OPTN | ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Policies

Contents

Policy 1: Administrative Rules and Definitions

1.1 Rules of Construction

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

1.1.A Time

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

1.1.B Headings, Notes, and History

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

1.1.C Reporting of Information to the OPTN Contractor

Members must report requested 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

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

A

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

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

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

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

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

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

Donor hospital
The hospital where the deceased or living donor is admitted.

Donor ID
A unique identification assigned to each deceased and living donor by the OPTN 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 deceased organ donation is defined as the death of a patient who meets *all* the following characteristics:

- Is 75 years old or less
- Is legally declared dead by neurologic criteria according to state or local law
- Has body weight of 5 kg or greater
- Has a body mass index (BMI) of 50 kg/m^2 or less
- Has at least one kidney, liver, heart or lung that is deemed to meet the eligible data definition as defined below:
  - The kidney would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
    - Greater than 70 years old
    - Age 50-69 years with history of type 1 diabetes for more than 20 years
    - Polycystic kidney disease
    - Glomerulosclerosis greater than or equal to 20% by kidney biopsy
    - Terminal serum creatinine greater than 4.0 mg/dL
    - Chronic renal failure
    - No urine output for 24 hours or longer
  - The liver would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
    - Cirrhosis
    - Terminal total bilirubin greater than or equal to 4 mg/dL
    - Portal hypertension
    - Macrosteatosis greater than or equal to 50% or fibrosis greater than or equal to stage II
    - Fulminant hepatic failure
    - Terminal AST/ALT greater than 700 U/L
  - The heart would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
    - Greater than 60 years old
    - 45 years old or older with a history of 10 or more years of HTN or 10 or more years of type 1 diabetes
    - History of coronary artery bypass graft (CABG)
    - History of coronary stent/intervention
    - Current or past medical history of myocardial infarction (MI)
    - Severe vessel diagnosis as supported by cardiac catheterization (that is more than 50 percent occlusion or 2+ vessel disease)
    - Acute myocarditis or endocarditis, or both
    - Heart failure due to cardiomyopathy
    - Internal defibrillator or pacemaker
    - Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair
    - Serial echo results showing severe global hypokinesis
    - Myxoma

    - Congenital defects (surgically corrected or not)
  - The lung would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
    - Greater than 65 years old
    - Diagnosed with COPD
    - Terminal PaO_2/FiO_2 less than 250 mmHg
    - Asthma (with daily prescription)
    - Asthma is the cause of death
    - Pulmonary fibrosis
    - Previous lobectomy
    - Multiple blebs documented on computed axial tomography (CAT) scan
    - Pneumonia as indicated on computed tomography (CT), X-ray, bronchoscopy, or cultures
    - Bilateral severe pulmonary contusions as per CT

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

- The donor goes to the operating room with intent to recover organs for transplant and all organs are deemed not medically suitable for transplant
- The donor exhibits *any* of the following active infections (with a specific diagnosis):
  - Bacterial: tuberculosis, gangrenous bowel or perforated bowel or intra-abdominal sepsis
  - Viral: HIV infection by serologic or molecular detection, rabies, reactive hepatitis B surface antigen, retroviral infections including viral encephalitis or meningitis, active herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia, acute epstein barr virus (mononucleosis), West Nile virus infection, or SARS. However, an HIV positive organ procured for transplantation into an HIV positive recipient at a transplant hospital that meets the requirements in *Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors* would still meet the requirements of an eligible death, according to the OPTN Final Rule.
  - Fungal: active infection with cryptococcus, aspergillus, histoplasma, coccidioides, active candidemia or invasive yeast infection
  - Parasites: active infection with trypanosoma cruzi (Chagas'), Leishmania, strongyloides, or malaria (*plasmodium sp.*)
  - Prion: Creutzfeldt-Jacob disease

The following are general exclusions:

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

Emergency

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

Exchange

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

Extra 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.

F

Final Rule

42 CFR 121 *et seq.*

G

Geographical Area

A physical area used to group potential transplant recipients in a classification. OPTN Policy uses the following geographical areas for organ allocation: *DSA, region, nation, and zones.*

Graft failure

Occurs when an organ is removed, a recipient dies, or a recipient is placed on a chronic allograft support system.

H

Histocompatibility Laboratory

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

Host Organ Procurement Organization (Host OPO)

The OPO responding to a deceased organ donor referral from a hospital.

I

Imminent neurological death

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

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

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

Inactive candidate

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

Independent living donor advocate (ILDA)

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

Intended incompatible

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

Intestine

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

Islet infusion

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

K

Kidney Paired Donation (KPD)

The donation and receipt of human kidneys under the following circumstances:

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

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

L

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

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

Living donor organ
An organ from a living donor.

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

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

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

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

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

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

Model for End Stage Liver Disease (MELD)
The scoring system used to measure illness severity in the allocation of livers to adults.

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

Month
Calendar month.

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

N

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

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

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

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

O

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

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

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

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

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), or vascularized composite allograft. 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,* and *Policy 12: Allocation of Vascularized Composite Allografts.*

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

community regarding organ sharing policies. The Organ Center operates 24 hours a day, 365 days a year.

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

Organ Procurement and Transplantation Network (OPTN)
The network established according to *Section 372* of the Social Security Act.

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

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

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

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

P

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

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

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

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

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

Patient
Includes *all* of the following:

1. Potential deceased donors undergoing an OPO's potential donor evaluation, donor management and procurement processes

2. Potential candidates and potential living donors undergoing a transplant program's evaluation process
3. Candidates
4. Living donors being followed by a transplant program
5. Recipients being followed by a transplant program

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

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

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

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

Primary waiting time
The longest time period a candidate registered on the waiting list has been waiting for a specific organ transplant procedure, after having met qualifying criteria to accrue waiting time for that organ.

