneys at the request of the accepting surgeon:

1. Wedge biopsy with the sample measuring approximately 10 mm (length) by 5 mm (width) and 5 mm (depth)
2. A sample that captures a minimum of 25 glomeruli
3. A frozen or fixed section slide, or the biopsy material, may accompany the kidney.

2.9.B Heart (3.7.12.2)

With each heart offer, the host OPO should provide *all* of the following information to the receiving transplant hospital:

1. Coronary angiography (for male donors over 40 years old or female donors over 45 years old)
2. Central venous pressure (CVP) or Swan Ganz instrumentation
3. Cardiology consult
4. Cardiac enzymes, including creatinine phosphokinase (CPK) isoenzymes

A transplant hospital should only request a heart catheterization of the deceased donor where the donor's medical or social history reveals at least *one* of the following past medical histories:

- Male over 40 years old or female over 45 years old
- Segmental wall motion abnormality on echo

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- Troponin elevation
- History of chest pain
- Abnormal electrocardiogram (ECG) consistent with ischemia or myocardial infarction
- History of *two or more* of the following:
  - Cocaine or amphetamine use
  - Diabetes
  - Hyperlipidemia
  - Hypertension
  - Intra-cerebral bleeding
  - Significant smoking
  - Strong family history of coronary artery disease

2.9.C Lung (3.7.12.4)

The host OPO should provide *all* of the following information to the receiving transplant hospital:

1. Measurement of chest circumference at the level of nipples
2. Measurement by chest x-ray vertically from the apex of the chest to the apex of the diaphragm and transverse at the level of the diaphragm
3. Mycology sputum smear
4. Non-contrast computed tomography (CT) scan of the chest

2.10 Post Recovery Follow Up and Reporting (2.2.5)

The host OPO must establish and implement procedures to do *both* of the following:

1. Obtain post-recovery deceased donor test results.
2. Report all positive screening or diagnostic tests to the transplant hospital's patient safety contact, within 24 hours of receipt by the OPO.

2.10.A Reporting Requirements (2.2.5, 2.2.6)

The host OPO is responsible for timely follow up and reporting of any new or changed deceased donor test results to the relevant transplant programs. The host OPO must report to the transplant programs *all* of the following:

1. Updates, such as the identification of any potential disease-causing organism and the sensitivity of the deceased donor to that organism, as the host OPO receives the information.
2. Medical-social history, testing, and laboratory assessments that identify malignant or infectious conditions that may adversely affect a potential transplant recipient.
3. Any known or suspected infectious or neoplastic conditions that may be transmitted to transplant recipients.

The host OPO must report to the OPTN Contractor's Patient Safety Portal any new disease or malignancy in the deceased donor that may be transmitted to transplant recipients.

2.11 Deceased Donor Management (2.3, 2.3.1, 2.3.2, 2.3.3, 2.3.4, 2.3.5)

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

1. Maintaining adequate 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

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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.

2.12 Organ Procurement

2.12.A Conflicts of Interest (3.4.1)

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

2.12.B Organ Procurement Procedures (2.5, 2.6, 2.5.2, 2.5.3, 2.5.4, 3.5.9.1, 5.8, 5.8.1, 5.8.2, 5.8.3, 5.8.4)

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, flush solution type
7. Document organ abnormalities, and surgical damage, if any

2.12.B.i Required Tissue Typing and Blood Type Verification Materials

The host OPO must establish a written policy with an OPTN member histocompatibility laboratory that includes specific details of the minimum tissue typing material, type of specimen, medium, and shipping requirements for these items. *Table 2-1* shows the requirements for each organ of this type.

Table 2-1: 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
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.

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2.12.C Authorization Requirement (2.7.1)

Organ recovery teams may only recover organs that they have received authorization to recover. An authorized organ should be recovered if it is transplantable or a 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.

2.12.D Non-renal Organ Procurement (2.7)

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.

2.12.E Multiple Organ Procurement (3.4.3)

After a member indicates its initial acceptance of an organ, the transplant hospitals and OPOs involved must agree on the time that multiple organ procurement will begin. If the members cannot agree on the procurement time, the host OPO may withdraw the offer from the transplant hospital or OPO unable to agree on the time for procurement to begin.

2.13 Donation after Circulatory Death (DCD) (2.8)

2.13.A Controlled DCD Recovery Protocol Model Elements

In order to recover organs from a DCD donor, a host OPO and transplant hospital must establish and follow a protocol that contains the standards in *Policies 2.7.B through 2.7.H* below.

2.13.B DCD Donor Suitability Criteria

The DCD protocol should include *all* the following donor suitability criteria:

1. A patient (aged newborn to the DSA's defined upper age limit, if applicable) who has a non-recoverable and permanent neurological injury resulting in ventilator dependency but not fulfilling brain death criteria may be a suitable DCD donor.
2. Other conditions that may lead to consideration of DCD eligibility include end-stage musculoskeletal disease, pulmonary disease, and high spinal cord injury.
3. The decision to withdraw life sustaining measures must be made by the hospital's patient care team and legal next of kin, and documented in the patient chart.
4. The assessment for DCD donor suitability should be conducted in collaboration with the local OPO and the patient's primary health care team. OPO determination of donor suitability may include consultation from the OPO medical director and transplant hospital teams that may be considering donor organs for transplantation.
5. An assessment should be made as to whether death is likely to occur after the withdrawal of life-sustaining measures within a period that allows for organ donation.

2.13.C Authorization

The DCD protocol should include *all* the following authorization elements:

1. The legal next of kin may elect to authorize procedures or drug administration for the purposes of organ donation. No donor related medications will be administered or donor related procedures performed without authorization.
2. Clearance from medical examiner/coroner must be obtained when applicable.

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3. There should be a plan for patient care if death does not occur within the established period after the withdrawal of life sustaining measures. This plan should include logistics and provisions for continued end of life care, including immediate notification of the family.
4. For purposes of these model elements, legal next of kin will also include the patient, a designated health care representative, legal next of kin, or appropriate surrogate.

2.13.D Withdrawal of Life Sustaining Measures

The DCD protocol should include *all* the following elements to address the withdrawal of life-sustaining measures:

1. A timeout is recommended prior to the initiation of the withdrawal of life sustaining measures. The intent of the timeout is to verify patient identification, roles and the respective roles and responsibilities of the patient care team, OPO staff, and organ recovery team personnel.
2. No member of the transplant team may be present for the withdrawal of life-sustaining measures.
3. No member of the organ recovery team or OPO staff may participate in the guidance or administration of palliative care, or the declaration of death.
4. There must be a determination of the location and process for withdrawal of life sustaining measures (for example, ETT removal, termination of blood pressure support medications) as a component of the patient management.
5. If applicable, placement of femoral cannulas and administration of pharmacologic agents (for example, regitine orheparin) for the sole purpose of donor organ function must be detailed in the authorization process.

2.13.E Declaration of Death

The DCD protocol should include *all* the following elements to address the declaration of death:

1. The patient care team member that is authorized to declare death must not be a member of the OPO or organ recovery team.
2. The method of declaring cardiac death must comply in all respects with the legal definition of death by a permanent cessation of circulatory and respiratory functions *before* the declaration of death.

2.13.F Organ Recovery

The organ recovery must not begin before the declaration of death by the hospital patient care team.

2.13.G Financial Considerations

OPO policy must ensure that no donation related charges are passed to the donor family.

2.13.H 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.C: Liver* 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.

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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.

History

Policy 2: *Minimum Procurement Standards for an Organ Procurement Organization*: 12/18/2007; 2/21/2008; 6/20/2008; 3/3/2009; 10/23/2009; 11/9/2010; 6/29/2011; 6/26/2012
Policy 2: Deceased Donor Organ Procurement:

Notes

- For requirement to prevent the acquisition of organs from individuals *42 C.F.R. § 121.11.*known to be infected with HIV, see *42 C.F.R. § 121.6*.
- For membership and personnel requirements for OPOs, see the *OPTN Bylaws, Appendix B*.
- For information about the patient safety contact, see *Policy 15: Identification of Transmissible Diseases*.
- For Host OPO's responsibilities concerning the identification of transmissible diseases in organ recipients, see *Policy 15: Identification of Transmissible Diseases*.
- For Host OPO's responsibilities concerning packaging, labeling and transporting of organs, vessels, and tissue typing materials, see *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.
- For additional data submission requirements see *Policy 18: Data Submission Requirements*.
- For Kidney Donor Profile Index (KDPI) information, see *Policy 8.5.B: Deceased Donor Classifications*.

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Policy 3: Candidate Registrations, Modifications, and Removals

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3.1 Access to Computer Systems (3.2.1.1, 3.2.1.2)

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 (3.2.1.2)

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 (3.2.3, 3.2.2.4)

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:

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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 (3.1.4.3)

Transplant programs must determine and report each transplant candidate's actual blood type before registering them on the waiting list.

3.3.A Blood Type Determination before Registration on the Waiting List (3.1.4.2)

Transplant programs must determine each candidate's blood type by testing at least two candidate blood samples prior to registration on the waiting list. Transplant programs must test at least two blood samples from two separate blood draws taken at two different times.

3.3.B Secondary Reporting of Candidate Blood Type (3.1.4)

After the candidate's blood type data are reported to the OPTN Contractor, the candidate will be added to the waiting list but will not be registered as an active candidate until secondary reporting and verification of the candidate's blood type has been completed.

Each transplant program must establish and implement a protocol for secondary reporting of blood type that is completed by someone:

1. Other than the individual who reported the candidate's blood type determination at registration on the waiting list.
2. Using source documents from the two blood samples used for the blood type testing.

The transplant program must maintain documentation of this verification.

3.4 Waiting List Registration

3.4.A Registration Fee (11.0)

The registration fee 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*.

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3.4.B Approved Transplant Program Requirement (3.2.1.3)

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 (3.2.1, 3.1.4.1, 3.1.13)

Transplant programs must do *all* of the following:

1. Register on the waiting list all candidates for deceased donor organ transplants, including candidates receiving directed donations from deceased donors.
2. Complete all candidate additions, modifications, and removals in the waiting list.

3.4.D Candidate Human Leukocyte Antigen (HLA) Requirements (3.2.1.5, 3.8.2.1)

The candidate's transplant program must report to the OPTN Contractor 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

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 (3.6.4.1, 3.7.3, 3.7.4, 3.11.1)

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 Multi-organ Candidate Registrations (3.9.3)

If a multi-organ transplant candidate requires a heart, lung, or liver the candidate must register on the waiting list separately for each required organ.

Multi-organ candidates who have been named as the recipient of a directed organ donation must appear on at least one of the deceased donor's match runs for at least one of the required organ types.

3.4.G Multiple Transplant Program Registrations (3.2.2, 3.2.2.2, 3.2.2.4)

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 Contractor 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.

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3.4.H *In Utero* Candidate Registrations (3.2.1.6, 3.2.1.7)

Transplant programs may register *in utero* candidates on the waiting list only if prenatal diagnostic tests confirm that the *in utero* candidate is viable and medically suitable to receive an organ transplant.

Transplant programs must identify *in utero* candidates when registering them on the waiting list. If an *in utero* thoracic candidate is born, then the candidate loses *in utero* status and the candidate's start date for accumulating waiting time is reset from the time of birth.

3.5 Patient Notification (3.2.7)

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 (3.2.6, 3.5.12.1, 3.5.11.1, 3.6.3, 3.7.4, 3.7.9.2, 3.7.9.3, 3.8.3.4, 3.8.7.2, 3.11.6)

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

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If the candidate is registered for the following organ…	Then the candidate accrues waiting time while inactive as follows…
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 (3.2.4.2)

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 (3.2.4.2)

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 a 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 on the date that is 90 days after the candidate's kidney transplant.

Kidney waiting time will be reinstated when the OPTN Contractor 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 Contractor will send a notice of waiting time reinstatement to the transplant hospital involved.

3.6.B.ii Non-function of a Transplanted Pancreas (3.8.5.3)

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

Pancreas waiting time will be reinstated when the OPTN Contractor 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 Contractor will send a notice of waiting time reinstatement to the transplant hospital involved.

3.6.B.iii Non-function of a Transplanted Intestine (3.11.5.1)

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.

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Intestine waiting time will be reinstated when the OPTN Contractor 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 Contractor will send a notice of waiting time reinstatement to the transplant hospital involved.

3.6.C Waiting Time Transfers (3.2.1.9, 3.2.2.1)

A candidate may transfer primary waiting time from one transplant hospital to another if it meets the requirements below and the candidate is not a kidney transplant candidate. Kidney transplant candidates can accrue waiting time when registered at multiple transplant hospitals according to *Policy 8.4: Waiting Time.*

A candidate's primary waiting time may be transferred from one transplant hospital to another transplant hospital as follows:

1. The candidate must be registered at both transplant hospitals.
2. One of the transplant hospitals must submit a Wait Time Transfer Form to the OPTN Contractor.
3. The OPTN Contractor will transfer the primary qualifying date and waiting time accrued from the earlier transplant hospital to the new transplant hospital.
4. If the candidate chooses not to have multiple registrations, the OPTN Contractor will remove the candidate from the waiting list of the earlier transplant hospital.

If the candidate chooses to have multiple registrations, the OPTN Contractor will exchange the primary waiting time from the transplant hospital that had the primary qualifying date and waiting time with the more recent transplant hospital.

The OPTN Contractor will send a notice of the primary waiting time transfer to each of the transplant hospitals involved.

3.7 Waiting Time Modifications (3.2.1.8)

3.7.A Applications for Modifications of Waiting Time (3.2.1.8.2, 3.2.1.8.4)

To apply for a waiting time modification, the candidate's transplant program must submit an application to the OPTN Contractor 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 Contractor will forward the application, without person-identified data, according to *Table 3-4* that follows:

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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
Thoracic	A subcommittee of the Thoracic Transplantation Committee, appointed by the Chair of the Thoracic Transplantation Committee
Pancreas	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 Contractor of the decision.
2. Upon notice, the OPTN Contractor 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 (3.2.1.8.1, 3.2.1.8.3)

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, Status 1A 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-	An islet infusion	Any previously accrued

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When:	And the candidate is registered for:	And the transplant program is requesting reinstatement of waiting time including:
registered on the islet waiting list		waiting time according to *Policy 11.4.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 Contractor 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 Contractor will implement the waiting time modification.
2. The OPTN Contractor 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.

3.8 Removing Candidates from the Waiting List (3.2.2.3, 3.2.4.1, 3.6.6, 3.7.13, 3.8.6, 3.11.5)

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 Contractor 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 Contractor 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*.

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3.8.A Removing Liver Candidates from the Waiting List (3.6.6)

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.

3.8.B Removing Pancreas Islets Candidates from the Waiting List (3.8.7.5)

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

History

Policy 3.2: UNOS Patient Waiting List: 6/25/2007; 6/20/2008; 3/3/2009; 11/17/2009; 11/9/2010; 11/15/2011; 6/26/2012; 11/13/2012

Policy 3: Candidate Registrations, Modifications, and Removals:

Notes

1. For acceptance and screening criteria, see *Policies 5.1: Minimum Acceptance Criteria* and *5.3: Additional Acceptance and Screening Criteria*.
2. For international exchange of organs, see *Policy 17: International Organ Transplantation*.
3. For criteria to accrue waiting time, see the organ specific *Policies 6* through *11*.

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Policy 4: Histocompatibility

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4.1 Guidelines for Written Contracts between Histocompatibility Laboratories and Transplant Programs (3.6.13, 3.7.16, 3.8.2.3, 12.7.8.1, 13.6.13, Appendix 3D)

Histocompatibility laboratories must have written contracts with at least one transplant program to perform histocompatibility testing. These guidelines summarize the recommended elements to be included in these agreements.

4.1.A Recommended Elements for Histocompatibility Contracts

Written agreements between histocompatibility laboratories and transplant programs should include *all* of the following elements:

1. A process to obtain accurate and current sensitization history for each patient.
2. The assay format that will be used for antibody screening and for crossmatching.
3. The frequency of periodic sample collection.
4. The frequency of antibody screenings.
5. The criteria and a process for establishing a risk category for each patient and the crossmatching strategy for each established risk category.
6. The criteria and a process for determining unacceptable antigens or acceptable antigens used during organ allocation.
7. A process for monitoring recipients post-transplant, or for monitoring desensitization protocols.
8. A process for blood type verification according *to Policy 3.3: Candidate Blood Type Determination and Reporting before Waiting List Registration*, if the laboratory registers candidates for the transplant program.

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4.1.B Sensitization History

Laboratories should evaluate the data in *Table 4-1* below when determining sensitization history.

Table 4-1: Determining Sensitization

If this event occurred:	Then the laboratory should evaluate:	And note:
Previous graft of solid organ, bone or tendon	Date of transplant and organs transplanted	
	Date of graft loss	Dates of graft removal, re-transplant, and return to dialysis.
	Cause of graft loss	
	HLA typing of donors	Used to identify potential unacceptable antigens.
	Rejection history, history of delayed function, history of non-compliance, or reduced immune-suppression due to infection	
Pregnancy	Number, year of each occurrence	Gravida/para.
Transfusions	Number, type of product, month and year of each occurrence	
Assist device placement	Type of device, date of placement, duration of treatment	Primarily for thoracic transplantation.
Disease	Identification of diseases causing end-stage organ failure	Auto-immunity may invalidate some laboratory assays.
Acute infections	Viral infection or bacterial infection requiring antibiotics	If the infection occurred since last antibody screening test. Induction of cells or antibodies with specificity for HLA or non-specific activation of memory.

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If this event occurred:	Then the laboratory should evaluate:	And note:
Chronic infections	Viral infection	Response to tolerance induction protocols.
Vaccinations	Type, date of each occurrence	Time passed since last antibody screening test.

4.1.C Detection of Antibodies

An antibody history is used in the antibody screening and crossmatching of donors and recipients. Laboratories may use the tests in *Table 4-2* below to create an antibody history and assess sensitization in transplant candidates.

Table 4-2: Assays to Identify Antibody Screening or Crossmatching

This assay:	Is used:
Standard complement-dependent lymphocytotoxicity (CDC)	To detect IgG antibodies known to cause hyperacute rejection *and* for panel measurements or crossmatch
Anti-human Globulin - enhanced cytotoxicity (AHG-CDC)	To improve detection of weak or low level antibodies and for panel measurements or crossmatch
Enzyme-Linked Immuno Sorbent Assay (ELISA)-based assays: • Mixed antigens • Cell equivalents • Single antigens • Solubilized cells	To provide a more sensitive test that does not depend on complement fixation: • For monitoring • To measure specificity • To measure specificity • For crossmatch
Flow cytometry-based assays: • Cell-based • Microparticle-based soluble antigens • Microparticle-based single HLA-antigen beads	The most sensitive test for antibody: • For crossmatch or panel measurements • For panel measurements without background from cell membranes • For high resolution antibody identification
Determine isotype of antibody: • IgG or IgM • Complement-fixing IgG?	For panel measurements or crossmatches
Rule out contribution by autoantibody: • Treatment of serum • Autologoum cells	For panel measurements or crossmatches

Assays should be used to:

1. Identify whether a patient has circulating antibodies to HLA class I and class II antigens:

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- Initial serial screening should include cytotoxicity and more sensitive tests to identify patients with antibodies.
- Several sera should be evaluated to establish a baseline.

2. Determine antibody specificity in patients with detectable circulating antibodies using some combination of:
   - A panel of representative cells for cytotoxicity.
   - ELISA tests for specificity.
   - Antigen-coated microparticles.

3. Monitor patients who do not currently have antibodies for the development of antibodies using:
   - Periodic screening of unsensitized patients to detect appearance of anti-HLA antibodies.
   - Characterization of antibody specificity.

4.1.D Periodic Sample Collection

Laboratories should collect monthly serum samples for candidates and maintain the samples to develop an antibody history and to facilitate final crossmatches.

4.1.E Crossmatching Strategies

The Histocompatibility Laboratory and the Transplant Program should collaborate to develop specific strategies for evaluating the relative risk of a rejection. When developing these strategies, the following should also be considered:

1. In thoracic transplantation, prospective crossmatches are not commonly used for patients with no detectable HLA antibodies.
2. In kidney transplantation, there may be exceptional cases when it is better to proceed with the transplant before a crossmatch can be completed. If after careful consideration a pre-transplant crossmatch is not completed, then the laboratory should perform a peri-transplant or retrospective crossmatch to guide post-transplant care.

Table 4-3 below lists elements that laboratories should include in developing crossmatching strategies. Strategies should be tailored to the level of risk.

Table 4-3: Recommended Elements for Crossmatching Strategies

Element:	Options:
Selection of technique(s)	Refer to *Table 4-2: Assays to Identify Antibody Screening or Crossmatching*.
Selection of serum	Stability of a candidate's antibody response incorporated into choice of time between serum collection and transplant. Use of historic serum.
Timing	Prior to transplant (number of hours or days). Peri-transplant or retrospective (number of hours or days). Timed to limit cold ischemia.

4.2 HLA Typing (Appendix 3D)

Table 4-4 below provides the requirements of HLA typing of HLA A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, and DQB Antigens. Laboratories should report splits for all loci shown in *Policy 4.16: Reference Tables of HLA Antigen Values and Split Equivalences*.

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Table 4-4: Requirements for HLA Typing

If a Laboratory:	Then the Laboratory Must:
Performs deceased donor typing for kidney, kidney-pancreas, pancreas, or pancreas islet allocation	Report serological split level and molecular typing results for all required antigens prior to organ offers.
Uses cytotoxicity techniques to perform HLA typing	Conform to all relevant standards in *Policy 4.8: Cytotoxicity Methods*.
Uses nucleic acid analysis, to perform HLA typing	Conform to all relevant standards in *Policy 4.10: Nucleic Acid Analysis*.
Uses alternative methods for HLA typing	Define the procedures, validate the procedures, and include sufficient controls to ensure accurate assignment of HLA types. The laboratory must conform to all relevant standards from the above sections.

4.2.A Typing Assignment

Laboratories must do *all* of the following:

1. Define each HLA antigen by a sufficient number of reagents to clearly define each antigen or allele group for which the laboratory tests.
2. Use a level of resolution of HLA typing that is appropriate for the clinical application.
3. Document the method of assignment of HLA phenotypes for each technique used.
4. Establish and adhere to a written policy that defines when antigen redefinition and retyping are required.
5. Maintain a list of antigens and alleles defined by each test used in the laboratory.

4.2.B Reagent Validation

Laboratories must do *all* of the following:

1. Have cell or deoxyribonucleic acid (DNA) panels of known HLA class I and class II phenotype available to validate new typing reagents.
2. Document and confirm, by external or internal quality control testing, the specificity of typing reagents obtained locally or from other sources and used for preparation of local trays.
3. Establish and employ detailed policies and procedures for evaluations of new commercial reagents.
4. Evaluate each lot and shipment of new commercial reagents.
5. Validate techniques used to define HLA class I antigens, class II antigens, and alleles.

4.2.C HLA Typing by Nucleic Acid Analysis

Laboratories must do *all* of the following:

1. Define the HLA alleles detected by each primer, probe, or template primer combination.
2. Test primers and probes with all alleles recognized by the World Health Organization's (WHO) *Nomenclature Committee for Factors of the HLA System*, if nucleotide sequences and reference DNA are readily available.
3. Have a process to recognize and document ambiguous combinations of alleles for each template, primer, or probe combination.

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4.2.D Typing by Sequenced Based Typing (SBT)

Laboratories must do *all* of the following:

1. Have sufficient specificity for a locus or allele to provide primary sequencing data for analysis.
2. Compare each unknown sequence with the sequences of all alleles recognized by the WHO *Nomenclature Committee for Factors of the HLA System* if the nucleotide sequences are readily available.
3. Maintain records that define the sequence database used to interpret the primary data. Laboratories must update this database at least annually. If a determined sequence has more than one possible interpretation of available data, then the report must indicate all possible allele combinations.

4.3 HLA Antigen Values and Split Equivalences

Laboratories must report candidate and donor antigens to the OPTN Contractor and compare the reported antigens to determine whether they are mismatches. For candidates with detected HLA antibodies to certain antigens, those antigens can be entered as unacceptable on the waiting list. Based on the unacceptable antigens entered for each candidate, the candidate will not be matched for donors that have those antigens.

Refer to *Tables 4-6, 4-7, 4-8, 4-9, 4-10, 4-11, 4-12*, and *4-13* in this Policy to determine the candidate-donor antigen combinations reported and whether they are mismatched.

HLA matching of A, B, and DR locus antigens is based on the antigens which are listed in *Policy 4.16: Reference Tables of HLA Antigen Values and Split Equivalences*. These tables will be updated annually by the Histocompatibility Committee. 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. Laboratories are encouraged to assign all splits.

4.4 Resolving Discrepant Donor and Recipient HLA Typing Results (Appendix 3C)

After laboratories report donor and recipient HLA typing results to the OPTN Contractor, the OPTN Contractor will provide a report to the laboratories including any discrepant HLA typing results. Laboratories must try to resolve these discrepancies.

The report includes *all* of the following donor information:

1. Donor ID
2. HLA typing result
3. Date of test
4. Test method
5. Laboratory Identifier
6. OPO Identifier (if applicable)

The report includes *all* of the following recipient information:

1. SSN
2. HLA typing result
3. Date of test
4. Test method
5. Laboratory identifier

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The laboratory director or designated staff must contact the other laboratory director or designated staff to resolve the discrepancies. If a resolution is reached, the laboratory with the correct typing results should report the corrected HLA typing to the OPTN Contractor as resolved. The laboratory must also identify the specific reason for the discrepant typing.
The OPTN Contractor will remove all discrepant flags from HLA typing results that have been resolved. Discrepancies that have not been resolved will remain flagged, and will be reviewed by the Histocompatibility Committee. The Histocompatibility Committee will review, at least annually, any outstanding discrepant typings recorded during the previous 12 months.

4.5 Antibody Screening (Appendix 3D)

Table 4-5 below summarizes the requirements of antibody screening.

Table 4-5: Requirements for Antibody Screening

Laboratories performing assays using:	Must conform to standards in:
Cytotoxicity	*Policy 4.8: Cytotoxicity Methods*
Flow cytometry	*Policy 4.11.A: Instrument Standardization and Calibration* and *Policy 4.11.B: Flow Cytometric Crossmatch Technique*
ELISA techniques	*Policy 4.12: ELISA*
Solid phase multichannel arrays	*Policy 4.13: Solid Phase Multi-channel Arrays*

4.5.A Techniques

Laboratories must do *all* of the following:

1. Determine the antibody specificities that can be identified by the techniques used.
2. Use a technique appropriate for the clinical application.
3. Use a method to detect antibodies to HLA class II antigens that distinguishes them from antibodies to HLA class I antigens.
4. Have a procedure in place to monitor and adjust for non-specific binding of antibody.
5. Use appropriate methods or controls to assess the impact of xenogeneic and monoclonal therapeutic antibodies.

4.5.B Sera Testing

Laboratories must do *all* of the following:

1. Test sera at concentrations determined to be optimal for detection of antibodies to HLA antigens.
2. Document the dilutions in the test records.
3. Include an appropriate positive and negative control.

4.5.C Panel and Target Selection

Laboratories must do *all* of the following:

1. Use a sufficient number of antigen panels that are in phenotypic distribution with respect to individual antigens or cross-reactive groups (CREGs) for the population served and for the intended use of the test results.
2. Maintain documentation of the HLA class I or class II phenotypes of the panel.

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3. Have appropriate target cells or purified HLA molecules for all assays intended to provide information on HLA antibody specificity.
4. Have sufficient concentration, condition, and phenotype of target cells or purified HLA molecules to ensure that the antibodies being tested for (either HLA class I or class II) can be detected.

4.6 Kidney and Pancreas Organ Transplantation (Appendix 3D)

4.6.A Personnel Requirements

If deceased donor transplants are performed, then the laboratory must have personnel for the required histocompatibility testing available 24 hours a day, seven days a week.

4.6.B HLA Typing

Laboratories must perform prospective typing of donors and candidates for HLA-A, B, Bw4, Bw6, and DR antigens. In addition, laboratories must perform prospective typing of donors for HLA-DR51, DR52, DR53, C, and DQB antigens. Laboratories should perform prospective typing of candidates for HLA-C and DQB antigens and for DR51, DR52, DR53.

4.6.C Antibody Screening

Laboratories must have *all* of the following:

1. A protocol in place to evaluate the extent of sensitization of each candidate at the time of initial evaluation and following potentially sensitizing events, based on the antibody characteristics that are clinically relevant to each Transplant Hospital's protocols.
2. A program to periodically screen serum samples from each candidate for antibody to HLA antigens.
3. A written protocol establishing the frequency of screening serum samples and data to support this policy.

Laboratories should do *all* of the following:

1. Collect serum samples monthly.
2. Test serum samples for antibody to HLA antigens.
3. Consider information about antibody specificity when evaluating the patient for transplant.
4. Use serum samples having defined class I or class II specificities in crossmatch testings.
5. Identify, report, and distinguish from antibodies to non-HLA antigens, the HLA class I and class II specificity of antibodies.

4.6.D Crossmatching (3.5.7.8)

Laboratories must do *both*:

1. Perform a prospective crossmatch when requested to by a physician or other authorized individuals, except when clinical circumstances prevent a prospective crossmatch.
2. Have a joint written protocol with their transplant programs on transplant candidate crossmatching strategies. This protocol must also identify the clinical circumstances when a prospective crossmatch may be omitted.

4.6.E Techniques

If a laboratory is determining donor-recipient compatibility, then the laboratory must use a crossmatching technique with increased sensitivity. Laboratories may also use the basic complement-dependent microlymphocytotoxicity test in addition to the crossmatching technique.

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Laboratories must also:

1. Perform crossmatches with potential donor T lymphocytes. Laboratories should also perform crossmatches with B lymphocytes using a method that distinguishes between reactions with T and reactions with B lymphocytes.
2. Establish and follow a written protocol determining the serum used in the final crossmatch that is supported by published data or data generated in the laboratory. The protocol must consider or include historic and current sensitizing events.

4.6.F Samples

Laboratories must do *both*:

1. Test sera at a dilution that is optimal for each assay.
2. Establish a policy for the storage and maintenance of recipient sera that defines the samples to be retained and the duration of storage.

4.7 Other Organ and Islet Cell Transplantation (Appendix 3D)

Laboratories must do *all* of the following:

1. Establish a written protocol with their transplant programs on transplant candidate antibody screening, antibody identification, and crossmatching strategies.
2. HLA type all potential transplant recipients and donors if a physician or other authorized individual requests it.
3. Perform a prospective crossmatch when requested by a physician or other authorized individuals, except when clinical circumstances prevent a prospective crossmatch.
4. Have a joint written policy with their transplant programs on transplant candidate crossmatching strategies. This protocol must also identify the clinical circumstances when a prospective crossmatch may be omitted.
5. Use techniques with increased sensitivity in comparison with the National Institute of Health's (NIH) complement-dependent microlymphocytotoxicity.
6. Screen any patient for the presence of anti-HLA antibodies at initial evaluation and following sensitizing events if a physician or other authorized individual requests it and should also identify any unacceptable antigens.

4.8 Cytotoxicity Methods (Appendix 3D)

4.8.A Percentage of Cell Killed

Laboratories must do *both*:

1. Record the results for each cell-serum combination in a manner that indicates the approximate percent of cells killed.
2. Have a written policy that assigns positive or negative results based on percentage of cells killed.

4.8.B Controls

Laboratories must include in each tray *both* of the following:

1. At least one positive control serum that reacts with all cells expressing the class of antigens being tested.
2. At least one negative control serum documented to be non-reactive under the specified test conditions.

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Cell viability in the negative control well at the end of incubation must be sufficient to ensure accurate interpretation of results.

Laboratories must use appropriate methods or controls to assess the impact of xenogeneic or monoclonal therapeutic antibodies in patient samples on the cytotoxicity assay.

4.8.C Target Cells

If a laboratory is testing enriched cell populations, then the level of purity must be sufficient to ensure accurate interpretation of results.

4.8.D Complement

Laboratories must do *all* of the following:

1. Test each lot and shipment of complement to determine that it mediates cytotoxicity in the presence of specific antibody, but is not cytotoxic in the absence of specific antibody.
2. Establish and document optimal performance.
3. Test complement separately for use with each type of target cell and with each test method used, since a different dilution or preparation may be required for optimal performance.

4.9 Blood Type Determination (Appendix 3D)

If a histocompatibility laboratory performs blood type testing, the testing must be performed in compliance with federal regulations.

If testing for the A_1 subgroup of type A blood is performed, the extract of *Dolichos biflorus* must be used at a dilution and with a technique documented not to agglutinate A_2 cells. Each assay or batch test run must include known A_1 and A_2 cells as controls.

If titration of anti-ABO antibodies is performed, the procedure and criteria for interpretation must be established and validated by the laboratory.

Laboratories using molecular techniques for blood type testing must conform to all pertinent standards in *Policy 4.10: Nucleic Acid Analysis*.

4.10 Nucleic Acid Analysis (Appendix 3D)

4.10.A Nucleic Acid Extraction

Laboratories must do *all* of the following:

1. Purify nucleic acids by standard methods that have been validated in the laboratory.
2. Have written guidelines specifying the minimum acceptable sample.
3. Conform to established protocols and independently validate all testing procedures, if a laboratory performs tests without prior purification of nucleic acids.
4. Stored samples under conditions that preserve their integrity if a laboratory does not use nucleic acids immediately after purification.
5. Use nucleic acids of sufficient quality to ensure reliable test results.

4.10.B Electrophoresis

Laboratories must include in each electrophoretic run negative and positive controls that are processed with each assay to verify adequate and appropriate polymerase chain reaction (PCR)

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amplification of target DNA.

If size of the resulting nucleic acid fragment is a critical factor in the analysis of the data, then the laboratory must do *all* of the following:

1. Load an amount of DNA in each lane that is within a range that ensures equivalent migration of DNA in all samples, including size markers.
2. Include in each gel size markers that produce discrete electrophoretic bands spanning and flanking the entire range of expected fragment sizes.
3. Establish criteria for accepting validity of each gel and of each lane of the gel and determine and validate acceptable electrophoretic conditions for each assay.

4.10.C Analysis

Laboratories must do *all* of the following:

1. Specify acceptable limits of signal intensity for positive and negative results. If these are not achieved, corrective action is required.
2. Use two independent interpretations of primary data.
3. Validate automated systems and computer programs prior to use.
4. Test automated systems and computer programs routinely for accuracy and reproducibility of manipulations.

4.10.D Template Amplification

4.10.D.i Facilities and Equipment

Laboratories performing amplification of nucleic acids must do *all* of the following:

1. Establish and employ protocols to prevent DNA contamination using physical or biochemical barriers.
2. Perform pre-amplification procedures in a work area that excludes amplified nucleic acid that has the potential to serve as a template in any amplification assays performed in the laboratory.
3. Use dedicated equipment and reagents as well as physical and biochemical barriers to prevent nucleic acid contamination (carry-over).
4. Perform procedures to remove carry-over contamination from work areas used for manipulation of pre-amplification reagents or samples.
5. Add the template for subsequent amplifications in an area isolated by physical or chemical barriers from both the pre-amplification work area and post-amplification work areas, when using methods that utilize two consecutive steps of amplification.
6. Have dedicated pipettors for each work area. Positive displacement pipettes or filter-barrier tips are recommended for pre-amplification and secondary amplification work areas.
7. Use thermal cycling instruments that precisely and reproducibly maintain the appropriate temperature of samples.
8. Verify the accuracy of temperature control for samples at least every 6 months.
9. Monitor incubators and water baths for accurate temperature maintenance every time the assay is performed.

4.10.D.ii Reagents

All reagents used in the amplification assay must:

1. Be dispensed in aliquots for single use or be dispensed in aliquots for multiple

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uses if documented to be free of contamination at each use.
2. Not expose reagents used for initial amplification to post-amplification work areas.
3. Store reagents used for secondary amplification in an area that prevents carry-over contamination.

4.10.E Primers

Primers must be stored under conditions that maintain specificity and sensitivity. Conditions that influence the specificity or quantity of amplified product must be demonstrated to be satisfactory for each set of primers.

Laboratories must also do *all* of the following:

1. Have a policy for quality control of each lot and shipment of primers using reference or well-characterized material.
2. Validate the specificity and robustness of the detection method for labeled primers.
3. Confirm periodically the performance of reagents stored for extended periods.

4.10.F Amplification Templates

Samples containing nucleic acids that will be amplified must be stored under conditions that do not result in artifacts, inhibition of the amplification reaction, and exposure to post-amplification work areas or any other sources of carry-over contamination. The acceptable range for the amount of target must be specified and validated.

4.10.G Contamination

Nucleic acid contamination must be monitored for the most common amplification products that are produced in the laboratory. Routine wipe tests of pre-amplification work areas must be performed. Monitoring must be performed using a method that is at least as sensitive as routine test methods. If amplified product is detected, the area must be cleaned to eliminate the contamination and retested. Corrective measures must be taken to prevent future contamination. At least one negative control (no nucleic acid) must be included in each amplification assay. Testing of open tubes in the work area is recommended.

4.10.H Controls and Quality Assurance

Laboratories must also do *all* of the following:

1. Monitor the quantity of specific amplification products.
2. Specify criteria for accepting or rejecting an amplification assay.
3. Include controls to detect amplification in every amplification mixture, if presence of an amplified product is used as the end result.
4. Monitor amplification specificity on a periodic basis, if presence of an amplified product is used as the end result.
5. Monitor the variation in the amount of amplified product (e.g., hybridization with a consensus probe or gel electrophoresis), if an amplified product is used as a nucleic acid target.
6. Specify the acceptable range for the amount of test DNA, if an amplified product is used as a nucleic acid target.