Q

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

Qualified specimen
A blood specimen without evidence of hemodilution.

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

R

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

Recipient
A candidate that has received an organ transplant.

Recovery hospital
A healthcare facility that recovers living donor organs.

Region
For 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.

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

T

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

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

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

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

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

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

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

U

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

United States Public Health Service (PHS) Guideline
The *PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) through Organ Transplantation* (2013).

V

Variance
An experimental policy that tests methods of improving allocation.

Vascularized Composite Allograft (VCA)
A transplant involving any body parts that meets *all* nine of the following criteria:

1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation.
2. Containing multiple tissue types.
3. Recovered from a human donor as an anatomical/structural unit.
4. Transplanted into a human recipient as an anatomical/structural unit.
5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement).
6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor).
7. Not combined with another article such as a device.
8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

W

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

Y

Year
Calendar year.

Z

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

1.3.A Acceptable Variances

Permissible variances include, but are not limited to:

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

The following principles apply to *all* variances:

1. Variances must comply with the NOTA and the Final Rule.
2. Members participating in a variance must follow all rules and requirements of the OPTN Policies and Bylaws.
3. If the Board later amends an OPTN Policy to contradict with a variance, the Policy amendment will not affect the existing variance.
4. 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

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

Members wishing to join an existing open variance must submit an application as dictated by the specific variance. When an open variance is created, it may set conditions for the OPTN Contractor to approve certain applications. However, if the application to join an existing open variance does not receive affirmative support from all of the members required to join by the

application, the OPTN Contractor may not approve the application and only the sponsoring Committee may approve the application.

1.3.D Reporting Requirements for Variances

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

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

Participating members must also provide a final report to the sponsoring Committee at least six months before the variance's expiration date. The sponsoring Committee must actively monitor and evaluate these reports to determine if the variance achieved of its stated purpose.

1.3.E Final Evaluation of Variances

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

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

1.3.F Terminating Variances

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

1.3.G Appeals of Variance Decisions

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

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

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

1.4 Allocation of Organs during Emergencies

1.4.A Regional and National Emergencies

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

When the OPTN 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

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

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

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

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

1.4.E OPTN Computer Match Program Outages

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. Must refer to recent matches of similar blood type and body size for ranking local transplant candidates.
2. Must 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

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: 11/12/2013 (2/1/2014); 3/7/2014; 06/23/2014 (7/3/2014-9/1/2015) and (9/1/2014); 6/2/2015 (9/1/2015); Policy 1.2: Definitions: 6/2/2015 (10/1/2015); 6/2/2015 (11/19/2015); 12/1/2015 (6/23/2016); 6/2/2015 (11/10/2016); 12/2/2015 (11/10/2016); 12/1/2015 (1/1/2017); 12/5/2016 (1/1/2017)

Pending Implementation

Policy 1.2: Definitions: 6/6/2016 6/1/2017)

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*.

Policy 2: Deceased Donor Organ Procurement

2.1 OPO Organ Acceptance Criteria

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

2.2 OPO Responsibilities

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

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Clinical management of 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. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to VCA transplants; instead, members must allocate VCAs according to *Policy 12.2: VCA Allocation*.

12. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
13. Ensuring that documentation for *all* of the following deceased donor information is submitted to the OPTN Contractor upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs:
    a. ABO source documentation
    b. ABO subtype source documentation
    c. Infectious disease results source documentation
    d. Death pronouncement source documentation
    e. Authorization for donation source documentation
    f. Human leukocyte antigen (HLA) type
    g. Donor evaluation and management
    h. Donor medical and behavioral history
    i. Organ intraoperative findings
14. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

2.3 Evaluating and Screening Potential Deceased Donors

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

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

2.4 Deceased Donor Medical and Behavioral History

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

1. Any testing and laboratory results used to identify the presence of transmissible diseases or malignancies, treated and untreated, or any other known condition that may be transmitted by the deceased donor organ and may reasonably impact the recipient.
2. Whether the potential deceased donor has factors associated with an increased risk for disease transmission, including blood-borne pathogens. If the deceased donor meets the criteria for increased risk for HIV, Hepatitis B, and Hepatitis C transmission set forth in the current *U.S. Public Health Services (PHS) Guideline* or the host OPO cannot obtain the information necessary to make this determination, the host OPO must identify the donor as having increased risk for transmission of HIV, Hepatitis B, and Hepatitis C and communicate this information to all transplant programs receiving organs from the deceased donor.
3. Whether the potential deceased donor has a history of prior exposure or treatment with non recombinant Human Pituitary Derived Growth Hormone (HPDGH). If so, the potential deceased donor has an increased risk of prion disease and the host OPO must communicate this information to all

transplant programs receiving organs from the donor.

2.5 Hemodilution Assessment

OPOs must use qualified (non-hemodiluted) blood samples for deceased donor serological screening tests if available. If a qualified sample is not available for testing, a hemodiluted sample may 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 *U.S. Public Health Services (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) 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

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

2.6.A Deceased Donor Blood Type Determination

The host OPO must ensure that each deceased donor's blood type is determined by testing at least two donor blood samples prior to the match run. The host OPO must develop and comply with a written protocol to resolve conflicting primary blood type results.