4.10.I Technique-Specific Standards

4.10.I.i Oligonucleotide Probe Assays

Laboratories must also do *all* of the following:

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1. Define the specificity and target sequence of oligonucleotide probes.
2. Store oligonucleotide probes under conditions that maintain specificity and sensitivity.
3. Use oligonucleotide probes under empirically determined conditions that achieve the defined specificity.
4. Perform quality control testing to confirm specificity for each lot and shipment of probe. Use reference material for quality control whenever possible.
5. Establish and document that oligonucleotide probe specificity and detection method sensitivity is reproducible before results are reported.
6. Perform hybridization under empirically determined conditions that achieve the defined specificity.
7. Validate a procedure for reuse of nucleic acids (probes or targets) bound to solid supports or in solution.
8. Use controls to ensure sensitivity and specificity of the assays are unaltered.

4.10.I.ii Sequence Specific Amplification

Each amplification reaction must include internal controls to detect technical failures, such as additional primers or templates that produce a product that can be distinguished from the typing product.

4.10.J Other Techniques

Appropriate controls must be included for each component of the test.

4.11 Flow Cytometry (Appendix 3D)

4.11.A Instrument Standardization and Calibration

Laboratories must also do *all* of the following:

1. Run an optical standard, consisting of latex beads or other uniform particles, to ensure proper focusing and alignment of all lenses in the path for both the exciting light source and signal (light scatter or fluorescence, etc.) detectors.
2. Run standards for each fluorochrome used to ensure adequate amplification of the fluorescent signals. These fluorescent standards may be incorporated in the beads or other particles used for optical standardization, or may be a separate bead or fixed cell preparation.
3. Run both the optical and fluorescent standards each time the instrument is turned on and at any time maintenance, adjustments, or problems have occurred during operation that could potentially affect instrument function.
4. Record the results of optical focusing and alignment in a daily quality control log.
5. Establish threshold values for acceptable optical and fluorescent standardization results for all relevant signals for each instrument used.
6. Have a written protocol detailing the corrective action required if a particular threshold value cannot be attained.
7. Use an appropriate procedure to compensate for overlap in emission spectra if performing analyses that require the simultaneous use of two or more fluorochromes.
8. Record laser power output and current input, in amplitudes, daily for each instrument.
9. Document acceptable thresholds and corrective action protocols.

4.11.B Flow Cytometric Crossmatch Technique

Laboratories must also do *all* of the following:

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1. Ensure the appropriate definition and purity of cell populations by the use of either a multi-color technique or other documented method.
2. Assess the binding of human immunoglobulin using a fluorochrome labeled reagent such as either an F(ab')2 anti-human IgG that is specific for the Fc region of the heavy chain or other documented method.
3. Base crossmatch results for a specific cell population on the use of a monoclonal antibody that detects an appropriate cluster designated antigen.
4. Establish and document the optimum serum-to-cell ratio.

4.11.C Controls

The negative control must be human serum documented to be non-reactive against the crossmatch target cells.

The positive control must be human antibody of the appropriate isotype for the assays and specific for the antigens that are targeted in the crossmatch. Positive controls must be used at a dilution appropriate for the assay, and must react with appropriate target cells from all humans.

The anti-human immunoglobulin reagent must be titered to determine the dilution with optimal activity (signal to noise ratio). If a multicolor technique is employed, the reagent must not demonstrate cross reactivity with the other immunoglobulin reagents used to label the cells.

Regardless of the method used for reporting raw data (mean, median, mode channel shifts, or quantitative fluorescence measurements), each laboratory must establish its own threshold for discriminating positive reactions. Any significant change in protocol, reagents, or instrumentation requires repeat determination of the positive threshold.

4.11.D Interpretation

Laboratories must also do *both*:

1. Define the criteria used to define positive and negative crossmatches.
2. Use appropriate methods or controls to assess the impact of xenogeneic and monoclonal therapeutic antibodies on flow crossmatches.

4.11.E Immunophenotyping By Flow Cytometry

Terminology used must conform to the most recent publication of the International Workshop of Differentiation Antigens of Human Leucocytes or other appropriate scientific organizations.

4.11.F Cell Preparation

The method used for cell preparation must yield enough viable cells to ensure accurate test results. For internal labeling, the method used to allow fluorochrome labeled antibodies to penetrate the cell membrane must be documented to be effective.

4.11.G Quality Control

Specificity controls, consisting of appropriate cell types known to be positive for selected standard antibodies must be run often enough to assure the proper performance of reagents.

A negative reagent control or controls must be identified for each test cell preparation. It is recommended that this control consist of monoclonal antibodies of the same species and subclass and be prepared and purified in the same way as the monoclonal used for phenotyping. For indirect labeling, it is recommended that the negative control reagent be an irrelevant primary antibody and the same secondary antibodies be conjugated with the same fluorochromes used.

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For direct labeling, it is recommended that the negative control reagent be an irrelevant antibody conjugated with the same fluorochrome and at the same fluorochrome: protein ratio used in all relevant test combinations.

Laboratories must also do *all* of the following:

1. Define acceptable time periods between processing, labeling and analysis of samples. Treat control samples alike.
2. Use gating strategies to assure that the population of interest is being selected without significant contamination.
3. Draw conclusions about abnormal proportions or abnormal numbers of cells bearing particular internal or cell surface markers only in comparison with local control data obtained with the same instrument, reagents and techniques.
4. Take into consideration the determination of percent positives of the negative control reagent.

4.11.H Reagents

Laboratories must also do *all* of the following:

1. Have a policy to validate the specificity of monoclonal antibodies, either by using appropriate controls or by testing in parallel with previous lots.
2. Determine the quantities of reagents used for each test sample by the manufacturer's recommendations or from published data, and whenever possible, that are verified by the laboratory using titration.
3. Process monoclonal antibodies, that have been reconstituted from lyophilized powder form for storage at 4°C, according to the manufacturer's instructions or locally documented procedures, to remove microaggregates prior to use in preparation of working stains.

4.12 ELISA (Appendix 3D)

4.12.A The ELISA Reader

Laboratories must also do *all* of the following:

1. Have a reader with a light source and filter that produces the intensity and wavelength of light required for the test system.
2. Perform and document calibration and verification of plate alignment and instrument linearity according to the manufacturer's instructions or at least once every 6 months and must be documented.
3. Check and document monthly the performance of the microplate washer, if used.

4.12.B ELISA Technique

Each assay must contain positive, negative, and reagent controls that are appropriate for the intended use of the assay and the test results. The dilution of reagents and test specimens must be documented. For an assay to be valid, all controls must meet or exceed established thresholds as specified in the assay procedure, and this must be documented.
Sample identity and proper plate orientation must be maintained throughout the procedure.

4.13 Solid Phase Multi-channel Arrays (Appendix 3D)

4.13.A Instrument Standardization/Calibration

Instruments must be standardized or calibrated as described *Policy 4.11.A: Instrument Standardization and Calibration.* Calibration and verification of plate alignment and instrument

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linearity must be performed according to the manufacturer's instructions or at least once every 6 months. The precise movement of the tray and plate must be documented.

If used, the microplate washer performance must be checked and its acceptable performance documented monthly.

4.13.B Reagents

Assays must use positive, negative, and reagent controls that are appropriate for the intended use of the assay and the test results. Document any dilution or optimization of reagents or test specimens.

For an assay to be valid it must meet or exceed established thresholds specified in the assay procedure, and this must be documented.

4.13.C Technique

Sample identity and proper plate orientation must be maintained throughout the procedure.

4.13.D PRA Determination

The quality control of the new system's reagents must adhere to the standards described in *Policy 4.10.D.ii: Reagents.*

4.13.E Histocompatibility Typing

If the typing system is probe based, all standards relating to SSO procedures are applicable and must be adhered to as outlined in *Policy 4.10.I.i: Oligonucleotide Probe Assays.*

4.14 Chimerism Analysis (Appendix 3D)

Laboratories performing engraftment and chimerism testing using nucleic acid analysis must conform to all pertinent standards in Section K- Nucleic Acid Analysis.

The specificity and sequence of primers must be defined. The genetic designation (e.g., locus) of the target amplified by each set of primers must be defined and documented. For each locus analyzed, the laboratory must have documentation that includes the chromosome location, the approximate number of known alleles, and the distinguishing characteristics (e.g., sizes, sequences) of the alleles that are amplified.

If sample processing involves the isolation of cell subsets or specific hematopoietic cell lineages, the laboratory should document the purity obtained whenever possible. If purity is not documented for a given sample, then this information must be provided on the patient report.

For each locus tested, patient and donor samples collected pre-transplant, and/or control samples demonstrated to have similar performance characteristics (e.g., sensitivity, competition in PCR) must be amplified and analyzed concurrently with patient samples collected post-transplant.

4.14.A Analysis and Reports

Potential for preferential amplification of different sized alleles must be assessed and considered in the analysis.

If more than one locus is amplified in a single amplification (multiplex), the effects of such amplification on each system must be assessed and considered in the analysis.

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Reports must identify the genetic loci analyzed according to standard nomenclature or published reference. For RFLP testing, the restriction endonuclease used and the fragment size must be identified.

If results are reported in a quantitative or semi-quantitative manner, criteria for evaluating the relative amounts of recipient and donor in a mixed chimeric sample must be established. When mixed chimerism is not detected, reports must state the sensitivity level of the assay.

4.15 Preservation of Zero Mismatch Tissue Typing Materials

(Appendix 3D)

For future studies of HLA identification, tissues suitable for the isolation of DNA or purified DNA itself, from both the organ donor and recipient, should be preserved for each 0 mismatched cadaveric kidney transplant. If tissue is preserved it should be preserved by the recipient transplant hospital's HLA laboratory, under conditions which maintain the integrity of the DNA, for at least 5 years. This rule is applicable only when biologic specimens available are in excess of that necessary for the performance of required biologic tests.

4.16 Reference Tables of HLA Antigen Values and Split Equivalences (Appendix 3D)

Tables 4-6, 4-7, and *4-8* show patient-donor antigen combination 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. Antigens with an * indicate an allele that may not have a World Health Organization (WHO)-approved serologic specificity. Antigens given **99 means the patient locus was not tested.

Table 4-6: HLA A Matching Antigen Equivalences

Patient A Locus Antigen	Equivalent Donor Antigens
1	1
2	2, 203
3	3
9	9
10	10
11	11
19	19
23	23
24	24, 2403
25	25
26	26
28	28, 69

Patient A Locus Antigen	Equivalent Donor Antigens
29	29
30	30
31	31
32	32
33	33
34	34
36	36
43	43
66	66, *6601, *6602
68	68
69	69, 28

Patient A Locus Antigen	Equivalent Donor Antigens
74	74
80	80
203	203, 2
210	210, 2
2403	2403, 24
*6601	*6601, 66
*6602	*6602, 66
** 99	(No equivalent)

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Table 4-7: HLA B Matching Antigen Equivalences

Patient B Locus Antigen	Equivalent Donor Antigens
5	5
7	7, 703, 2708
8	8
12	12
13	13
14	14, 64, 65
15	15
16	16
17	17
18	18
21	21
22	22
27	27
35	35
37	37
38	38
39	39, 3901, 3902, *3905
40	40, 61
41	41
42	42
44	44
45	45
46	46

Patient B Locus Antigen	Equivalent Donor Antigens
47	47
48	48
49	49
50	50, 4005
51	51, 5102, 5103
52	52
53	53
54	54
55	55
56	56
57	57
58	58
59	59
60	60
61	61, 40
62	62
63	63
64	64
65	65
67	67
70	70, 71, 72
71	71, 70
72	72, 70
73	73

Patient B Locus Antigen	Equivalent Donor Antigens
75	75, 15
76	76, 15
77	77, 15
78	78
81	81
82	82, *8201
703	703, 7
*0804	*0804, 8
*1304	*1304, 15, 21, 49, 50
2708	2708, 27, 7
3901	3901, 39
3902	3902, 39
*3905	*3905, 39
4005	4005, 50
5102	5102, 51, 53
5103	5103, 51
7801	7801
*8201	*8201, 82
** 99	(No equivalent)

Table 4-8: HLA DR Matching Antigen Equivalences

Patient DR Locus Antigen	Equivalent Donor Antigens
1	1, 103
2	2
3	3
4	4
5	5
6	6
7	7
8	8

Patient DR Locus Antigen	Equivalent Donor Antigens
9	9
10	10
11	11
12	12
13	13
14	14, 1403, 1404
15	15

Patient DR Locus Antigen	Equivalent Donor Antigens
16	16, 2
17	17, 3
18	18, 3
103	103, 1
1403	1403, 14, 6
1404	1404, 14, 6
** 99	(No equivalent)

Tables 4-9 through *4-13* show patient-donor antigen combination and whether they are mismatches. For each candidate unacceptable antigen, the donor antigens that are unacceptable are listed below. All other combinations are considered acceptable. Items that being with an * indicate an allele without a WHO-approved serologic specificity.

If a patient has antibodies to all splits of a broad antigen, enter the broad antigen as well as the splits as unacceptable antigens, or enter only the broad antigen as an unacceptable antigen.

Patient unacceptable antigen Bw4 will exclude donor equivalent antigens B5, B13, B17, B27, B37, B38, B44, B47, B49, B51, B52, B53, B57, B58, B59, B63, B77, and Bw4.

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Patient unacceptable antigen donor equivalent antigens Bw6 will exclude: B7, B8, B14, B18, B22, B35, B39, B40, B41, B42, B45, B48, B50, (B*4005), B54, B55, B56, B60, B61, B62, B64, B65, B67, B70, B71, B72, B75, B76, B78, B81, and Bw6.

Table 4-9: HLA A Unacceptable Antigen Equivalences

Patient's Unacceptable A Locus Antigen	Donor Equivalent Antigens
1	1
2	2, 203, 210
3	3
9	9, 23, 24, 2403
10	10, 25, 26, 34, 66, *6601, *6602
11	11
19	19, 29, 30, 31, 32, 33, 74
23	23, 9

Patient's Unacceptable A Locus Antigen	Donor Equivalent Antigens
24	24, 2403, 9
25	25, 10
26	26, 10
28	28, 68, 69
29	29
30	30
31	31
32	32
33	33
34	34
36	36
43	43

Patient's Unacceptable A Locus Antigen	Donor Equivalent Antigens
66	66, *6601, *6602, 10
68	68, 28
69	69, 28
74	74
80	80
203	203
210	210
2403	2403
*6601	*6601, 66
*6602	*6602, 66

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Table 4-10: HLA B Unacceptable Antigen Equivalences

Patient's Unacceptable B Locus Antigen	Donor Equivalent Antigens
5	5, 51, 5102, 5103, 52,78
7	7, 703, 2708
8	8
12	12, 44, 45
13	13
14	14, 64, 65
15	15, 62, 63, 75, 76, 77
16	16, 38, 39
17	17, 57, 58
18	18
21	21, 49, 50, 4005
22	22, 54, 55, 56
27	27, 2708
35	35
37	37
38	38, 16
39	39, 3901, 3902, *3905, 16
40	40, 60, 61
41	41

Patient's Unacceptable B Locus Antigen	Donor Equivalent Antigens
42	42
44	44, 12
45	45, 12
46	46
47	47
48	48
49	49, 21
50	50, 4005, 21
51	51, 5102, 5103
52	52
53	53
54	54, 22
55	55, 22
56	56, 22
57	57, 17
58	58, 17
59	59
60	60, 40
61	61, 40
62	62, 15
63	63, 15
64	64, 14
65	65, 14
67	67

Patient's Unacceptable B Locus Antigen	Donor Equivalent Antigens
70	70, 71, 72
71	71, 70
72	72, 70
73	73
75	75
76	76
77	77
78	78
81	81
82	82, *8201
703	703
*0804	*0804
*1304	*1304
2708	2708
3901	3901
3902	3902
*3905	*3905
4005	4005
5102	5102
5103	5103
7801	7801
*8201	*8201
Bw4	Bw4
Bw6	Bw6

Table 4-11: HLA C Unacceptable Antigen Equivalences

Patient's Unacceptable C Locus Antigen	Donor Equivalent Antigens
w1	w1
w2	w2
w3	w3, w9, w10
w4	w4
w5	w5
w6	w6

Patient's Unacceptable C Locus Antigen	Donor Equivalent Antigens
w7	w7
w8	w8
w9	w9
w10	w10
*12	*12
*13	*13

Patient's Unacceptable C Locus Antigen	Donor Equivalent Antigens
*14	*14
*15	*15
*16	*16
*17	*17
*18	*18

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Table 4-12: HLA DR Unacceptable Antigen Equivalences

Patient's Unacceptable DR Locus Antigen	Donor Equivalent Antigens
1	1, 103
2	2, 15, 16
3	3, 17, 18
4	4
5	5, 11, 12
6	6, 13, 14, 1403, 1404
7	7
8	8
9	9

Patient's Unacceptable DR Locus Antigen	Donor Equivalent Antigens
10	10
11	11
12	12
13	13, 6
14	14, 1403, 1404, 6
15	15, 2
16	16, 2
17	17, 3
18	18, 3

Patient's Unacceptable DR Locus Antigen	Donor Equivalent Antigens
103	103
1403	1403, 6
1404	1404, 6
51*	51, 2, 15, 16
52*	52, 3, 5, 6, 11, 12, 13, 14, 17, 18
53*	53, 9

Table 4-13: HLA DQ Unacceptable Antigen Equivalences

Patient's Unacceptable DQ Locus Antigen	Donor Equivalent Antigens
1	1, 5, 6
2	2
3	3, 7, 8, 9
4	4

Patient's Unacceptable DQ Locus Antigen	Donor Equivalent Antigens
5	5, 1
6	6, 1
7	7, 3
8	8, 3

Patient's Unacceptable DQ Locus Antigen	Donor Equivalent Antigens
9	9, 3

History

Appendix 3A: HLA Antigen Values and Split Equivalence: 9/17/2007; 11/9/2010
Appendix 3D: Guidelines for the Development of Joint Written Agreements between Histocompatibility Laboratories and Transplant Programs: 11/17/2008; 6/26/2012
Policy 4: Histocompatibility:

Notes

- For donor crossmatching requirements, see *Policy 2.3: Evaluating and Screening Potential Deceased Donors.*
- For heart donor HLA requirements, see *Policy 6: Allocation of Hearts and Heart-Lungs*.
- For candidate HLA requirements, see *Policy 3: Candidate Registrations, Modifications, and* Removals.
- For KPD histocompatibility requirements, see *Policy 13: Kidney Paired Donation (KPD)* .
- For histocompatibility reporting requirements see *Policy 18: Data Submission Requirements.*
- For the release of HLA information, see Policies *19.11: Release of Human Leukocyte Antigen (HLA) Type of a Recipient's Prior Donor* and *19.12: Release of HLA Type of Donors and Recipients with Laboratory Name and Identifier.*

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Policy 5: Organ Offers, Acceptance, and Verification

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5.1 Minimum Acceptance Criteria

Minimum acceptance criteria define which import deceased donor organs will be offered by the Organ Center to transplant hospitals from OPOs outside the receiving transplant hospital's Donation Service Area (DSA).

5.1.A Kidney Minimum Acceptance Criteria (3.3.3)

Kidney transplant programs must report to the OPTN Contractor annually minimum kidney acceptance criteria. The kidney minimum acceptance criteria will not apply to imported zero antigen mismatched kidney offers.

5.1.B Minimum Acceptance Criteria for Other Transplant Programs (3.3.2)

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

5.2 Maximum Mismatched Antigens (3.3.4)

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 Contractor will only offer organs from deceased donors with mismatched antigens equal to or less than the maximum specified.

5.3 Additional Acceptance and Screening Criteria

5.3.A Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA) (3.8.4.1)

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

- Define the criteria for unacceptable antigens that are considered as contraindications for transplant. This may include clarification of unacceptable antigens based on solid phase

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testing, consideration of prior donor antigens or non-self antigens involved in pregnancies, and unexpected positive crossmatches.
- 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 hospitals 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 Informed Consent for Kidneys Based on KDPI Greater than 85% (3.5.5.3)

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.

5.3.C Liver Acceptance Criteria (3.2.5, 3.6.1, 3.6.2, 3.6.2.2, 3.6.10, 3.6.11)

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 Contractor.

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. If a blood type O candidate will accept a liver from a deceased donor with non-A_1 blood type
4. For status 1A or 1B candidates, if they will accept a liver from a deceased donor with any blood type
5. 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
6. If a candidate will accept a liver for other methods of hepatic support
7. If a candidate is willing to accept a segmental graft

5.3.D Pediatric Heart Acceptance Criteria (3.7.8, 3.7.8.1)

A transplant hospital may specify whether a candidate is willing to accept a heart from any blood type deceased donor. The candidate will be eligible for heart offers from deceased donors of any blood type if the candidate meets at least *one* of the following conditions:

1. Candidate is *in utero*

2. Candidate is less than one year old, and meets *both* of the following:
   a. Is registered as status 1A or 1B.
   b. Has reported current isohemagglutinin titer information for A or B blood type antigens to the OPTN Contractor within the last 30 days.

3. Candidate is at least one year old, and meets *all* of the following:
   a. Is registered prior to turning two years old.
   b. Is assigned status 1A or 1B.
   c. Has reported current isohemagglutinin titer levels less than or equal to 1:4 for A or B blood type antigens to the OPTN Contractor within the last 30 days.

d. Has *not* received treatments within the last 30 days that may have reduced titer values to 1:4 or less.

If a transplant hospital indicates that a pediatric candidate is willing to accept a heart from any blood type deceased donor, and the candidate meets at least one of the eligibility conditions, anti-A or anti-B titers must be reported as follows:

- At the time of registration (except *in utero* candidates).
- Every 30 days after registration (except *in utero* candidates).
- At transplant (all candidates).
- If graft loss or death occurs within one year of the transplant (all candidates transplanted with an incompatible blood type heart).

5.3.E Pancreas Candidates after Kidney Transplant Acceptance Criteria (3.8.1.2)

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 Contractor.

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.

5.4 Organ Offers

5.4.A Nondiscrimination in Organ Allocation (6.2.1)

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, race, sex, religion, or financial status.

5.4.B Order of Allocation (3.1.5, 3.2.1.4, 3.2.4, 3.3.1, 3.4.6)

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 recipients in the order that the potential recipients 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 their candidates' data with the OPTN Contractor. The host OPO may run an updated match run and allocate the organ according to the updated candidate data.
5. If no transplant program within the DSA or through an approved regional sharing arrangement accepts the organ, the Organ Center will allocate an abdominal organ first regionally and then nationally, according to allocation Policies. The Organ Center will allocate thoracic organs according to *Policy 6: Allocation of Hearts and Heart-Lungs* and *Policy 10: Allocation of Lungs .*

6. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all potential recipients on the match run. Members must submit the *Organ Export Verification Form* to the OPTN Contractor prior to exporting deceased donor organs.

5.4.C Liver Offers (3.6.5.1, 3.6.7)

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 *either* 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

Any re-execution of the match system for the same deceased donor for other reasons must be retrospectively reviewed by the Regional Review Board (RRB).

5.4.D Multiple Organ Procurement and Offers (3.4.3, 3.4.5)

If an OPO has permission to procure all organs from a deceased donor, that OPO must offer those organs unless, in the OPO's medical judgment, the organs are not suitable for transplant.

After the organs have been accepted, all receiving transplant hospitals must agree on when the multiple organ procurement will begin. If they cannot agree on a start time for the procurement, the host OPO may withdraw the offer from the transplant hospitals that accepted the organs.

5.4.E Backup Organ Offers (3.3.5)

OPOs may make backup offers for all organs. Transplant hospitals 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 hospital refuses to consider or does not respond to a backup offer, the offer will be considered refused.

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

5.4.F Allocation to Candidates Not on the Match Run (3.1.13, 3.2.4)

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. That the transplant hospital verified the medical suitability between the deceased donor organ and recipient prior to transplant 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

The transplant hospital must maintain all related documentation.

5.4.G Local Conflicts (3.6.8, 3.7.14, 3.9.4)

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 Receiving and Accepting Organ Offers

5.5.A Receiving and Reviewing Organ Offers (3.1.2, 3.4.7)

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

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

5.5.B Time Limit for Acceptance (3.4.2, 3.6.5)

A transplant hospital must access deceased donor information in the match system within one hour of receiving the initial organ offer notification. If the transplant hospital does not access the match system within this time, the offer will be considered refused.

Transplant hospitals must either accept or refuse the organ within one hour of accessing the deceased donor information required for an organ according to *Policy 2.3: Evaluating and Screening Potential Deceased Donors*. If the transplant hospital does not respond within this time, the offer expires and the organ may be offered to the transplant hospital for the candidate that appears next on the match run.

5.5.C Effect of Acceptance (3.3.6)

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.

5.6 Blood Type Verification upon Receipt (3.1.2, 5.7, 12.7.7)

When the organ arrives at the transplant hospital and prior to transplant, the transplant hospital must verify the accuracy of the deceased donor ID and blood type against the potential recipient's blood type. Blood subtype accuracy for deceased donor and potential recipient must also be verified if used for allocation. The transplant hospital must document that these verifications occurred.

5.7 Released Organs (3.2.4, 3.6)

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 originally designated recipient or release the deceased donor organs back to and notify the host OPO or the OPTN Contractor for further distribution. If a transplant program released an organ, it must explain to the OPTN Contractor the reason for refusing the organ for that candidate. The host OPO must then allocate the organ to other candidates according to the organ-specific policies. The host OPO may delegate this responsibility to the OPTN Contractor or to the OPO serving the candidate transplant program's DSA.

5.8 Allocation of Multi-Organ Combinations (3.9.3)

Candidates registered for multiple organs must appear on the heart, lung, or liver match run to be eligible to receive a heart, lung, or liver.

When multi-organ candidates other than heart-lung candidates are eligible to receive a heart, lung, or liver, the second required organ will be allocated to the multi-organ candidate from the same donor if the donor's DSA is the same DSA where the multi-organ candidate is registered. Heart-lung combinations are allocated according to *Policy 6.5.E: Allocation of Heart-Lungs*.

If the multi-organ candidate is on a waiting list outside the donor's DSA, voluntary sharing of the second organ is recommended. When the second organ is shared, the same organ of an identical blood type must be paid back to the host OPO from the next acceptable donor procured by the recipient OPO, unless the second organ is a kidney. If the second organ is a kidney, then there is no payback obligation.

5.9 Allocation of Other Organs

5.9.A Statuses and Points (3.9, 3.9.1)

For the allocation of organs not specifically addressed in other policies, points are assigned for medical urgency according to *Table 5-1* below.

Table 5-1: Medical Urgency Points for Other Organs

If a candidate meets these criteria:	Then the candidate is this status:	And receives this many points:
At home, functioning normally, and transplant surgery would be an elective procedure.	1	4
Homebound and requiring continuous medical care which can be self-administered. Short hospitalizations for simultaneous or intervening conditions are not considered justification for a change in status.	2	8
Homebound and requiring continuous medical care which requires the assistance of an attendant. Short hospitalizations for simultaneous or intervening conditions are not considered justification for a change in status.	3	12
Requires continuous hospitalization because of	4	16

If a candidate meets these criteria:	Then the candidate is this status:	And receives this many points:
the candidate's medical condition.		
Requires continuous hospitalization as well as intravenous inotropic drug therapy.	5	20
Requires continuous hospitalization and a mechanical assist device for survival.	6	24

5.9.B Points for Distance (3.9.2)

For the allocation of organs not specifically addressed in other policies, deceased donors and recipients receive points for the distance between the transplant hospital and the deceased donor or recipient. The point values are assigned according to *Table 5.2* below.

Table 5-2: Distance Points for Other Organs

If the distance to the transplant hospital is:	Then the deceased donor receives:	And the recipient receives:
0 – 50 miles	12 points	6 points
50 – 500 miles	10 points	5 points
500 – 1000 miles	8 points	4 points
1000 – 1500 miles	6 points	3 points
1500 – 2000 miles	4 points	2 points
2000 – 2500 miles	2 points	1 points
Greater than 2500 miles	0 points	0 points

History

Policy 3.3: Acceptance Criteria: 6/25/2007; 9/17/2007; 11/18/2008; 10/23/2009; 6/26/2012
Policy 3.9: Allocation Systems for Organs Not Specifically Addressed: 6/20/2008; 3/3/2009; 11/9/2010
Policy 5: Organ Offers, Acceptance, and Verification:

Notes

- For information on directed donations, see *Policy 1: Administrative Rules and Definitions* and *Policy 3: Candidate Registrations, Modifications, and Removals*.
- For information on required deceased donor information that must be provided for an organ, see *Policy 2.3: Evaluating and Screening Potential Deceased Donors.*
- For information on KDPI Scores, see *Policy 8: Allocation of Kidneys*.
- For information on donation after circulatory death (DCD), see *Policy 2.13: Donation after Circulatory Death (DCD)*.

Policy 6: Allocation of Hearts and Heart-Lungs

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6.2 Status Updates 72
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6.4 Waiting Time 74
6.5 Heart Allocation Classifications and Rankings 75

6.1 Status Assignments (3.7.3, 3.7.4)

Each heart transplant candidate is assigned a status that reflects the candidate's medical urgency for transplant.

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

- Adult status 1A
- Adult status 1B
- Adult status 2
- Inactive status

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 of any age is assigned a pediatric status if the candidate was registered on the waiting list before turning 18 years old and has not yet received a heart transplant.

6.1.A Adult Heart Status 1A Requirements (3.7.3)

To assign a candidate adult status 1A, the candidate's transplant program must submit a *Heart Status 1A Justification Form* to the OPTN Contractor. A candidate is not assigned adult status 1A 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 1A if *either* of the following conditions is met:

1. The candidate is admitted to the transplant hospital that registered the candidate on the waiting list, or an affiliated Veteran's Administration (VA) hospital, and the candidate also meets at least *one* of the requirements in *Table 6-1* below.

Table 6-1: Adult Status 1A Requirements for Candidates Currently Admitted to the Transplant Hospital

If the candidate meets this condition:	Then adult status 1A is valid for:
Has one of the following mechanical circulatory support	14 days, and must be recertified

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If the candidate meets this condition:	Then adult status 1A is valid for:
devices in place: • Total artificial heart (TAH) • Intra-aortic balloon pump • Extracorporeal membrane oxygenation (ECMO)	by an attending physician every 14 days from the date of the candidate's initial registration as adult status 1A to extend the adult status 1A registration.
Requires continuous mechanical ventilation	14 days, and must be recertified by an attending physician every 14 days from the date of the candidate's initial registration as adult status 1A to extend the Status 1A registration.
Requires continuous infusion of a single high-dose intravenous inotrope or multiple intravenous inotropes, and requires continuous hemodynamic monitoring of left ventricular filling pressures. The OPTN Contractor will maintain a list of the OPTN-approved qualifying inotropes and doses.	7 days, and may be renewed for additional 7 day periods for each occurrence of an adult status 1A listing under this criterion for this candidate.

2. A candidate who is at least 18 years old at the time of registration, and may or may not be currently admitted to the transplant hospital, may be assigned adult status 1A if the candidate meets at least *one* of the requirements in *Table 6-2* below.

Table 6-2: Adult Status 1A Requirements for Candidates- Current Hospitalization Not Required

If the candidate meets this condition:	Then the status is valid for:
Has *one* of the following mechanical circulatory support devices in place: • Left ventricular assist device (LVAD) • Right ventricular assist device (RVAD) • Left and right ventricular assist devices (BiVAD)	30 days, and the candidate may be registered as adult status 1A for 30 days at any point after being implanted once an attending physician determines the candidate is medically stable. The 30 days do not have to be consecutive. However, if the candidate undergoes a procedure to receive another device, then the candidate qualifies for a new term of 30 days. Any 30 days granted by the new device would substitute and not supplement any time remaining from the previous adult status 1A classification.
Candidate has mechanical circulatory support and there is medical evidence of significant device-related complications including, but not limited to, thromboembolism, device infection, mechanical failure, or life-threatening ventricular arrhythmias. A candidate's sensitization is not an acceptable device-related complication to qualify as adult status 1A. If a transplant program reports a complication that is not listed here, the registration will be retrospectively reviewed by the heart regional review board (RRB)	14 days, and must be recertified by an attending physician every 14 days from the date of the candidate's initial registration as adult status 1A to extend the adult status 1A registration.

If the attending physician does not update the qualifications for adult status 1A registration when required according to *Tables 6-1* and *6-2* above, then the candidate's adult status 1A will expire and the candidate will be downgraded to adult status 1B.

6.1.B Adult Heart Status 1B Requirements (3.7.3)

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

The candidate's transplant program may assign the candidate as adult status 1B if the candidate is at least 18 years old at the time of registration and has at least *one* of the following devices or therapies in place:

1. Left ventricular assist device (LVAD)
2. Right ventricular assist device (RVAD)
3. Left and right ventricular assist devices (BiVAD)
4. Continuous infusion of intravenous inotropes

Candidates that continue to qualify for adult status 1B may retain this status for an unlimited period and this status does not require any recertification, unless the candidate's medical condition changes as described in *Policy 6.2: Status Updates*.

6.1.C Adult Heart Status 2 Requirements (3.7.3)

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

The candidate may retain adult status 2 for an unlimited period and this status does not require recertification, unless the candidate's medical condition changes as described in *Policy 6.2: Status Updates*.

6.1.D Pediatric Heart Status 1A Requirements (3.7.4)

To register a candidate as pediatric status 1A, the candidate's transplant program must submit a *Heart Status 1A Justification Form* to the OPTN Contractor. 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 assistance of a mechanical ventilator
2. Requires assistance of a mechanical assist device
3. Requires assistance of a balloon pump
4. Is less than six months old with congenital or acquired heart disease exhibiting reactive pulmonary hypertension at greater than 50% of systemic level. The candidate may be treated with prostaglandin E (PGE) to maintain patency of the ductus arteriosus.
5. Requires infusion of a single high-dose of an intravenous inotrope or multiple intravenous inotropes. The OPTN Contractor will maintain a list of OPTN-approved specific qualifying inotropes and doses.
6. Has a life expectancy without a heart transplant of less than 14 days.

A candidate meeting the requirement for pediatric status 1A due to a life expectancy without transplant of less than 14 days will be reviewed retrospectively by the regional review board (RRB) if any additional 14 days periods are received, according to *Policy 6.3: Status Exceptions*.

Pediatric status 1A is valid for 14 days from the date of the candidate's initial registration as pediatric status 1A and must be recertified by an attending physician every 14 days from the date of the candidate's initial registration as pediatric status 1A to extend the status 1A registration.

When a candidate's pediatric status 1A expires, the candidate will be assigned pediatric status 1B. The attending physician must classify the candidate as pediatric status 2 or inactive status if the candidate's medical condition does not qualify for pediatric status 1B.

6.1.E Pediatric Heart Status 1B Requirements (3.7.4)

To assign a candidate pediatric heart status 1B, the candidate's transplant program must submit a *Heart Status 1B Justification Form* to the OPTN Contractor. 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 low dose single inotropes. The OPTN Contractor will maintain a list of the OPTN-approved specific qualifying inotropes and doses.
2. Is less than six months old and does not meet the criteria for pediatric status 1A.
3. Is in the less than 5th percentile for the candidate's expected height or weight according to the most recent Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics pediatric clinical growth chart.
4. Is 1.5 or more standard deviations below the candidate's expected height growth or weight growth according to the most recent CDC National Center for Health Statistics pediatric clinical growth chart

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 as described in *Policy 6.2*.

6.1.F Pediatric Heart Status 2 Requirements (3.7.4)

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 as pediatric status 2.

The candidate may retain pediatric status 2 for an unlimited period and this status does not require any recertification.

6.1.G Inactive Adult and Pediatric Candidates (3.7.3, 3.7.4)

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.

6.2 Status Updates (3.7.3, 3.7.4)

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 Contractor within 24 hours of the change in medical condition.

6.3 Status Exceptions (3.7.1, 3.7.3, 3.7.4)

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

Table 6-3: Exception Qualification and Periods

Requested Status:	Qualification:	Duration:	Extensions:
Adult 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	14 days	• Require RRB approval for each successive 14 day period • RRBs will review and decide extension requests retrospectively • If no extension request is submitted, candidate will be downgraded to adult status 1B
Adult 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	Indefinite	• Not required as long as candidate's medical condition remains the same
Pediatric status 1A	• Candidate life expectancy of less than 14 days without a heart transplant	14 days	• One 14 day extension by submitting an updated application to the OPTN Contractor • Successive extensions then require the transplant physician to submit an application to the OPTN Contractor for RRB review • If no extension request is submitted, the candidate will be downgraded to 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	Indefinite	• Not required as long as candidate's medical condition remains the same

The candidate's transplant physician must submit an application to the OPTN Contractor with the requested status and the rationale for granting the status exception.

6.3.A RRB and Committee Review of Status Exceptions

The heart RRB reviews all applications for status exceptions retrospectively. If a status exception is not approved by the RRB, the candidate's transplant program may override the decision and list the candidate at the requested status, subject to review by the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee may review the RRB's decisions and rationale, and may refer any case to the Membership and Professional Standards Committee (MPSC) for further review.

6.3.B Exceptions to Allocation for Sensitized Patients (3.7.1.1)

A transplant program may allocate a heart to sensitized candidates within a DSA out of sequence as defined in *Policy 6.5: Heart Allocation Classifications and Rankings* if:

1. The candidate's transplant surgeon or physician determines that the candidate's antibodies would react adversely to certain human leukocyte antigens (HLA).
2. All heart transplant programs and the OPO within the DSA agree to allocate a heart from a compatible deceased donor to the sensitized candidate.
3. The candidate's transplant program, all heart transplant programs, and the OPO within the DSA agree upon the level of sensitization at which a candidate qualifies for the sensitization exception.

Sensitization alone does not qualify a candidate to be assigned any status exception as described in *Policies 6.3* above.

6.4 Waiting Time (3.7.9.1)

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.

As a result, waiting time accrued at a higher status will be added to any time accumulated at a lower status, but waiting time accumulated at a lower status will not be added to any higher status.

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

Waiting time does not accrue while the candidate is inactive.

6.4.A Waiting Time for Multi-organ Candidates

The OPTN Contractor may assign multi-organ candidates waiting time from one waiting list to another waiting list according to *Table 6-4* below.