Deceased donor blood samples must:

1. Be drawn on two separate occasions
2. Have different collection times
3. Be submitted as separate samples
4. Have results indicating the same blood type

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

2.6.B Deceased Donor Blood Subtype Determination

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

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

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

Deceased donor blood samples for subtyping must:

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

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

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

2.6.C Reporting of Deceased Donor Blood Type and Subtype

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

1. Two different qualified health care professionals, as defined in the host OPO's protocol, must each make an independent report of the donor's blood type to the OPTN Contractor.
2. If the donor's blood subtype will be used for allocation, a qualified health care professional must report the subtype to the OPTN Contractor. This report must be verified by a different qualified health care professional according to the OPO's protocol.
3. Both qualified health care professionals must use all blood type and subtype determination source documents to verify they:
   a. Contain blood type and subtype (if used for allocation) results for the donor
   b. Indicate the same blood type and subtype (if used for allocation) on the two test results
   c. Match the result reported to the OPTN Contractor

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

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

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

2.7 HIV Screening of Potential Deceased Donors

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

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

2.7.A Exceptions to HIV Screening Requirement

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

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

1. Provide all available deceased donor medical and social history to the transplant program.
2. Treat the deceased donor as having an increased risk for disease transmission based on current *U.S. Public Health Services (PHS) Guideline*.

In this case the receiving transplant hospital must:

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

2.7.B Informing Personnel

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

2.8 Required Deceased Donor General Risk Assessment

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

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

2.9 Required Deceased Donor Infectious Disease Testing

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

1. Blood and urine cultures

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

3. If the donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to *the U.S. Public Health Services (PHS) Guideline*. HIV RNA by donor screening or diagnostic NAT or HIV antigen/antibody (Ag/Ab) combination is *also* required unless *either of the following* is true:

   - The donor has already been tested for HIV using the HIV Ag/Ab combination test according to section 2.a above.
   - The donor's only increased risk factor is having received hemodialysis within the past 12 months.

2.10 Additional Deceased Donor Testing

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

2.11 Required Deceased Donor Information

The host OPO must obtain *all* of the following information for each potential deceased donor:

1. Age
2. Diagnosis (or cause of brain death)
3. Sex

2.11.A Required Information for Deceased Kidney Donors

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

1. Donor name
2. Donor ID
3. Date of admission for the current hospitalization
4. Ethnicity
5. Relevant past medical or social history
6. Current history of abdominal injuries and operations
7. Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria
8. Current medication and transfusion history
9. Anatomical description, including number of blood vessels, ureters, and approximate length of each
10. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers
11. Indications of sepsis

12. Injuries to or abnormalities of blood vessels, ureters, or kidney
13. Assurance that final blood and urine cultures are pending
14. Final urinalysis
15. Final blood urea nitrogen (BUN) and creatinine
16. Recovery blood pressure and urine output information
17. Recovery medications
18. Type of recovery procedure, flush solution and method, and flush storage solution
19. Warm ischemia time and organ flush characteristics

2.11.B Required Information for Deceased Liver Donors

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

1. Donor name
2. Donor ID
3. Ethnicity
4. Height
5. Weight
6. Vital signs, including blood pressure, heart rate and temperature
7. Social history, including drug use
8. History of treatment in hospital including current medications, vasopressors, and hydration
9. Current history of hypotensive episodes, urine output, and oliguria
10. Indications of sepsis
11. Aspartate aminotransferase (AST)
12. Bilirubin (direct)
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)
14. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens in the timeframe specified by the transplant program

If a transplant program requests HLA typing for a deceased liver donor, it must communicate this request to the OPO and the OPO must provide the HLA information listed above. The transplant program must document requests for donor HLA typing, including the turnaround time specified for reporting the donor HLA typing results. The OPO must document HLA typing provided to the requesting transplant program.

2.11.C Required Information for Deceased Heart Donors

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

1. Height
2. Weight
3. Vital signs, including blood pressure, heart rate, and temperature
4. History of treatment in hospital including vasopressors and hydration
5. Cardiopulmonary, social, and drug activity histories

6. Details of any documented cardiac arrest or hypotensive episodes
7. 12-lead interpreted electrocardiogram
8. Arterial blood gas results and ventilator settings
9. Cardiology consult or echocardiogram, if the hospital has the facilities
10. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to the final organ acceptance

For heart deceased donors, if a transplant program requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and document the request. The OPO must provide the HLA information listed above and document that the information was provided to the transplant program.

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.

2.11.D Required Information for Deceased Lung Donors

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

1. Height
2. Weight
3. Vital signs, including blood pressure, heart rate, and temperature
4. History of medical treatment in hospital including vasopressors and hydration
5. Smoking history
6. Cardiopulmonary, social, and drug activity histories
7. Arterial blood gases and ventilator settings on 5 cm/H_20/PEEP including PO_2/FiO_2 ratio and preferably 100% FiO_2, within 2 hours prior to the offer
8. Bronchoscopy results
9. Chest x-ray interpreted by a radiologist or qualified physician within 3 hours prior to the offer
10. Details of any documented cardiac arrest or hypotensive episodes
11. Sputum gram stain, with description of sputum
12. Electrocardiogram
13. Echocardiogram, if the OPO has the facilities
14. HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to final organ acceptance

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 program requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and document the request. The OPO must provide the HLA information listed above and document that the information was provided to the transplant program.

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

2.11.E Required Information for Deceased Pancreas Donors

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

1. Donor name
2. Donor ID
3. Ethnicity
4. Weight
5. Date of admission for the current hospitalization
6. Alcohol use (if known)
7. Current history of abdominal injuries and operations including pancreatic trauma
8. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria
9. Current medication and transfusion history
10. Pertinent past medical or social history including pancreatitis
11. Familial history of diabetes
12. Insulin protocol
13. Indications of sepsis
14. Serum amylase
15. Serum lipase
16. HLA information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers

2.12 Requested Deceased Donor Information

2.12.A Kidney

With each kidney offer, the host OPO should provide the receiving transplant program with the following biopsy information for 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.