Table 6-4: Waiting Time Assignments for Multi-organ Candidates

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

Heart-lung	Lung

6.5 Heart Allocation Classifications and Rankings

6.5.A Allocation of Hearts by Blood Type (3.7.8)

Within each heart status, hearts will be allocated to candidates according to the primary blood type matching requirements in *Table 6-5* below:

Table 6-5: Primary Blood Type Matching Requirements

Hearts from Donors with:	Are Allocated to Candidates with:
Blood Type O	Blood type O *or* blood type B
Blood Type A	Blood type A or blood type AB
Blood Type B	Blood type B or blood type AB
Blood Type AB	Blood type AB

After hearts are allocated to primary blood type candidates, they are allocated to any secondary blood type compatible candidates, then to any eligible incompatible blood type candidates.

Allocation to *in utero* candidates eligible for any blood type deceased donors is initiated after all eligible born candidates have received offers

6.5.B Sorting Within Each Classification (3.7.9, 3.7.9.1)

Candidates are sorted within each classification by the total amount of waiting time that the candidate has accumulated at that status.

6.5.C Allocation of Hearts from Donors at Least 18 years Old (3.7.8, 3.7.10)

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

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

Classification	Candidates that are within the:	And are:
1	OPO's DSA	Adult or pediatric status 1A and primary blood type match with the donor
2	OPO's DSA	Adult or pediatric status 1A and secondary blood type match with the donor
3	OPO's DSA	Adult or pediatric status 1B and primary blood type match with the donor
4	OPO's DSA	Adult or pediatric status 1B and secondary blood type match with the donor
5	Zone A	Adult or pediatric status 1A and primary blood type match with the donor
6	Zone A	Adult or pediatric status 1A and secondary blood type match with the donor
7	Zone A	Adult or pediatric status 1B and primary blood type match with the donor
8	Zone A	Adult or pediatric status 1B and secondary blood type match with the donor
9	OPO's DSA	Adult or pediatric status 2 and primary blood type match with the donor
10	OPO's DSA	Adult or pediatric Status 2 and secondary blood type match with the donor
11	Zone B	Adult or pediatric status 1A and primary blood type match with the donor
12	Zone B	Adult or pediatric status 1A and secondary blood type match with the donor
13	Zone B	Adult or pediatric status 1B and primary blood type match with the donor
14	Zone B	Adult or pediatric status 1B and secondary blood type match with the donor
15	Zone A	Adult or pediatric status 2 and primary blood type match with the donor
16	Zone A	Adult or pediatric status 2 and secondary blood type match with the donor
17	Zone B	Adult or pediatric status 2 and primary blood type match with the donor
18	Zone B	Adult or pediatric status 2 and secondary blood type match with the donor
19	Zone C	Adult or pediatric status 1A and primary blood type match with the donor
20	Zone C	Adult or pediatric status 1A and secondary blood type match with the donor
21	Zone C	Adult or pediatric status 1B and primary blood type match with the donor

22	Zone C	Adult or pediatric status 1B and secondary blood type match with the donor
23	Zone C	Adult or pediatric status 2 and primary blood type match with the donor
24	Zone C	Adult or pediatric status 2 and secondary blood type match with the donor
25	Zone D	Adult or pediatric status 1A and primary blood type match with the donor
26	Zone D	Adult or pediatric status 1A and secondary blood type match with the donor
27	Zone D	Adult or pediatric status 1B and primary blood type match with the donor
28	Zone D	Adult or pediatric status 1B and secondary blood type match with the donor
29	Zone D	Adult or pediatric status 2 and primary blood type match with the donor
30	Zone D	Adult or Pediatric Status 2 and secondary blood type match with the donor
31	Zone E	Adult or pediatric status 1A and primary blood type match with the donor
32	Zone E	Adult or pediatric status 1A and secondary blood type match with the donor
33	Zone E	Adult or pediatric status 1B and primary blood type match with the donor
34	Zone E	Adult or pediatric status 1B and secondary blood type match with the donor
35	Zone E	Adult or pediatric status 2 and primary blood type match with the donor
36	Zone E	Adult or pediatric status 2 and secondary blood type match with the donor
37	OPO’s DSA or Zone A	Pediatric Status 1A and blood type incompatible with the donor
38	OPO’s DSA or Zone A	Pediatric Status 1B and blood type incompatible with the donor
39	Zone B	Pediatric Status 1A and blood type incompatible with the donor
40	Zone B	Pediatric Status 1B and blood type incompatible with the donor
41	Zone C	Pediatric Status 1A and blood type incompatible with the donor
42	Zone C	Pediatric Status 1B and blood type incompatible with the donor
43	Zone D	Pediatric Status 1A and blood type incompatible with the donor
44	Zone D	Pediatric Status 1B and blood type incompatible with the donor

45	Zone E	Pediatric Status 1A and blood type incompatible with the donor
46	Zone E	Pediatric Status 1B and blood type incompatible with the donor
47	OPO's DSA and Zone A	*In utero* and primary blood type match with the donor
48	OPO's DSA and Zone A	*In utero* and secondary blood type match with the donor
49	OPO's DSA and Zone A	*In utero* and blood type incompatible with the donor
50	Zone B	*In utero* and primary blood type match with the donor
51	Zone B	*In utero* and secondary blood type match with the donor
52	Zone B	*In utero* and blood type incompatible with the donor
53	Zone C	*In utero* and primary blood type match with the donor
54	Zone C	*In utero* and secondary blood type match with the donor
55	Zone C	*In utero* and blood type incompatible with the donor
56	Zone D	*In utero* and primary blood type match with the donor
57	Zone D	*In utero* and secondary blood type match with the donor
58	Zone D	*In utero* and blood type incompatible with the donor
59	Zone E	*In utero* and primary blood type match with the donor
60	Zone E	*In utero* and secondary blood type match with the donor
61	Zone E	*In utero* and blood type incompatible with the donor

6.5.D Allocation of Hearts from Donors Less Than 18 Years Old (3.7.5, 3.7.8, 3.7.10.1)

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 6-7* below.

Table 6-7: Allocation of Hearts from Donors Less Than 18 Years Old

Classification	Candidates that are within the:	And are:
1	OPO's DSA or Zone A	Pediatric status 1A and primary blood type match with the donor
2	OPO's DSA or Zone A	Pediatric status 1A and secondary blood type match with the donor
3	OPO's DSA	Adult status 1A and primary blood type match with the donor
4	OPO's DSA	Adult status 1A and secondary blood type match with the donor
5	OPO's DSA or Zone A	Pediatric status 1B and primary blood type match with the donor
6	OPO's DSA or Zone A	Pediatric Status 1B and secondary blood type match with the donor
7	OPO's DSA	Adult Status 1B and primary blood type match with the donor
8	OPO's DSA	Adult Status 1B and secondary blood type match with the donor
9	Zone A	Adult Status 1A and primary blood type match with the donor
10	Zone A	Adult Status 1A and secondary blood type match with the donor
11	Zone A	Adult Status 1B and primary blood type match with the donor
12	Zone A	Adult Status 1B and secondary blood type match with the donor
13	OPO's DSA	Pediatric status 2 and primary blood type match with the donor
14	OPO's DSA	Pediatric status 2 and secondary blood type match with the donor
15	OPO's DSA	Adult status 2 and primary blood type match with the donor
16	OPO's DSA	Adult status 2 and secondary blood type match with the donor
17	Zone B	Pediatric status 1A and primary blood type match with the donor
18	Zone B	Pediatric status 1A and secondary blood type match with the donor
19	Zone B	Adult status 1A and primary blood type match with the donor
20	Zone B	Adult status 1A and secondary blood type match with the donor
21	Zone B	Pediatric status 1B and primary blood type match with the donor
22	Zone B	Pediatric status 1B, secondary blood type match with the donor

Classification	Candidates that are within the:	And are:
23	Zone B	Adult status 1B and primary blood type match with the donor
24	Zone B	Adult status 1B and secondary blood type match with the donor
25	Zone A	Pediatric status 2 and primary blood type match with the donor
26	Zone A	Pediatric status 2 and secondary blood type match with the donor
27	Zone A	Adult status 2 and primary blood type match with the donor
28	Zone A	Adult status 2 and secondary blood type match with the donor
29	Zone B	Pediatric status 2, primary blood type match with the donor
30	Zone B	Pediatric status 2 and secondary blood type match with the donor
31	Zone B	Adult status 2 and primary blood type match with the donor
32	Zone B	Adult status 2 and secondary blood type match with the donor
33	Zone C	Pediatric status 1A and primary blood type match with the donor
34	Zone C	Pediatric status 1A and secondary blood type match with the donor
35	Zone C	Adult status 1A and primary blood type match with the donor
36	Zone C	Adult status 1A and secondary blood type match with the donor
37	Zone C	Pediatric status 1B and primary blood type match with the donor
38	Zone C	Pediatric status 1B and secondary blood type match with the donor
39	Zone C	Adult status 1B and primary blood type match with the donor
40	Zone C	Adult status 1B and secondary blood type match with the donor
41	Zone C	Pediatric status 2 and primary blood type match with the donor
42	Zone C	Pediatric status 2 and secondary blood type match with the donor
43	Zone C	Adult status 2 and primary blood type match with the donor
44	Zone C	Adult status 2 and secondary blood type match with the donor

Classification	Candidates that are within the:	And are:
45	Zone D	Pediatric status 1A and primary blood type match with the donor
46	Zone D	Pediatric status 1A and secondary blood type match with the donor
47	Zone D	Adult status 1A and primary blood type match with the donor
48	Zone D	Adult status 1A and secondary blood type match with the donor
49	Zone D	Pediatric status 1B and primary blood type match with the donor
50	Zone D	Pediatric status 1B and secondary blood type match with the donor
51	Zone D	Adult status 1B and primary blood type match with the donor
52	Zone D	Adult status 1B and secondary blood type match with the donor
53	Zone D	Pediatric status 2 and primary blood type match with the donor
54	Zone D	Pediatric status 2 and secondary blood type match with the donor
55	Zone D	Adult status 2 and primary blood type match with the donor
56	Zone D	Adult status 2 and secondary blood type match with the donor
57	Zone E	Pediatric status 1A and primary blood type match with the donor
58	Zone E	Pediatric status 1A and secondary blood type match with the donor
59	Zone E	Adult status 1A and primary blood type match with the donor
60	Zone E	Adult status 1A and secondary blood type match with the donor
61	Zone E	Pediatric status 1B and primary blood type match with the donor
62	Zone E	Pediatric status 1B and secondary blood type match with the donor
63	Zone E	Adult status 1B and primary blood type match with the donor
64	Zone E	Adult status 1B and secondary blood type match with the donor
65	Zone E	Pediatric status 2 and primary blood type match with the donor
66	Zone E	Pediatric status 2 and secondary blood type match with the donor

Classification	Candidates that are within the:	And are:
67	Zone E	Adult status 2 and primary blood type match with the donor
68	Zone E	Adult status 2 and secondary blood type match with the donor
69	OPO's DSA or Zone A	Pediatric status 1A and blood type incompatible with the donor
70	OPO's DSA or Zone A	Pediatric status 1B and blood type incompatible with the donor
71	OPO's DSA or Zone A	Pediatric status 2 and blood type incompatible with the donor
72	Zone B	Pediatric status 1A and blood type incompatible with the donor
73	Zone B	Pediatric status 1B and blood type incompatible with the donor
74	Zone C	Pediatric status 1A and blood type incompatible with the donor
75	Zone C	Pediatric status 1B and blood type incompatible with the donor
76	Zone D	Pediatric status 1A and blood type incompatible with the donor
77	Zone D	Pediatric status 1B and blood type incompatible with the donor
78	Zone E	Pediatric status 1A and blood type incompatible with the donor
79	Zone E	Pediatric status 1B and blood type incompatible with the donor
80	OPO's DSA or Zone A	*In utero* and primary blood type match with the donor
81	OPO's DSA or Zone A	*In utero* and secondary blood type match with the donor
82	OPO's DSA or Zone A	*In utero* and blood type incompatible with the donor
83	Zone B	*In utero* and primary blood type match with the donor
84	Zone B	*In utero* and secondary blood type match with the donor
85	Zone B	*In utero* and blood type incompatible with the donor
86	Zone C	*In utero* and primary blood type match with the donor
87	Zone C	*In utero* and secondary blood type match with the donor
88	Zone C	*In utero and* blood type incompatible with the donor

Classification	Candidates that are within the:	And are:
89	Zone D	*In utero* and primary blood type match with the donor and
90	Zone D	*In utero* and secondary blood type match with the donor
91	Zone D	*In utero* and blood type incompatible with the donor
92	Zone E	*In utero* and primary blood type match with the donor
93	Zone E	*In utero* and secondary blood type match with the donor
94	Zone E	*In utero* and blood type incompatible with the donor

6.5.E Allocation of Heart-Lungs (3.7.7)

When a heart-lung candidate is allocated a heart, the lung from the same deceased donor must be allocated to the heart-lung candidate. When the heart-lung candidate is allocated a lung, the heart from the same deceased donor may only be allocated to the heart-lung candidate if no suitable Status 1A isolated heart candidates are eligible to receive the heart.

The blood type matching requirements described in *Policy 6.5.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* applies to heart-lung candidates when the candidates appear on the lung match run.

6.5.F Allocation of Domino Donor Hearts (3.7.15)

If a transplant program recovers the native heart of a heart-lung recipient, then the transplant program that recovers this heart may transplant it into a second candidate registered at the same transplant program.

If, however, the transplant program does not transplant the recovered, native heart into one of its candidates, then the heart will be allocated according to *Policy 6.5: Heart Allocation Classifications and Rankings*. For the purposes of allocating these hearts, the DSA of allocation is the DSA where the native heart of the heart-lung transplant recipient is recovered.

Notes

1. For membership and personnel requirements for heart programs, see the *OPTN Bylaws, Appendix H*.
2. For heart acceptance criteria, see *Policy 5: Organ Offers, Acceptance, and Verification*.
3. For potential heart deceased donor testing requirements, see *Policy 2.3: Evaluating and Screening Potential Deceased Donors*.
4. For the CDC clinical growth chart, see http://www.cdc.gov/growthcharts/clinical_charts.htm.

History

Policy 3.7: Allocation of Thoracic Organs: 3/22/2007; 12/18/2007; 6/20/2008; 6/23/2009; 10/23/2009; 11/17/2009; 11/9/2010; 6/29/2011; 11/15/2011; 6/26/2012; 11/13/2012; 5/1/2013

Policy 6: Allocation of Hearts and Heart-Lungs:

Policy 7: Allocation of Intestines

7.1 Status Assignments 84

7.2 Waiting Time 84

7.3 Intestine Allocation Classifications and Rankings 84

7.1 Status Assignments (3.11.1, 3.11.3)

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 (3.11.1)

To assign an intestine candidate status 1, the candidate's transplant program must submit a *Status 1 Justification Form* to the OPTN Contractor. 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 (3.11.1)

Any active candidate that does not meet the criteria for status 1 must be registered as status 2.

7.1.C Inactive Status (3.11.1, 3.11.6)

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 (3.11.1)

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 (3.11.2)

Intestines are allocated to candidates according to *Table 7-1* below.

Public Comment Draft

Table 7-1: Allocation of Intestines

Classification	Candidates that are within the:	And are:
1	OPO's DSA	Status 1 and a blood type identical to the donor
2	OPO's DSA	Status 1 and a blood type compatible with the donor
3	OPO's DSA	Status 2 and a blood type identical to the donor
4	OPO's DSA	Status 2 and a blood type compatible with the donor
5	OPO's region	Status 1 and a blood type identical to the donor
6	OPO's region	Status 1 and a blood type compatible with the donor
7	OPO's region	Status 2 and a blood type identical to the donor
8	OPO's region	Status 2 and a blood type compatible with the donor
9	Nation	Status 1 and a blood type identical to the donor
10	Nation	Status 1 and a blood type compatible with the donor
11	Nation	Status 2 and a blood type identical to the donor
12	Nation	Status 2 and a blood type compatible with the donor

History

Policy 3.11: Intestinal Organ Allocation: 6/20/2008;
Policy 7: Allocation of Intestines:

Notes

For combined liver-intestinal organ allocation, see *Policy 9: Allocation of Livers and Liver-Intestines*.

Policy 8: Allocation of Kidneys

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8.1 Calculated Panel Reactive Antibody (CPRA) (3.5.1)

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 Contractor according to *Policy 5.3.A: Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA)*.

8.2 Exceptions

8.2.A Exceptions Due to Medical Urgency (3.5.2)

Prior to receiving an organ offer from a deceased donor in the same DSA, a candidate's transplant physician may use medical judgment to transplant a candidate out of sequence due to medical urgency.

If there is more than one kidney transplant program in the DSA, then the candidate's physician must receive agreement from the other kidney transplant programs in the DSA to allocate the kidney out of sequence and must maintain documentation of this agreement in the candidate's medical record.

8.2.B Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings (3.5.7.7)

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, the kidney may be allocated according to the original HLA typing, or the recipient transplant hospital may reallocate the kidney locally, according to *Policy 8: Allocation of Kidneys*.

8.3 Points (3.5.3)

Candidates receive points according to *Tables 8-1* and *8-2* below.

Public Comment Draft

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

*Donors with only one antigen identified at an HLA locus (A, B, and DR) are presumed “homozygous” at that locus.

Table 8-2: Points for CPRA

If the candidate’s CPRA score is:	Then the candidate receives this many points:
0	0.00
1-9	0.00
10-19	0.00
20-29	0.08
30-39	0.21
40-49	0.34
50-59	0.48
60-69	0.81
70-74	1.09
75-79	1.58
80-84	2.46
85-89	4.05
90-94	6.71
95	10.82
96	12.17
97	17.30
98	24.40
99	50.09

If the candidate's CPRA score is:	Then the candidate receives this many points:
100	202.10

8.4 Waiting Time (3.5.4)

8.4.A Waiting Time for Candidates Registered at Age 18 Years or Older (3.5.4.1)

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 (3.5.4.2)

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 Waiting Time for Kidney Recipients (3.5.4.1, 3.5.4.2)

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 (3.5.6)

8.5.A Candidate Classifications (3.5.5.1)

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 Contractor 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 Contractor's KDRI-to-KDPI 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 Contractor on or before June 1 of each calendar year.

8.5.B Deceased Donor Classifications (3.5.5.2)

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 8-3* below.

Table 8-3: 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

This deceased donor characteristic:	Applies to:	KDRI score component
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 Contractor's KDRI-to-KDPI mapping table

The KDRI 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 Contractor 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 Contractor on or before June 1 of each calendar year.

8.5.C Informed Consent for Kidneys Based on KDPI Greater than 85% (3.5.5.3)

Prior to receiving an offer for a kidney with a 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.

8.5.D Sorting Within Each Classification (3.5.5.4)

Within each classification, 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.E Allocation of Kidneys by Blood Type (3.5.5.5)

Transplants are restricted by blood type in certain circumstances. Kidneys will be allocated to candidates according to the blood type matching requirements in *Table 8-4* below:

Table 8-4: Allocation of Kidneys by Blood Type

Hearts from Donors with:	Are Allocated to Candidates with:
Blood Type O	Blood type O. For offers made to candidates in zero mismatch categories, blood type O kidneys may be transplanted into candidates who have blood types other than O.
Blood Type A	Blood type A or blood type AB.
Blood Type B	Blood type B. For offers made to candidates in zero 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 type non-A_1 and 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 non-A_1 or non-A_1B blood type kidney. 2. The transplant program establishes a written policy regarding its program's titer threshold for transplanting non-A_1 and 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.F Prior Living Organ Donors (3.5.5.6, 12.9.4)

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 Contractor:

    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.G Highly Sensitized Candidates (3.5.5.7)

Before a candidate with a CPRA score of 99% or 100% can receive offers in allocation classifications 1 through 10 in allocation sequences in *Table 8-6*, 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.H Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20% (3.5.6.1)

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 8-5* below.

Table 8-5: Allocation of Kidneys from Deceased Donors with KDPI Less Than or Equal To 20%

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
1	OPO's DSA	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	Any
2	OPO's DSA	CPRA equal to 100%, blood type identical or permissible	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	Any
4	OPO's region	CPRA equal to 100%, blood type identical or permissible	Any
5	Nation	0-ABDR mismatch, CPRA equal 100%, blood type identical or permissible	Any
6	Nation	CPRA equal to 100%, blood type identical or permissible	Any
7	OPO's DSA	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	Any
8	OPO's DSA	CPRA equal to 99%, blood type identical or permissible	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	Any
10	OPO's region	CPRA equal to 99%, blood type identical or permissible	Any
11	OPO's DSA	0-ABDR mismatch, CPRA equal to 98%, blood type identical or permissible	Any
12	OPO's DSA	CPRA equal to 98%, blood type identical or permissible	Any
13	OPO's DSA	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, and blood type identical	Any
14	OPO's region	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80% but no	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
		greater than 100%, and blood type identical	
15	Nation	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
16	OPO's region	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	Any
17	Nation	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 identical	Any
18	OPO's region	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	Any
19	Nation	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	Any
20	OPO's region	0-ABDR mismatch, top 20% EPTS or 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 identical	Any
21	Nation	0-ABDR mismatch, top 20% EPTS or 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 identical	Any
22	OPO's DSA	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, and blood type B	O
23	OPO's region	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
24	Nation	0-ABDR mismatch, top 20% EPTS or less than 18 years at time of match run, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
25	OPO's region	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	O
26	Nation	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	O

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
27	OPO's region	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	O
28	Nation	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	O
29	OPO's region	0-ABDR mismatch, top 20% EPTS or less than 18 years old at the time of the match, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
30	Nation	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
31	OPO's DSA	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, and blood type permissible	Any
32	OPO's region	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
33	Nation	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
34	OPO's region	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	Any
35	Nation	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	Any
36	OPO's region	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	Any
37	Nation	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	Any
38	OPO's region	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 21% but no	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
		greater than 79%, and blood type permissible	
39	Nation	0-ABDR mismatch, top 20% EPTS or less than 18 years old at the time of match run, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
40	OPO's DSA	Prior living donor, blood type permissible or identical	Any
41	OPO's DSA	Registered prior to 18 years old, blood type permissible or identical	Any
42	OPO's DSA	Top 20% EPTS, blood type B	A2 or A2B
43	OPO's DSA	Top 20% EPTS, blood type permissible or identical	Any
44	OPO's DSA	0-ABDR mismatch, EPTS greater than 20%, blood type identical	Any
45	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
46	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
47	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
48	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
49	OPO's DSA	0-ABDR mismatch, EPTS greater than 20%, and blood type B	O
50	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
51	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
52	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
53	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
54	OPO's DSA	0-ABDR mismatch, EPTS greater than 20%, and blood type permissible	Any
55	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
56	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
57	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
58	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
59	OPO's DSA	EPTS greater than 20%, blood type B	A2 or A2B
60	OPO's DSA	All remaining candidates, blood type permissible or identical	Any
61	OPO's region	Registered prior to 18 years old, blood type permissible or identical	Any
62	OPO's region	Top 20% EPTS, blood type B	A2 or A2B
63	OPO's region	Top 20% EPTS, blood type permissible or identical	Any
64	OPO's region	EPTS greater than 20%, blood type B	A2 or A2B
65	OPO's region	All remaining candidates, blood type permissible or identical	Any
66	Nation	Registered prior to 18 years old, blood type permissible or identical	Any
67	Nation	Top 20% EPTS, blood type B	Any
68	Nation	Top 20% EPTS, blood type permissible or identical	Any
69	Nation	All remaining candidates, blood type permissible or identical	Any

8.5.I Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35% (3.5.6.2)

Kidneys from deceased donors with KDPI scores greater than 20% but less than 35% are allocated to candidates according to *Table 8-6* below.

Table 8-6: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
1	OPO's DSA	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
2	OPO's DSA	CPRA equal to 100%, blood type permissible or identical	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
4	OPO's region	CPRA equal to 100%, blood type permissible or identical	Any
5	Nation	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
6	Nation	CPRA equal to 100%, blood type permissible or identical	Any
7	OPO's DSA	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
8	OPO's DSA	CPRA equal to 99%, blood type permissible or identical	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
10	OPO's region	CPRA equal to 99%, blood type permissible or identical	Any
11	OPO's DSA	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	Any
12	OPO's DSA	CPRA equal to 98%, blood type permissible or identical	Any
13	OPO's DSA	0-ABDR mismatch, blood type identical	Any
14	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
16	OPO's region	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	Any
17	Nation	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	Any
18	OPO's region	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	Any
19	Nation	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	Any
20	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
21	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
22	OPO's DSA	0-ABDR mismatch, blood type B	O
23	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
24	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
25	OPO's region	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	O
26	Nation	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	O
27	OPO's region	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	O

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
28	Nation	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	O
29	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
30	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
31	OPO's DSA	0-ABDR mismatch, blood type permissible	Any
32	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
33	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
34	OPO's region	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	Any
35	Nation	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	Any
36	OPO's region	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	Any
37	Nation	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	Any
38	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
39	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
40	OPO's DSA	Prior living donor, blood type	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
		permissible or identical	
41	OPO's DSA	Registered prior to 18 years old, blood type permissible or identical	Any
42	OPO's DSA	Blood type B	A2 or A2B
43	OPO's DSA	All remaining candidates, blood type permissible or identical	Any
44	OPO's region	Registered prior to 18 years old, blood type permissible or identical	Any
45	OPO's region	Blood type B	A2 or A2B
46	OPO's region	All remaining candidates, blood type permissible or identical	Any
47	Nation	Registered prior to 18 years old, blood type permissible or identical	Any
48	Nation	Blood type B	A2 or A2B
49	Nation	All remaining candidates, blood type permissible or identical	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%

(3.5.6.3)

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 8-7* below.

Table 8-7: 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 within the:	And are:	And the donor is this blood type:
1	OPO's DSA	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
2	OPO's DSA	CPRA equal to 100%, blood type permissible or identical	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
4	OPO's region	CPRA equal to 100%, blood type permissible or identical	Any
5	Nation	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
6	Nation	CPRA equal to 100%, blood type permissible or identical	Any
7	OPO's DSA	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
8	OPO's DSA	CPRA equal to 99%, blood type permissible or identical	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
10	OPO's region	CPRA equal to 99%, blood type permissible or identical	Any
11	OPO's DSA	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	Any
12	OPO's DSA	CPRA equal to 98%, blood type permissible or identical	Any
13	OPO's DSA	0-ABDR mismatch, blood type identical	Any
14	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
16	OPO's region	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	Any
17	Nation	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	Any
18	OPO's region	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	Any
19	Nation	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	Any
20	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
21	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
22	OPO's DSA	0-ABDR mismatch, and blood type B	O
23	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
24	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
25	OPO's region	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	O
26	Nation	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	O

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
27	OPO's region	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	O
28	Nation	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	O
29	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
30	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
31	OPO's DSA	0-ABDR mismatch, blood type permissible	Any
32	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
33	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
34	OPO's region	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	Any
35	Nation	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	Any
36	OPO's region	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	Any
37	Nation	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	Any
38	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
39	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
40	OPO's DSA	Prior living donor, blood type permissible or identical	Any
41	OPO's DSA	Blood type B	A2 or A2B
42	OPO's DSA	All remaining candidates, blood type permissible or identical	Any
43	OPO's region	Blood type B	A2 or A2B

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
44	OPO's region	All remaining candidates, blood type permissible or identical	Any
45	Nation	Blood type B	A2 or A2B
46	Nation	All remaining candidates, blood type permissible or identical	Any

8.5.K Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85% (3.5.6.4)

With the exception of 0-ABDR mismatches, kidneys from deceased donors with KDPI scores greater than 85% will be allocated to adult candidates only.

Kidneys from deceased donors with KDPI scores greater than 85% are allocated to candidates according to *Table 8-8* below.

Table 8-8: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 85%

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
1	OPO's DSA	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
2	OPO's DSA	CPRA equal to 100%, blood type permissible or identical	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
4	OPO's region	CPRA equal to 100%, blood type permissible or identical	Any
5	Nation	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
6	Nation	CPRA equal to 100%, blood type permissible or identical	Any
7	OPO's DSA	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
8	OPO's DSA	CPRA equal to 99%, blood type permissible or identical	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
10	OPO's region	CPRA equal to 99%, blood type permissible or identical	Any
11	OPO's DSA	CPRA equal to 98%, blood type permissible or identical	Any
12	OPO's DSA	CPRA equal to 98%, blood type permissible or identical	Any
13	OPO's DSA	0-ABDR mismatch, blood type permissible or identical	Any
14	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
16	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
17	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
18	OPO's DSA	0-ABDR mismatch, blood type B	O
19	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
20	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
21	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
22	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
23	OPO's DSA	0-ABDR mismatch, blood type permissible	Any
24	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
25	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
26	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
27	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
28	OPO's region	Blood type B	A2 or A2B
29	OPO's region	All remaining candidates, blood type permissible or identical	Any
30	Nation	Blood type B	A2 or A2B
31	Nation	All remaining candidates, blood type permissible or identical	Any

8.6. Double Kidney Allocation (3.5.6.5)

An OPO must offer kidneys individually through one of the allocation sequences in *Policies 8.5.K: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%* and *8.5.H: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%* before offering both kidneys

to a single candidate unless the OPO reports to the OPTN Contractor prior to allocation that the deceased donor meets *at least two* of the following criteria:

- Age is greater than 60 years
- Estimated creatinine clearance is less than 65 mL/min based upon serum creatinine at admission
- Rising serum creatinine (greater than 2.5 mg/dl) at time of organ recovery
- History of longstanding hypertension or diabetes mellitus
- Glomerulosclerosis greater than 15% and less than 50%

The kidneys will be allocated according to sequence of the deceased donor's KDPI.

8.7 Administrative Rules

8.7.A Mandatory Sharing (3.5.7.1)

Kidneys shared as zero mismatches or for candidates with CPRA greater than or equal to 99% in classifications 1 through 10 in allocation sequences in *Table 8-5* through *8.8* above must be offered within the following time limits according to *Table 8-9* below.

Table 8-9: Organ Offer Limit

If the donor is:	The OPO must make at least this many offers :	Then the OPO must offer the kidneys within this many hours of procurement:
KDPI ≤ 85%	10	8 hours
KDPI >85%	5	3 hours

8.7.B Choice of Right versus Left Donor Kidney (3.5.7.2)

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 zero mismatched candidate, a candidate with a CPRA greater than or equal to 99% in classifications 1 through 10 in allocation sequences according to *Tables 8-5* through *8-8* above, 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.C National Kidney Offers (3.5.7.3)

With the exception of zero mismatched kidneys and kidneys shared nationally for 100% CPRA candidates, if a kidney is not placed in the donor hospital's DSA, then the host OPO must contact the Organ Center to assist with national placement.

The importing OPO must select any alternate candidates according to Policy *8.5: Kidney Allocation Classifications and Rankings* if the kidney cannot be transplanted into the original intended candidate.

8.7.D Kidney-Non-renal Organs Allocated and Not Transplanted (3.5.7.6)

If a combination kidney-non-renal organ is allocated but the transplant is not performed, the kidney allocated for that transplant must be immediately offered for zero antigen mismatched candidates.

History

Policy 3.5: Allocation of Deceased Kidneys: 9/17/2007; 12/18/2007; 6/20/2008; 6/22/2010; 11/9/2010; 6/29/2011; 11/15/2011; 6/26/2012; 11/13/2012

Policy 8: Allocation of Kidneys:

Notes

- For membership and personnel requirements for kidney programs, see the *OPTN Bylaws, Appendix E*.
- For information on reporting candidate's unacceptable antigens to the OPTN Contractor, see *Policy 5.3.A: Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA).*
- For requirements to have a candidate's waiting time reinstated for immediate and permanent non function of a transplanted kidney, see *Policy 3.6.B.i: Non-function of a Transplanted Kidney*.
- For allocation of multi-organs that include a kidney, see *Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets* .

Policy 9: Allocation of Livers and Liver-Intestines

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9.1 Status and Score Assignments (3.6, 3.6.4)

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 may be assigned any of the following:

- Adult status 1A
- Inactive status
- Calculated MELD score
- Exception MELD score
- Pediatric status 1A or 1B with pediatric classification, if the candidate is initially registered on the waiting list when less than 18 years old and remains on the waiting list, or registers again after turning 18 years old or older and meets the requirements for that status.

Liver candidates less than 18 years old may be assigned *any* of the following:

- Pediatric status 1A
- Pediatric status 1B
- Inactive status
- Calculated MELD or PELD score
- Exception MELD or PELD score

9.1.A Adult Status 1A Requirements (3.6, 3.6.4.1)

To assign a candidate adult status 1A, the candidate's transplant hospital must submit a *Liver Status 1A Justification Form* to the OPTN Contractor. A candidate is not registered as status 1A until this form is submitted.

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:

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a. Fulminant liver failure, without pre-existing liver disease and currently in the intensive care unit (ICU), defined as the onset of hepatic encephalopathy within 8-weeks of the first symptoms of liver disease, and has at least *one* of the following criteria:
   i. Is ventilator dependent
   ii. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
   iii. Has an international normalized ratio (INR) greater than 2.0

b. Primary non-function of a transplanted liver within 7-days of transplant, evidenced by at least *one* of the following:
   i. Anhepatic
   ii. Aspartate aminotransferase (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.

c. 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:
   i. Anhepatic
   ii. International normalized ratio (INR) greater than or equal to 2.5
   iii. Arterial pH less than or equal to 7.30
   iv. Venous pH less than or equal to 7.25
   v. Lactate greater than or equal to 4 mMol/L

d. Hepatic artery thrombosis (HAT) within 7-days of transplant, evidenced by *either* of the following:
   i. Anhepatic
   ii. Aspartate aminotransferase (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 any tests required above must be from the same blood draw taken 24 hours to 7 days after the transplant.

   Candidates with HAT in a transplanted liver within 14 days of transplant not meeting the above criteria will be listed with a MELD of 40.

e. Acute decompensated Wilson's disease

9.1.B Pediatric Status 1A Requirements (3.6.4.2)

To assign a candidate pediatric status 1A, the candidate's transplant hospital must submit a *Liver Status 1A Justification Form* to the OPTN Contractor. 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 initial registration. This includes candidates who are currently 18 years old and greater but remain on the waiting list, or have returned to the waiting list after initial registration.
2. The candidate has at least *one* of the following conditions:

    a. Fulminant liver failure without pre-existing liver disease, defined as the onset of hepatic encephalopathy within 8 weeks of the first symptoms of liver disease and has at least *one* of the following criteria:
        i. Is ventilator dependent
        ii. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
        iii. 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. Acidiosis, 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.

        Diagnosis of hepatic artery thrombosis (HAT) in a transplanted liver within 14 days of transplant.

    c. Acute decompensated Wilson's disease

9.1.C Pediatric Status 1B (3.6.4.2, 3.6.4.3)

To assign a candidate pediatric status 1B, the candidate's transplant hospital must submit a *Liver Status 1B Justification Form* to the OPTN Contractor. 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 initial registration. This includes candidates who are currently 18 years old and greater but remain on the waiting list or have returned to the waiting list after initial registration.
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 a MELD or PELD exception score of 30 points for at least 30 days.

c. Chronic liver disease with a MELD greater than 25 for adolescent candidates 12 to 17 years old or older or a PELD greater than 25 for candidates less than 12 years old 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: Combined 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 (3.6.4.1)

Candidates who are at least 12 years old receive a MELD score equal to:

$$0.957 \times \text{Log}_e(\text{creatinine mg/dL}) + 0.378 \times \text{Log}_e(\text{bilirubin mg/dL}) + 1.120 \times \text{Log}_e(\text{INR}) + 0.643$$

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.

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 week
- Candidates who received 24 hours of continuous veno-venous hemodialysis (CVVHD) within the prior week

9.1.E PELD Score (3.6.4.2)

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

$$0.436\,(\text{Age } (<1 \text{ YR.})) - 0.687 \times \text{Log}_e(\text{albumin g/dL}) + 0.480 \times \text{Log}_e(\text{total bilirubin mg/dL}) + 1.857 \times \text{Log}_e(\text{INR}) + 0.667\,(\text{Growth failure } (<- 2 \text{ Std. Deviations present}))$$

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 for any age less than one year 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 Combined Liver-Intestine Candidates (3.6.4.7)

Candidates awaiting a combined liver-intestine transplant who are registered and active on both waiting lists 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 a 23 point increase in their calculated MELD or PELD score instead of the 10 percentage point increase. The transplant hospital must verify that an intestinal transplant is required and took place.

9.2 Status and Laboratory Values Update Schedule (3.6.4.1, 3.6.4.1.1, 3.6.4.2, 3.6.4.2.1, 3.6.6)

The OPTN Contractor will notify the transplant hospital within 48 hours 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*. These data must be based on the most recent clinical information, laboratory tests, and diagnosis and include the dates of all laboratory tests.

When reporting laboratory values to the OPTN Contractor, 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 48-hour period.

Table 9-1: Liver Status Update Schedule

If the candidate is:	The new laboratory values must be reported every:	And the new laboratory values must be no older than:
Status 1A or 1B	7 days	48 hours
MELD 25 or greater (ages 18 or older)	7 days	48 hours
MELD/PELD 25 or greater (less than 18 years old)	14 days	72 hours
MELD/PELD 19 to 24	1 Month	7 days
MELD/PELD 11 to 18	3 months	14 days
MELD/PELD 10 or less	12 months	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 three months 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 Contractor 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 within the donation service area (DSA) 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* or a metabolic disease in *Policy 9.3.E: Pediatric Liver Candidates with Metabolic Diseases*.

9.2.B Reporting of Final Laboratory Value at Removal from Waiting List (3.6.6)

The transplant hospital must report final laboratory values reported for certification to the OPTN Contractor before removing the candidate from the waiting list as transplanted or deceased.

9.3 Score and Status Exceptions (3.6.4.1, 3.6.4.2)

If a candidate's transplant program believes that a candidate's MELD or PELD score does not appropriately reflect the candidate's medical urgency, the transplant physician may apply to the Regional Review Board (RRB) for a MELD or PELD score exception.

If a candidate's transplant program believes that a candidate's status does not appropriately reflect the candidate's medical urgency, the transplant physician may register a candidate at the exceptional status. However, the Liver and Intestinal Organ Transplantation Committee will retrospectively review candidates registered as status 1A or 1B according to the criteria in *Policy 9.3: Score and Status Exceptions*. The Liver and Intestinal Organ Transplantation Committee may refer these cases to the Membership and Professional Standards Committee (MPSC) for review according to *Appendix L* of the OPTN Bylaws.

9.3.A Pediatric Status Exception for Candidates 18 Years or Older

Liver candidates with a MELD score initially registered on the waiting list when less than 18 years old who remain on the waiting list or are registered again after turning 18 years old may be assigned the appropriate pediatric classification by exception. The transplant hospital must apply for the exception and include justification to the applicable RRB that the candidate is considered, by consensus medical judgment and using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates having pediatric classification.

9.3.B MELD/PELD Exception Applications (3.6.4.1, 3.6.4.2)

An exception application must:

1. Include a request for a specific MELD or PELD score.
2. Justify why accepted medical criteria supports that the candidate has a higher MELD or PELD score and explain how the patient's current condition and potential for benefit would be comparable to that of other candidates with that MELD or PELD score.

9.3.C Review of Exceptions by the RRB and Committees (3.6.4.2, 3.6.4.5)

Each RRB must review applications within 21 days of the date the application is submitted to the OPTN Contractor. If the RRB does not approve the application within 21 days, then the candidate's transplant physician may *either*:

- Appeal the decision.
- Register the candidate at the requested MELD or PELD score following a conference call with the RRB. However, these cases will be automatically referred to the Liver and Intestinal Organ Transplantation Committee. The Liver and Intestinal Organ Transplantation Committee may refer these cases to the MPSC for appropriate action according to *Appendix L* of the OPTN Bylaws.

The RRB will report its decisions and justifications to the Liver and Intestinal Organ Transplantation Committee and the MPSC. The Committees determine whether the MELD or PELD score exceptions are consistently evaluated and applied within OPTN regions and across the country. Additionally, the Committees evaluate whether existing MELD or PELD score criteria continue to be appropriate.

9.3.D Specific MELD/PELD Exceptions (3.6.4.5, 3.6.4.5.1, 3.6.4.5.2, 3.6.4.5.3, 3.6.4.5.4, 3.6.4.5.5, 3.6.5.6)

Candidates meeting the criteria in *Table 9-2*: Specific Standardized MELD/PELD Exceptions are eligible for MELD or PELD score exceptions that do not require evaluation by the full RRB. The transplant program must submit a request for a specific MELD or PELD score exception with a written narrative that supports the requested score. Additionally, a candidate may receive a higher MELD or PELD score if the RRB has an existing agreement for the diagnosis. These agreements must be renewed on an annual basis.

Table 9-2: Specific Standardized MELD/PELD Exceptions

If the candidate has:	And submits to the OPTN Contractor evidence that includes:	Then the candidate:
Cholangiocarcinoma	*The information required according to Policy 9.3.F: Candidates with Cholangiocarcinoma.*	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.

If the candidate has:	And submits to the OPTN Contractor evidence that includes:	Then the candidate:
Cystic Fibrosis	The candidate has signs of reduced pulmonary function with forced expiratory volume at one second (FEV_1) that falls below 40 percent.	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.
Familial Amyloid Polyneuropathy (FAP)	*All* of the following: Clear diagnosis of FAP. Echocardiogram showing the candidate has an ejection fraction greater than 40 percent. Ambulatory status. Identification of transthyretin (TTR gene) mutation (Val30Met vs. non-Val30Met). Biopsy- proven amyloid in the involved organ.	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.
Hepatic Artery Thrombosis (HAT)	Candidate has HAT within 14 days of transplant but does not meet criteria for status 1A in Policy *9.1.A: Adult Status 1A Requirements*.	Will receive a MELD score of 40.
Hepatocellular Carcinoma (HCC)	*The information required according to Policy 9.3.G: Candidates with Hepatocellular Carcinoma (HCC)*.	*See Policy 9.3.G: Candidates with Hepatocellular Carcinoma (HCC)*.
Hepatopulmonary Syndrome (HPS)	*All* of the following: Clinical evidence of portal hypertension. Evidence of a shunt. PaO_2 less than 60 mmHg on room air. No significant clinical evidence of underlying primary pulmonary disease.	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months that the candidate's PaO_2 remains under 60 mmHg.
Metabolic Disease	The information required according to *Policy 9.3.E: Pediatric Liver Candidates with Metabolic Diseases.*	See *Policy 9.3.E: Pediatric Liver Candidates with Metabolic Diseases.*

If the candidate has:	And submits to the OPTN Contractor evidence that includes:	Then the candidate:
Portopulmonary Syndrome	The candidate has a mean pulmonary arterial pressure (MPAP) below 35 mmHg following intervention. The diagnosis should also include *all* of the following: Initial mean pulmonary arterial pressure (MPAP) level. Initial pulmonary vascular resistance (PVR) level. Initial transpulmonary gradient to correct for volume overload. Documentation of treatment. Post-treatment MPAP less than 35 mmHg. Post treatment PVR less than 400 dynes/sec/cm^{-5}..	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months if a repeat heart catheterization confirms that the mean pulmonary arterial pressure (MPAP) remains below 35 mmHg.
Primary Hyperoxaluria	The candidate has *all* of the following: Is registered for a combined liver-kidney transplant. Alanine glyoxylate aminotransferase (AGT) deficiency proven by liver biopsy using sample analysis or genetic analysis. Glomerular filtration rate (GFR) less than or equal to 25 mL/min, by six variable Modification of Diet in Renal Disease formula (MDRD6) or direct measurement of iothalamate or iohexol, for six weeks or more.	Will receive a MELD score of 28 or PELD score of 41; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.

9.3.E Pediatric Liver Candidates with Metabolic Diseases (3.6.4.3)

A pediatric liver transplant candidate with a urea cycle disorder or organic acidemia will receive a MELD/PELD score of 30. If the candidate does not receive a transplant within 30 days of being registered with a MELD/PELD of 30, then the candidate's transplant physician may register the candidate as a status 1B.

If a candidate has a different metabolic disease and the candidate's transplant program believes that a candidate's MELD/PELD score does not appropriately reflect the candidate's medical urgency, then the transplant physician may request an exception according to *Policy 9.3: Score and Status Exceptions*. However, the RRB will review these applications based on standards jointly developed by the Liver and Intestinal Organ Transplantation Committee and the Pediatric Transplantation Committee.

9.3.F Candidates with Cholangiocarcinoma (3.6.4.5.2)

A candidate will receive the MELD/PELD exception in *Table 9-2: Specific MELD/PELD Exceptions* for cholangiocarcinoma, if the candidate's transplant hospital meets *all* the following qualifications:

1. Submit a written protocol for patient care to the Liver and Intestinal Organ Transplantation Committee that should include *all* of the following:
   a. Candidate selection criteria
   b. Administration of neoadjuvant therapy before transplantation
   c. Operative staging to exclude any patient with regional hepatic lymph node metastases, intrahepatic metastases, or extrahepatic disease
   d. Any data requested by the Liver and Intestinal Organ Transplantation Committee

2. Document that the candidate meets the diagnostic criteria for hilar CCA with a malignant appearing stricture on cholangiography and *one* of the following:
   a. Biopsy or cytology results demonstrating malignancy
   b. Carbohydrate antigen 19-9 greater than 100 U/mL in absence of cholangitis
   c. Aneuploidy

   The tumor should be considered un-resectable because of technical considerations or underlying liver disease.

3. If cross-sectional imaging studies demonstrate a mass, the mass should be less than three cm.
4. Intrahepatic and extrahepatic metastases should be excluded by cross-sectional imaging studies of the chest and abdomen at the time of the initial application for the MELD/PELD exception and every three months before the MELD/PELD score increases.
5. Regional hepatic lymph node involvement and peritoneal metastases should be assessed 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) should be avoided because of the high risk of tumor seeding associated with these procedures.

9.3.G Candidates with Hepatocellular Carcinoma (HCC) (3.6.4.4)

Upon submission of the required information to the OPTN Contractor, candidates with Hepatocellular Carcinoma (HCC) that have stage T2 lesions and meet the criteria according to Policies 9.3.G.i through vi below will receive an initial MELD or PELD score equivalent to a 15 percent risk of 3-month mortality.

9.3.G.i Eligible Candidates Definition of T2 Lesions

Stage T2 lesions include *any* 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 greater than or equal to 1 cm and less than or equal to 3 cm in size

9.3.G.ii Initial Assessment for Registration

Prior to applying for an exception, the candidate must undergo a thorough assessment that includes *all* of the following:

1. An evaluation of the number and size of tumors using a dynamic contrast enhanced computed tomography (CT) or magnetic resonance imaging (MRI)
2. A CT, ultrasound, or MRI to rule out any extrahepatic spread or macrovascular involvement
3. A CT of the chest to rules out metastatic disease
4. An indication that the candidate is not eligible for resection
5. The candidate's alpha-fetoprotein level

9.3.G.iii Recommended Minimum Specifications 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 application should meet the criteria in *Table 9-3* and *Table 9-4* and 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/PELD exception.

Table 9-3: Recommendations for Dynamic Contrast-enhanced CT of the Liver

Feature:	CT scans should meet the below specifications:
Scanner type	Multidetector row scanner
Detector type	Minimum of 8 detector rows and must be able to image the entire liver during brief late arterial phase time window
Slice thickness	Minimum of 5 mm reconstructed slice thickness
Injector	Power injector, preferably dual chamber injector with saline flush and bolus tracking recommended
Contrast injection rate	3 mL/sec minimum, better 4-6 mL/sec with minimum of 300 mg I/mL or higher, for dose of 1.5 mL/kg body weight
Mandatory dynamic phases on contrast-enhanced CT or MRI	.Late arterial phase: artery fully enhanced, beginning contrast enhancement of portal vein .Portal venous phase: portal vein enhanced, peak liver parenchymal enhancement, beginning contrast enhancement of hepatic veins .Delayed phase: variable appearance, greater than 120 seconds after initial injection of contrast
Dynamic phases (Timing)	Use the bolus tracking or timing bolus

Table 9-4: Recommendations for Dynamic Contrast-enhanced MRI of the Liver

Feature	MRIs should meet the below specifications:
Scanner type	1.5T Tesla or greater main magnetic field strength. Low field magnets are not suitable.
Coil type	Phased array multichannel torso coil, unless patient-related factors precludes its use.
Minimum sequences	Pre-contrast and dynamic post gadolinium T1-weighted gradient echo sequence (3D preferable), T2 (with and without fat saturation), T1-weighted in and out of phase imaging.
Injector	Dual chamber power injector with bolus tracking recommended.

Feature	MRIs should meet the below specifications:
Contrast injection rate	2-3 mL/sec of extracellular gadolinium chelate that does not have dominant biliary excretion, preferably resulting in vendor-recommended total dose.
Mandatory dynamic phases on contrast-enhanced CT or MRI	Pre-contrast T1W: do not change scan parameters for post contrast imaging. Late arterial phase: artery fully enhanced, beginning contrast enhancement of portal vein. Portal venous phase: portal vein enhanced, peak liver parenchymal enhancement, beginning contrast enhancement of hepatic veins. Delayed phase: variable appearance, greater than 120 seconds after initial injection of contrast.
Dynamic phases (Timing)	The use of the bolus tracking method for timing contrast arrival for late arterial phase imaging is preferable. Portal vein phase images should be acquired 35 to 55 seconds after initiation of late arterial phase. Delayed phase images should be acquired 120 to 180 seconds after the initial contrast injection.
Slice thickness	5 mm or less for dynamic series, 8 mm or less for other imaging.
Breath-holding	Maximum length of series requiring breath-holding should be about 20-seconds with a minimum matrix of 128 x 256. Technologists must understand the importance of patient instruction about breathholding before and during scan.

9.3.G.iv Imaging Requirements for Class 5 Lesions

Nodules found on images of cirrhotic livers are classified according to *Table 9-5*. Use the largest dimension of each tumor to report the size of Hepatocellular Carcinoma (HCC) lesions. Nodules less than 1 cm are indeterminate and cannot be considered for additional priority.

Table 9-5: Classification System for Nodules Seen on Imaging of Cirrhotic Livers

Class	Description
0	Incomplete or technically inadequate study
5A	Must meet *all* of the following: Single nodule greater than or equal to1 cm and less than 2 cm. The maximum diameter of lesions should be measured on late arterial or portal phase images. Increased contrast enhancement on late arterial phase (relative to hepatic parenchyma). Washout during the later contrast phases and peripheral rim enhancement (capsule/pseudocapsule) on delayed phase *or* a biopsy. (A pre-listing biopsy is not mandatory.)
5A-g (growth)	Must meet *all* of the following: Single nodule greater than or equal to 1 cm and less than 2 cm. The maximum diameter of lesions should be measured on late arterial or portal phase images. Increased contrast enhancement on late arterial phase (relative to hepatic parenchyma). Growth (maximum diameter increase) by 50 % or more documented on serial MRI or CT obtained less than or equal to 6 months apart.

Class	Description
	Growth criteria do not apply to ablated lesions.
5B	Must meet *all* of the following: 1. Single nodule diameter greater than or equal to 2 cm. and less than or equal to 5 cm. The maximum diameter of lesions should be measured on late arterial or portal phase images. 2. Increased contrast enhancement on late hepatic arterial images (relative to hepatic parenchyma). 3. *One* of the following: Washout on portal venous/delayed phase. Late capsule or pseudocapsule enhancement. Growth (maximum diameter increase in the absence of ablative therapy) by 50% or more documented on serial MRI or CT obtained ≤ 6 month apart. Serial imaging and measurements should be performed on corresponding contrast phases with the same modality preferred. Growth criteria do not apply to previously ablated lesions. Biopsy. (A pre-listing biopsy is not mandatory.)
5T (Treated)	Any OPTN Class 5 or biopsy-proven HCC lesion that was automatically approved upon initial application or extension and has subsequently undergone loco-regional treatment. OPTN Class 5T nodules qualify for continued priority points based on the pre-treatment classification of the nodules and are defined as: Past loco-regional treatment for HCC (OPTN Class 5 lesion or biopsy proven prior to ablation). Evidence of persistent/recurrent HCC such as, but not limited to, nodular or crescentic extra-zonal or intra-zonal enhancing tissue on late arterial imaging (relative to hepatic parenchyma) may be present.
5X	Lesions that meet radiologic criteria for HCC but are outside stage T2 as defined above will be considered Class 5X and are not eligible for automatic exception points.

9.3.G.v HCC Lesions Eligible for Automatic Upgrade

Individual Class 5B and 5T are eligible for automatic priority. A single OPTN Class 5A nodule corresponds to T1 stage hepatocellular carcinoma and does not qualify for automatic priority MELD points but must be considered towards the overall staging of the patient according to criteria listed above. Combinations of Class 5A nodules that meet stage T2 criteria as described above are eligible for automatic priority.

9.3.G.vi Extensions of HCC Exceptions

A candidate will receive additional MELD or PELD points equivalent to a 10 percentage point increase in the candidate's mortality risk every three months after receiving an HCC exception until the candidate receives a transplant or is unsuitable for transplantation based on the candidate's HCC progression.

To receive the extension, the transplant program must submit an updated MELD exception application every three months that contains all of the following:

1. Submit an Hepatocellular Carcinoma (HCC) MELD/PELD score exception application with an updated narrative
2. Document the tumor using a CT, ultrasound, scan, or MRI

3. Specify the type of treatment if the number of tumors decreased since the last application.

Invasive studies such as biopsies or ablative procedures and repeated chest CT scans are not required after the initial application is approved. If a candidate's tumors have been resected since the previous application, then the transplant program must submit the extension application to its RRB for prospective review.

Candidates with Class 5T lesions will receive a MELD or PELD equivalent to a 10 percentage point increase in the candidate's mortality risk every three months, without RRB review, even if the estimated size of residual viable tumors falls below stage T2 criteria due to ablative therapy.

9.3.G.vii Candidates Not Meeting Criteria (Class 5X)

A candidate not meeting the above criteria may continue to be considered a liver transplant candidate according to each transplant hospital's own specific policy, but the candidate must be registered at the calculated MELD or PELD score with no additional priority given because of the HCC diagnosis. All such candidates with HCC, including those with downsized tumors whose original or presenting tumor was greater than a stage T2, must be referred to the applicable RRB for prospective review in order to receive additional priority.

9.3.G.viii Appeal for Candidates not Meeting Criteria

If the RRB denies the initial HCC exception application, the transplant program may appeal with the RRB but the candidate will not receive the additional MELD or PELD priority until approved by the RRB. The RRB will may refer the matter to the Liver and Intestinal Organ Transplantation Committee for further review and possible action if the RRB finds the transplant program to be noncompliant with these Policies.

Applications and appeals not resolved by the RRB within 21 days will be referred to the Liver and Intestinal Organ Transplantation Committee for review. The Liver and Intestinal Organ Transplantation Committee may refer these matters to the MPSC for appropriate action according to *Appendix L* of the OPTN Bylaws.

9.3.G.ix Compliance Monitoring

The transplant hospital must maintain documentation of the radiologic characteristics of each OPTN Class 5 nodule. If growth criteria are used to classify a nodule as HCC, the radiology report must contain the prior and current dates of imaging, type of imaging and measurements of the nodule.

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 Explants Pathology Form* to the OPTN Contractor 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.

9.3.H MELD/PELD Score Exception Extensions (3.6.4.5)

Transplant hospitals may apply for a MELD or PELD score exception extension to receive the equivalent of a 10 percentage point increase in candidate mortality every 3 months as long as the candidate continues to meet the exception criteria. Extensions must be prospectively reviewed by the RRB.

A candidate's approved exception score will be maintained if the transplant hospital enters the extension application more than 3 days before the due date according to *Table 9-1: Liver Status and Score Update Schedule,* even if the RRB does not act before the due date.. If the extension application is later denied then the candidate will be assigned the calculated MELD or PELD score based on the most recent reported laboratory values.

9.4 Waiting Time (3.6.3)

9.4.A Waiting Time for Liver Candidates (3.6.3)

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 9.5.A: Points for Waiting Time*.

9.4.B Waiting Time for Liver-Intestine Candidates (3.11.4.1)

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.

9.5 Points

Points are used for sorting liver candidates according to *Policy 9.6.D: Sorting Within Each Classification*.

9.5.A Points for Waiting Time (3.6.3)

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

9.5.B Points Assigned by Blood Type (3.6.2)

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 non-A_1 blood type donor will receive 5 points for blood type incompatible matching. Within each MELD or PELD score, donor livers will be offered to transplant candidates with blood types identical to the deceased donor first, then to candidates who are blood type compatible, followed by candidates who are blood type incompatible with the deceased donor.

9.6 Liver Allocation, Classifications, and Rankings (3.6, 3.6.2, 3.6.3)

Livers from pediatric deceased donors are first allocated to pediatric potential transplant recipients with respect to geographical proximity to donor and medical urgency, according to *Tables 9-7* and *9-8.*

9.6.A Segmental Transplant and Allocation of Liver Segments (3.6, 3.6.11)

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 and how the vessels are used.

9.6.B Allocation of Livers for Other Methods of Hepatic Support (3.6.10)

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 Contractor, the OPTN Contractor will offer the liver for other methods of hepatic support to status 1A and 1B candidates, followed by all candidates in order of their MELD or PELD scores. Livers allocated for other methods of hepatic support will be offered first locally, then regionally, and then nationally in descending point order.

9.6.C Allocation of Livers by Blood Type (3.6.2.1, 3.6.2.2)

Livers from blood type O deceased donors may be offered to *any* of the following:

- Status 1A and 1B candidates.
- Blood type O candidates.

- Blood type B candidates with a MELD or PELD score greater than or equal to 30.
- Any remaining blood type compatible candidates once the blood type O and B candidates on the match run have been exhausted at the regional and national level.

For status 1A or 1B candidates or candidates with a MELD or PELD score of 30 and greater, 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 9.5.B: Points Assigned by Blood Type*.

9.6.D Sorting Within Each Classification

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

1. Total points, highest to lowest (waiting time points, plus blood type compatibility 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 points (highest to lowest)
2. Total waiting time at status 1B (highest to lowest)

Within each allocation MELD or PELD score classification, candidates with a score less than or equal to six are sorted in the following order:

1. Identical blood types, compatible blood types, then incompatible blood types
2. Total waiting time (highest to lowest)
3. Then those waiting list positions assigned to candidates with a MELD or PELD score less than or equal to six are redistributed between the pediatric candidates, according to their PELD or MELD score (highest to lowest).

Within each allocation classification, all other candidates are sorted in the following order:

1. MELD/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. Total waiting time (highest to lowest).

9.6.E Allocation of Livers from Deceased Donors at Least 18 Years Old

Livers from deceased donors at least 18 years old are allocated to candidates according to *Table 9-6* below.

Table 9-6: Allocation of Livers from Deceased Donors at Least 18 Years Old

Classification	Candidates that are within the:	And are:
1	OPO's region	Adult or pediatric status 1A
2	OPO's region	Pediatric status 1B
3	OPO's DSA	MELD/PELD of 40
4	OPO's region	MELD/PELD of 40
5	OPO's DSA	MELD/PELD of 39

Classification	Candidates that are within the:	And are:
6	OPO's region	MELD/PELD of 39
7	OPO's DSA	MELD/PELD of 38
8	OPO's region	MELD/PELD of 38
9	OPO's DSA	MELD/PELD of 37
10	OPO's region	MELD/PELD of 37
11	OPO's DSA	MELD/PELD of 36
12	OPO's region	MELD/PELD of 36
13	OPO's DSA	MELD/PELD of 35
14	OPO's region	MELD/PELD of 35
15	OPO's DSA	MELD/PELD of at least 15
16	OPO's region	MELD/PELD of at least 15
17	Nation	Adult or Pediatric status 1A
18	Nation	Pediatric status 1B
19	Nation	MELD/PELD of at least 15
20	OPO's DSA	MELD/PELD less than 15
21	OPO's region	MELD/PELD less than 15
22	Nation	MELD/PELD less than 15
23	OPO's DSA	MELD/PELD at least 40 and compatible blood type
24	OPO's region	MELD/PELD at least 40 and compatible blood type
25	OPO's DSA	MELD/PELD of 39 and compatible blood type
26	OPO's region	MELD/PELD of 39 and compatible blood type
27	OPO's DSA	MELD/PELD of 38 and compatible blood type
28	OPO's region	MELD/PELD of 38 and compatible blood type
29	OPO's DSA	MELD/PELD of 37 and compatible blood type
30	OPO's region	MELD/PELD of 37 and compatible blood type
31	OPO's DSA	MELD/PELD of 36 and compatible blood type
32	OPO's region	MELD/PELD of 36 and compatible blood type
33	OPO's DSA	MELD/PELD of 35 and compatible blood type
34	OPO's region	MELD/PELD of 35 and compatible blood type
35	OPO's DSA	MELD/PELD of at least 15 and compatible blood type
36	OPO's region	MELD/PELD of at least 15 and compatible blood type
37	Nation	MELD/PELD of at least 15 and compatible blood type
38	OPO's DSA	MELD/PELD less than 15 and compatible blood type
39	OPO's region	MELD/PELD less than 15 and compatible blood type
40	Nation	MELD/PELD less than 15 and compatible blood

Classification	Candidates that are within the:	And are:
		type
41	OPO's DSA	Adult or pediatric status 1A and in need of other method of hepatic support
42	OPO's DSA	Pediatric status 1B and in need of other method of hepatic support
43	OPO's DSA	Any MELD/PELD and in need of other method of hepatic support
44	OPO's region	Adult or pediatric status 1A and in need of other method of hepatic support
45	OPO's region	Pediatric status 1B and in need of other method of hepatic support
46	OPO's region	Any MELD/PELD and in need of other method of hepatic support
47	Nation	Adult or pediatric status 1A and in need of other method of hepatic support
48	Nation	Pediatric status 1B and in need of other method of hepatic support
49	Nation	Any MELD/PELD and in need of other method of hepatic support
50	OPO's DSA	Any MELD/PELD in need of other method of hepatic support, and a blood type compatible with the donor
51	OPO's region	Any MELD/PELD in need of other method of hepatic support, and blood type compatible with the donor
52	Nation	Any MELD/PELD in need of other method of hepatic support, and blood type compatible with the donor

9.6.F Allocation of Livers from Deceased Donors 11 to 17 Years Old

Livers from deceased donors 11 to 17 years old are allocated to candidates according to *Table 9-7* below.

Table 9-7: Allocation of Livers from Deceased Donors 11 to 17 Years Old

Classification	Candidates that are within the:	And are:
1	OPO's DSA	Pediatric status 1A
2	OPO's region	Pediatric status 1A
3	OPO's DSA	Adult status 1A
4	OPO's region	Adult status 1A
5	OPO's DSA	Pediatric status 1B
6	OPO's region	Pediatric status 1B
7	OPO's DSA or region	Any PELD
8	OPO's DSA	MELD of at least 15 and 12 to 17 years old
9	OPO's DSA	MELD of at least 15 and at least 18 years old

Classification	Candidates that are within the:	And are:
10	OPO's region	MELD of at least 15 and 12 to 17 years old
11	OPO's region	MELD of at least 15 and at least 18 years old
12	OPO's DSA	MELD less than 15 and 12 to 17 years old
13	OPO's DSA	MELD less than 15 and least 18 years old
14	OPO's region	MELD less than 15 and 12 to 17 years old
15	OPO's region	MELD less than 15 and at least 18 years old
16	Nation	Pediatric status 1A
17	Nation	Adult status 1A
18	Nation	Pediatric status 1B
19	Nation	Any PELD
20	Nation	Any MELD and 12 to 17 years old
21	Nation	Any MELD and at least 18 years old
22	OPO's region	Any PELD, and compatible blood type
23	OPO's DSA	MELD at least 15, 12 to 17 years old, and Compatible blood type
24	OPO's DSA	MELD at least 15, at least 18 years old, and compatible blood type
25	OPO's region	MELD at least 15, 12 to 17 years old, and compatible blood type
26	OPO's region	MELD at least 15, at least 18 years old, and compatible blood type
27	OPO's DSA	MELD less than 15, 12 to 17 years old, and compatible blood type
28	OPO's DSA	MELD less than 15, at least 18 years old, and compatible blood type
29	OPO's region	MELD less than 15, 12 to 17 years old, and compatible blood type
30	OPO's region	MELD less than 15, at least 18 years old, and compatible blood type
31	Nation	0 to 11 years old and compatible blood type
32	Nation	12 to 17 years old and compatible blood type
33	Nation	Any MELD, at least 18 years old, and compatible blood type
34	OPO's DSA	Adult or pediatric status 1A and in need of other method of hepatic support
35	OPO's DSA	Pediatric status 1B and in need of other method of hepatic support
36	OPO's DSA	Any MELD/PELD and in need of other method of hepatic support
37	OPO's region	Adult or pediatric status 1A and in need of other method of hepatic support
38	OPO's region	Pediatric status 1B and in need of other method of

Classification	Candidates that are within the:	And are:
		hepatic support
39	OPO's region	Any MELD/PELD and in need of other method of hepatic support
40	Nation	Adult or pediatric status 1A and in need of other method of hepatic support
41	Nation	Pediatric status 1B and in need of other method of hepatic support
42	Nation	Any MELD/PELD and in need of other method of hepatic support
43	OPO's DSA	Any MELD/PELD in need of other method of hepatic support, and compatible blood type
44	OPO's region	Any MELD/PELD in need of other method of hepatic support, and compatible blood type
45	Nation	Any MELD/PELD in need of other method of hepatic support, and compatible blood type

9.6.G Allocation of Livers from Deceased Donors Less than 11 Years Old

Livers from donors less than 11 years old are allocated to candidates according to *Table 9-8* below.

Table 9-8: Allocation of Livers from Deceased Donors less than 11 Years Old

Classification	Candidates that are within the…	And are…
1	OPO's region	Pediatric status 1A
2	Nation	Pediatric status 1A (0-11)
3	OPO's DSA	Adult status 1A
4	Region	Adult status 1A
5	Region	Pediatric status 1B
6	Region	Any PELD
7	OPO's DSA	MELD of at least 15 and 12 to 17 years old
8	OPO's DSA	MELD of at least 15 and at least 18 years old
9	Region	MELD of at least 15 and at least 12 to 17 years old
10	Region	MELD of at least 15 and at least 18 years old
11	OPO's DSA	MELD less than 15 and 12 to 17 years old
12	OPO's DSA	MELD less than 15 and at least 18 years old
13	Region	MELD less than 15 and 12 to 17 years old
14	Region	MELD less than 15 and at least 18 years old
15	Nation	Status 1A and 12 to 17 years old
16	Nation	Status 1A and at least 18 years old
17	Nation	Status 1B and 0 to 17 years old

Classification	Candidates that are within the…	And are…
18	Nation	Any PELD
19	Nation	Any MELD and 12 to 17 years old
20	Nation	Any MELD and at least 18 years old
21	Region	Any PELD and compatible blood type
22	OPO's DSA	MELD of at least 15, 12 to 17 years old, and compatible blood type
23	OPO's DSA	MELD of at least 15, at least 18 years old, and compatible blood type
24	Region	MELD of at least 15, 12 to 17 years old, and compatible blood type
25	Region	MELD of at least 15, at least 18 years old, and compatible blood type
26	OPO's DSA	MELD less than 15, 12 to 17 years old, and compatible blood type
27	OPO's DSA	MELD less than 15, at least 18 years old, and compatible blood type
28	Region	MELD less than 15, 12 to 17 years old, and compatible blood type
29	Region	MELD less than 15, at least 18 years old, and compatible blood type
30	Nation	Any PELD and compatible blood type
31	Nation	Any MELD, 12 to 17 years old, and compatible blood type
32	Nation	Any MELD, at least 18 years old, and compatible blood type
33	OPO's DSA	Adult or pediatric status 1A and in need of other method of hepatic support
34	OPO's DSA	Pediatric status 1B and in need of other method of hepatic support
35	OPO's DSA	Any MELD/PELD and in need of other method of hepatic support
36	OPO's region	Adult or pediatric status 1A and in need of other method of hepatic support
37	OPO's region	Pediatric status 1B and in need of other method of hepatic support
38	OPO's region	Any MELD/PELD, any age, and in need of other method of hepatic support
39	Nation	Adult or pediatric status 1A and in need of other method of hepatic support
40	Nation	Pediatric status 1B and in need of other method of hepatic support
41	Nation	Any MELD/PELD, any age, and in need of other method of hepatic support
42	OPO's DSA	Any MELD/PELD, any age, in need of other method

Classification	Candidates that are within the…	And are…
		of hepatic support, and compatible blood type
43	OPO's region	Any MELD/PELD, any age, in need of other method of hepatic support, and compatible blood type
44	Nation	Any MELD/PELD, any age, in need of other method of hepatic support, and compatible blood type

9.6.H Allocation of Liver-Intestines (3.6.4, 3.6.4.7, 3.6.4.8, 3.11.4, 3.11.4.2)

Adult candidates awaiting a combined liver-intestine transplant who are registered and active on both waiting lists will automatically receive an additional increase in their MELD/PELD score equivalent to a 10% risk of 3-month mortality. Candidates less than 18 years old will receive a 23-point increase in their calculated MELD/PELD score instead of the 10% increase. The transplant hospital must verify that an intestinal transplant is required and took place.

9.6.I Allocation of Liver-Intestines from Deceased Donors at Least 18 Years Old

Livers and intestines from deceased donors at least 18 years old are allocated to candidates according to *Table 9-9* below:

Table 9-9: Allocation of Liver-Intestines from Deceased Donors at Least 18 Years Old

Classification	Candidates that are within the:	And are:
1	OPO's region	Liver or liver-intestine, adult or pediatric status 1A
2	OPO's region	Liver or liver-intestine, pediatric status 1B
3	OPO's DSA	Liver or liver-intestine, MELD/PELD of 40
4	OPO's region	Liver or liver-intestine, MELD/PELD of 40
5	OPO's DSA	Liver or liver-intestine, MELD/PELD of 39
6	OPO's region	Liver or liver-intestine, MELD/PELD of 39
7	OPO's DSA	Liver or liver-intestine, MELD/PELD of 38
8	OPO's region	Liver or liver-intestine, MELD/PELD of 38
9	OPO's DSA	Liver or liver-intestine, MELD/PELD of 37
10	OPO's region	Liver or liver-intestine, MELD/PELD of 37
11	OPO's DSA	Liver or liver-intestine,
12	OPO's region	Liver or liver-intestine, MELD/PELD of 36
13	OPO's DSA	Liver or liver-intestine, MELD/PELD of 35
14	OPO's region	Liver or liver-intestine, MELD/PELD of 35
15	OPO's DSA	Liver or liver-intestine, MELD/PELD of at least 29
16	Nation	Liver or liver-intestine, LI/IN status 1A
17	Nation	Liver or liver-intestine, LI/IN status 1B
18	Nation	Liver or liver-intestine, LI/IN MELD/PELD (highest to lowest)
19	OPO's DSA	Liver or liver-intestine, MELD/PELD of at least 15
20	OPO's region	Liver or liver-intestine, MELD/PELD less than 15

Classification	Candidates that are within the:	And are:
21	Nation	Liver or liver-intestine, adult or pediatric status 1A
22	Nation	Liver or liver-intestine, pediatric status 1B
23	Nation	Liver or liver-intestine, MELD/PELD of at least 15
24	OPO's DSA	Liver or liver-intestine, MELD/PELD less than 15
25	OPO's region	Liver or liver-intestine, MELD/PELD less than 15
26	Nation	Liver or liver-intestine, MELD/PELD less than 15
27	OPO's DSA	Liver or liver-intestine, MELD/PELD at least 40 and compatible blood type
28	OPO's region	Liver or liver-intestine, MELD/PELD at least 40 and compatible blood type
29	OPO's DSA	Liver or liver-intestine, MELD/PELD of 39 and compatible blood type
30	OPO's region	Liver or liver-intestine, MELD/PELD of 39 and compatible blood type
31	OPO's DSA	Liver or liver-intestine, MELD/PELD of 38 and compatible blood type
32	OPO's region	Liver or liver-intestine, MELD/PELD of 38 and compatible blood type
33	OPO's DSA	Liver or liver-intestine, MELD/PELD of 37 and compatible blood type
34	OPO's region	Liver or liver-intestine, MELD/PELD of 37 and compatible blood type
35	OPO's DSA	Liver or liver-intestine, MELD/PELD of 36 and compatible blood type
36	OPO's region	Liver or liver-intestine, MELD/PELD of 36 and compatible blood type
37	OPO's DSA	Liver or liver-intestine, MELD/PELD of 35 and compatible blood type
38	OPO's region	Liver or liver-intestine, MELD/PELD of 35 and compatible blood type
39	OPO's DSA	Liver or liver-intestine, MELD/PELD of at least 15 and compatible blood type
40	OPO's region	Liver or liver-intestine, MELD/PELD of at least 15 and compatible blood type
41	Nation	Liver or liver-intestine, MELD/PELD of at least 15 and compatible blood type
42	OPO's DSA	Liver or liver-intestine, MELD/PELD less than 15 and compatible blood type
43	OPO's region	Liver or liver-intestine, MELD/PELD less than 15 and compatible blood type
44	Nation	Liver or liver-intestine, MELD/PELD less than 15 and compatible blood type
45	OPO's DSA	Liver or liver-intestine, adult or pediatric status 1A

		and in need of other method of hepatic support
46	OPO's DSA	Liver or liver-intestine, pediatric status 1B and in need of other method of hepatic support
47	OPO's DSA	Liver or liver-intestine, any MELD/PELD and in need of other method of hepatic support
48	OPO's region	Liver or liver-intestine, adult or pediatric status 1A and in need of other method of hepatic support
49	OPO's region	Liver or liver-intestine, pediatric status 1B and in need of other method of hepatic support
50	OPO's region	Liver or liver-intestine, any MELD/PELD and in need of other method of hepatic support
51	Nation	Liver or liver-intestine, adult or pediatric status 1A and in need of other method of hepatic support
52	Nation	Liver or liver-intestine, pediatric status 1B and in need of other method of hepatic support
53	Nation	Liver or liver-intestine, any MELD/PELD and in need of other method of hepatic support
54	OPO's DSA	Liver or liver-intestine, any MELD/PELD in need of other method of hepatic support, and a blood type compatible with the donor
55	OPO's region	Liver or liver-intestine, any MELD/PELD in need of other method of hepatic support, and blood type compatible with the donor
56	Nation	Liver or liver-intestine, any MELD/PELD in need of other method of hepatic support, and blood type compatible with the donor

9.6.J Allocation of Liver-Intestines from Donors less than 11 Years Old

(3.11.4.2)

Livers and intestines from donors less than 11 years old are allocated to candidates according to *Table 9-10* below.