2.12.B Heart

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 may 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
- 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

2.12.C Lung

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, if requested by the transplant hospital

2.13 Post Procurement Follow Up and Reporting

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

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

2.14 Deceased Donor Management

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

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

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

2.15 Organ Procurement

2.15.A Conflicts of Interest

The organ recovery procedure and the transplantation of organs must *not* be performed by *either* of the following:

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

2.15.B Pre-Recovery Verification

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

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

Table 2-2: Pre-Recovery Verification Requirements

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

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

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

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

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

2.15.C Organ Procurement Procedures

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

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

2.15.D 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 2-4* shows the requirements for each organ of this type.

Table 2-4: Minimum Typing Materials

The host OPO must provide:	For this organ:
One 7 to 10 mL clot red top tube	Any organ
Two acid-citrate-dextrose (ACD) yellow top tubes	Kidney or pancreas
If available, one 2 by 4 cm wedge of spleen in culture medium	Kidney or pancreas
Three to five lymph node samples	Each kidney or pancreas Any organ, if the receiving transplant hospital requests and they are available.

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

2.15.E Authorization Requirement

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.

This policy does not apply to VCA transplants.

Recovery of vascularized composite allografts for transplant must be specifically authorized from individual(s) authorizing donation whether that be the donor or a surrogate donation decision-maker consistent with applicable state law. The specific authorization for VCA must be documented by the host OPO.

2.15.F Non-renal Organ Procurement

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

2.15.G Start Time for Organ Procurement

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

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

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

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

2.16.A Agreement

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

2.16.B Protocols

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

2.16.C Potential DCD Donor Evaluation

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

2.16.D Consent for DCD

Conditions involving a potential DCD donor being medically treated/supported in a conscious mental state will require that the OPO confirms that the healthcare team has assessed the

patient's competency and capacity to make withdrawal/support and other medical decisions.

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

2.16.E Authorization for DCD

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

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

2.16.F Withdrawal of Life Sustaining Medical Treatment or Support

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

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

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

2.16.G Pronouncement of Death

The donor hospital healthcare team member who is authorized to declare death must not be a member of the OPO or the organ recovery team. Circulatory death is death defined as the irreversible cessation of circulatory and respiratory functions. Death is declared in accordance with hospital policy and applicable state and local statutes or regulation.

2.16.H Organ Recovery

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

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

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

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

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

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

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: 11/12/2013 (2/1/2014); 1/30/2014 (2/1/2014); 6/23/2014 (7/3/14); 6/23/2014 (12/4/2014); 11/12/2014; (2/1/2015); 11/12/2014 (5/1/2015); 11/12/2014 (8/10/2015); 6/2/2015 (9/1/2015); Policy 2.9: Required Deceased Donor Infectious Disease Testing: 6/2/2015 (11/19/2015); *Policy 2.7: HIV Screening of Potential Deceased Donors:* 11/16/2015 (11/21/2015); *Policy 2.7.A: Exceptions to HIV Screening Requirements*: 6/2/2015 (11/21/2015); *Policy 2.11: Required Deceased Donor Information:* 11/12/2014 (1/21/2016); 12/1/2015 (3/1/2016); *Policy 2.2: OPO Responsibilities:* 12/1/2015 (3/1/2016); *Policies 2.6: Deceased Donor Blood Type Determination and Reporting* and *2.15.B: Pre-recovery Verification*: (6/2/2015 (6/23/2016); *2.13: Post Recovery Follow Up and Reporting:* 6/6/2016 (9/1/2016); *Policy 2.11: Required Deceased Donor Information:* 11/12/2014 (9/29/2016); *Policy 2.15.B: Pre-Recovery Verification*: 12/5/2016 (3/1/2017); *Policy 2.9: Required Deceased Donor Infectious Disease Testing*: 6/6/2016 (4/6/2017); *2.11.C: Required Information for Deceased Heart Donors*: 6/6/2016 (4/6/2017)

Pending Implementation

Policy 2.2 OPO Responsibilities: 6/6/2016 (7/1/2017); *Policy 2.9: Required Deceased Donor Infectious Disease Testing*: 6/2/2015 (TBD)

Notes

- For requirement to prevent the acquisition of organs from individuals 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.*

Policy 3: Candidate Registrations, Modifications, and Removals

3.1 Access to Computer Systems

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

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

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

3.1.A Non-member Access

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

1. The non-member is assisting the member with facilitating organ transplants, placing organs for purposes other than transplantation, or reporting data to the OPTN.
2. The member has a data use agreement (DUA) with the non-member with *all* of the following elements:
    a. Data confidentiality and security requirements
    b. Data rights
    c. Access to patient-identified data
    d. Data use
    e. Procedures for securing data confidentiality
    f. Storage or disposal of data upon completion of contracted task
    g. Procedures to protect patient-identified data in the event of a data breach, inadvertent or otherwise
    h. Remedies in the event of a violation of the DUA

The member must maintain copies of all DUAs with non-members.

3.2 Notifying Patients of Their Options

As part of the evaluation process, transplant programs must inform and provide each patient it evaluates

with information and written materials explaining *all* of the following options:

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

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

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

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

3.3 Candidate Blood Type Determination and Reporting before Waiting List Registration

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

3.3.A Candidate Blood Type Determination

The transplant program must ensure that each candidate's blood type is determined by testing at least two candidate blood samples prior to registration on the waiting list. The transplant program must develop and comply with a written protocol to resolve conflicting primary blood type results.

Candidate blood samples must:

1. Be drawn on two separate occasions
2. Have different collection times
3. Be submitted as separate samples
4. Have results indicating the same blood type

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

3.3.B Reporting of Candidate Blood Type

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

1. Two different qualified health care professionals, as defined in the transplant program's protocol, must each make an independent report of the candidate's blood type to the OPTN Contractor
2. Both qualified health care professionals must use all blood type determination source documents to verify they:
   a. Contain blood type results for the candidate
   b. Indicate the same blood type on the two test results
   c. Match the result reported to the OPTN Contractor

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

3.4 Waiting List Registration

3.4.A Registration Fee

The registration fee of $834 for the registration of a transplant candidate is authorized by *42 C.F.R. § 121.5(c)* and *OPTN Bylaws Section 1.2(D): Registration Fees*.

3.4.B Approved Transplant Program Requirement

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

3.4.C Candidate Registrations

Transplant programs must:

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

3.4.D Candidate Human Leukocyte Antigen (HLA) Requirements

The candidate's transplant program must report to the OPTN 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
Pancreas islet alone	Required

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

3.4.E Inactive Status

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

3.4.F Multiple Transplant Program Registrations

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

Transplant hospitals may access a report from the OPTN 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.

3.5 Patient Notification

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

Table 3-2: Transplant Hospital Patient Notification Requirements

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

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

3.6 Waiting Time

3.6.A Waiting Time for Inactive Candidates

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

Table 3-3: Waiting Time for Inactive Candidates

If the candidate is registered for the following organ...	Then the candidate accrues waiting time while inactive as follows...
Heart	No time
Intestine	Up to 30 cumulative days
Kidney	Unlimited time
Kidney-pancreas	Unlimited time
Liver	No time
Lung and is at least 12 years old	No time
Lung and is less than 12 years old	Unlimited time
Pancreas	Unlimited time
Pancreas islet	Unlimited time
All other organs	Up to 30 days

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

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

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

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

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

Kidney waiting time will be reinstated when the OPTN 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

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

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

Intestine waiting time will be reinstated when the OPTN 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 Individual Waiting Time Transfers

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

1. The candidate must be registered at the new transplant program.
2. The candidate must currently be, or have previously been, registered at the earlier transplant program.

3. The candidate must sign a Wait Time Transfer Form, requesting transfer of primary waiting time to the new transplant program.
4. One of the transplant programs must submit a Wait Time Transfer Form to the OPTN Contractor.

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

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

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

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

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

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

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

3.7 Waiting Time Modifications

3.7.A Applications for Modifications of Waiting Time

To apply for a waiting time modification, the candidate's transplant program must submit an application to the OPTN 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:

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	Kidney or Pancreas Waiting Time Modifications Subcommittee
Intestine	A subcommittee of the Liver and Intestinal Organ Transplantation Committee, appointed by the Chair of the Liver and Intestinal Organ Transplantation Committee

Waiting list modification applications will be reviewed as follows:

1. The reviewer will determine if it is appropriate to modify the candidate's waiting time as requested in the application and will notify the OPTN 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

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-registered on the islet waiting list	An islet infusion	Any previously accrued waiting time according to

When:	And the candidate is registered for:	And the transplant program is requesting reinstatement of waiting time including:
		Policy 11.3.C Islet Waiting Time Criteria.
The candidate needs a second organ	Heart, liver, or lung	Modified waiting time for the second organ that includes the waiting time accrued for the first organ.
The candidate needs a second organ, routine alternative therapies are not possible, and the other transplant programs within the OPO and the OPO itself agree to the modified waiting time	Kidney, pancreas, or intestine	Modified waiting time for the second organ that includes the waiting time for the first organ.

Additionally, applications must meet any additional requirements outlined in the organ-specific allocation policies. If an application does not comply with the requirements of *Policy 3.7: Waiting Time Modifications*, then the OPTN 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.

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

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

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

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

3.8 Collective Patient Transfers

The OPTN Contractor may collectively transfer patients from transplant programs with a status of long-term inactive, withdrawal, or termination, and in other circumstances upon request to one or more transplant programs according to *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of the OPTN Bylaws. Candidates transferred as part of a collective transfer will retain waiting time according to *Appendix K.6: Transferred Candidates Waiting Time.*

3.9 Removing Candidates from the Waiting List

If a candidate receives a transplant or dies while awaiting a transplant then the registering transplant hospitals must remove the candidate from the hospital's organ waiting lists and notify the OPTN 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*.

3.9.A Removing Liver Candidates from the Waiting List

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

3.9.B Removing Pancreas Islets Candidates from the Waiting List

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

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: 11/12/2013 (2/1/2014); 3/7/14; 6/23/2014 (9/1/2014); 11/8/2010 (10/30/2014); 6/24/2013 (12/4/2014); 6/2/2015 (9/1/2015); 6/2/2015 (10/1/2015); *Policy 3.4.D: Candidate Human Leukocyte Antigen (HLA) Information:* 11/9/2010 (10/30/2014); 11/12/2014 (1/21/2016); *Policy 3.4.C: Candidate Registrations*: 3/14/2016 (4/14/2016); *Policy 3.3: Candidate Blood Type Determination before Waiting List Registration:* 6/2/2015 (6/23/2016); *Policy 3.4.G: In Utero Candidate Registrations*: 6/23/2014 (7/7/2016); *Policy 3.4.A: Registration* Fee: 6/6/2016 (10/1/2016)

Pending Implementation

Policy 3.7.B: Required Expedited Modifications of Waiting Time: 12/5/2016 (TBD)

Notes

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

Policy 4: Histocompatibility

4.1 Requirements for Laboratory Review of Reports

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

4.2 Requirements for Waiting List Data Verification

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

4.3 Requirements for Performing and Reporting HLA Typing

Laboratories must ensure that all HLA typing is accurately determined and report HLA typing results to the OPO or Transplant Program according to the turnaround time specified in the written agreement between the laboratory and any affiliated OPO or transplant program.