Table 9-10: Allocation of Combined Liver-Intestines from Donors less than 11Years Old

Classification	Candidates that are within the:	And are:
The following classifications appear for all blood types		
1	OPO's region	Liver or liver-intestine, Pediatric Status 1A
2	Nation	Liver or liver-intestine, Pediatric Status 1A, and 0 to less than 12 years of age
3	Nation	Liver-intestine, Pediatric Status 1A, and 12 to less than 18 years of age
4	OPO's DSA	Liver or liver-intestine, Adult Status 1A
5	OPO's region	Liver or liver-intestine, Adult Status 1A
6	Donor hospital's	Liver or liver-intestine, Pediatric Status 1B

Classification	Candidates that are within the:	And are:
	region	
7	OPO's region	Liver or liver-intestine, PELD greater than 20, and 0 to less than 12 years of age
8	Nation	Liver-intestine, Pediatric Status 1B
9	Nation	Liver-intestine, PELD greater than 20
10	OPO's region	Liver or liver-intestine, PELD of less than 21
11	OPO's DSA	Liver or liver-intestine, MELD of at least 15, and 12 to less than 18 years of age
12	OPO's DSA	Liver or liver-intestine, MELD of at least 15, and at least 18 years of age
13	OPO's region	Liver or liver-intestine, MELD of at least 15, and 12 to less than 18 years of age
14	OPO's region	Liver or liver-intestine, MELD of at least 15, and at least 18 years of age
15	OPO's DSA	Liver or liver-intestine, MELD less than 15, and 12 to less than 18 years of age
16	OPO's DSA	Liver or liver-intestine, MELD less than 15, and at least 18 years of age
17	OPO's region	Liver or liver-intestine, MELD less than 15, and 12 to less than 18 years of age
18	OPO's region	Liver or liver-intestine, MELD less than 15, and at least 18 years of age
19	Nation	Liver, Pediatric Status 1A, and 12 to less than 18 years of age
20	Nation	Liver or liver-intestine, Adult Status 1A
21	Nation	Liver, Pediatric Status 1B
22	Nation	Liver or liver-intestine, with any PELD
23	Nation	Liver or liver-intestine, with any MELD/PELD, and 12 to less than 18 years of age
24	Nation	Liver or liver-intestine, with any MELD, and at least 18 years of age
The following classifications only appear on O blood type donor matches		
25	OPO's region	Liver or liver-intestine, with any PELD, and compatible blood type match with the donor
26	OPO's DSA	Liver or liver-intestine, MELD of at least 15, 12 to less than 18 years of age, and compatible blood type match with the donor
27	OPO's DSA	Liver or liver-intestine, MELD of at least 15, at least

Classification	Candidates that are within the:	And are:
		18 years of age, and compatible blood type match with the donor
28	OPO's region	Liver or liver-intestine, MELD of at least 15, 12 to less than 18 years of age, and compatible blood type match with the donor
29	OPO's region	Liver or liver-intestine, MELD of at least 15, at least 18 years of age, and compatible blood type match with the donor
30	OPO's DSA	Liver or liver-intestine, MELD less than 15, 12 to less than 18 years of age, and compatible blood type match with the donor
31	OPO's DSA	Liver or liver-intestine, MELD less than 15, at least 18 years of age, and compatible blood type match with the donor
32	OPO's region	Liver or liver-intestine, MELD less than 15, 12 to less than 18 years of age, and compatible blood type match with the donor
33	OPO's region	Liver or liver-intestine, MELD less than 15, at least 18 years of age, and compatible blood type match with the donor
34	Nation	Liver or liver-intestine, with any PELD, and compatible blood type match with the donor
35	Nation	Liver or liver-intestine, with any MELD, 12 to less than 18 years of age, and compatible blood type match with the donor
36	Nation	Liver or liver-intestine, with any MELD, at least 18 years of age, and compatible blood type match with the donor
The following classifications appear for all blood types		
37	OPO's DSA	Liver or liver-intestine, Adult or Pediatric Status 1A, and in need of other method of hepatic support
38	OPO's DSA	Liver or liver-intestine, Pediatric Status 1B, and in need of other method of hepatic support
39	OPO's DSA	Liver or liver-intestine, with any MELD/PELD, and in need of other method of hepatic support
40	OPO's region	Liver or liver-intestine, Adult or Pediatric Status 1A, and in need of other method of hepatic support
41	OPO's region	Liver or liver-intestine, Pediatric Status 1B, and in need of other method of hepatic support
42	OPO's region	Liver or liver-intestine, with any MELD/PELD, and in need of other method of hepatic support

Classification	Candidates that are within the:	And are:
43	Nation	Liver or liver-intestine, Adult or Pediatric Status 1A, and in need of other method of hepatic support
44	Nation	Liver or liver-intestine, Pediatric Status 1B, and in need of other method of hepatic support
45	Nation	Liver or liver-intestine, with any MELD/PELD, and in need of other method of hepatic support
The following classifications only appear on O blood type donor matches		
46	OPO's DSA	Liver or liver-intestine, with any MELD/PELD, in need of other method of hepatic support, and compatible blood type match with the donor
47	OPO's region	Liver or liver-intestine, with any MELD/PELD, in need of other method of hepatic support, and compatible blood type match with the donor
48	Nation	Liver or liver-intestine, with any MELD/PELD, in need of other method of hepatic support, and compatible blood type match with the donor

Blood type matches for combined liver-intestine allocation are determined according to *Policy 9.6.C: Allocation of Livers by Blood Type*.

9.6.K Allocation of Liver-Intestine from Donors at Least 11 Years of age (3.6.4.8)

For combined liver-intestine allocation from donors at least 11 years of age, the liver must first be offered as follows:

1. According to *Policy 9.6.F: Allocation of Livers from Deceased Donors 11 to 17 Years Old*
2. Sequentially to *each* potential liver recipient, including all MELD/PELD potential recipients, through national Status 1A and 1B offers

The liver may then be offered to combined liver-intestine potential recipients sequentially according to the intestine match run.

9.7 Administrative Rules

9.7.A Registration Accuracy (3.6.9.2)

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 host OPO's applicable regional review board (RRB). The RRB will retrospectively review the allocation or status.

If the RRB receives two or more reports about a member within any one year period, the RRB will report it to the Membership and Professional Standards (MPSC) Committee and request an on-site review of the member.

9.7.B Review of Status 1A and 1B Candidate Registrations (3.6.4.6)

If the regional review boards reject three or more status 1A or 1B candidate registrations at a transplant program and each of the candidates receive a transplant while registered at the rejected status, then the OPTN Contractor will conduct an on-site review of the transplant program's status 1A and 1B candidate registrations. If the OPTN Contractor finds a Policy violation or inappropriate registrations, the transplant program will reimburse all necessary and reasonable expenses incurred by the OPTN Contractor in performing this review.

9.7.C Rights Conferred by the Allocation System (3.6)

No individual or property rights are conferred by the liver allocation system.

9.8 Variances

9.8.A Open Variance for Segmental Liver Transplantation (3.6.12)

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.

History

Policy 3.6: Allocation of Livers: 9/17/2007; 6/20/2008; 3/3/2009; 6/23/2009; 11/17/2009; 6/22/2010; 11/15/2011; 3/13/2012; 6/26/2012; 11/13/2012
Policy 9: Allocation of Livers and Liver-Intestines:

Notes

- For liver acceptance and screening criteria, see *Policy 5: Organ Offers, Acceptance, and Verification*.
- For information on liver waiting time applied to waiting time for a liver-intestinal transplant see *Policy 9.4: Waiting Time*.
- For CDC clinical growth chart, see http://www.cdc.gov/growthcharts/cdc_charts.htm.
- For Membership and Personnel Requirements for Liver Transplant Programs, *see OPTN Bylaws, Appendix F*.
- For the American College of Radiology Imaging network (ACRIN) protocol regarding the Diagnosis of Hepatocellular Carcinoma, see http://www.acrin.org/Portals/0/Protocols/6690/ACRIN6690_Amend1_v090110_master_ForOnline.pdf.

Policy 10: Allocation of Lungs

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10.1 Priorities and Score Assignments for Lung Candidates

(3.7.6)

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 (3.7.6.2)

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 Contractor 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 (3.7.6.2)

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.

Public Comment Draft

10.1.C Priority and Clinical Data Update Schedule for Candidates Less than 12 Years Old (3.7.6.2)

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 catherization, 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 (3.7.6.1)

Candidates who are at least 12 years old 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 (3.7.6.3)

When registering a candidate who is at least 12 years old for a lung transplant, transplant programs must report to the OPTN Contractor 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 Contractor 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. The first six-month period begins six months from the date of the candidate's initial registration, 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 is reported.

LAS covariate data obtained by heart catheterization does not need to be reported to the OPTN Contractor 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 Contractor.

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 missing, expired, or below the threshold value:	Then the LAS calculation will use this substituted value:
Bilirubin	0.7 mg/dL if the actual value is missing, expired, or less than 0.7 mg/dL
Body mass index (BMI)	100 kg/m^2 if the actual value is missing or expired
Cardiac index	3.0 L/min/m^2 if the actual value is missing
Central venous pressure (CVP)	5 mm Hg if the actual value is missing or less than 5 mm Hg
Continuous mechanical ventilation	No mechanical ventilation in the waiting list model if the actual value is missing or expired Continuous mechanical ventilation in the post-transplant survival measure if the actual value is missing or expired
Creatinine: serum	0.1 mg/dL in the waiting list model if the actual value is missing or expired 40 mg/dL in the post-transplant survival measure for candidates at least 18 years old if the actual value is missing or expired 0 mg/dL in the post-transplant survival measure for candidates less than 18 years old if the actual value is missing or expired
Diabetes	No diabetes if the actual value is missing or expired
Forced vital capacity (FVC)	150% for Diagnosis Group D if the actual value is missing or expired, according to *Policy 10.1.F.i: Lung Disease Diagnosis Groups*
Functional status	No assistance needed in the waiting list model if the actual value is missing or expired Some or total assistance needed in the post-transplant survival measure if the actual value is missing or expired
Oxygen needed at rest	No supplemental oxygen needed in the waiting list model

If this covariate's value is missing, expired, or below the threshold value:	Then the LAS calculation will use this substituted value:
	if the actual value is missing or expired 26.33 L/min in the post-transplant survival measure if the actual value is missing or expired
PCO_2	40 mm Hg if the actual value is missing, expired, or if less than 40 mm Hg
Pulmonary artery (PA) systolic pressure	20 mm Hg if the actual value is missing or less than 20 mm Hg
Six-minute-walk distance	4,000 feet in the waiting list urgency measure if the actual value is missing or expired 0 feet in the post-transplant survival measure if the actual value is missing or expired

10.1.F. The LAS Calculation (3.7.6.1.1)

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:

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

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.*

Where…	Includes…
$S_{TX}(t) = S_{TX,0}(t)^{e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \ldots + \alpha_q Y_q}}$	$S_{TX}(t)$ = the expected post-transplant survival probability at time t for an individual candidate. Y_i = the value of the jth 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 10-5: Baseline Waiting List Survival (SWL(t)) Probability*. $S_{TX,0}(t)$ = the baseline post-transplant survival probability at time t, according to *Table 10-6: 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 ith 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:
1. Age (year)	0.0083990318885565*age
2. Bilirubin (mg/dL)	0.0431682188302477*(bilirubin – 1) if bilirubin is more than 1.0 mg/dL 0 when bilirubin is 1.0 mg/dL or less
3. Bilirubin increase of at least 50%	1.4144058906830200 for Diagnosis Group B 0 for Diagnosis Groups A, C, and D
4. Body mass index (BMI) (kg/m^2)	0.1261444133358100*(20 – BMI) for BMI less than 20 kg/m^2 0 if BMI is at least 20 kg/m^2

For this covariate:	The following coefficient is used in the LAS calculation:
5. Cardiac index prior to any exercise	0.5435368888028200 if the cardiac index is less than 2 L/min/m^2 0 if the cardiac index is at least 2 L/min/m^2
6. Central venous pressure (CVP) (mm Hg) at rest, prior to any exercise	0.0173841981251578*(CVP – 7) for CVP greater than 7 mm Hg (Diagnosis Group B only) 0 if less than or equal to 7 mm Hg for Diagnosis Group B 0 for candidates in Diagnosis Groups A, C, and D
7. Ventilation status if candidate is hospitalized	1.6771121096052300 if continuous mechanical ventilation needed 0 if no continuous mechanical ventilation needed
8. Creatinine (serum) (mg/dL)	0.5034346761960600* creatinine if candidate is at least 18 years old 0 if candidate is less than 18 years old
9. Diabetes	0.4680254026735700 if diabetic 0 if not diabetic
10. Diagnosis Group A	0
11. Diagnosis Group B	1.5774243292137200
12. Diagnosis Group C	1.2313926484343600
13. Diagnosis Group D	0.6259577164157700
14. Detailed diagnosis: Bronchiectasis (Diagnosis Group A only)	0.6680518055684700
15. Detailed diagnosis: Eisenmenger's syndrome (Diagnosis Group B only)	-0.6278657824830000
16. Detailed diagnosis: Lymphangioleiomyomatosis (Diagnosis Group A only)	-0.3162937838984600
17. Detailed Diagnosis: Obliterative bronchiolitis (not-retransplant) (Diagnosis Group D only)	0.4453284411081100
18. Detailed Diagnosis: Pulmonary fibrosis, not idiopathic (Diagnosis Group D only)	-0.2091170018125500
19. Detailed Diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Diagnosis Group D only)	-0.4577749354638600
20. Detailed Diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Diagnosis Group A only)	0.9330846239906700

For this covariate:	The following coefficient is used in the LAS calculation:
21. Forced vital capacity (FVC)	0.1829476350587400*(80 – FVC)/10 if FVC is less than 80% for Diagnosis Group D 0 if FVC is greater than or equal to 80% for Diagnosis Group D 0 for candidates in Diagnosis Groups A, B, and C
22. Functional Status	-0.4471034284458400 if no assistance needed with activities of daily living 0 if some or total assistance needed with activities of daily living
23. Oxygen needed to maintain adequate oxygen saturation (80% or greater) at rest (L/min)	0.0213187586203456*O_2 for Diagnosis Group B 0.1188479817592500 for Diagnosis Groups A, C, and D
24. PCO_2 (mm Hg): current	0.1104609835819100*PCO_2/10 if PCO_2 is at least 40 mm Hg
25. PCO_2 increase of at least 15%	0.2331149280428300 if PCO_2 increase is at least 15% 0 if PCO_2 increase is less than 15%
26. Pulmonary artery (PA) systolic pressure (10 mm Hg) at rest, prior to any exercise	0.4155116686114300*(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 0.0462410402627318*PA systolic/10 for Diagnosis Groups B, C, and D
27. 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.	-0.0844896372724000*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.

Table10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients

For this variable:	The following is used in the LAS calculation:
1. Age (years)	0.0246579831271869*(age–45) if candidate is greater than 45 years old 0 if candidate is 45 years old or younger

For this variable:	The following is used in the LAS calculation:
2. Creatinine (serum) at transplant (mg/dL)	0.0895569900508900*creatinine if candidate is at least 18 years old 0 if candidate is less than 18 years old
3. Creatinine increase of at least 150%	0.7708616024698100 if increase in creatinine is at least 150%, and when the higher value determining this increase is at least 1 mg/dL 0 if increase in creatinine of 150% if the higher value determining this increase is less than 1 mg/dL 0 if increase in creatinine less than 150% or creatinine decreases
4. Cardiac index (L/min/m^2) at rest, prior to any exercise	0.3499381679822400 if less than 2 L/min/m^2 0 if at least 2 L/min/m^2
5. Ventilation status if candidate is hospitalized	0.6094478988424900 if continuous mechanical ventilation needed 0 if no continuous mechanical ventilation needed
6. Diagnosis Group A	0
7. Diagnosis Group B	0.6115547319209300
8. Diagnosis Group C	0.3627014422464200
9. Diagnosis Group D	0.4641392063023200
10. Detailed diagnosis: Bronchiectasis (Diagnosis Group A only)	0.1889100379099400
11. Detailed diagnosis: Eisenmenger's syndrome (Diagnosis Group B only)	0.9146727886744700
12. Detailed diagnosis: Lymphangioleiomyomatosis (Diagnosis Group A only)	-1.5194416206749400
13. Detailed diagnosis: Obliterative bronchiolitis (not-retransplant, Diagnosis Group D only)	-1.2050508750702600
14. Detailed diagnosis: Pulmonary fibrosis, not idiopathic (Diagnosis Group D only)	-0.0723596761367600
15. Detailed diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Diagnosis Group D only)	-0.0437880049066331
16. Detailed diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Diagnosis Group A only)	-0.1389363636019300

For this variable:	The following is used in the LAS calculation:
17. Oxygen needed to maintain adequate oxygen saturation (80% or greater) at rest (L/min)	0.0747978926517300*O_2 for Diagnosis Group A 0.0164276945879309 for Diagnosis Groups B, C, and D
18. Functional Status	-0.1900086366785100 if no assistance needed with activities or daily living 0 if some or total assistance needed with activities or daily living
19. 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.	0.0004594953809594*(1200-6mw) 0 if six-minute-distance-walked is at least 111111,200 feet

See *Policy 10.5: Probability Data Used in the LAS Calculation* for *Tables 10-8* and *10-9* that provide data used in the LAS calculation.

10.1.F.i Lung Disease Diagnosis Groups (3.7.6.1.2)

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 mean pulmonary artery pressure of 30 mm Hg or less
- 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
- Primary 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
- Bronchoalveolar carcinoma (BAC)
- Carcinoid tumorlets
- Chronic pneumonitis of infancy
- Constrictive bronchiolitis
- 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 telangiectasia – restrictive
- Rheumatoid disease
- Sarcoidosis with mean pulmonary artery pressure higher than 30 mm Hg
- Scleroderma – restrictive
- Secondary pulmonary fibrosis: (specify cause)
- Silicosis
- Sjogren's syndrome
- Surfactant protein B mutation
- Surfactant protein C mutation
- Teratoma
- Wegener's granuloma – restrictive

10.1.F.ii PCO_2 in the LAS (3.7.6.1.3)

The LAS calculation uses two measures of PCO_2:

1. Current PCO_2
2. Increase in PCO_2

Current PCO_2

Current PCO_2 is the PCO_2 value reported to the OPTN Contractor with the most recent test date. 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.

The LAS calculation uses the PCO_2 value with the most recent test date. If an arterial value and either a venous value, or an arterial value and a capillary value, have the same test date, the LAS calculation will use the arterial value.

Increase in PCO_2 Calculations

There are two Increase in PCO_2 calculations:

- The Increase-in-PCO_2 Calculation
- The Threshold Change Maintenance Calculation

The Increase-in-PCO_2 Calculation

An increase in PCO_2 that is at least 15% will impact a candidate's LAS. The increase-in-PCO_2 calculation uses the highest and lowest values of PCO_2 as follows:

- The test date of the lowest value must be earlier than the test date of the highest value.
- Test dates of these highest and lowest values cannot be more than six months apart.
- The increase-in-PCO_2 calculation will use an expired lowest value, but not 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 increase-in-PCO_2 calculation. The equation for the increase-in-PCO_2 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 increase-in-PCO_2 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 increase-in-PCO_2 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 reported to the OPTN Contractor. For this calculation, the lowest and highest values that were used in the increase-in-PCO_2 calculation can be expired. The current PCO_2 value can be the highest one that was used in the increase-in-PCO_2 calculation. If a current PCO_2 value expires, the candidate's LAS will no longer be affected by the increase in PCO_2.

If a transplant hospital reports a new current PCO_2 value for a candidate who has lost the impact from the increase-in-PCO_2 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 increase-in-PCO_2 calculation, the candidate's LAS will again be affected by the increase-in-PCO_2 calculation.

Normal PCO_2 Value

The normal clinical PCO_2 value is 40mmHg. If a PCO_2 value is below 40 mmHg, or if the PCO_2 value is missing or expired, the LAS calculation will use the normal clinical PCO_2 value.

10.1.F.iii Bilirubin in the Lung Allocation Score LAS (3.7.6.1.4)

The LAS calculation uses two measures of total bilirubin:

- Current bilirubin (for all candidates)
- Increase in bilirubin (for diagnosis Group B only)

Current Bilirubin

Current bilirubin is the total bilirubin value with the most recent test date and time reported to the OPTN Contractor. A current bilirubin value of at least 1.0 mg/dL will impact candidate's LAS.

Increase in Bilirubin (Diagnosis Group B Only)

There are two Increase in Bilirubin calculations:

- Increase-in-Bilirubin Calculation
- Threshold Change Maintenance Calculation

Increase-in-Bilirubin Calculation

For candidates in diagnosis Group B, an increase-in-bilirubin that is at least 50% impacts the candidate's LAS . The increase-in-bilirubin calculation uses the highest and lowest values of bilirubin. The test date of the lowest bilirubin value reported to the OPTN used in the increase-in-bilirubin calculation Contractor must be earlier than the test date of the highest bilirubin value reported to the OPTN. The highest value must be at least 1.0 mg/dL. Test dates of these highest and lowest values cannot be more than 6 months apart. The increase-in-bilirubin calculation will use an expired lowest value, but not an expired highest value. If a value is less than 0.7 mg/dL, the increase-in-bilirubin calculation will use the normal clinical value of 0.7 mg/dL. The equation for this increase-in-bilirubin calculation is:

$$\frac{\text{Highest Bilirubin-Lowest Bilirubin}}{\text{Lowest Bilirubin}}$$

Threshold Change Maintenance Calculation

When a 50% or greater increase in bilirubin impacts a candidate's LAS, the LAS threshold change maintenance calculation assesses whether to maintain that impact. To maintain the impact of the bilirubin increase, the candidate's current bilirubin value must be at least 50% higher than the lowest value used in the increase-in-bilirubin calculation. The equation for the threshold change maintenance calculation is:

$$\frac{\text{Current Bilirubin-Lowest Bilirubin}}{\text{Lowest Bilirubin}}$$

The increase maintenance calculation occurs either when the current bilirubin 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 bilirubin value is entered. For this calculation, the lowest and highest values that were used in the increase-in-bilirubin calculation can be expired. The current bilirubin value can be the highest one

that was used in the increase-in-bilirubin calculation. If a current bilirubin value expires, the candidate's LAS will no longer be affected by the increase in bilirubin.

If a transplant hospital reports a new current bilirubin value for a candidate who has lost the impact from the increase-in-bilirubin calculation, the LAS will perform the threshold change maintenance calculation. If the new current bilirubin value is at least 50% higher than the lowest value used in the increase-in-bilirubin calculation, the candidate's LAS will again be affected by the increase-in-bilirubin calculation.

Normal Bilirubin Value

The normal clinical current bilirubin value is 0.7 mg/dL. If a current bilirubin value is below 0.7 mg/dL, or if the current bilirubin value is missing or expired, the LAS calculation will use the normal clinical current bilirubin value.

10.1.F.iv. Creatinine in the LAS (3.7.6.1.5)

The LAS calculation uses two measures of creatinine:

1. Current creatinine (only for candidates who are at least 18 years old)
2. Increase in creatinine (for all candidates)

Current Creatinine

Current creatinine is the serum creatinine value with the most recent test date and time reported to the OPTN Contractor for candidates who are at least 18 years old.

Increase in Creatinine

There are two Increase in Creatinine calculations:

1. Increase-in-Creatinine Calculation
2. Threshold Change Maintenance Calculation

The Increase-in-Creatinine Calculation

An increase in creatinine that is at least 150% will impact a candidate's LAS. The increase-in-creatinine calculation uses the highest and lowest values of creatinine. For this variable to impact a candidate's LAS, the test date of the lowest value reported to the OPTN Contractor used in the increase-in-creatinine calculation must be earlier than the test date of the highest value used in the increase-in-creatinine calculation. The highest value must be at least 1.0 mg/dL. Test dates of these highest and lowest values cannot be more than 6 months apart. The increase-in-creatinine calculation will use an expired lowest value, but not an expired highest value. The equation for this increase-in-creatinine calculation is:

$$\frac{\text{Highest Creatinine-Lowest Creatinine}}{\text{Lowest Creatinine}}$$

The Threshold Change Maintenance Calculation

When an increase-in-creatinine calculation impacts a candidate's LAS, the threshold change maintenance calculation assesses whether to maintain that impact. To maintain the impact of the increase in creatinine, the candidate's current creatinine value must be at least 150% higher than the lowest value used in the increase-in-creatinine calculation. The equation for the threshold change maintenance calculation is:

$$\frac{\text{Current Creatinine-Lowest Creatinine}}{\text{Lowest Creatinine}}$$

If the current creatinine value expires or a new creatinine value is entered, then the increase maintenance calculation will occur.

10.1.G Reporting Additional Data for Candidates with an LAS of 50 or Higher (3.7.6.3.1)

A transplant program must report data for three key variables to the OPTN Contractor no more than 14 days after a candidate's LAS becomes 50 or higher:

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

The transplant program is only required to report an updated PCO_2 value if the test was performed within those 14 days. While the candidate's LAS score remains 50 or higher, the transplant program must continue to assess and report any observed changes in the three clinical key variables every 14 days.

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

10.2 Priority and Score Exceptions (3.7.1.1, 3.7.6.4)

10.2.A Allocation Exception for Sensitized Patients (3.7.1.1)

Lungs may be allocated to sensitized candidates within a DSA out of the sequence required by the match run to sensitized candidates within a DSA if:

1. The candidate's transplant surgeon or physician determines that the candidate's antibodies would react adversely to certain human leukocyte antigens (HLA) antigens.
2. All lung transplant programs and the OPO within the DSA agree to allocate the lung from a compatible deceased donor to the sensitized candidate because the results of a crossmatch between the blood serum of that the candidate and cells of the lung donor are negative.
3. The candidate's transplant program, all lung transplant programs, and the OPO within a DSA agree upon the level of sensitization at which a candidate qualifies for the sensitization exception.

Sensitization alone does not qualify a candidate to qualify for an exception as described in *Policy 10.2.B*: *Lung Candidates with Exceptional Cases* below.

10.2.B Lung Candidates with Exceptional Cases (3.7.6.4)

The Thoracic Organ 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.D: Allocation of Lungs from Deceased Donors 12 to Less Than 18 Years Old*. Candidates receiving this exception will also maintain their pediatric classification for the purposes of *Policy 10.4.E: Allocation of Lungs from Deceased Donors Less than 12 Years Old*.

10.2.B.i LRB Review Process

Requests for approval of estimated values, diagnoses, or specific LAS require prospective review by the LRB. The transplant hospital must submit requests for LRB review to the OPTN Contractor, 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 Contractor 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 Contractor 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 Contractor will send the request or appeal to the Thoracic Organ 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 Contractor will send the request or appeal to the Thoracic Organ Transplantation Committee for review. This review by the Thoracic Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee (MPSC). If the MPSC agrees with the Thoracic Organ 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 Thoracic Committee will are valid until an actual value is reported to the OPTN Contractor or a new estimated value is reported to the OPTN Contractor.

10.2.B.iv LAS Values and Diagnoses Approved by the LRB

A diagnosis that has been approved by the LRB or the Thoracic Organ 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 Thoracic 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 Contractor.

10.3 Waiting Time

Waiting time for lung candidates begins when the candidate is registered on the waiting list. Candidates awaiting a lung transplant on the waiting list at inactive status and will not accrue any waiting time while 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 (3.7.9.2)

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 Contractor.

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 Contractor.

10.3.B Lung Candidates Less than 12 Years Old (3.7.6.2, 3.7.9.3)

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 (3.7.7)

10.4.A Sorting Within Each Classification (3.7.11, 3.7.11.1)

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 (3.7.8.2)

A candidate whose blood type is identical to the donor's will receive the single or double lung offer before a candidate whose blood type is compatible but not identical with the donor's.

10.4.C Allocation of Lungs from Deceased Donors at Least 18 Years Old (3.7.2)

Single and double lungs from deceased donors at least 18 years old are allocated according to *Table 10-5* below.

Table 10-5: Allocation of Lungs from Deceased Donors at Least 18 Years Old

Classification	Candidates that are included within the:	And are:
1	OPO's DSA	At least 12 years old, blood type identical to the donor
2	OPO's DSA	At least 12 years old, blood type compatible with the donor
3	OPO's DSA	Priority 1, blood type identical to the donor
4	OPO's DSA	Priority 1, blood type compatible with the donor
5	OPO's DSA	Priority 2, blood type identical to the donor
6	OPO's DSA	Priority 2, blood type compatible with the donor
7	Zone A	At least 12 years old, blood type identical to the donor
8	Zone A	At least 12 years old, blood type compatible with the donor
9	Zone A	Priority 1, blood type identical to the donor
10	Zone A	Priority 1, blood type compatible with the donor
11	Zone A	Priority 2, blood type identical to the donor
12	Zone A	Priority 2, blood type compatible with the donor
13	Zone B	At least 12 years old, blood type identical to the donor
14	Zone B	At least 12 years old, blood type compatible with the donor
15	Zone B	Priority 1, blood type identical to the donor
16	Zone B	Priority 1, blood type compatible with the donor
17	Zone B	Priority 2, blood type identical to the donor
18	Zone B	Priority 2, blood type compatible with the donor
19	Zone C	At least 12 years old, blood type identical to the donor

Classification	Candidates that are included within the:	And are:
20	Zone C	At least 12 years old, blood type compatible with the donor
21	Zone C	Priority 1, blood type identical to the donor
22	Zone C	Priority 1, blood type compatible with the donor
23	Zone C	Priority 2, blood type identical to the donor
24	Zone C	Priority 2, blood type compatible with the donor
25	Zone D	At least 12 years old, blood type identical to the donor
26	Zone D	At least 12 years old, blood type compatible with the donor
27	Zone D	Priority 1, blood type identical to the donor
28	Zone D	Priority 1, blood type compatible with the donor
29	Zone D	Priority 2, blood type identical to the donor
30	Zone D	Priority 2, blood type compatible with the donor
31	Zone E	At least 12 years old, blood type identical to the donor
32	Zone E	At least 12 years old, blood type compatible with the donor
33	Zone E	Priority 1, blood type identical to the donor
34	Zone E	Priority 1, blood type compatible with the donor
35	Zone E	Priority 2, blood type identical to the donor
36	Zone E	Priority 2, blood type compatible with the donor

10.4.D Allocation of Lungs from Deceased Donors 12 to Less Than 18 Years Old

Single and double lungs from deceased donors at least 12 years old to less than 18 years old are allocated according to *Table 10-6* below.

Table 10-6: Allocation of Lungs from Deceased Donors 12 to Less Than 18 Years Old

Classification	Includes Candidates that are within the:	And are:
1	OPO's DSA	12 to less than 18 years old, blood type identical to the donor
2	OPO's DSA	12 to less than 18 years old, blood type compatible with the donor
3	OPO's DSA	Priority 1, blood type identical to the donor
4	OPO's DSA	Priority 1, blood type compatible with the donor
5	OPO's DSA	Priority 2, blood type identical to the donor
6	OPO's DSA	Priority 2, blood type compatible with the donor
7	OPO's DSA	At least 18 years old, blood type identical to the

Classification	Includes Candidates that are within the:	And are:
		donor
8	OPO's DSA	At least 18 years old, blood type compatible with the donor
9	Zone A	12 to less than 18 years old, blood type identical to the donor
10	Zone A	12 to less than 18 years old, blood type compatible with the donor
11	Zone A	Priority 1, blood type identical to the donor
12	Zone A	Priority 1, blood type compatible with the donor
13	Zone A	Priority 2, blood type identical to the donor
14	Zone A	Priority 2, blood type compatible with the donor
15	Zone A	At least 18 years old, blood type identical to the donor
16	Zone A	At least 18 years old, blood type compatible with the donor
17	Zone B	12 to less than 18 years old, blood type identical to the donor
18	Zone B	12 to less than 18 years old, blood type compatible with the donor
19	Zone B	Priority 1, blood type identical to the donor
20	Zone B	Priority 1, blood type compatible with the donor
21	Zone B	Priority 2, blood type identical to the donor
22	Zone B	Priority 2, blood type compatible with the donor
23	Zone B	At least 18 years old, blood type identical to the donor
24	Zone B	At least 18 years old, blood type compatible with the donor
25	Zone C	Less than 18 years old, blood type identical to the donor
26	Zone C	Less than 18 years old, blood type compatible with the donor
27	Zone C	Priority 1, blood type identical to the donor
28	Zone C	Priority 1, blood type compatible with the donor
29	Zone C	Priority 2, blood type identical to the donor
30	Zone C	Priority 2, blood type compatible with the donor
31	Zone C	At least 18 years old, blood type identical to the donor
32	Zone C	At least 18 years old, compatible with the donor
33	Zone D	12 to less than 18 years old, blood type identical to the donor
34	Zone D	12 to less than 18 years old, blood type

Classification	Includes Candidates that are within the:	And are:
		compatible with the donor
35	Zone D	12 to less than 18 years old, blood type identical to the donor
36	Zone D	Priority 1, blood type compatible with the donor
37	Zone D	Priority 2, blood type identical to the donor
38	Zone D	Priority 2, blood type compatible with the donor
39	Zone D	At least 18 years old, blood type identical to the donor
40	Zone D	At least 18 years old, blood type compatible with the donor
41	Zone E	12 to less than 18 years old, blood type identical to the donor
42	Zone E	12 to less than 18 years old, blood type compatible with the donor
43	Zone E	Priority 1, blood type identical to the donor
44	Zone E	Priority 1, blood type compatible with the donor
45	Zone E	Priority 2, blood type identical to the donor
46	Zone E	Priority 2, blood type compatible with the donor
47	Zone E	At least 18 years old, blood type identical to the donor
48	Zone E	At least 18 years old, blood type compatible with the donor

10.4.E Allocation of Lungs from Deceased Donors Less than 12 Years Old

Single and double lungs from deceased donors less than 12 years old are allocated according to *Table 10-7* below.