4.3.A Deceased Donor HLA Typing

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

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

Table 4-1: Deceased Donor HLA Typing Requirements

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

4.3.B HLA Typing for Candidates

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

4.4 Resolving Discrepant Donor and Recipient HLA Typing Results

Laboratories must submit donor and recipient histocompatibility forms to the OPTN Contractor after transplant according to *Policy 18.0: Data Submission Requirements*. After laboratories submit 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.

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

1. Donor id
2. HLA typing results
3. Date of tests
4. Test methods
5. Laboratory Identifiers
6. OPO Identifier (if applicable)

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

1. SSN
2. HLA typing results
3. Date of tests
4. Test methods
5. Laboratory identifier

Laboratories must resolve discrepancies within 30 days of notification of discrepant HLA typing results. The Laboratory Director or designated staff must contact the other Laboratory Director or designated staff to resolve the discrepancies. Each laboratory involved in the HLA typing discrepancy must identify and report the reason for the discrepancy to the OPTN Contractor.

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. The Histocompatibility Committee will review, at least every three months, any outstanding discrepant typing recorded since the last review. The committee will use the results of these reviews to determine whether policy modifications are required.

4.5 Antibody Screening and Reporting

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

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

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

4.6 Crossmatching

4.6.A Crossmatching for Kidney Transplants

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

4.6.B General Crossmatching Requirements

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

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

4.7 Blood Type Determination

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

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

4.8 Preservation of Excess Specimens

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

4.9 HLA Antigen Values and Split Equivalences

HLA matching of A, B, and DR locus antigens is based on the antigens which are listed in *Policy 4.10: Reference Tables of HLA Antigen Values and Split Equivalences*. The Histocompatibility Committee must review and recommend any changes needed to the tables on or before June 1 of each year. For matching purposes, split antigens not on this list will be indicated on the waiting list as the parent antigens and will match only with the corresponding parent antigens.

4.10 Reference Tables of HLA Antigen Values and Split Equivalences

Tables 4-2, 4-3, and *4-4* show candidate-donor antigen 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 4-2: 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

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

Patient A Locus Antigen	Equivalent Donor Antigens
68	68
69	69
74	74
80	80
203	203, 2
210	210, 2
2403	2403, 24
*6601	*6601, 66
*6602	*6602, 66
** 99	(No equivalent)

Table 4-3: HLA B Matching Antigen Equivalences

Patient B Locus Antigen	Equivalent Donor Antigens
5	5
7	7, 703
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

Patient B Locus Antigen	Equivalent Donor Antigens
42	42
44	44
45	45
46	46
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

Patient B Locus Antigen	Equivalent Donor Antigens
62	62
63	63
64	64
65	65
67	67
70	70, 71, 72
71	71, 70
72	72, 70
73	73
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

Patient B Locus Antigen	Equivalent Donor Antigens
3901	3901, 39
3902	3902, 39
*3905	*3905, 39
4005	4005, 50

Patient B Locus Antigen	Equivalent Donor Antigens
5102	5102, 51, 53
5103	5103, 51
7801	7801
*8201	*8201, 82

Patient B Locus Antigen	Equivalent Donor Antigens
** 99	(No equivalent)

Table 4-4: 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
17	17
18	18
103	103, 1
1403	1403, 14, 6
1404	1404, 14, 6
** 99	(No equivalent)

*** Indicates an allele; may not have a WHO-approved serologic specificity**

**** Code 99 means not tested**

Examples of how "Matching Antigen Equivalences" works:

If patient has B70: Donors with B70, B71, and B72 are considered not mismatched.

If patient has B71: Donors with B71 and B70 are considered not mismatched. Donors with B72 are considered mismatched.

Table 4-5: 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, 43
11	11
19	19, 29, 30, 31, 32, 33, 74
23	23
24	24
25	25
26	26
28	28, 68, 69
29	29
30	30
31	31
32	32
33	33
34	34
36	36
43	43
66	66, *6601, *6602
68	68
69	69
74	74
80	80
203	203
210	210
2403	2403
*6601	*6601
*6602	*6602

Table 4-6: HLA B Unacceptable Antigen Equivalences

Patient's Unacceptable B Locus Antigen	Donor Equivalent Antigens
5	5, 51, 5103, 52,78
7	7, 703
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
35	35
37	37
38	38
39	39, 3901, 3902, *3905
40	40, 60, 61
41	41
42	42
44	44
45	45
46	46
47	47
48	48
49	49
50	50, 4005
51	51, 5103
52	52
53	53
54	54
55	55
56	56
57	57
58	58
59	59
60	60
61	61
62	62
63	63
64	64
65	65
67	67
70	70, 71, 72
71	71
72	72
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, 50
5102	5102
5103	5103
7801	7801, 78
*8201	*8201, 82
Bw4	Bw4, 5, 13, 17, 27, 37, 38, 44, 47,49, 51, 52, 53, 57, 58, 59, 63, 77

Patient's Unacceptable B Locus Antigen	Donor Equivalent Antigens
Bw6	Bw6, 7, 8, 14, 18, 22, 2708, 35, 39, 40, 41, 42, 45, 48, 50, *4005, 54, 55, 56, 60, 61, 62, 64, 65, 67, 70, 71, 72, 75, 76, 78, 81, 82