Table 10-7: Allocation of Lungs from Deceased Donors Less than 12 Years Old

Classification	Candidates that are included within the:	And are:
1	OPO's DSA, Zone A, or Zone B	Priority 1, blood type identical to the donor
2	OPO's DSA, Zone A, or Zone B	Priority 1, blood type compatible with the donor
3	OPO's DSA, Zone A, or Zone B	Priority 2, blood type identical to the donor
4	OPO's DSA, Zone A, or Zone B	Priority 2, blood type compatible with the donor
5	OPO's DSA or Zone A	12 to less than 18 years old, blood type identical to the donor
6	OPO's DSA or Zone A	12 to less than 18 years old, blood type

Classification	Candidates that are included within the:	And are:
		compatible with the donor
7	OPO's DSA	At least 18 years, blood type identical to the donor
8	OPO's DSA	At least 18 years, blood type compatible with the donor
9	Zone A	At least 18 years old, blood type identical to the donor
10	Zone A	At least 18 years old, blood type compatible with the donor
11	Zone B	12 to less than 18 years old, blood type identical to the donor
12	Zone B	12 to less than 18 years old, blood type compatible with the donor
13	Zone B	At least 18 years old, blood type identical to the donor
14	Zone B	At least 18 years old, blood type compatible with the donor
15	Zone C	Priority 1, blood type identical to the donor
16	Zone C	Priority 1, blood type compatible with the donor
17	Zone C	Priority 2, blood type identical to the donor
18	Zone C	Priority 2, blood type compatible with the donor
19	Zone C	12 to less than 18 years old, blood type identical to the donor
20	Zone C	12 to less than 18 years old, blood type compatible with the donor
21	Zone C	At least 18 years old, blood type identical to the donor
22	Zone C	At least 18 years old, blood type compatible with the donor
23	Zone D	Priority 1, blood type identical to the donor
24	Zone D	Priority 1, blood type compatible with the donor
25	Zone D	Priority 2, blood type identical to the donor
26	Zone D	Priority 2, blood type compatible with the donor
27	Zone D	12 to less than 18 years old, blood type identical to the donor
28	Zone D	12 to less than 18 years old, blood type compatible with the donor
29	Zone D	At least 18 years old, blood type identical to the donor

Classification	Candidates that are included within the:	And are:
30	Zone D	At least 18 years old, blood type compatible with the donor
31	Zone E	Priority 1, blood type identical to the donor
32	Zone E	Priority 1, blood type compatible with the donor
33	Zone E	Priority 2, blood type identical to the donor
34	Zone E	Priority 2, blood type compatible with the donor
35	Zone E	12 to less than 18 years old, blood type identical to the donor
36	Zone E	12 to less than 18 years old, blood type compatible with the donor
37	Zone E	At least 18 years old, blood type identical to the donor
38	Zone E	At least 18 years old, blood type compatible with the donor

10.5 Probability Data Used in the LAS Calculation

Table 10-8: Baseline Waiting List Survival (SWL(t)) Probability

Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$
0	1.000000	**49**	0.996644	**98**	0.993160	**147**	0.990540	**196**	0.987299
1	0.999991	**50**	0.996543	**99**	0.993098	**148**	0.990540	**197**	0.987263
2	0.999925	**51**	0.996518	**100**	0.993061	**149**	0.990540	**198**	0.987155
3	0.999867	**52**	0.996397	**101**	0.993005	**150**	0.990540	**199**	0.987122
4	0.999746	**53**	0.996397	**102**	0.993005	**151**	0.990540	**200**	0.986530
5	0.999598	**54**	0.996363	**103**	0.992938	**152**	0.990384	**201**	0.986530
6	0.999499	**55**	0.996305	**104**	0.992938	**153**	0.990333	**202**	0.986480
7	0.999371	**56**	0.996191	**105**	0.992883	**154**	0.990333	**203**	0.985963
8	0.999305	**57**	0.996119	**106**	0.992883	**155**	0.990333	**204**	0.985926
9	0.999218	**58**	0.995942	**107**	0.992851	**156**	0.990245	**205**	0.985926
10	0.999085	**59**	0.995942	**108**	0.992762	**157**	0.990245	**206**	0.985820
11	0.998990	**60**	0.995909	**109**	0.992724	**158**	0.990245	**207**	0.985820
12	0.998887	**61**	0.995909	**110**	0.992643	**159**	0.990145	**208**	0.985742
13	0.998816	**62**	0.995873	**111**	0.992643	**160**	0.989689	**209**	0.985742
14	0.998730	**63**	0.995846	**112**	0.992562	**161**	0.989689	**210**	0.985742
15	0.998660	**64**	0.995846	**113**	0.992089	**162**	0.989652	**211**	0.985708
16	0.998588	**65**	0.995614	**114**	0.992064	**163**	0.989575	**212**	0.985708
17	0.998455	**66**	0.995553	**115**	0.992040	**164**	0.989575	**213**	0.985541
18	0.998362	**67**	0.995553	**116**	0.991997	**165**	0.988903	**214**	0.985541
19	0.998259	**68**	0.995553	**117**	0.991966	**166**	0.988873	**215**	0.985541
20	0.998220	**69**	0.995500	**118**	0.991940	**167**	0.988873	**216**	0.985450
21	0.998068	**70**	0.995479	**119**	0.991940	**168**	0.988784	**217**	0.985450
22	0.998036	**71**	0.995349	**120**	0.991940	**169**	0.988722	**218**	0.985450
23	0.997972	**72**	0.995293	**121**	0.991514	**170**	0.988695	**219**	0.985330
24	0.997868	**73**	0.995136	**122**	0.991514	**171**	0.988695	**220**	0.985265
25	0.997770	**74**	0.994965	**123**	0.991514	**172**	0.988695	**221**	0.985265
26	0.997742	**75**	0.994821	**124**	0.991514	**173**	0.988655	**222**	0.985265
27	0.997667	**76**	0.994774	**125**	0.991488	**174**	0.988655	**223**	0.985265
28	0.997626	**77**	0.994702	**126**	0.991462	**175**	0.988655	**224**	0.985265
29	0.997540	**78**	0.994702	**127**	0.991393	**176**	0.988625	**225**	0.984621
30	0.997473	**79**	0.994634	**128**	0.991307	**177**	0.988548	**226**	0.984549
31	0.997391	**80**	0.994565	**129**	0.991307	**178**	0.988548	**227**	0.984549
32	0.997327	**81**	0.994547	**130**	0.991270	**179**	0.988548	**228**	0.984549
33	0.997297	**82**	0.994465	**131**	0.991236	**180**	0.988062	**229**	0.984549
34	0.997274	**83**	0.994465	**132**	0.991236	**181**	0.988062	**230**	0.984489
35	0.997242	**84**	0.994297	**133**	0.991053	**182**	0.988062	**231**	0.984489
36	0.997242	**85**	0.994297	**134**	0.991012	**183**	0.988021	**232**	0.984396
37	0.997181	**86**	0.994297	**135**	0.991012	**184**	0.987934	**233**	0.984324
38	0.997137	**87**	0.994297	**136**	0.990978	**185**	0.987885	**234**	0.984280
39	0.997121	**88**	0.994181	**137**	0.990978	**186**	0.987885	**235**	0.984079
40	0.997121	**89**	0.994077	**138**	0.990978	**187**	0.987885	**236**	0.984079
41	0.997019	**90**	0.994035	**139**	0.990936	**188**	0.987885	**237**	0.984015
42	0.996946	**91**	0.994008	**140**	0.990901	**189**	0.987856	**238**	0.984015
43	0.996916	**92**	0.993866	**141**	0.990901	**190**	0.987856	**239**	0.984015
44	0.996849	**93**	0.993831	**142**	0.990811	**191**	0.987856	**240**	0.984015
45	0.996849	**94**	0.993807	**143**	0.990739	**192**	0.987856	**241**	0.983835
46	0.996820	**95**	0.993715	**144**	0.990595	**193**	0.987856	**242**	0.983835
47	0.996780	96	0.993308	**145**	0.990595	**194**	0.987608	**243**	0.983792
48	0.996731	**97**	0.993220	**146**	0.990540	**195**	0.987359	**244**	0.983753

Table 10-8: Baseline Waiting List Survival ($S_{WL}(t)$) Probability (Continued)

Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$
245	0.983753	**269**	0.982960	**293**	0.981827	**317**	0.980218	**341**	0.978597
246	0.983753	**270**	0.982960	**294**	0.981827	**318**	0.980129	**342**	0.978597
247	0.983697	**271**	0.982797	**295**	0.981573	**319**	0.980129	**343**	0.978301
248	0.983636	**272**	0.982797	**296**	0.981319	**320**	0.980016	**344**	0.978250
249	0.983636	**273**	0.982797	**297**	0.980775	**321**	0.980016	**345**	0.978250
250	0.983636	**274**	0.982797	**298**	0.980775	**322**	0.980016	**346**	0.978250
251	0.983636	**275**	0.982700	**299**	0.980519	**323**	0.979773	**347**	0.978117
252	0.983243	**276**	0.982603	**300**	0.980397	**324**	0.979773	**348**	0.978037
253	0.983243	**277**	0.982603	**301**	0.980397	**325**	0.979671	**349**	0.978037
254	0.983243	**278**	0.982511	**302**	0.980397	**326**	0.979671	**350**	0.978037
255	0.983097	**279**	0.982457	**303**	0.980397	**327**	0.979164	**351**	0.978037
256	0.983097	**280**	0.982457	**304**	0.980397	**328**	0.979164	**352**	0.977937
257	0.983097	**281**	0.982457	**305**	0.980397	**329**	0.979164	**353**	0.977937
258	0.983097	**282**	0.982413	**306**	0.980397	**330**	0.979164	**354**	0.977937
259	0.983097	**283**	0.982323	**307**	0.980339	**331**	0.979100	**355**	0.977855
260	0.983097	**284**	0.982323	**308**	0.980339	**332**	0.979100	**356**	0.977855
261	0.983097	**285**	0.982323	**309**	0.980339	**333**	0.978935	**357**	0.977855
262	0.983052	**286**	0.982323	**310**	0.980339	**334**	0.978935	**358**	0.977710
263	0.983052	**287**	0.982323	**311**	0.980339	**335**	0.978817	**359**	0.977710
264	0.983052	**288**	0.982323	**312**	0.980339	**336**	0.978817	**360**	0.976881
265	0.983052	**289**	0.982323	**313**	0.980339	**337**	0.978817	**361**	0.976881
266	0.983052	**290**	0.982323	**314**	0.980339	**338**	0.978817	**362**	0.976881
267	0.983052	**291**	0.981916	**315**	0.980218	**339**	0.978817	**363**	0.976709
268	0.982960	**292**	0.981878	**316**	0.980218	**340**	0.978817	**364**	0.976709

Table 10-9: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability

Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$
0	1.000000	**48**	0.981882	**97**	0.972415	**146**	0.965165	**195**	0.958585
0	0.998946	**49**	0.981394	**98**	0.972415	**147**	0.965018	**196**	0.958585
1	0.997558	**50**	0.981115	**99**	0.972128	**148**	0.965018	**197**	0.958511
2	0.996895	**51**	0.980836	**100**	0.971984	**149**	0.964724	**198**	0.958361
3	0.996364	**52**	0.980416	**101**	0.971769	**150**	0.964651	**199**	0.958062
4	0.995498	**53**	0.980207	**102**	0.971697	**151**	0.964504	**200**	0.958062
5	0.995165	**54**	0.980137	**103**	0.971553	**152**	0.964357	**201**	0.957987
6	0.994565	**55**	0.979926	**104**	0.971337	**153**	0.964063	**202**	0.957987
7	0.994164	**56**	0.979646	**105**	0.971265	**154**	0.963843	**203**	0.957913
8	0.993963	**57**	0.979436	**106**	0.971193	**155**	0.963696	**204**	0.957763
9	0.993360	**58**	0.979085	**107**	0.971121	**156**	0.963475	**205**	0.957613
10	0.993159	**59**	0.978874	**108**	0.971049	**157**	0.963328	**206**	0.957538
11	0.992487	**60**	0.978733	**109**	0.970977	**158**	0.963107	**207**	0.957388
12	0.992353	**61**	0.978452	**110**	0.970761	**159**	0.962738	**208**	0.957313
13	0.991949	**62**	0.978382	**111**	0.970689	**160**	0.962517	**209**	0.957238
14	0.991679	**63**	0.978170	**112**	0.970617	**161**	0.962443	**210**	0.957163
15	0.991207	**64**	0.978100	**113**	0.970545	**162**	0.962296	**211**	0.957163
16	0.990531	**65**	0.977959	**114**	0.970473	**163**	0.962074	**212**	0.956938
17	0.990260	**66**	0.977818	**115**	0.970329	**164**	0.961927	**213**	0.956863
18	0.989921	**67**	0.977818	**116**	0.969968	**165**	0.961705	**214**	0.956788
19	0.989582	**68**	0.977536	**117**	0.969824	**166**	0.961631	**215**	0.956713
20	0.989514	**69**	0.977254	**118**	0.969679	**167**	0.961557	**216**	0.956638
21	0.988902	**70**	0.977042	**119**	0.969607	**168**	0.961483	**217**	0.956488
22	0.988220	**71**	0.976971	**120**	0.969390	**169**	0.961483	**218**	0.956263
23	0.987810	**72**	0.976901	**121**	0.969101	**170**	0.961409	**219**	0.956263
24	0.987469	**73**	0.976759	**122**	0.968956	**171**	0.961113	**220**	0.956187
25	0.987263	**74**	0.976547	**123**	0.968667	**172**	0.961113	**221**	0.956112
26	0.987058	**75**	0.976476	**124**	0.968594	**173**	0.961039	**222**	0.956037
27	0.986578	**76**	0.976193	**125**	0.968377	**174**	0.960965	**223**	0.955887
28	0.986304	**77**	0.975909	**126**	0.968159	**175**	0.960891	**224**	0.955736
29	0.986030	**78**	0.975767	**127**	0.968086	**176**	0.960743	**225**	0.955736
30	0.985961	**79**	0.975625	**128**	0.967868	**177**	0.960595	**226**	0.955736
31	0.985755	**80**	0.975483	**129**	0.967796	**178**	0.960446	**227**	0.955661
32	0.985480	**81**	0.975483	**130**	0.967504	**179**	0.960446	**228**	0.955661
33	0.985136	**82**	0.975483	**131**	0.967359	**180**	0.960372	**229**	0.955510
34	0.984929	**83**	0.974985	**132**	0.967140	**181**	0.960298	**230**	0.955510
35	0.984515	**84**	0.974985	**133**	0.967140	**182**	0.960149	**231**	0.955209
36	0.984446	**85**	0.974700	**134**	0.966994	**183**	0.960075	**232**	0.955209
37	0.984170	**86**	0.974700	**135**	0.966702	**184**	0.959852	**233**	0.955134
38	0.983825	**87**	0.974415	**136**	0.966483	**185**	0.959778	**234**	0.954983
39	0.983479	**88**	0.973987	**137**	0.966483	**186**	0.959703	**235**	0.954832
40	0.983202	**89**	0.973845	**138**	0.966410	**187**	0.959629	**236**	0.954681
41	0.983063	**90**	0.973630	**139**	0.966263	**188**	0.959554	**237**	0.954530
42	0.982855	**91**	0.973416	**140**	0.966190	**189**	0.959480	**238**	0.954455
43	0.982716	**92**	0.973416	**141**	0.966190	**190**	0.959256	**239**	0.954228
44	0.982578	**93**	0.973202	**142**	0.965971	**191**	0.959107	**240**	0.954228
45	0.982300	**94**	0.973059	**143**	0.965751	**192**	0.959033	**241**	0.954077
46	0.982160	**95**	0.972916	**144**	0.965678	**193**	0.959033	**242**	0.954077
47	0.981952	**96**	0.972629	**145**	0.965311	**194**	0.958735	**243**	0.953925

Table 10-9: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability (Continued)

Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$
244	0.953850	**269**	0.951190	**293**	0.948589	**317**	0.946359	**341**	0.943729
245	0.953850	**270**	0.950961	**294**	0.948359	**318**	0.946359	**342**	0.943651
246	0.953774	**271**	0.950656	**295**	0.948282	**319**	0.946204	**343**	0.943573
247	0.953774	**272**	0.950579	**296**	0.948128	**320**	0.946204	**344**	0.943418
248	0.953698	**273**	0.950427	**297**	0.948052	**321**	0.946127	**345**	0.943341
249	0.953623	**274**	0.950274	**298**	0.947975	**322**	0.946050	**346**	0.943108
250	0.953395	**275**	0.950121	**299**	0.947821	**323**	0.946050	**347**	0.943030
251	0.953319	**276**	0.950121	**300**	0.947667	**324**	0.945896	**348**	0.943030
252	0.953016	**277**	0.949815	**301**	0.947667	**325**	0.945818	**349**	0.942952
253	0.953016	**278**	0.949662	**302**	0.947360	**326**	0.945587	**350**	0.942719
254	0.952712	**279**	0.949662	**303**	0.947360	**327**	0.945432	**351**	0.942719
255	0.952712	**280**	0.949585	**304**	0.947360	**328**	0.945432	**352**	0.942719
256	0.952712	**281**	0.949585	**305**	0.947360	**329**	0.945355	**353**	0.942641
257	0.952484	**282**	0.949432	**306**	0.947283	**330**	0.945278	**354**	0.942485
258	0.952408	**283**	0.949355	**307**	0.947283	**331**	0.945123	**355**	0.942485
259	0.952332	**284**	0.949279	**308**	0.947206	**332**	0.945123	**356**	0.942173
260	0.952256	**285**	0.949279	**309**	0.947129	**333**	0.944968	**357**	0.942017
261	0.952180	**286**	0.949202	**310**	0.946975	**334**	0.944891	**358**	0.941783
262	0.952104	**287**	0.949202	**311**	0.946821	**335**	0.944736	**359**	0.941705
263	0.951876	**288**	0.949126	**312**	0.946821	**336**	0.944581	**360**	0.941627
264	0.951800	**289**	0.949049	**313**	0.946821	**337**	0.944504	**361**	0.941549
265	0.951648	**290**	0.948896	**314**	0.946744	**338**	0.944194	**362**	0.941549
266	0.951648	**291**	0.948819	**315**	0.946590	**339**	0.944039	**363**	0.941315
267	0.951572	**292**	0.948819	**316**	0.946436	**340**	0.943961	**364**	0.941315
268	0.951495								

History

Policy 3.7: Allocation of Thoracic Organs: 3/22/2007; 12/18/2007; 6/20/2008; 6/23/2009; 10/23/2009; 11/17/2009; 11/9/2010; 6/29/2011; 11/15/2011; 6/26/2012; 11/13/2012; 5/1/2013

Policy 10: Allocation of Lungs:

Notes

- For membership and personnel requirements for lung programs, see the *OPTN Bylaws, Appendix I*.

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

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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 Points (3.8.7.2)

No allocation priority is assigned to pancreas, kidney-pancreas, or islet candidates based on points.

11.3 Waiting List Registration

11.3.A Pancreas Registration (3.8.1.1)

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 (3.8.1.3)

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 (3.8.7.1)

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.

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If a candidate's clinical condition changes and the candidate becomes inactive, the transplant hospital must report this to the OPTN Contractor 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 every six months 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. The test date and results must be documented in the candidate's medical record.

11.4 Waiting Time (3.8.1, 3.8.6)

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 (3.8.1.4.1)

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 (3.8.1.4, 3.8.4.3)

To accrue waiting time for a kidney-pancreas transplant, a kidney-pancreas candidate, who is at least 18 years old at the time of kidney-pancreas registration, must meet *all* of the following conditions:

1. Qualify for a kidney transplant according to *Policy 8.4: Waiting Time.*

2. Meet *one* of the following criteria:
   a. Is on insulin and C-peptide less than or equal to 2 ng/mL
   b. Is on insulin and C-peptide greater than 2 ng/mL and has a body mass index (BMI) less than or equal to the maximum allowable BMI.

      The maximum allowable BMI, for accruing waiting time, for a kidney-pancreas candidate, who is at least 18 years old at the time of kidney-pancreas registration, is 28 kg/m^2. Every six months, the OPTN Contractor will determine the percent of kidney-pancreas candidates that meet criterion 2.b above. The OPTN Contractor will then modify the maximum allowable BMI according to *Table 11-1* below.:

Table 11-1: Maximum Allowable BMI

If the percent of active kidney-pancreas candidates that meet criterion 2.b:	Then the OPTN Contractor will:
Is greater than 15% nationally	Reduce the maximum allowable BMI by 2 kg/m^2

If the percent of active kidney-pancreas candidates that meet criterion 2.b:	Then the OPTN Contractor will:
Is less than 10% nationally	Increase the maximum allowable BMI by 2 kg/m^2

The OPTN Contractor may not modify the maximum allowable BMI to exceed 30 kg/m^2. If the OPTN Contractor modifies the maximum allowable BMI, it must publish the modification and notify all kidney programs and pancreas programs.

Once a kidney-pancreas candidate qualifies for waiting time, the candidate will remain qualified for waiting time regardless of any changes to the maximum allowable BMI.

For candidates who qualify for kidney-pancreas waiting time, waiting time will begin when the candidate qualifies for waiting time according to this Policy. Transplant programs must document when and how a kidney-pancreas candidate qualified for waiting time.

11.4.C Islet Waiting Time Criteria (3.8.4.3, 3.8.7.2)

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 Multi-Organ Candidates (3.8.5, 3.8.5.1, 3.8.5.2)

The OPTN Contractor may assign multi-organ candidates waiting time from one waiting list to another waiting list according to *Table 11-2* below.

Table 11-2: 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	Pancreas Islets; if criteria in *Policy 11.4.D.i* below are met.
Pancreas Islets	Pancreas; if criteria in *Policy 11.4.D.ii* below are met.

Waiting time accrued by an isolated pancreas candidate or a pancreas 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*.

Additionally, a kidney-pancreas candidate who received a kidney transplant and subsequently registered on the pancreas or pancreas 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 (3.8.5.2)

Waiting time accrued by an isolated pancreas transplant candidate while registered on the waiting list will be assigned to the registration for pancreatic islet cell transplant after consideration and approval of a request for transfer by the OPTN/UNOS 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 (3.8.5.2)

Waiting time accrued by a islet cell 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/UNOS 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 (3.8.3.3, 3.8.3.6)

11.5.A Kidney-Pancreas Allocation Order (3.8.3.1)

If a host OPO has both a kidney and a pancreas to offer for allocation, then the host OPO must offer the kidney and pancreas in the following order:

1. The host OPO must offer the kidney and pancreas according to classifications 1–5 in *Tables 11-4: 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 *11-5: Allocation of Kidneys and Pancreas from Donors more than 50 Years Old or with a BMI greater than 30 kg/m*.

2. Then, the host OPO may do *either*:
   a. Continue to offer the kidney and pancreas according to the remaining classifications in Table 11-4.
   b. Offer the pancreas to pancreas and islet candidates, but not kidney-pancreas candidates, according to the remaining classifications *Table 11-4* 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.

11.5.B Pancreas Allocation When a Kidney is Unavailable (3.8.3.1)

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 11-4: 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 *11-5: 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 (3.8.3.5)

Any pancreas that will be shared as zero antigen mismatches, either alone or in combination with kidneys, must be offered within eight hours after procurement.

If there are at least 10 zero antigen mismatched potential recipients on the match run, the pancreas must be offered to the first 10 zero antigen mismatched potential recipients. If there are less than 10 zero antigen mismatched potential recipients, the pancreas must be offered to all zero antigen mismatched potential recipients.

If these offers are not accepted then the Host OPO must:

- Allocate the organ according to the match run under *Policy 8.5: Kidney Allocation Classifications and Rankings* and allocate the pancreas according to *Policy 11.5: Pancreas, Kidney-Pancreas, and Islet Allocation Classifications and Rankings*.
- Allocate the organ for the remaining zero antigen mismatched potential recipients.

11.5.D Blood Type for Kidney-Pancreas Allocation (3.8.3.2, 3.8.4.2)

Within each classification, kidney-pancreas will be allocated to candidates according to the blood type matching requirements in *Table 11-3* below:

11-3: Allocation of Kidney-Pancreas by Blood Type

Kidney-Pancreas from Deceased Donors with:	Are Allocated to Candidates with:
Blood Type O	Blood type O
Blood Type O	Blood type A, B, or AB if the candidate has a zero antigen 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 (3.8.3.4)

Within each allocation classification, pancreas, kidney-pancreas, and islet candidates are sorted based on waiting time (longest to shortest).

11.5.F Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m2 (3.8.3.3)

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 11-4* based on waiting time.

Table 11-4: 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 within the:	And are:
1	OPO's DSA	Zero antigen mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates
2	OPO's DSA	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates
3	OPO's region	Zero antigen mismatch, CPRA greater than or equal to 80%, and are either pancreas or kidney-pancreas candidates
4	Nation	Zero antigen mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates
5	OPO's DSA	Pancreas or kidney-pancreas candidates
6	OPO's region	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates
7	OPO's region	Pancreas or kidney-pancreas candidates
8	Nation	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates
9	Nation	Pancreas or kidney-pancreas candidates
10	OPO's DSA	Islet candidates
11	OPO's Region	Islet candidates
12	Nation	Islet candidates

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 11-5* based on waiting time.

Table 11-5: 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 within the:	And are:
1	OPO's DSA	Zero antigen mismatch, CPRA greater than or equal

Classification	Candidates that are within the:	And are:
		to 80%, and either pancreas or kidney-pancreas candidates
2	OPO's DSA	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates
3	OPO's region	Zero antigen mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates
4	Nation	Zero antigen mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates
5	OPO's DSA	Pancreas or kidney-pancreas candidates
6	OPO's DSA	Islet candidates
7	OPO's region	Islet candidates
8	Nation	Islet candidates
9	OPO's region	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates
10	OPO's region	Pancreas or kidney-pancreas candidates
11	Nation	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates
12	Nation	Pancreas or kidney-pancreas candidates

11.6 Reallocation of Unsuitable Islets (3.8.7.3, 3.8.7.4)

Islets must be allocated to the most medically suitable candidate based on the transplant hospital's Investigational New Drug (IND) application, as approved by the United States Food and Drug Administration (FDA). After islet processing is completed, the transplant hospital must determine and document *both*:

1. Whether the islet preparation meets the transplant hospital'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 hospital must document the reason the islets were determined to be medically unsuitable for the candidate.

If the transplant hospital determines that the islets are medically unsuitable for the candidate, the transplant hospital 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 hospital covered by the same IND
3. The candidate's waiting time (ranked longest to shortest)

The transplant hospital that reallocates the islets must document that it followed this Policy.

11.7 Administrative Rules

11.7.A Facilitated Pancreas Allocation (3.8.3.4)

The OPO can use facilitated pancreas allocation to allocate a pancreas if *either* occurs:

- No candidate accepts a pancreas offer from the Organ Center within five hours of the first offer
- The Organ Center is notified that procurement of the pancreas will occur within one hour

The Organ Center must then offer the pancreas to pancreas candidates in the order of the match run who meet *both* of the following criteria:

1. Have not previously received an offer for that pancreas.
2. Are registered at a transplant hospital that previously agreed to accept any pancreas offered using the facilitated pancreas allocation and that may have been procured outside of the transplant hospital's DSA. The transplant hospital must document this agreement in writing.

History

Policy 3.8: Pancreas Allocation: 6/20/2008; 3/3/2009; 11/9/2010; 11/15/2011
Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets:

Notes

- For membership requirements for pancreas and islet transplant programs, see *OPTN Bylaws Appendix G*.
- For potential pancreas donor testing requirements, see *Policy 2.3: Evaluating and Screening Potential Deceased Donors*.
- For pancreas acceptance criteria, see *Policy 5: Organ Offers, Acceptance, and Verification*.

Policy 12:

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Policy 13: Kidney Paired Donation (KPD)

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13.1 Candidate Requirements for Participation (13.2.1)

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 (13.2.2)

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 Candidates

Reserved

13.4 Informed Consent for Potential Donors

Reserved

13.5 Histocompatibility Testing

Reserved

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13.6 Matching within the OPTN KPD Program (13.6)

13.6.A Requirements for Match Run Eligibility for Candidates (13.6.1)

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 *5.5.A: Receiving and Reviewing Organ Offers* and *5.5.D: Blood Type Verification upon Receipt*
2. The candidate's transplant hospital must complete the informed consent process according to KPD Operational Guidelines
3. The candidate's transplant hospital must submit *all* the information for these required fields to the OPTN Contractor:

    a. Candidate details, including *all* of the following:
    - Last name
    - First name
    - SSN
    - Date of birth
    - Gender
    - Ethnicity/Race
    - ABO
    - Whether the candidate has signed an agreement to participate in the OPTN KPD program
    - Whether the candidate has signed a release of protected health information
    - Whether the candidate is a prior living donor
    - KPD status

    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
    - 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 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

4. The candidate must have current active status in the OPTN KPD program
5. The candidate must have at least one active and eligible potential KPD donor registered in the OPTN KPD program
6. The candidate's transplant hospital must submit a response for all previous match offers for the candidate in the OPTN KPD program
7. 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 (13.6.2)

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 14.4.A: Living Donor Blood type Determination* 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. Someone, other than the person who 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 actual 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 KPD Operational Guidelines
3. The transplant hospital registering the potential KPD donor must complete the medical 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/Race
        - ABO
        - Height and weight
        - Whether the potential KPD donor is a non-directed donor or a paired donor
        - If the potential KPD donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential KPD donor's relationship to the candidate
        - Whether the potential KPD donor has signed an agreement to participate in the OPTN KPD program
        - Whether the potential KPD donor has signed a release of protected health information
        - Whether the potential KPD donor has signed an informed consent as required in policy
        - Whether the potential KPD donor has undergone a medical evaluation as required in *Policy 14: Living Donation*
        - Whether the potential KPD donor has had all age appropriate cancer screenings as defined by the American Cancer Society

- KPD status

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, 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
   - 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

5. The potential KPD donor must have current active status in the OPTN KPD program
6. The potential KPD donor must be paired to an active and eligible candidate registered in the OPTN KPD program
7. 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
8. The potential KPD donor must not be in a pending exchange in the OPTN KPD program

13.7 KPD Screening Criteria (13.6.3)

13.7.A Blood Type (13.6.3.1)

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: Liver Allocation by Blood Type

Donors with:	Are Matched to Candidates with:
Blood Type O	Blood type O Blood types A, A_1, A_2, B, AB, A_1B, or A_2B
Blood Type A	Blood types A, A_1, A_2 Blood types AB, A_1B, or A_2B
Blood Type A_1	Blood types A, A_1, A_2 Blood types AB, A_1B, or A_2B
Blood Type A_2	Blood types A, A_1, A_2 Blood types AB, A_1B, or A_2B Blood type O or B if the candidate meets the requirements in *Policy 13.7.B: A_2 and*

Donors with:	Are Matched to Candidates with:
	A_2B Matching.
Blood Type B	Blood type B Blood types AB, A_1B, or A_2B
Blood Type AB	Blood types AB, A_1B, or A_2B
Blood Type A_1B	Blood types AB, A_1B, or A_2B
Blood Type A_2B	Blood types AB, A_1B, or A_2B Blood type B if the candidate meets the requirements in *Policy 13.7.B: A_2 and A_2B Matching*.

13.7.B A_2 and A_2B Matching (13.6.3.2)

In order for a blood type B candidate to be eligible to be matched to a blood type A_2 or A_2B potential donor, or for a blood type O candidate to be eligible to match to a blood type A_2 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 (13.6.3.3)

A transplant hospital may specify any unacceptable antigens it will not accept for its candidates. The OPTN Contractor will not match the 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 (13.6.3.4)

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 Prioritization Points (13.6.4)

Reserved

13.8 Two- and Three-Way Matches (13.6.5)

13.8.A Match Size (13.6.5.1)

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 (13.6.5.2)

In two-way or three-way exchanges in the OPTN KPD program, all KPD donor surgeries involved in the exchange must begin on the same day and only after all donor surgeons involved in the

exchange agree to proceed.

13.9 Donor Chains (13.6.6)

13.9.A Chain Size (13.6.6.1)

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

13.9.B Logistical Requirements (13.6.6.2)

In KPD donor chains in the OPTN KPD program, surgeries may or may not occur simultaneously. A KPD candidate will receive a kidney before or the same day his paired KPD donor donates. A KPD candidate-donor pair will always have the option to have surgery on the same day. KPD donor surgeries must be scheduled to occur within 3 weeks of the day the paired candidate receives a transplant.

A chain must end with a donation to a KPD candidate on the deceased donor waiting list at the transplant hospital that entered the non-directed donor (NDD) that started that chain or with a KPD bridge donor who will be included in a later match run. The transplant hospital that enters the NDD can choose whether the chain can end with a bridge donor or a donation to the deceased donor waitlist. The transplant hospital registering the potential KPD donor may refuse to allow the potential KPD donor to serve as a bridge donor at any point in the process.

13.9.C What to Do When a Chain Breaks (13.6.6.3)

In the OPTN KPD program, a donor chain will proceed until a KPD candidate or KPD potential donor refuses a match offer.

If a KPD candidate or potential KPD donor in a chain refuses a match offer, then the chain's last donor, who is in a match that has been accepted before a KPD candidate or potential KPD donor refuses a match, may donate to the deceased donor waiting list or may be a bridge donor as outlined in *Policy 13.9.B: Logistical Requirements*.

13.10 Crossmatching Protocol (13.7)

The KPD candidate's transplant hospital must perform a preliminary crossmatch for candidates in the OPTN KPD program before the matched KPD donor's recovery procedure.

The transplant hospital registering the potential KPD donor is responsible for arranging shipment of the potential KPD donor's blood sample to the matched candidate's transplant hospital or the laboratory specified by the matched candidate's transplant hospital.

The KPD candidate's transplant hospital is responsible for performing the crossmatch and reporting the results to the OPTN Contractor and the matched KPD donor's transplant hospital.

13.11 Transportation of Kidneys (13.8)

For any KPD exchange, the recovery hospital is responsible for packaging, labeling, and transporting kidneys from donors according to *Policy 16.2: 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.

13.12 OPTN Member Facilitated Donors and Recipients Engagement (13.9)

The following rules apply to engagement facilitated by an OPTN member 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 engagement such as meeting; correspondence via email, phone or anonymous letter writing between KPD donors and 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 engagement agree on conditions of the meeting or correspondence.
2. The meeting occurs after the donor kidney recovery and transplant surgeries have been completed.
3. The transplant hospital establishes and implements a written protocol for when KPD donors and recipients can engage. This protocol must include, at a minimum, the timing of the meeting and what staff must attend the meeting. Separate requirements must be written for exchanges occurring at the same hospitals versus different hospitals.
4. Transplant hospital complies with the written protocol for when KPD donors and recipients can engage. The transplant hospital must maintain documentation of compliance in the KPD donor's or recipient's medical record.

History

Policy 13: Kidney Paired Donation: 11/13/2012

Policy 14: Living Donation

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14.1 Required Protocols for Recovery Hospitals

14.1.A Required Protocols for Kidney Recovery Hospitals (12.10)

Kidney recovery hospitals must develop and comply with written protocols to address all phases of the living donation process.

14.1.B Required Protocols for Liver Recovery Hospitals (12.11)

Liver recovery hospitals must develop and comply with written protocols to address all phases of the living donation process. Specific protocols must include the evaluation, pre-operative, operative, and post-operative care, and submission of required follow-up forms at 6 months, one-year, and two-years post-donation.

Liver recovery hospitals must document that all phases of the living donation process were performed in adherence to the hospital's protocols. This documentation must be maintained by the recovery hospital.

14.2 Independent Living Donor Advocate (ILDA) Requirements

14.2.A ILDA Requirements for Kidney Recovery Hospitals (12.4, 12.4.1)

The living kidney donor recovery hospital must provide each potential 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 must assist the potential living kidney donor with the evaluation process, focusing on the living donor's needs and questions. The ILDA must be knowledgeable about the risks and benefits associated with all phases of the donation process. The ILDA's responsibilities include, but are not limited to, *all* the following:

1. Promoting the best interests of the potential living donor
2. Advocating for the rights of the potential living donor
3. Assisting the potential living donor in obtaining and understanding information about the:
   a. Consent process

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b. Evaluation process
c. Surgical procedure
d. Medical risks
e. Psychosocial risks
f. Benefit of follow-up
g. Need for follow-up

14.2.B ILDA Required Protocols for Liver Recovery Hospitals (12.11)

Liver recovery hospitals must develop and comply with written protocols for the duties and responsibilities of the ILDA that include, but are not limited to, *all* the following elements:

1. Promoting the best interests of the potential living donor
2. Advocating for the rights of the living donor
3. Assisting the potential donor in obtaining and understanding information about the:
   a. Consent process
   b. Evaluation process
   c. Surgical procedure
   d. Benefit of follow-up
   e. Need for follow-up

14.3 Informed Consent Requirements (12.2)

Education is important so that the potential living donor understands all aspects of the donation process, especially the risks and benefits.

14.3.A Informed Consent of Living Kidney Donors (12.2)

Informed consent is required to ensure that a potential living kidney donor understands:

1. That the living donor will undertake risk and will receive no medical benefit from donating a kidney.
2. That there are both the general risks of the surgery as well as hospital-specific risks.

14.3.A.i Living Kidney Donor Informed Consent Requirements (12.2)

The kidney recovery hospital must obtain informed consent from any potential living kidney donor that must include written assurance by the potential living donor of *all* of the following:

1. That the potential donor is willing to donate
2. That the potential donor is free from inducement and coercion.
3. That the potential donor has been informed that the potential living donor may decline to donate at any time.

The potential living donors must be offered an opportunity to stop the donor consent or evaluation process and to do so in a way that is protected and confidential. The ILDA must be available to assist the potential living donor during this process, according to *Policy 14.2*.

The kidney recovery hospital must document in the potential donor's medical record that the hospital provided the potential donor with *all* of the following:

1. Instruction about all phases of the living donation process, including consent, medical, and psychosocial evaluations, pre- and post-operative care, and required post-operative follow-up according to *Policy 18.5: Living Donor*. Teaching or instructional material may include any media, or one-on-one or small group interaction. Teaching or instruction must be provided in a language in which the potential living donor is able to engage in a meaningful dialogue with the transplant program recovery hospital's staff.
2. The disclosure that the recovery hospital will take all reasonable precautions to maintain confidentiality for the potential living donor and recipient.
3. 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.
4. Disclosure that the recovery hospitals must provide an ILDA.
5. The transplant recipient outcome and transplanted kidney survival data according to *Table 14-1* that follows:

Table 14-1: Required Recipient Outcome and Transplanted Kidney Survival Data

If the recovery hospital and the recipient hospital:	Then:	Including *all* the following information:
Are the same	The recovery hospital must provide the potential living donor with both national and that hospital's program-specific transplant recipient outcomes from the most recent SRTR hospital-specific reports.	1. National 1-year patient and transplanted kidney survival 2. The hospital's 1-year patient and transplanted kidney survival 3. Notification about all CMS outcome requirements not being met by the transplant hospital
Will not be the same and the recipient hospital is known	The recovery hospital must provide the potential living donor with both national and the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR hospital-specific reports.	1. National 1-year patient and transplanted kidney survival 2. The recipient hospital's 1-year patient and transplanted kidney survival 3. Notification about all CMS outcome requirements not being met by the recipient hospital

6. Education about expected post-donation kidney function, and how impact of chronic kidney disease (CKD),), and end-stage renal disease (ESRD) on the potential living donor, that includes the following: might potentially impact the living donor in the future, to include:

    a. On average, living donors may have a 25-35% permanent loss of kidney function at after donation.
    b. Baseline risk of ESRD for prior living kidney donors does not exceed that of the general population with the same demographic profile.

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 potential 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 when reaching if the donor develops ESRD.
f. Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to *Policy 8.3: Points* if they become kidney transplant candidates.

7. The disclosure of alternate procedures or courses of treatment for the recipient, including deceased donor transplantation, and that:

   a. A deceased donor kidney might become available for the recipient before the recovery hospital completes the potential living donor's evaluation is completed or the living donor transplant occurs.
   b. Any transplant candidate might have risk factors for increased morbidity or mortality that are not disclosed to the potential living donor.

8. The disclosure that the potential living donor will receive a thorough medical and psychosocial evaluation.

9. The disclosure that health information obtained during the potential living donor's evaluation will be subject to the same regulations as all medical records and could reveal conditions that the transplant hospital must report to local, state, or federal public health authorities.

10. The disclosure that recovery hospitals are required to:

    a. Report living donor follow-up information, at the time intervals specified in *Policy 18.5: Living Donor*.
    b. Have the potential living donor commit to post-operative follow-up testing coordinated by the living donor recovery hospital.

11. The disclosure that any infectious disease or malignancy pertinent to acute recipient care discovered during the potential living donor's first two years of post-operative follow-up care:

    a. Will be disclosed to the living donor
    b. May need to be reported to local, state or federal public health authorities
    c. Will be disclosed to the recipient's transplant hospital
    d. Will be reported to the OPTN Improving Patient Safety Portal.

14.3.A.ii Living Kidney Donor Informed Consent for Evaluation of Potential Living Donors (12.2.1)

The kidney recovery hospital must maintain documentation in the living donor's medical record that it the recovery hospital informed the potential living donor of *all* of the following:

1. That the potential living donor must undergo a medical evaluation according to *Policy 14.4* and psychosocial evaluation as required in *Policy 14.5*.

2. That the recovery hospital may refuse the potential living donor. In such cases, the recovery hospital must inform the potential living donor that a different recovery hospital may evaluate the potential living donor using different selection criteria.

3. That the following are inherent risks to the potential living donor 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 potential donor
    e. Discovery of certain abnormalities that may require more testing at the potential living donor's expense or may create the need for unexpected decisions on the part of the transplant team

4. That the following surgical, medical, psychosocial, and financial risks are associated with living kidney donation. This disclosure must state that these risks 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, pain, fatigue, and other consequences typical of any surgical procedure
        iii. Decreased kidney function
        iv. Abdominal symptoms such as bloating, nausea, and developing bowel obstruction
        v. Kidney failure and the need for dialysis or kidney transplant for the donor
        vi. Obesity, hypertension, or other donor-specific medical conditions may impact morbidity and mortality of the potential donor

    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 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 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

14.3.B Living Liver Donor Required Protocols for Informed Consent for Evaluation (12.11)

Liver recovery hospitals must develop and comply with written protocols for the informed consent process and for the living donor liver recovery that must include, but are not limited to, *all* the following elements:

1. A discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor.
2. The assurance that all communication between the potential living donor and the transplant hospital will remain confidential.
3. A discussion of the potential living donor's right to opt out at any time during the donation process.
4. A discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance.
5. The disclosure by the liver recovery hospital that it is required, at a minimum, to submit *Living Donor Follow-up* forms addressing the health information of each living donor at 6 months, one -year, and two -years post donation. .
6. A plan to collect the required follow-up information about each donor.
7. Providing the toll-free Patient Services Line that is available for living donors to report concerns or grievances to the OPTN.
8. 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. This documentation must be maintained in the potential donor's official medical record.