Table 4-7: 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

Patient's Unacceptable C Locus Antigen	Donor Equivalent Antigens
w6	w6
w7	w7
w8	w8
w9	w9
w10	w10
*12	*12

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

Table 4-8: HLA DR Unacceptable Antigen Equivalences

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

Patient's Unacceptable DR Locus Antigen	Donor Equivalent Antigens
9	9
10	10
11	11
12	12
13	13
14	14, 1403, 1404
15	15
16	16

Patient's Unacceptable DR Locus Antigen	Donor Equivalent Antigens
17	17
18	18
103	103
1403	1403
1404	1404
51*	51
52*	52
53*	53

Table 4-9: 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
5	5, 1
6	6, 1
7	7, 3
8	8, 3
9	9, 3

***Indicates an allele; may not have a WHO-approved serologic specificity**

*****Please refer to the end of this section for information**

Examples of how "Unacceptable Antigen Equivalences" works:

If a patient has B70 listed as an "unacceptable antigen": Donors typed as B70, B71, and B72 are considered unacceptable. Donors typed as B73 and B75 are considered acceptable.

Additional Unacceptable Antigen Equivalences to be used in the Calculated PRA Only:
DR51 should also include DR2, DR15, and DR16.
DR52 should also include DR3, DR5, DR6, DR11, DR12, DR13, DR14, DR17, and DR18.
DR53 should also include DR4, DR7, and DR9.

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: 11/12/2013 (2/1/2014); 6/23/2014 (9/1/2014); *Policy 4.8: Reference Tables of HLA Antigen Values and Split Equivalences*: 11/12/2013 (4/16/2015); *Policy 4.2: Resolving Discrepant Donor and Recipient HLA Typing Results*: 6/23/2014 (6/24/2015); 6/2/2015 (9/1/2015); *Policy 4.2: Requirements for Performing and Reporting HLA Typing*: 11/12/2014 (1/21/2016); Policy 4: Histocompatibility: 12/1/2015 (3/1/2016)

Pending Implementation

Policies 4.9: HLA Antigen Values and Split Equivalences and *4.10: Reference Tables of HLA Antigen Values and Split Equivalences*: 12/1/2015 (TBD); *4.10: Reference Tables of HLA Antigen Values and Split Equivalences*: 6/6/2016 (TBD)

Notes

- 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 permissible crossmatching pursuant to federal regulations, see Code of Federal Regulations, Public Health, *title 42, sec. 493.1278.*

Policy 5: Organ Offers, Acceptance, and Verification

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

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

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

5.2 Maximum Mismatched Antigens

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

5.3 Additional Acceptance and Screening Criteria

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

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

1. Define the criteria for unacceptable antigens that are considered as contraindications for transplant. This may include clarification of unacceptable antigens based on solid phase testing, consideration of prior donor antigens or non-self antigens involved in pregnancies, prior blood transfusion, and unexpected positive crossmatches.

2. Base unacceptable antigens on laboratory detection of human leukocyte antigen (HLA) specific antibodies using at least one solid phase immunoassay with purified HLA molecules.

Transplant programs may establish criteria for additional unacceptable antigens including, but not limited to, multiple unexpected positive crossmatches. CPRA will be derived from HLA antigen/allele group and haplotype frequencies for the different racial and ethnic groups in proportion to their representation in the national deceased donor population. CPRA values will be rounded to the nearest one hundredth percentage.

5.3.B Infectious Disease Screening Criteria

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

Table 5-1: Donor Infectious Disease Screening Options

If the donor tests positive for:	Then candidates may choose not to receive offers on the following match runs:
Cytomegalovirus (CMV)	Intestine
Hepatitis B core antibody (HBcAb)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis B Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis C (HCV) Antibody	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis C Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Human Immunodeficiency Virus (HIV); Organs from HIV positive donors may only be recovered and transplanted according to the requirements in the Final Rule	Kidney, Liver; Use of HIV positive donor organs is only permissible for kidney and liver transplantation at this time

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

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

5.3.D Liver Acceptance Criteria

The responsible transplant surgeon must determine the acceptable deceased donor weight for each of its liver candidates, and the determined acceptable weight must be reported to the OPTN 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 blood type A, non-A_1
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
8. If a candidate is willing to accept an HIV positive liver as part of an institutional review board approved research protocol that meets the requirement in the OPTN Final Rule

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

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

5.3.F Pancreas Candidates after Kidney Transplant Acceptance Criteria

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

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

5.4.B Order of Allocation

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

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.
3. OPOs must first offer organs to potential 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 candidates' data with the OPTN Contractor. The host OPO must re-execute the match run to allocate the organ.
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.

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

5.4.C Liver Offers

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

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

5.4.D Backup Organ Offers

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

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

5.4.E Allocation to Candidates Not on the Match Run

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

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

1. The reason for transplanting an organ into a candidate who did not appear on the match run
2. The reason the candidate did not appear on the match run
3. Whether the transplant hospital is willing to accept a kidney from a deceased donor with a KDPI score greater than 85% or from a donation after circulatory death (DCD) donor, if applicable
4. Prior to transplant, the transplant hospital must verify the medical suitability between the deceased donor organ and recipient in at least, but not limited to, *all* the following areas according to organ type:

    - Blood type
    - Blood subtype, when used for allocation
    - Donor HLA and candidate's unacceptable antigens
    - Donor height

- Donor weight
- Infectious disease test results
- For HIV positive deceased donor kidneys and livers, the OPO and transplant hospital must also do *both* of the following:

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

The transplant hospital must maintain all related documentation.