14.4 Medical Evaluation Requirements for Living Donors (12.3)

14.4.A Living Donor Blood type Determination (12.3.1)

The recovery hospital must ensure that blood typing of each living donor is performed on two separate occasions before the recovery. Two separate occasions are defined as two blood samples taken at different times, and sent to the same or different laboratories.

14.4.A.i Living Donor Blood Subtype Determination (12.3.2)

The recovery hospital subtyping a living donor whose initial subtype test indicates the donor to be non-A_1 (negative for A_1) or non-A_1B (negative for A_1B), must ensure a second determination test is performed prior to living donation to assess the accuracy of the result. Blood samples for subtype testing must be taken on two separate occasions, defined as two samples taken at different times. Samples tested must not be taken after a blood transfusion. When the initial and second determination subtypings are the same result, the result can be used to determine transplant compatibility with the intended recipient or any other potential recipient. If the initial and second determination subtyping results are not the same, the donor must be allocated based on the primary blood type, A or AB.

14.4.B Living Kidney Donor Medical Evaluation Requirements (12.3.4)

A medical evaluation of the potential living kidney donor must be performed by the recovery hospital and by a physician or surgeon experienced in living donation. The goals of the medical evaluation are *all* of the following:

1. To assess the immunologic compatibility of the living donor to the recipient

2. To assess the general health and surgical risk of donation to the living donor including screening for conditions that may predict future complications from having only one kidney
3. To determine if there are diseases present that may be transmitted from the living donor to the recipient
4. To assess the anatomy and function of the living donor's kidneys

Documentation of the medical evaluation must be maintained in the donor medical record.

The medical evaluation must include *all* of the components in *Table 14-2* below.

Table 14-2: Requirements for Living Kidney Donor Medical Evaluations

This evaluation must be completed:	Including evaluation for and assessment of this information:
A general living 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 2. History of infections 3. A kidney-specific personal history including: a. Genetic renal diseases b. Kidney disease, protein uria, hematuria c. Kidney injury d. Diabetes including gestational diabetes e. Nephrolithiasis f. Recurrent urinary tract infections 4. Active and past medications with special consideration for known nephrotoxic medications 5. Allergies 6. An evaluation for coronary artery disease
General family history	The living donor's family history of coronary heart disease and cancer
Kidney-specific family history	The living donor's family history of: • Coronary heart disease and cancer • Kidney disease • Diabetes • Hypertension • Kidney Cancer

This evaluation must be completed:	Including evaluation for and assessment of this information:
Social history	The living donor's history of: • Occupation, employment status, health insurance status, living arrangements, and social support • Smoking, alcohol and drug use and abuse • High risk behavior as defined by the US PHS • Psychiatric illness, depression, suicide attempts
Physical Exam	A physical exam of the living donor including: • Height • Weight • BMI • Examination of all major organ systems • Blood pressure taken on at least two different occasions or 24-hour or overnight blood pressure monitoring
General laboratory tests	• Complete blood count (CBC) with platelet count • Blood type and screen • 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)
Other metabolic testing	• Fasting blood glucose • Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol) • Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high risk individuals

Kidney-specific tests	• Urinalysis or urine microscopy
	• Urine culture if clinically indicated
	• Measurement of urinary protein and albumin excretion
	• Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection
	• Hospitals must develop and comply with a protocol for polycystic kidney disease or other inherited renal disease as indicated by family history
	• Patients with a history of nephrolithiasis or nephrolithiasis (>3mm) 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 excretion

This evaluation must be completed:	Including evaluation for and assessment of this information:
Anatomic assessment	An assessment to 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. The choice of test for radiologic imaging may be determined based on the local radiological expertise and surgical preference, and may include CT angiogram or MR angiogram.
Transmissible disease screening	Infectious disease testing must include *all* the following: 1. CMV (Cytomegalovirus) antibody 2. EBV (Epstein Barr Virus) antibody 3. HIV 1,2 (Human Immunodeficiency Virus) antibody testing 4. HepBsAg (Hepatitis B surface antigen) 5. HepBcAB (Hepatitis B core antibody) 6. HepBsAB (Hepatitis B surface antibody) 7. HCV (Hepatitis C Virus) antibody testing 8. RPR (Rapid Plasma Reagin test for syphilis) Living donor recovery hospitals must determine if the potential donor is at increased risk for tuberculosis (TB) and if so testing must include screening for latent TB using either intradermal PPD or Interferon Gamma Release Assay (IGRA).
Endemic transmissible diseases	For the following infectious diseases, recovery hospitals must determine if the potential donor is from an endemic area, and if so must test for: • Strongyloides • Trypanosoma cruzi • West Nile
Cancer screening	Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) to screen for: • Cervical cancer • Breast cancer • Prostate cancer • Colon cancer • Skin cancer • Lung cancer

This evaluation must be completed:	Including evaluation for and assessment of this information:
Exclusion criteria	Kidney 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. Kidney 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 • Uncontrollable hypertension or history of hypertension with evidence of end stage organ damage • HIV • Diabetes • 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) • Diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality

14.4.C Required Medical Evaluation Protocols for Liver Recovery Hospitals (12.11)

Liver recovery hospitals must develop and comply with written protocols for the medical evaluation of potential living donors that must include, but are not limited to, *all* the following elements:

1. A thorough medical evaluation by a physician or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which must include a screen for any evidence of occult liver disease..
2. A psychosocial evaluation of the potential living donor by a psychiatrist, psychologist or social worker with experience in transplantation must be provided to assess decision making capacity, screen for any pre-existing psychiatric illness, and evaluate the potential living donor for signs of potential coercion to donate.
3. Screening for evidence of transmissible diseases such as cancers and infections.
4. A radiographic assessment to ensure adequate anatomy and volume of the donor and the remaining liver segment.

14.5 Psychosocial Evaluation Requirements for Living Donors

14.5.A Living Kidney Donor Psychosocial Evaluation Requirements (12.3.3)

This living kidney donor psychosocial evaluation must be performed by a psychiatrist, psychologist, or clinical social worker. Documentation of the psychosocial evaluation must be maintained in the living donor 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 to identify potential risks for poor psychosocial outcome
2. An evaluation for the presence of high-risk behaviors as defined by the US Public Health Service (PHS) that have the potential to increase the risk of disease transmission to the recipient
3. A review of the living donor's history of smoking, alcohol, and drug use, abuse, and dependency
4. The identification of factors that warrant educational or therapeutic intervention prior to the final donation decision
5. The determination that the potential 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 potential 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 potential donor has a realistic plan for donation and recovery, with social, emotional and financial support available as recommended
8. A review of the potential living donor's occupation, employment status, health insurance status, living arrangements, and social support
9. The determination that the potential living donor understands the potential financial implications of living donation

14.6 Registration and Blood Type Verification of Living Donors before Donation (12.8.1.1)

Recovery hospitals must use source documents from both an initial and second determination blood typings and subtypings (when used to determine transplant compatibility), to enter the living donor's blood type data on the *Living Donor Feedback Form*. Additionally, each living donor program must develop and comply with a protocol to verify that the living donor's blood type and type was correctly entered on *the Living Donor Feedback Form* with both the initial and second determination blood typing and subtyping source documents by an individual other than the person initially entering the donor's blood type data.

Recovery hospitals must document that each blood typing and subtyping entry was performed according to the program's protocol and must maintain this documentation.

14.7 Placement of Living Donor Organs (12.5, 12.5.1)

14.7.A Prospective Crossmatching prior to Kidney Placement (12.5.1.1)

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*.

14.7.B Placement of Non-directed Living Donor Organs Kidneys (12.5.6)

Prior to determining the placement of a non-directed living donor kidney, 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 kidney is allocated, the recovery hospital must document how the organ is allocated and the rationale for allocation.

This requirement does not apply to non-directed living kidney donors who consent to participate in a Kidney Paired Donation (KPD) arrangement.

14.7.C Transplant Hospital Acceptance of Living Donor Organs (12.6)

Transplant hospitals that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member recovery hospitals that are approved to perform living donor recovery for that organ type. If the OPTN does not have approval criteria for a living donor recovery hospital for a particular organ type, then transplant hospitals that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member transplant hospitals with current transplant program approval for that organ type.

14.8 Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials (12.7)

Recovery hospitals are responsible for packaging and labeling any living donor organs, tissue typing specimens, or vessels that are recovered from living donors according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage* when *either* of the following occurs:

- Living donor organs, tissue typing specimens, or vessels are recovered and must be transported outside the recovery hospital
- A living donor organ requires repackaging by a transplant hospital for transport outside the transplant hospital

14.8.A Living Donor Vessel Recovery and Transplant (12.7.10, 12.7.10.1)

A recovery hospital may only recover extra vessels for transplant if the living donor consents to the removal of extra vessels for transplant. The vessels from a living donor can only be used for the implantation or modification of a solid organ transplant for the original intended recipient.

14.8.B Living Donors Vessel Storage (12.7.10.2)

Any vessels recovered from living donors must be stored according to *Policy 16.7: Vessel Recovery, Transplant, and Storage.*

14.9 Reporting Requirements

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

History

Policy 12: Living Donation: 6/23/2009; 11/17/2009; 11/9/2010; 6/29/2011; 11/15/2011; 5/29/2012; 6/26/2012; 11/13/2012; 5/1/2013
Policy 14: Living Donation:

Notes

- For priority given for prior living kidney donors on the waiting list, see *Policy 8.3: Points.*
- For membership and personnel requirements for kidney program that perform living donor recoveries, see *Bylaws, Appendix E, Section E.5.*
- For membership and personnel requirements for liver program that perform living donor recoveries, see *Bylaws, Appendix F, Section F.6*.
- For requirements regarding data reporting of living donors, see *Policy 18: Data Submission Requirements*.
- For requirements regarding living donor mechanisms, see *42 USC § 273a*.
- For reporting requirements regarding the long-term health effects of living organ donor, see *42 USC § 273b*.
- For reimbursement of travel and subsistence expenses incurred toward living organ donation, see *42 USC § 274f*.
- For Scientific Registry of Transplant Recipients reports, see www.srtr.org.

Policy 15: Identification of Transmissible Diseases

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15.1 Patient Safety Contact (4.4)

Each OPO and transplant program must identify a patient safety contact and develop a 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 Contractor.
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.

Transplant programs and OPOs must make this information available to the OPTN Contractor on request.

15.2 Potential Candidate Screening Requirements (2.2.3.5, 4.1, 4.1.1, 4.1.2)

To be eligible for an organ transplant, potential transplant candidates must be tested for human immunodeficiency virus (HIV), hepatitis B, and hepatitis C, unless the testing would violate state or federal laws. Potential candidates who test positive for HIV, hepatitis B, or hepatitis C should be offered appropriate counseling.

A potential candidate who tests positive for HIV may still receive an organ transplant unless there is a documented recommendation against transplant based on state law or the transplant hospital's policies. A transplant program should inform health care personnel who care for a potential candidate or candidate that tests positive for HIV only when necessary to make medical decisions.

15.3 Informed Consent of Transmissible Disease Risk (4.2., 4.2.3)

Transplant programs must obtain informed consent before transplant of an organ when, in the transplant program's medical judgment, *any* of the following occurs:

- The deceased donor has a known medical condition that may be transmissible to the recipient, with the exception of HIV, which must be handled according to *Policy 2.7: HIV Screening of Potential Deceased Donors*.
- The deceased donor meets the guidelines for an increased-risk of transmissible disease as specified in the *U.S. Public Health Services (PHS) Guideline.*
- When a hemodiluted specimen is used for deceased donor HIV, hepatitis B, or hepatitis C screening, according to *Policy 2.5: Hemodilution Assessment*.

Transplant programs must also inform potential 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 only required to undergo testing for the diseases listed in *Policy 2.3: Evaluating and Screening Potential Deceased Donors*.
2. Living Donors are only required to undergo screening for the diseases listed in *Policy 14.4: Medical Evaluation Requirements for Living Donors*.
3. That there is no comprehensive way to screen potential deceased and living donors for all transmissible diseases.
4. That transmissible diseases and malignancies may be identified after transplant.

The transplant program must do *both* of the following:

1. Explain these risks and obtain informed consent from the potential candidate or candidate's agent before transplant.
2. Document consent in the potential candidate's medical record.

15.3.A Deceased Donors with Additional Risk Identified Pre-transplant (4.2.1)

If additional deceased donor disease or malignancy transmission risk is identified pre-transplant, the transplant program must do *all* of the following:

1. Explain the risks and obtain informed consent from the potential transplant recipient or the potential recipient's agent before transplant.
2. Document this consent in the potential recipient's medical record.
3. Follow any recipient of the deceased donor organs for the development of potential donor-derived disease after transplantation.

15.3.B Deceased Donors at Increased Risk for Transmission of Blood-borne Pathogens (4.2.2, 4.3.1)

If a deceased donor is found to have an increased risk for transmitting blood borne pathogens, the transplant program must offer recipients of the donor organs *all* of the following:

1. Additional post-transplant testing for HIV, hepatitis C, and hepatitis B as appropriate based on the recipient's pre-transplant status.
2. Treatment of or prophylaxis for the transmissible disease, when available.
3. Routine post-transplant follow-up care.

15.4 Reporting of Potential and Proven Disease Transmissions (4.5)

15.4.A Transplant Program Requirements (4.5, 4.5.2)

When an organ recipient is suspected to have, is confirmed positive for, or has died from a potential transmissible disease or medical condition, including infections and malignancies, and there is substantial concern that it could be of deceased donor origin, then the transplant program must do *both* of the following:

1. Notify the living donor recovery hospital (for living donor recipients) or host OPO (for deceased donor recipients), without waiting for all medical documentation that may eventually become available. This notification must occur by phone and the transplant program must

provide available documentation to the living donor hospital or host OPO as soon as possible but no later than 24 hours after learning of the event.
2. Report the event through the OPTN Improving Patient Safety Portal.

Any transplant program treating recipients that received organs from a donor who is the subject of a potential disease transmission report is responsible for *all* of the following:

1. Responding to host OPO, living donor recovery hospital, and OPTN patient safety staff requests for information regarding all recipients in a timely fashion and communicating updated information regarding recipient condition, test results, diagnosis, and plans for treatment and follow-up.
2. Submitting copies of any relevant test results (including cultures, serologies, imaging studies, or autopsy results) to OPTN patient safety staff.
3. Notifying recipients involved in cases of confirmed disease transmissions and documenting this notification in the recipient medical record according to *15.3.A: Requirements for Identified Increased Risk of Transmissible Disease*.
4. If requested by the Ad Hoc Disease Transmission Advisory Committee, submission of a *Potential Disease Transmission Recipient Follow-Up Report* within 45 days of the initial date the potential transmission was reported.

OPTN patient safety staff may request additional information related to the recipient beyond 45 days, in an effort to determine the probability of donor-derived disease transmission, depending on the potentially transmitted disease or malignancy.

15.4.B Living Donor Recovery Hospital and Host OPO Requirements (4.5, 4.5.1)

The living donor recovery hospital or host OPOs responsible for *all* the following:

1. Communication of the suspected donor's and affected recipient's test results and diagnosis that may be relevant to acute patient care as soon as possible, but no more than 24 hours, to any transplant programs, 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 recovery. The living donor recovery hospital or host OPO must document that this information is shared with all recipient transplant hospitals and tissue banks.

2. Notification of the event to the OPTN Improving Patient Safety Portal as soon as possible, but no later than 24 hours.

3. Potential disease transmission follow-up communication as follows, including:

    a. For deceased donors, completion and submission of the *Potential Disease Transmission Report Form* no later than 24 hours after reporting the event through the OPTN Improving Patient Safety Portal to identify. This must include:
        i. The specific recipient transplant program patient safety contact and tissue bank staff that were notified of the potential transmission
        ii. Disposition of all organs, tissues, and vessels
        iii. Any preliminary information available regarding any remaining deceased donor samples for additional testing, notification to state or local health department as appropriate for nationally notifiable infectious diseases, and whether an autopsy was performed on the deceased donor.

4. A follow up review of the event, in partnership with OPTN patient safety staff, to determine

whether the deceased or living donor was diagnosed with a potentially transmissible disease or condition.

For all living and deceased donors, the Ad Hoc Disease Transmission Advisory Committee may request submission of a *Potential Disease Transmission Donor Follow-Up Report* 45 days after the initial reporting date. Patient safety staff may request additional information related to the living donor beyond 45 days, including pending test results, depending on the potentially transmitted disease or condition.

If a host OPO learns new information regarding a deceased donor as part of its required living donor follow-up that indicates risk of potential transmission of disease or malignancy, the host OPO must report the information through the OPTN Improving Patient Safety Portal.

If a 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 recovery hospital must do *all* of the following:

1. Disclose to the living donor that a potential disease transmission or malignancy must be reported to the recipient transplant hospital and the OPTN Improving Patient Safety Portal
2. Notify the recipient transplant hospital
3. Report the potential transmission through the OPTN Improving Patient Safety Portal

The recovery hospital may also need to report the new information to local, state, or federal public health authorities.

15.5 Requirements for Post-Transplant Discovery of Donor Disease or Malignancy (4.3)

If any new, clinically relevant findings about a deceased or living donor are discovered after transplant, the transplant program must complete *all* of the following:

1. Notify the recipient, or the recipient's agent, of the risk of transmissible disease that was not previously identified and is noted as clinically relevant by the recipient's care team.
2. Document new information about the donor and potential risk for disease or malignancy in the recipient's medical record.
3. Follow a recipient at increased risk for disease or malignancy for the development of the disease or malignancy after transplant.
4. Offer the recipient additional testing, monitoring, and treatment as appropriate, in addition to routine follow-up care.

History

Policy 4: Identification of Transmissible Diseases in Organ Recipients: 12/18/2007; 6/20/2008; 11/9/2010; 11/13/2012
Policy 15: Identification of Transmissible Diseases:

Notes

- For the requirement to prevent the acquisition of organs from individuals known to be infected with HIV, see *42 CFR §121.6*.
- For identification of transmissible diseases in organ donors, see *Policy 2: Deceased Donor Organ Procurement*.

- For information on using hemodiluted samples for donor testing, see *Policy 2.3: Evaluating and Screening Potential Deceased Donors*.
- For the requirements of donor follow-up see, see *Policy 2.10: Post Recovery Follow Up and Reporting*.
- For restrictions on the use of organs from donors infected with HIV, see *Policy 2.7: HIV Screening of Potential Deceased Donors*.
- For guidance for HTLV-1 screening and confirmation in potential donors and reporting potential HTLV-1 infection see the OPTN website.
- For guidance for reporting potential donor-derived disease transmission events, see the OPTN website.

Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage

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16.1 Organs Not Requiring Transport (5.9, 5.9.1, 12.7.9, 12.7.9.1)

The transplant hospital and host OPO (if applicable) must develop and follow a protocol to ensure that the correct living or deceased donor organ is transplanted into the correct recipient when *either* of the following occurs:

- Organs are recovered from a deceased donor and remain in the same operating suite as the intended recipient
- Organs are recovered from a living donor and remain in the same facility as the intended recipient

Time outs must occur:

1. Before the organ leaves the deceased or living donor operating room
2. Again when the organ arrives at the potential recipient's operating room, before the transplant occurs

During these time outs and before the transplant occurs, the transplant hospital must confirm and document that a member of the transplant team identified the correct organ for the correct potential recipient prior to transplant according to *Policy 5.6: Blood Type Verification upon Receipt*.

16.2 Organs Recovered by Living Donor Recovery Hospitals (12.7, 12.7.8.3, 12.7.8.4)

Living donor recovery hospitals must follow all of the requirements for packaging, labeling, and transporting organs, tissue typing material, and vessels according to this Policy, with these differences:

1. While OPOs are responsible for packaging, labeling, and transporting deceased donor organs, vessels, and tissue typing samples, recovery hospitals are responsible for packaging, labeling, and transporting living donor organs, vessels, and tissue typing samples.
2. When a member repackages a living donor organ, they are not required to notify the member that originally packaged the organ.
3. Instead of the list of documents in *Policy 16.5: Documentation Accompanying the Organ or Vessel*, living donor organs must contain the blood type source documents, donor informed consent form, and the complete medical record of the living donor. 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 must contain the donor ID and *one* of the following three identifiers: donor date of

birth, donor initials, or a locally assigned unique ID. Each sample should 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.

16.3 Packaging and Labeling Responsibilities (5.0, 5.1)

The host OPO or recovery hospital is responsible for packaging and labeling organs, tissue typing material, and vessels that travel outside the recovery facilities. The host OPO or recovery hospital must make reasonable efforts to package and label organs, tissue typing specimens, and vessels in a timely fashion.

If a transplant hospital repackages an organ for transport, it must package, label, and transport the organ according to this Policy and immediately notify the host OPO of the repackaging.

Transplant hospital staff may not leave the operating room without allowing the host OPO to package and label deceased donor organs, tissue typing specimens, and vessels according to this Policy. If a transplant hospital fails to comply with this Policy, the host OPO must submit a report through the OPTN Improving Patient Safety Portal.

16.4 Packaging and Labeling (5.1, 5.2, 5.4.3, 12.7.1, 12.7.2)

The host OPO must package all organs, tissue typing material, and vessels 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 vessels with or separate from organs.

The transplant center 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.

16.4.A Internal Packaging (5.2, 5.4.3, 12.7.2)

A triple sterile barrier must protect organs and vessels. A sterile rigid container may be used as one layer of the triple sterile barrier for all organs and must be used as one layer when packaging kidneys, pancreas, and vessels that are packaged separately from the organ.

16.4.B Internal Labeling of Organs (5.4.1, 5.8.2, 12.7.4.1)

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 holding each organ. The OPTN Contractor distributes a standardized label that must be used for this purpose. In addition to the specific contents of the package, the label information must include the, donor ID, donor blood type and blood subtype, if used for allocation.

16.4.C Internal Labeling of Blood and Tissue Typing Materials (5.4.2, 5.8.2, 12.7.4.2, 12.7.8.2)

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. 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 but must not be included on blood samples. 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.

16.4.D Internal Labeling of Vessels (5.4.3, 12.7.4.3)

The rigid container holding the vessels and the outermost layer of the triple sterile barrier must have a completed OPTN vessel label. The OPTN Contractor distributes a standardized label that must be used for this purpose. The label must contain *all* of the following information:

1. Donor ID
2. Donor blood type
3. Donor blood subtype, if used for allocation
4. Recovery date
5. All infectious disease testing results
6. Description of the container contents
7. Whether the vessels are from a donor that meets the high-risk criteria in the U.S. Public Health Service (PHS) Guideline.
8. That the vessel is for use in organ transplantation only

16.4.E External Packaging (5.1,12.7.1)

Only disposable shipping boxes, coolers, or mechanical preservation machines must be used as external transport containers.

16.4.E.i Disposable Shipping Box (5.1.1, 12.7.1.1)

If organs, tissue typing materials, or vessels 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.

16.4.E.ii Mechanical Preservation Machine (5.1.3, 12.7.1.3)

When transporting an organ using a mechanical preservation machine, the cassette containing the organ must be labeled with the organ type, UNOS ID, blood type, and blood subtype if used for allocation. Mechanical preservation machines may be reused only if all labels from previous donor organs are removed.

16.4.E.iii Cooler (5.1.2, 5.3, 12.7.1.2)

If a member of the organ recovery team is accompanying the organ to the potential recipient's transplant hospital, they can transport the organs, tissue typing material, and vessels 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.

16.4.F External Labeling (5.1.1, 5.1.2, 5.1.3, 5.3, 12.7.3)

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 contain *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

16.5 Documentation Accompanying the Organ or Vessel (12.7.5)

16.5.A Organ Documentation (5.5.1, 12.7.5.1)

Each external transport container holding an organ must be sent with the complete deceased or living donor record that includes, including *all* of the following:

1. Blood type source documentation
2. Blood subtype source documentation, if used for allocation
3. Infectious disease testing results
4. Medical and behavioral history information
5. Donor evaluation information
6. Donor authorization form
7. Organ quality information as noted in *Policy 2.12.B: Organ Procurement Procedures*.

Donor 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

When a deceased or living donor organ is transported, the host OPO or the transplant hospital

must include the source documentation with the donor documentation.

16.5.B Vessel Documentation (5.5.2)

If vessels are not shipped in the same external container as the organ, then the vessel container must include the same complete donor documentation as the organ.

16.6 Verification of Information before Shipping (5.6.1, 12.7.6.1)

Each OPO or recovery hospital must establish and then implement a protocol for verifying the accuracy of organ and vessel 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 vessels and the host OPO or recovery hospital must document that verification.

16.7 Vessel Recovery, Transplant, and Storage

16.7.A Deceased Donor Vessel Recovery and Transplant Use (5.10.1, 5.10.2)

To recover and use vessels in an organ transplant, the deceased donor authorization forms must include language indicating that the vessels will be used for transplant. The vessels can only be used for transplant or modification of an organ transplant.

Transplant hospitals may share vessels. If sharing occurs between transplant hospitals, the receiving transplant hospital must submit a detailed explanation to the OPTN Contractor that justifies why the sharing occurred. The Membership and Professional Standards Committee (MPSC) will review the explanation. If the receiving transplant hospital later disposes of any vessels, it must notify the OPTN Contractor.

16.7.B Vessel Storage (5.10.2)

Transplant hospitals may not store for later use any hepatitis C antibody positive (HCV) or hepatitis B surface antigen positive (HBsAg) extra vessels. If the transplant hospital stores vessels and later uses the vessels for the intended recipient or another recipient, it must notify the OPTN Contractor.

The Transplant hospital must designate a person to do *all* of the following:

1. Monitor and maintain all records relating to the use and management of vessels
2. Monitor the refrigerator where the vessels are stored
3. Destroy expired vessels
4. Report the vessel's use or disposal to the OPTN Contractor within seven days of the transplant hospital's use or disposal of the vessels.

Additionally, the transplant hospitals must do *all* of the following:

1. Store vessels in a Food and Drug Administration (FDA) approved preservation solution
2. Package and label vessels as required by Policy *16.4.A: Internal Packaging*
3. Store 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
4. Monitor vessels daily with documented security and temperature checks

5. Destroy unused vessels within 14 days from after the recovery date
6. Maintain a log of stored vessels.
7. Have accessible at all times the vessel deceased donor information for the transplant surgeon prior to using the vessels in any recipient other than the originally intended recipient.

16.7.C Blood Type Verification Prior to Transplant of Deceased Donor Vessels (5.10.1)

The transplant hospital must verify the blood type, all serology results, container contents, date of expiration, and the Donor ID of the vessels with the blood type and all serology results of the recipient prior to transplant. The documentation of these verifications must be maintained in the recipient medical record.

16.7.D Recovery and Storage of Vessels from Living Donors (5.10,1, 12.7.10.1)

A recovery hospital may only recover extra vessels for transplant if the living donor consents to the removal of extra vessels for transplant. The vessels from a living donor can only be used for transplant or modification of an organ transplant for the original intended recipient and may not share them with anybody else. Transplant hospitals must store vessels recovered according to *Policy 16.7.B: Vessel Storage*.

16.7.E Blood Type Verification Prior to Transplant of Living Donor Vessels (12.7.7)

Prior to transplant, the recovery hospital must verify *all* of the following:

1. The living donor's blood type
2. The living donor's blood subtype, if used for allocation
3. All serology results
4. Container contents
5. Date of expiration
6. Donor ID

The transplant hospital must also verify the blood type and subtype of the intended recipient, if used for allocation, and all serology results of the recipient prior to transplant. The documentation of these verifications must be maintained in the recipient medical record.

16.8 Transportation Responsibilities (5.11)

16.8.A Transportation Arrangements (2.5.8)

The host OPO is responsible for determining that non-local procurement teams have transportation to and from the local airport.

16.8.B Transportation Costs for Deceased Donor Kidneys (5.11.1, 5.11.2, 5.11.3)

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.

16.8.C Transportation Costs for Living Donor Kidneys (12.7.11.1)

The organ recipient's transplant hospital is responsible for transportation costs for living donor kidneys and associated tissue typing material according to CMS regulations.

16.8.D Transportation Costs for all other Organs (5.11.2, 12.7.11.2, 12.7.11.3)

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.

16.8.E Transportation Costs for Tissue Typing Material (12.7.11.3)

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.

History

Policy 5: *Standardized Packaging, Labeling, and Transporting of Organs, Vessels, and Tissue Typing Materials* : 6/25/2007; 2/21/2008; 6/20/2008; 11/17/2009; 11/9/2010; 6/29/2011; 11/15/2011; 6/26/2012; 11/13/2012

Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage:

Notes

- For tissue typing requirements, see *Policy 4: Histocompatibility*.
- For living donor packaging and labeling requirements, see *Policy 14.8: Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials*.
- For packing exemption for organs, see IATA Packaging Requirement 3.6.2.2.3.5.
- For OPTN guidance on organ transplant labeling and packaging, see the OPTN website.

Policy 17: International Organ Transplantation

17.1 Registration and Transplants of Non-US Citizens/Non-US Residents 204
17.2 Importation of Deceased Donor Organs from Foreign Sources 204

17.1 Registration and Transplants of Non-US Citizens/Non-US Residents

17.1.A Referrals (6.2.2)

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 (6.3)

The Ad Hoc International Relations Committee will review all citizenship data reported to the OPTN Contractor. 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 (6.3.1)

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 (6.4)

Members may import deceased donor organs from foreign sources according to the requirements in these Policies.

17.2.A Formal Deceased Donor Import Agreement (6.4.1)

A member that wishes to enter into a formal, deceased donor organ import agreement with a foreign entity must

1. Have approval of the agreement by the Board of Directors
2. Submit a proposal to the Ad Hoc International Relations Committee for review

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 met 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 (6.4.1.1)

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 match run.
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 (6.4.2)

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 Contractor:

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.

History

Policy 6: Transplantation of Non-Resident Aliens: 6/26/2012
Policy 17: International Organ Transplantation:

Notes

- For more on the issue of international organ transplantation, see *the Declaration of Istanbul*.

Policy 18 Data Submission Requirements

18.1 Data Submission Requirements 207
18.2 Timely Collection of Data 209
18.3 Recording and Reporting the Outcomes of Organ Offers 209
18.4 Data Submission Standard 209
18.5 Living Donor 210

18.1 Data Submission Requirements (3.2.4.1, 7.0, 7.1.3, 7.2, 7.3.1, 7.4.1, 7.4.2, 7.5.1, 7.6, 7.7, 12.8.3, 12.8.3.1)

OPOs must provide donor information required for organ placement to the OPTN Contractor in an electronic data format as defined and required by the computer system. Deceased donor information required for organ placement must submitted prior to organ allocation.

Members must report data to the OPTN using standardized forms. *Table 18-1* shows the member responsible for submitting each data form and when the Member must submit the following materials to the OPTN Contractor.

Table 18-1: Data Submission Requirements

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For the following groups:
Histocompatibility Laboratory	*Donor histocompatibility* (DHS)	30-days after the OPO submits the deceased donor registration	For each donor typed by the laboratory
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*	For each 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	For 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	For 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 Contractor	For each deceased donor organ that is offered to a potential recipient

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For the following groups:
Host OPO	*Deceased donor feedback*	5 business days after the procurement date	
Host OPO	*Deceased donor registration* (DDR)	30 days after the *deceased donor feedback* form is submitted and disposition is reported for all organs	For all deceased donors and authorized but not recovered potential deceased donors
Recovery Hospitals	*Living donor feedback*	The time prior to donation surgery	For each potential living donor organ recovered at the hospital
Recovery Hospitals	*Living donor registration* (LDR)	60 days after the Recovery Hospital submits the *living donor feedback* form	For each living donor organ recovered at the hospital
Recovery Hospitals	*Living donor follow-up* (LDF)	*See Policy 18.5.A: Reporting Requirements after Donation*	For each living donor organ recovered at the hospital
Transplant hospitals	*Organ specific transplant recipient follow-up* (TRF)	1. 30-days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure 2. 14-days from notification of the recipient's death or graft failure	For each recipient followed by the hospital
Transplant hospitals	*Organ specific transplant recipient registration* (TRR)	60-days after transplant hospital submits the *recipient feedback* form	For each recipient transplanted by the hospital
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60-days after transplant hospital submits the *recipient feedback* form	For each liver recipient transplanted by the hospital
Transplant hospitals	*Recipient feedback*	24-hours after the transplant	For each 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	For each 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	For each candidate on the waiting list or recipient transplanted by the hospital

18.2 Timely Collection of Data (7.1.5, 7.3.1)

Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients is based on recipient 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 six-weeks following the transplant date, whichever is first
Transplant hospitals	*Living donor registration* (LDR)	When the living donor is discharged from the hospital or six-weeks following the transplant date, whichever is first
Recovery Hospitals	*Living donor follow-up* (LDF)	within the 60-days prior to or after the form due date

18.3 Recording and Reporting the Outcomes of Organ Offers

(7.6.1, 7.6.1.2, 7.6.2, 7.6.2.1, 7.6.2.2)

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 Contractor within 30 days of the match run date OPOs, transplant hospitals, and the OPTN Contractor may report this information.

The OPO or the OPTN Contractor 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 Contractor will use the transplant hospital's refusal code for data analysis purposes.

If the OPTN reports the refusal code, then the transplant hospital will not be required to validate the refusal code.

18.4 Data Submission Standard

18.4.A Timely Data Submission (7.1.5, 7.8.1, 7.8.2, 7.9)

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

18.5.A Reporting Requirements after Donation (12.8, 12.8.1, 12.8.2, 12.8.3.1)

The follow-up period for living donors will be a minimum of two years.
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

Donor Status and Clinical Information:

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 LDF form was submitted?
5. Kidney complications

6. Maintenance dialysis
7. Donor developed hypertension requiring medication
8. Diabetes
9. Cause of death, if applicable and known

Kidney Laboratory Data:

1. Serum creatinine
2. Urine protein

Follow-up rates will be calculated separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.

18.5.B Submission of Living Donor Death and Organ Failure (12.8.4)

Recovery hospitals must report all instances of a living donor's death or failure of the living donor's remaining organ function within 72 hours after the hospital becomes aware of the living donor death or failure of the living donor's remaining organ function. Living donor's remaining organ failure is defined as registering for liver transplant for liver donors, and as transplant, listing for transplant or the need for dialysis for kidney donors. Recovery hospitals must report these incidents through the OPTN Contractor's Patient Safety System for a period of two years from the date of the donation. The MPSC will review and report all adverse events to the OPTN Board of Directors.

18.5.C Reporting of Non-transplanted Living Donor Organs (12.8.5)

The recovery hospital must report any time a living donor organ is recovered but not transplanted into any recipients. Recovery hospitals must report these incidents through the OPTN Patient Safety System within 72 hours of organ recovery. The MPSC will review and report all cases of non-transplanted living donor organs to the OPTN Board of Directors.

18.5.D Reporting of Living Donor Organs Not Transplanted in the Intended Recipient (12.8.6)

If a living donor organ is recovered for an intended recipient but ultimately redirected and transplanted to a different recipient, then all required donor and recipient information must still be reported to the OPTN Contractor.

Transplant hospitals must report these incidents through the OPTN Patient Safety System within 72 hours of organ recovery. The Membership and Professional Standards Committee will review and report all cases of redirected living donor organs to the OPTN Board of Directors.

Table 18-4: Living Donor Adverse Event Reporting

Recovery hospitals must report to the Patient Safety System when:	Within 72 hours after:
A living donor dies within 2 years after organ donation	The program becomes aware
A living liver donor is listed on the liver waitlist within 2 years after organ donation	The program becomes aware
A living kidney donor is listed on the kidney wait list or begins chronic	The program becomes

Recovery hospitals must report to the Patient Safety System when:	Within 72 hours after:
dialysis within 2 years after organ donation	aware
A living donor organ is recovered but not transplanted	Organ recovery
A living donor organ is recovered and transplanted into someone other than the intended recipient	Organ recovery

The Membership and Professional Standards Committee will review all cases reported under *Policy 18.5.B* through *18.5.D* and report to the OPTN Board of Directors.

History

Policy 7: Data Submission Requirements: 6/25/2007; 2/21/2008; 6/20/2008; 6/29/2011; 3/13/2012; 6/26/2012; 11/13/2012

Policy 18: Data Submission Requirements:

Notes

- For OPO reporting requirements, see *42 CFR 486.328*.
- For federal requirements regarding data collection, see the Paperwork Reduction Act (*44 U.S.C. chapter 35* and *5 CFR Part 1320*).

Policy 19: Data Release

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19.1 Mailing Lists (9.1)

Lists showing members' or program directors' names with addresses or telephone numbers may be released, only if both of the following requirements are met:

1. The Executive Director deems the request to be for a legitimate, non-commercial purpose furthering the objectives of the OPTN.
2. The OPTN Contractor receives an executed agreement restricting the use of the information for the permitted purpose.

19.2 Composite Demographic Data (9.2, 9.2.1, 9.2.2, 9.2.3)

The OPTN Contractor may release to the public any composite demographic national, regional, or state data that is provided to HRSA through the OPTN Contract, such as the following:

- The number of transplant recipients, according to organ type, ethnicity, blood type, gender, and age
- The number of candidates on the Waiting List according to organ type, ethnicity, blood type, gender, and age
- The number and outcome of organs recovered

19.3 Organ Center Data (9.3, 9.3.1, 9.3.2, 9.3.3)

The OPTN Contractor may release to the public composite Organ Center information such as the following:

- The number of organs allocated through the Organ Center
- Data reflecting Organ Center activity
- The number and final destination of kidneys placed internationally through the Organ Center

19.4 Sharing Arrangements (9.4)

The OPTN Contractor may release to the public the names of members participating in variances approved by the Board of Directors.

19.5 Members (9.5)

The OPTN Contractor may release to the public listings of members (including names of personnel).

19.6 Public Release of Transplant Hospital and OPO Activity (9.6, 9.6.1 - 9.6.9)

The OPTN Contractor may release to the public, without obtaining permission from each member, the analysis results containing the following data:

1. Updated transplant hospital-specific waiting list activity, by organ type, including but not limited to the number of candidates on the waiting list at the initiation of a period; the number of candidates added to the list; and the number of candidates removed from the list for death, transplant, and other reasons and, to the extent relevant to the organ type, the probability of survival on the waiting list within a specific period of time stratified by demographic and medical factors as determined appropriate by the Policy Oversight Committee (POC). These data may be presented on a calendar year basis and for such portions of a calendar year as determined by the POC.
2. Updated transplant hospital-specific waiting list size, by organ type, stratified by demographic and medical factors as determined appropriate by the POC
3. Updated transplant hospital-specific or OPO-specific waiting time information, by organ type, stratified by demographic and medical variables as determined appropriate by the POC, and the probability of receiving a transplant within a specific period of time stratified by demographic and medical factors as determined appropriate by the POC.
4. Updated transplant hospital-specific risk adjusted survival rate information, along with percentage of transplants with follow-up information, using data that may be validated by the member through the OPTN Contractor, by organ type, assessing transplants performed during a period that allows the OPTN Contractor sufficient time to collect the data and compute the rates as determined by the POC. The adjusted, transplant hospital-specific survival rate information may include, to the extent relevant to the organ type, the probability of survival pre-transplant, post-transplant and the probability of survival with or without a transplant. An appropriate period of analysis also will be determined by the POC.
5. Updated transplant hospital-validated transplant volumes as may be validated by the member through the OPTN Contractor, by organ type, stratified by demographic and medical factors as determined appropriate by the POC. These data may be presented on a calendar year basis and for such portions of the calendar year as determined by the POC. At a minimum, the OPTN Contractor may release the following transplant hospital volume information:

    - Transplant hospital-specific transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, for recipients of a particular age.
    - Transplant hospital-specific transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, for recipients with a particular diagnosis.
    - Transplant hospital-specific transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, by deceased and living donor transplant.
    - Transplant hospital-specific multi-organ transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor.

- Transplant hospital-specific non-resident alien transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, by deceased and living donor transplant.
- Transplant hospital-specific waiting list size on any given day, by organ type, according to the waiting list.
- OPO-specific data on the number of non-U.S. citizen organ donors, by year and by organ type, using data that may be validated by the members through the OPTN Contractor. Transplant hospital- and OPO-specific data submission compliance rates.
- Updated OPO-specific donor procurement volumes, using data validated by the member through the OPTN Contractor, including organ-specific authorization, procurement, and utilization volumes, by OPO; and numbers of donors by OPO, using data validated by the member through the OPTN Contractor, stratified by demographic and medical factors for such period(s) as determined appropriate by the POC.
- Updated OPO-specific organ transplant volume, using data validated by the member through the OPTN Contractor, showing number of organs procured, number of organs imported into the OPO, and number of organs exported from the OPO. These data may be presented on a calendar year basis and for such portions of a calendar year as determined by the POC. OPO-specific organ transplant volume and size of waiting list, using data validated by the member through the OPTN Contractor, by organ type, stratified by demographic and medical factors for such period(s) as determined appropriate by the POC.
- Transplant hospital, OPO, or other organization-specific data as approved by the Executive Committee, which the OPTN anticipates will be otherwise duly released by the Department of Health and Human Services (HHS) to the public, together with such explanatory or other text or material as the Executive Committee deems appropriate to assist readers in understanding the data.

19.7 Release of Transplant Hospital Specific Data (9.7)

The OPTN Contractor may release to OPO members such transplant hospital specific data as are required for the OPOs to prepare reports or other documents required by the OPTN for the purposes of assessing the impact of variances, alternative local units and sharing agreements on organ allocation.

19.8 Review of Member Specific Data (9.8)

During the data validation process, the OPTN Contractor may release to members for their review such primary data as may be needed for member-specific reports for public release. For example, donor and histocompatibility data about transplants performed at a transplant hospital may be sent to that transplant hospital for review (but not for modification without instruction to the OPTN Contractor by the original institution submitters). Conversely, for these purposes, laboratories and OPOs may receive relevant data submitted to the OPTN Contractor by transplant hospitals. The members that receive the data will not publish or publicly disseminate outcomes of specific recipients, physicians, or institutions.

19.9 Access to Recipient Outcomes Data (9.9, 9.9.1, 9.9.2, 9.9.3, 9.9.4)

OPOs may receive recipient outcomes data, without permission from the transplant hospital, for each deceased donor organ transplanted. This information would be used in determining the appropriateness of deceased donor selection and management techniques as well as quality assurance of the procurement process. The data would be accessed and downloaded through the OPTN Contractor. The members that receive the data will not publish or publicly disseminate outcomes of specific recipients, physicians, or institutions. These data fields are located on the *Transplant Recipient Registration* forms and include all of the following:

Recipient status (all organs)

- Living – date of hospital report
- Dead – date and cause of death
- Re-transplanted prior to hospital discharge – date
- Cause of retransplant (thoracic only)

Clinical information at discharge (kidneys only)
- Most recent serum creatinine prior to discharge
- Did kidney produce >40 mL of urine in first 24 hours?
- Did recipient need dialysis within first week?
- Did creatinine decline by 25% or more in first 24 hours on two separate serum samples taken within first 24 hours?

Transplanted kidney, liver or pancreas status at
- Functioning or failed
- If failed, date and cause
- Preservation Information (all organs)

19.10 Information before the Board of Directors (9.10)

The OPTN Contractor may release to the public any information brought before the Board of Directors in public sessions.

19.11 Release of Human Leukocyte Antigen (HLA) Type of a Recipient's Prior Donor (9.11)

The OPTN Contractor may release a recipient's prior donor's HLA type to a transplant hospital if the recipient is under that transplant hospital's care, or to the laboratory that provides services to that transplant hospital, without obtaining permission from the transplant hospital that performed the original transplant or the laboratory that performed the donor's typing.

19.12 Release of HLA Type of Donors and Recipients with Laboratory Name and Identifier (9.12)

The OPTN Contractor may release, without obtaining permission from each member laboratory, the HLA type of deceased donors and recipients with the name and identifier of the laboratory that performed the typing to member laboratories for the purpose of resolving discrepant donor and recipient HLA typing results as set out in *Policy 4.4: Resolving Discrepant Donor and Recipient HLA Typing Results*.

19.13 Access to Database (10.1)

Only OPTN Contractor staff, or individuals engaged by or adjunct to Contractor staff who are bound by contracts that prohibit competing interests and breaches of confidentiality, will be permitted to program or have direct access to data within the OPTN computer match program, or waiting list, or maintained in any other form. Members requesting access to data regarding their own candidates and recipients will be provided access to that information when practicable as determined by the OPTN Project Director. Unless permitted elsewhere in policy, neither individuals nor members will be given access to individual candidate, recipient, or member-specific information other than that from their own organization, without prior written approval from those individuals or members identified. Candidate, recipient, and institution-identified data will be made available to the Scientific Registry for Transplant Recipients (SRTR) Contractor.

19.14 Transfer of Information (10.2)

All requests for data should be made through the Data Request System.
Requests involving twenty hours or more of programming time or any statistical analyses that are considered to be extensive may be subject to the additional requirements in *Policy 19.15*: Specific Projects.

Unless permitted by this Policy, data will be provided with the deletion of all candidate, recipient and transplant hospital specific identifying information. Comprehensive datasets with transplant hospital and candidate and recipient identifying information encrypted may be given out for research purposes with the approval of the POC.

Under some circumstances, transplant hospital-specific data (standard analysis files) not otherwise releasable may be provided to bona fide researchers, subject to the approval of the POC using as guidance the Agreement for Release of Data, as approved by the POC. In order to obtain these data, the submitting individual must meet the conditions for their release and sign an Agreement for Release of Data, which sets forth confidentiality and security stipulations for the data's release and use. Such data may be provided on a cost reimbursement basis.

Use of such data must meet the requirements of *Policy 19.16: Public Use, Presentations, and Publications.*

As required by the OPTN contract, the OPTN Contractor may release records which are identifiable as to candidate, recipient, transplant hospital or OPO without a signed Agreement for Release of Data only pursuant to official requests for data from the Department of Health and Human Services in accordance with federal or state laws and regulations.

19.15 Specific Projects (10.3)

Any individual or group requesting data requiring twenty or more hours of programming time and/or any statistical analysis of a specific question by the OPTN Contractor staff may be asked to submit a written concept paper to the POC. The POC (its chair plus representative committee members) will vote to approve or disapprove each request, and may also prioritize approved requests, based on scientific or clinical merit, importance to the OPTN, and the potential ability to address the question. The approval and priority status of each request will be provided to the submitting individual. Upon approval, the submitting individual will be notified of the OPTN Contractor staff assigned to complete the request. The submitting individual must indicate to the assigned staff whether he/she wishes to be directly involved in the analysis and the project work group.

Data will be provided with the deletion of all candidate and recipient specific identifying information. Transplant hospital identifiers may be provided to bona fide researchers who meet the conditions specified in Agreement for Release of Data, which sets forth confidentiality and security stipulations for the data's release and use. Such data may be provided on a cost reimbursement basis. Use of such data will require written acknowledgment of the source of the data and the date it was provided, as required by *Policy 19.16: Public Use, Presentations, and Publications*.

19.16 Public Use, Presentations, and Publications (10.4)

All scientific data provided and/or analyses performed by the OPTN Contractor utilizing data collected for the OPTN must adhere to the following specific requirements regarding approval, content, confidentiality, and authorship.

19.16.A Public Use or Presentation of Specific Projects or Studies (10.4.1)

The scientific and analytical content of all abstracts or manuscripts developed from customized data requests, comprehensive encrypted datasets, or standard analysis files must be approved by the POC and any ad hoc work group appointed by that Committee prior to their public presentation or publication If the analysis has not been provided prior to release by the investigator or institution, the OPTN Contractor cannot assume responsibility for the correctness of the findings or interpretations. Failure to include the OPTN Contractor in pre-release preparation may be an adverse consideration in subsequent applications by the investigator or institution for additional data. Any contractor staff that makes a significant intellectual contribution to a study abstract, presentation, or manuscript should be offered the opportunity to be included as an author. Contractor staff may not be listed as study authors without obtaining written permission from the appropriate staff. A copy of all published abstracts, manuscripts, or news releases should be submitted to staff and/or the POC for informational purposes as soon as practicable.

19.16.B Data Obtained Through the Data Request System (10.4.2)

Abstracts and manuscripts prepared using routinely available data obtained through the data request system do not require approval by the POC. Routinely available data will comprise *all* of the following:

1. Data provided in regularly updated standard reports
2. Data requested by OPTN members regarding their own institution or candidates and recipients
3. Data requested by the Department of Health and Human Services

However, the source and date of the data obtained must be acknowledged in text or graphic presentations. A copy of each published abstract, manuscript, or news release should be submitted to OPTN Contractor and/or the POC for informational purposes as soon as practicable. Publications that use data collected for the OPTN will include the following notice: *The data reported here have been supplied by [XXX], the OPTN Contractor*. The interpretation and reporting of these data are the responsibility of the authors and in no way should be seen as an official Policy or interpretation of the OPTN, or the U.S. Government.

19.17 Committee Access to Data (10.5)

Confidential Information, as herein defined, will not be made available in a public meeting. In a non-public forum or meeting setting, access to Confidential Information will be limited to members of the Board of Directors, members of permanent standing or ad hoc committees, OPTN Contractor staff and individuals engaged as an adjunct to Contractor staff. Access will be limited to the above described individuals, provided that these individuals are performing functions on behalf of the OPTN and are either bound by a fiduciary responsibility to the OPTN or a contractual obligation to the OPTN Contractor to maintain the confidentiality of such data and information. These individuals will have no ownership right in or to any of the Confidential Information and maintenance of the Confidential Information will be a private and confidential matter which is required for the continued success of the OPTN and its business. This Confidential Information includes but is not limited to financial data and information; data and information relating to procedural and substantive needs, problems, developments and projects; and data and information regarding deceased and living organ donors and recipients and institutions and medical personnel involved in organ transplantation, which constitute sensitive medical data or information subject to federal or state confidentiality statutes and regulations, all of which constitute trade secrets or confidential information of the OPTN. All such data and information together with business practices and procedures of the OPTN will be referred to collectively as "Confidential Information."

At such time as it becomes necessary to present or review candidate and recipient specific or transplant

hospital specific data or other Confidential Information, such data or Confidential Information will be provided in individual packets for review at that non-public meeting only. At the conclusion of the meeting all individual packets will be collected by the administrative staff, and no such data or Confidential Information will be permitted outside the meeting room except that maintained by administrative staff and adjunct personnel. When practicable, the Confidential Information will be displayed electronically via overhead projection or slide projection for discussion purposes thereby eliminating the need for individualized sets of the Confidential Information. Only OPTN Contractor staff, or government staff pursuant to contractual requirements, will be able to retain the data or Confidential Information in written or electronic form.

In no event will any person, other than OPTN Contractor staff and adjunct personnel in attendance in any non-public meeting be permitted to have access to these data or confidential information outside the meeting room. Cooperation and compliance with these procedures will ensure the integrity of the OPTN and foster the trust of those who are associated with or who have dealings with the OPTN.

History

Policy 9: Release of Information to the Public: 6/26/2012
Policy 10: Access to Data:
Policy 19: Data Release:

Notes

- For data submission requirements see *Policy 18: Data Submission Requirements*.
- For the Privacy Act of 1974, see *5 U.S.C. § 552a*.
- For the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule), see *45 CFR Parts 160 et seq.*

Policy 20: Travel Expense and Reimbursement

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20.1 Eligibility for Reimbursement (8.1)

20.1.A General Eligibility Requirements (8.1.1)

The OPTN Contractor will reimburse approved travel costs for members, contractors, and OPTN Contractor staff who are traveling for OPTN Contractor 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 Contractor sponsored events.

20.1.B Multiple Meetings in the Same City (8.1.2)

If the OPTN Contractor holds a meeting in a city where the traveler will attend another organization's meeting, the OPTN Contractor will pay only for the traveler's additional expenses incurred as a direct result of attending the OPTN Contractor meeting.

20.2 Airfare and Rail Reimbursement (8.2)

20.2.A Booking Travel (8.2)

OPTN Contractor staff and members must use *UNOS Meeting Partners* to arrange all OPTN Contractor 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 Contractor will reimburse only up to the amount *UNOS Meeting Partners* would have paid.

Travelers should book airline reservations at least one month in advance of travel.

20.2.B Air Travel (8.2.1, 8.2.2, 8.2.3, 8.2.4, 8.2.5, 8.2.7, 8.2.8)

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 Contractor will pay for additional fees resulting from airline ticket changes if the changes result from OPTN Contractor business. Travelers who request ticket changes for reasons unrelated to OPTN Contractor 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 Contractor 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.

UNOS Meeting Partners will not book back-to-back tickets or round-trip airfares for a one-way trip.

The OPTN Contractor 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 Contractor would only reimburse the amount of the low cost coach fare.

20.2.C International Travel (8.2.6)

The OPTN Contractor will approve international travel on a case-by-case basis.

20.3 Hotel Reimbursement (8.3)

The OPTN Contractor will reimburse overnight accommodations for the number of nights necessary to conduct OPTN Contractor 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 (8.4)

20.4.A Mileage (8.4.1)

The OPTN Contractor will reimburse mileage at the applicable IRS rate based on the dates travelled.

20.4.B Transportation To and From the Airport (8.4.2, 8.6.1)

The OPTN Contractor 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 should use the least expensive, convenient option to travel to and from airports. The OPTN Contractor will not reimburse limousines unless the cost is shared with another traveler and the total cost to the OPTN Contractor is no more expensive than cab fare.

20.4.C Rental Cars (8.4.3)

The OPTN Contractor will not reimburse rental cars if less expensive modes of travel are available. The traveler must elect rental car insurance coverage and should minimize additional rental car fees. If the traveler elects to rent a car when less expensive modes of travel are available, the OPTN Contractor will reimburse up to the amount of the estimated cab fare needed for the duration of the stay.

20.4.D Provided Ground Transportation (8.4.4)

The OPTN Contractor will not reimburse the cost of any other ground transportation if the OPTN Contractor provides ground transportation between an airport and a meeting site and the person traveling could reasonably take advantage of this transportation.

20.5 Meals (8.5)

20.5.A Meal Cost (8.5.1)

The OPTN Contractor 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 (8.5.2)

The OPTN Contractor will reimburse evening meal costs up to $45. This limit includes the cost of the meal and gratuities. The OPTN Contractor 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.

20.6 Miscellaneous Expenses

20.6.A Telecommunication Charges (8.6.2)

The OPTN Contractor will reimburse OPTN Contractor business and personal phone calls of a reasonable length. The OPTN Contractor will reimburse Internet connection charges if the traveler is conducting OPTN Contractor business.

20.6.B Other Reasonable Expenses (8.6.3)

The OPTN Contractor will reimburse reasonable, out-of-pocket expenses incurred as a direct result of traveling for OPTN Contractor business.

20.7 Non-Reimbursable Expenses (8.7)

The OPTN Contractor will not reimburse costs for in-room movies, valet parking, fitness center, dry cleaning, laundering, or any other personal charges. The OPTN Contractor will not reimburse charges incurred for personal travel days.

20.8 Filing Expense Reports (8.8)

20.8.A Expense Reimbursement Form (8.8.1)

To request reimbursement from the OPTN Contractor, the traveler must complete and submit an OPTN Contractor expense reimbursement form with 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 (8.8.2)

The expense report must have original receipts for expenses attached. If one traveler has a meal receipt that includes other OPTN Contractor travelers, the receipt must include the names of all travelers.

History

Policy 8: Travel Expense and Reimbursement: 6/23/2009, 11/1/2003; 11/15/2011
Policy 20: Travel Expense and Reimbursement:

Crosswalk – Current Policy to Rewrite

Policy 1

Current	Rewrite
1	Bylaws
1.1	Bylaws

Policy 2

Current	Rewrite
2.1	2.2
2.1	2.3
2.2	2.2
2.2	2.3
2.2.1	1.2
2.2.1	2.2
2.2.2	2.3
2.2.2.1	2.3
2.2.2.1	2.4
2.2.2.2	2.3
2.2.2.3	2.3
2.2.3	2.3
2.2.3.1	1.2
2.2.3.1	2.5
2.2.3.2	2.7
2.2.3.3	2.7
2.2.3.4	2.7.A
2.2.3.5	15.2
2.2.3.5	2.7.B
2.2.4	2.8
2.2.4.1	2.8
2.2.4.2	2.8
2.2.4.3	2.8
2.2.4.4	2.8
2.2.4.5	2.8
2.2.4.6	2.8
2.2.5	2.10
2.2.5	2.10.A
2.2.6	2.10.A
2.3	2.11
2.3.1	2.11
2.3.2	2.11
2.3.3	2.11
2.3.4	2.11
2.5.5	1.1
2.3.5	2.11
2.4	1.1
2.4	2.2
2.5	2.12.B
2.5.1	2.2
2.5.2	2.12.B
2.5.3	2.12.B
2.5.4	2.12.B
2.5.5	1.1
2.5.6	1.1
2.5.6	2.2
2.5.7	2.2
2.5.8	16.8.A
2.6	2.12.B
2.7	2.12.D
2.7.1	2.12.C
2.8	2.13
2.9	2.2

Policy 3.1

Current	Rewrite
3.1	Bylaws
3.1.1	1.2
3.1.2	1.2
3.1.2	5.5.A
3.1.2	5.6
3.1.3	1.2
3.1.4	1.2
3.1.4	3.3.B
3.1.4.1	1.4
3.1.4.1	3.4.C
3.1.4.2	3.3.A
3.1.4.3	3.3
3.1.5	1.2
3.1.5	5.4.B

Current	Rewrite
3.1.6	1.2
3.1.7	1.2
3.1.8	1.2
3.1.9	1.2
3.1.10	1.2
3.1.11	1.2
3.1.12	1.2
3.1.13	1.2
3.1.13	3.4.C
3.1.13	5.4.F

Policy 3.2

Current	*Rewrite*
3.2.1	*3.4.C*
3.2.1.1	*3.1*
3.2.1.2	*1.2*
3.2.1.2	*3.1*
3.2.1.2	*3.1.A*
3.2.1.3	*3.4.B*
3.2.1.4	*5.4.B*
3.2.1.5	*3.4.D*
3.2.1.6	*3.4.H*
3.2.1.7	*3.4.H*
3.2.1.8	*3.7*
3.2.1.8.1	*3.7.B*
3.2.1.8.2	*3.7.A*
3.2.1.8.3	*3.7.B*
3.2.1.8.4	*3.7.A*
3.2.1.9	*3.6.C*
3.2.2	*3.4.G*
3.2.2.1	*3.6.C*
3.2.2.2	*3.4.G*
3.2.2.3	*3.8*
3.2.2.4	*3.2*
3.2.2.4	*3.4.G*
3.2.3	*3.2*
3.2.4	*2.6*
3.2.4	*5.4.B*
3.2.4	*5.4.F*
3.2.4	*5.7*
3.2.4.1	*3.8*

Current	*Rewrite*
3.2.4.2	*3.6.B.i*
3.2.4.2	*3.6.B*
3.2.5	*5.3.C*
3.2.6	*3.6.A*
3.2.7	*3.5*
3.2.8	*Deleted*
3.2.9	*Deleted*

Policy 3.3

Current	*Rewrite*
3.3.1	*2.1*
3.3.1	*5.4.B*
3.3.2	*5.1.B*
3.3.3	*5.1.A*
3.3.4	*5.2*
3.3.5	*5.4.E*
3.3.6	*5.5.C*
3.3.6.1	*2.13.H*
3.3.6.1.1	*2.13.H*

Policy 3.4

Current	*Rewrite*
3.4	*1.1*
3.4.1	*2.12.A*
3.4.2	*5.5.B*
3.4.3	*2.12.E*
3.4.3	*5.4.D*
3.4.4	*1.5*
3.4.5	*5.4.D*
3.4.6	*5.4.B*
3.4.7	*5.5.A*
3.4.8	*1.3*
3.4.8.1	*1.3.A*
3.4.8.2	*1.3.B*
3.4.8.2	*1.3.C*
3.4.8.3	*1.3.D*
3.4.8.4	*1.3.E*
3.4.6.5	*1.3.F*
3.4.8.6	*1.3.G*
3.4.9	*Deleted*
3.4.10	*Deleted*

Current	*Rewrite*
3.4.11	*1.4*
3.4.11.1	*1.4.A*
3.4.11.2	*1.4.B*
3.4.11.2	*1.4.C*
3.4.11.2	*1.4.D*
3.4.11.3	*1.4.E*

Policy 3.5

Current	*Rewrite*
3.5	*8*
3.5.1	*8.1*
3.5.2	*8.2.A*
3.5.3	*8.3*
3.5.4	*8.4*
3.5.4.1	*8.4.A*
3.5.4.1	*8.4.C*
3.5.4.2	*8.4.B*
3.5.4.2	*8.4.C*
3.5.5.1	*8.5.A*
3.5.5.2	*8.5.B*
3.5.5.3	*5.3.B*
3.5.5.3	*8.5.C*
3.5.5.4	*8.5.D*
3.5.5.5	*8.5.E*
3.5.5.6	*8.5.F*
3.5.5.7	*8.5.G*
3.5.6	*8.5*
3.5.6.1	*8.5.H*
3.5.6.2	*8.5.I*
3.5.6.3	*8.5.J*
3.5.6.4	*8.5.K*
3.5.6.5	*8.6*
3.5.7.1	*8.7.A*
3.5.7.2	*8.7.B*
3.5.7.2	8.7.B
3.5.7.3	*8.7.C*
3.5.7.4	*2.8.A*
3.5.7.6	8.7.D
3.5.7.7	8.2.B
3.5.7.8	4.6.D
3.5.8	*Deleted*

Current	*Rewrite*
3.5.9.1 (pre KAS)	*2.12.B*
3.5.9.2 (pre KAS)	*2.9.A*

Policy 3.6

Current	Rewrite
3.6	1.2
3.6	9.1
3.6	9.1.A
3.6	9.6
3.6	9.6.A
3.6	9.7.C
3.6	5.7
3.6.1	5.3.C
3.6.2	9.5.B
3.6.2	9.6
3.6.2	5.3.C
3.6.2.1	9.6.C
3.6.2.2	9.6.C
3.6.2.2	5.3.C
3.6.3	3.6.A
3.6.3	9.4.A
3.6.3	9.5.A
3.6.3	9.6
3.6.4	9.1
3.6.4.1	3.4.E
3.6.4.1	9.1.A
3.6.4.1	9.1.D
3.6.4.1	9.2
3.6.4.1	9.3
3.6.4.1	9.3.B
3.6.4.1.1	9.2
3.6.4.2	9.1.B
3.6.4.2	9.1.C
3.6.4.2	9.1.E
3.6.4.2	9.2
3.6.4.2	9.3
3.6.4.2	9.3.B
3.6.4.2	9.3.C
3.6.4.2.1	9.2
3.6.4.3	9.1.C
3.6.4.3	9.3.E

Current	Rewrite
3.6.4.4	9.3.G
3.6.4.4.1	Deleted
3.6.4.5	9.3.C
3.6.4.5	9.3.D
3.6.4.5	9.3.H
3.6.4.5.1	9.3.D
3.6.4.5.2	9.3.D
3.6.4.5.2	9.3.F
3.6.4.5.3	9.3.D
3.6.4.5.4	9.3.D
3.6.4.5.5	9.3.D
3.6.4.5.6	9.3.D
3.6.4.6	9.7.B
3.6.4.7	9.1.F
3.6.4.8	9.6.H
3.6.4.8	9.6.J
3.6.5	5.5.B
3.6.5.1	5.4.C
3.6.6	3.8
3.6.6	9.2
3.6.6	9.2.B
3.6.7	5.4.C
3.6.8	5.4.G
3.6.9.1	2.8.B
3.6.9.2	9.7.A
3.6.10	9.6.B
3.6.10	5.3.C
3.6.11	9.6.A
3.6.11	5.3.C
3.6.12	9.8.A
3.6.13	4.1

Policy 3.7

Current	Rewrite
3.7.1	1.3
3.7.1	6.3
3.7.1.1	6.3.B
3.7.1.1	10.2
3.7.1.1	10.2.A
3.7.2	1.2
3.7.2	10.4.C

Current	Rewrite
3.7.3	3.4.E
3.7.3	6.1
3.7.3	6.1.A
3.7.3	6.1.B
3.7.3	6.1.C
3.7.3	6.1.G
3.7.3	6.2
3.7.3	6.3
3.7.4	3.4.E
3.7.4	3.6.A
3.7.4	6.1
3.7.4	6.1.D
3.7.4	6.1.E
3.7.4	6.1.F
3.7.4	6.1.G
3.7.4	6.2
3.7.4	6.3
3.7.5	6.5.D
3.7.6	10.1
3.7.6.1	10.1.D
3.7.6.1.1	10.1.F
3.7.6.1.2	10.1.F.i
3.7.6.1.3	10.1.F.ii
3.7.6.1.4	10.1.F.iii
3.7.6.1.5	10.1.F.iv
3.7.6.2	10.1.A
3.7.6.2	10.1.B
3.7.6.2	10.1.C
3.7.6.2	10.3.B
3.7.6.3	10.1
3.7.6.3	10.1.E
3.7.6.3.1	10.1.G
3.7.6.3.2	Deleted
3.7.6.4	10.2
3.7.6.4	10.2.B
3.7.7	6.5.E
3.7.7	10.4
3.7.8	5.3.D
3.7.8	6.5.A
3.7.8	6.5.C

Current	Rewrite
3.7.8	6.5.D
3.7.8.1	5.3.D
3.7.8.2	10.4.B
3.7.9	6.5.B
3.7.9.1	6.4
3.7.9.1	6.5.B
3.7.9.2	3.6.A
3.7.9.2	10.3.A
3.7.9.3	3.6.A
3.7.9.3	10.3.B
3.7.10	6.5.C
3.7.10.1	6.5.D
3.7.11	10.4.A
3.7.11.1	10.4.A
3.7.12.2	2.9.B
3.7.12.4	2.9.C
3.7.13	3.8
3.7.14	5.4.G
3.7.15	6.5.F
3.7.16	4.1

Policy 3.8

Current	*Rewrite*
3.8	*11*
3.8	*1.2*
3.8.1	*11.4*
3.8.1.1	*11.3.A*
3.8.1.2	*5.3.E*
3.8.1.3	*11.3.B*
3.8.1.4	*11.4.B*
3.8.1.4.1	*11.4.A*
3.8.2	*2.8*
3.8.2.1	*2.8.E*
3.8.2.1	*3.4.D*
3.8.2.2	*2.8.E*
3.8.3.1	*11.5.A*
3.8.3.1	*11.5.B*
3.8.3.2	*11.5.D*
3.8.2.3	*4.1*
3.8.3.3	*11.5*
3.8.3.4	*3.6.A*

Current	*Rewrite*
3.8.3.4	*11.7.A*
3.8.3.5	*11.5.C*
3.8.3.6	*11.5*
3.8.4	*3.6.A*
3.8.4.1	*5.3.A*
3.8.4.2	*11.5.D*
3.8.4.3	*11.4.B*
3.8.4.3	*11.4.C*
3.8.5	*11.4.D*
3.8.5.1	*11.4.D*
3.8.5.2	*11.4.D*
3.8.5.2	*11.4.D.i*
3.8.5.2	*11.4.D.ii*
3.8.5.3	*3.6.B.ii*
3.8.6	*3.8*
3.8.6	*11.4*
3.8.7.1	*11.3.C*
3.8.7.2	*3.6.A*
3.8.7.2	*11.2*
3.8.7.2	*11.4.C*
3.8.7.3	*11.6*
3.8.7.4	*11.6*
3.8.7.5	*3.8*
3.8.7.5	*3.8.B*

Policy 3.9

Current	*Rewrite*
3.9	*5.9.A*
3.9.1	*5.9.A*
3.9.2	*5.9.B*
3.9.3	*3.4.F*
3.9.3	*5.8*
3.9.4	*5.4.G*

Policy 3.10

Current	*Rewrite*
3.10	*Bylaws*

Policy 3.11

Current	Rewrite
3.11	1.2
3.11.1	3.4.E

Current	**Rewrite**
3.11.1	7.1
3.11.1	7.1.A
3.11.1	7.1.B
3.11.1	7.1.C
3.11.1	7.2
3.11.2	7.3.B
3.11.3	7.1
3.11.4	9.6.H
3.11.4.1	9.4.B
3.11.4.2	9.6.I
3.11.5	3.8
3.11.5.1	3.6.B.iii
3.11.6	3.6.A
3.11.6	7.1.C

Appendices 3A-3D

Current	***Rewrite***
Appendix 3A	*4.3*
Appendix 3A	*4.15*
Appendix 3B	*Deleted*
Appendix 3C	*4.4*
Appendix 3D	*4.1*
Appendix 3D	*4.2*
Appendix 3D	*4.5*
Appendix 3D	*4.6*
Appendix 3D	*4.7*
Appendix 3D	*4.8*
Appendix 3D	*4.9*
Appendix 3D	*4.14*
Appendix 3D	*4.10*
Appendix 3D	*4.11*
Appendix 3D	*4.12*
Appendix 3D	*4.13*
Appendix 3D	*4.15*

Policy 4

Current	Rewrite
4	15
4.1	15.2
4.2	15.3
4.3	15.5

Current	Rewrite
4.1.1	15.2
4.1.2	15.2
4.2.1	15.3.A
4.2.2	15.3.B
4.2.3	15.3
4.3.1	15.3.B
4.4	15.1
4.5	15.4
4.5	15.4.A
4.5	15.4.B
4.5.1	15.4.B
4.5.2	15.4.A

Policy 5

Current	Rewrite
5.0	16.3
5.1	16.3
5.1	16.4
5.1	16.4.E
5.1.1	16.4.E.i
5.1.1	16.4.F
5.1.2	16.4.E.iii
5.1.2	16.4.F
5.1.3	16.4.E.ii
5.1.3	16.4.F
5.2	16.4
5.2	16.4.A
5.3	16.4.E.iii
5.3	16.4.F
5.4.1	16.4.B
5.4.2	16.4.C
5.4.3	16.4
5.4.3	16.4.A
5.4.3	16.4.D
5.5.1	16.5.A
5.5.2	16.5.B
5.6.1	16.6
5.7	5.6
5.8	2.12.B
5.8.1	2.12.B
5.8.2	2.12.B

Current	Rewrite
5.8.2	16.4.B
5.8.2	16.4.C
5.8.3	2.12.B
5.8.4	2.12.B
5.9	16.1
5.9.1	16.1
5.10	Deleted
5.10.1	16.7.A
5.10.1	16.7.C
5.10.2	16.7.A
5.10.2	16.7.B
5.11.1	16.8.B
5.11.2	16.8.B
5.11.2	16.8.D
5.11.3	16.8.B

Policy 6

Current	**Rewrite**
6	17
6.1	1.2
6.1.1	1.2
6.1.2	1.2
6.2	17.1.A
6.2.1	5.4.A
6.2.2	17.1.A
6.3	17.1.B
6.3.1	17.1.C
6.4	17.2
6.4.1	17.2.A
6.4.1.1	17.2.B
6.4.2	17.2.C

Policy 7

Current	**Rewrite**
7	18
7	18.1
7.1	1.2
7.1.1	1.2
7.1.2	1.2
7.1.3	18.1
7.1.4	1.2

Current	**Rewrite**
7.1.5	18.4.A
7.1.6	1.2
7.1.7	1.2
7.2	18.1
7.3.1	18.1
7.3.1	18.2
7.4.1	18.1
7.4.2	18.1
7.5	1.1.D
7.5	2.2
7.5.1	18.1
7.6	18.1
7.6.1	18.3
7.6.1.1	18.3
7.6.1.2	18.3
7.6.2	18.3
7.6.2.1	18.3
7.6.2.2	18.3
7.7	18.1
7.8.1	18.4.A
7.8.2	18.4.A
7.9	18.4.A

Policy 8

Current	Rewrite
8.0	20
8.1	20.1
8.1.1	20.1.A
8.1.2	20.1.B
8.2	20.2
8.2	20.2.A
8.2.1	20.2.B
8.2.2	20.2.A
8.2.3	20.2.B
8.2.4	20.2.B
8.2.5	20.2.B
8.2.6	20.2.C
8.2.7	20.2.B
8.2.8	20.2.B
8.3	20.3
8.4	20.4

Current	Rewrite
8.4.1	20.4.A
8.4.2	20.4.B
8.4.3	20.4.C
8.4.4	20.4.D
8.5	20.5
8.5.1	20.5.A
8.5.2	20.5.B
8.5.3	20.5.C
8.6.1	20.4.B
8.6.2	20.6.A
8.6.3	20.6.B
8.7	20.7
8.8	20.8
8.8.1	20.8.A
8.8.2	20.8.B

Policy 9

Current	Rewrite
9.1	19.1
9.2	19.2
9.2.1	19.2
9.2.2	19.2
9.2.3	19.2
9.3	19.3
9.3.1	19.3
9.3.2	19.3
9.3.3	19.3
9.4	19.4
9.5	19.5
9.6	19.6
9.6.1	19.6
9.6.2	19.6
9.6.3	19.6
9.6.4	19.6
9.6.4.1	19.6
9.6.4.2	19.6
9.6.4.3	19.6
9.6.4.4	19.6
9.6.4.5	19.6
9.6.4.6	19.6
9.6.4.7	19.6

Current	Rewrite
9.6.5	19.6
9.6.6	19.6
9.6.7	19.6
9.6.8	19.6
9.6.9	19.6
9.9	19.9
9.9.1	19.9
9.9.2	19.9
9.9.3	19.9
9.9.4	19.9
9.10	19.10
9.11	19.11
9.12	19.12

Policy 10

Current	**Rewrite**
10.1	19.3
10.2	19.14
10.3	19.15
10.4	19.16
10.4.1	19.16.A
10.4.2	19.16.B
10.5	19.17

Policy 11

Current	**Rewrite**
11	3.4.A

Policy 12

Current	Rewrite
12	14
12.1	1.2
12.2	14.3
12.2	14.3.A
12.2	14.3.A.i
12.2.1	14.3.A.ii
12.3	14.4
12.3.1	14.4.A
12.3.2	14.4.A.i
12.3.3	14.5.A
12.3.4	14.4.B
12.4	14.2.A

Current	Rewrite
12.4.1	14.2.A
12.5	14.7
12.5.1	14.7
12.5.1.1	14.7.A
12.5.2	Deleted
12.5.3	Deleted
12.5.4	Deleted
12.5.5	Deleted
12.5.6	14.7.B
12.6	14.7.C
12.7	14.8
12.7	16.2
12.7.1	16.4
12.7.1	16.4.E
12.7.1.1	16.4.E.i
12.7.1.2	16.4.E.iii
12.7.1.3	16.4.E.ii
12.7.2	16.4
12.7.2	16.4.A
12.7.3	16.4.F
12.7.4.1	16.4.B
12.7.4.2	16.4.C
12.7.4.3	16.4.D
12.7.5	16.5
12.7.5.1	16.5.A
12.7.6.1	16.7.E
12.7.7	5.6
12.7.8.1	4.1
12.7.8.2	16.4.C
12.7.8.3	16.2
12.7.8.4	16.2
12.7.9	16.1
12.7.9.1	16.1
12.7.10	14.8.A
12.7.10.1	14.8.A
12.7.10.1	16.7.D
12.7.10.2	14.8.B
12.7.11.1	16.8.C
12.7.11.2	16.8.D
12.7.11.3	16.8.D

Current	Rewrite
12.7.11.3	16.8.E
12.8	18.5
12.8.1	18.5.A
12.8.1.1	14.6
12.8.2	18.5.A
12.8.3	18.1
12.8.3.1	18.1
12.8.3.1	18.5.A
12.8.4	18.5.B
12.8.5	18.5.C
12.8.6	18.5.D
12.9	Deleted
12.9.1	Deleted
12.9.2	Deleted
12.9.3	9.5.F
12.9.4	8.5.F
12.10	14.1.A
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