5.4.F Local Conflicts

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

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

5.5.A (*Reserved*)

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

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

1. When a deceased donor organ has *not* been accepted for a potential transplant recipient, then the OPO must do *all* of the following for each organ being allocated:

    a. Stop allocation on the original match run for this donor
    b. Re-execute the match run according to the infectious disease screening options as follows:
        i. A new positive Cytomegalovirus (CMV) result will apply to re-execution of the intestine match run
        ii. A new positive hepatitis B (HBcAb or HBV NAT) or hepatitis C (HCV Ab or HCV NAT) result will apply to re-execution of *all* organ types
    c. Allocate the organ using this updated match run

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

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

When the transplant hospital is notified by the host OPO of these new positive infectious disease results, it must do *both* of the following:

1. Notify the host OPO whether the organ will be accepted or declined, within one hour of receipt of the new test result
2. Meet the requirements of *Policy 15.3.A: Deceased Donors with Additional Risk Identified Pre-Transplant* if the potential transplant recipient proceeds with transplantation of the organ.

5.5.C OPO Requirements for Positive HIV Results

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

1. Stop allocation on the original match run for this donor
2. Re-execute the kidney and liver match runs in order to include *only* HIV-positive candidates participating in an institutional review board approved research protocol that meets the requirements in the Final Rule regarding the recovery of organs from individuals known to be infected with HIV according to *Policy 15.6.A: Requirements for Allocating HIV Positive Deceased Donor Organs*
3. Withdraw any pending offers to candidates who are not HIV positive *and* also participating in an institutional review board approved research protocol that meets the requirements in the OPTN Final Rule according to *Policy 15.6.C: Transplant Hospital Requirements for Transplantation of HIV Positive Organs*
4. Allocate *only* kidneys and livers from HIV positive donors

5.6 Receiving and Accepting Organ Offers

5.6.A Receiving and Reviewing Organ Offers

Transplant hospitals must view organ offers and respond to these offers through the match system. The previous sentence does not apply to VCA transplants.

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

5.6.B Time Limit for Acceptance

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.

This policy does not apply to VCA transplants.

5.6.C Effect of Acceptance

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

5.7 Organ Check-In

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

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

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

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

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

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

5.8 Pre-Transplant Verification

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

5.8.A Pre-Transplant Verification Prior to Organ Receipt

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

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

Transplant hospitals must use at least one of the acceptable sources during the pre-transplant

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

The transplant hospital must verify all of the following information:	Using at least *one* of the following:	By the following individuals:
Expected donor ID	• OPTN computer system • Recipient medical record	Two licensed health care professionals
Expected organ (and lung laterality if applicable)	• OPTN computer system	Two licensed health care professionals

	• Recipient medical record	
Expected donor blood type and subtype (if used for allocation)	• Donor blood type and subtype source documents • OPTN computer system	Two licensed health care professionals
Recipient unique identifier	• Recipient identification band	Two licensed health care professionals
Recipient blood type	• OPTN computer system • Recipient blood type and subtype source documents • Recipient medical record	Two licensed health care professionals
Expected donor and recipient are blood type compatible (or intended incompatible).	• OPTN computer system • Recipient medical record • Attestation following verification of donor and recipient blood types	Two licensed health care professionals

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

5.8.B Pre-Transplant Verification Upon Organ Receipt

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

1. The intended recipient must be present in the operating room
2. The verification must occur after the organ arrives in the operating room, but prior to anastomosis of the first organ
3. Transplant hospitals must use at least one of the acceptable sources during the pre-transplant verification upon organ receipt to verify all of the following information according to *Table 5-3* below. Transplant hospitals may use the OPTN organ tracking system to assist with completion of this verification.

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

The transplant hospital must verify all of the following information:	Using at least *one* of the following:	By *both* of the following individuals:
Donor ID	• External and internal organ package labels • Documentation with organ	Transplant surgeon Licensed health care professional
Organ (and laterality if applicable)	• Organ received	1. Transplant surgeon 2. Licensed health care professional
Donor blood type and subtype (if used for allocation)	• Donor blood type and subtype source documents	1. Transplant surgeon 2. Licensed health care professional
Recipient unique identifier	• Recipient identification band	1. Transplant surgeon 2. Licensed health care

		professional
Recipient blood type	• Recipient blood type source documents • Recipient medical record	1. Transplant surgeon 2. Licensed health care professional
Donor and recipient are blood type compatible (or intended incompatible)	• OPTN computer system • Recipient medical record • Attestation following verification of donor and recipient blood types	1. Transplant surgeon 2. Licensed health care professional
Correct donor organ has been identified for the correct recipient	• Recipient medical record • OPTN computer system • Attestation following verification of donor ID, organ, and recipient unique identifier	1. Transplant surgeon 2. Licensed health care professional

The transplant hospital must document that the pre-transplant verification upon organ receipt was completed according to the hospital's protocol and the above requirements.

5.9 Released Organs

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

The transplant program must transplant all accepted, deceased donor organs into the 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.

5.10 Allocation of Multi-Organ Combinations

5.10.A Allocation of Heart-Lungs

Heart-lung combinations are allocated according to *Policy 6.5.F: Allocation of Heart-Lungs*.

5.10.B Other Multi-Organ Combinations

When multi-organ candidates are registered on the heart, lung, or liver waiting list, the second required organ will be allocated to the multi-organ candidate from the same donor if the donor's DSA is the same DSA where the multi-organ candidate is registered.

If the multi-organ candidate is on a waiting list outside the donor's DSA, it is permissible to allocate the second organ to the multi-organ candidate receiving the first organ.

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: 11/12/2013 (2/1/2014); 3/7/14; 06/23/14 (7/3/14); 6/24/13 (12/11/14); 11/12/2014 (5/1/2015); 6/2/2015 (9/1/2015) *Policy 5.3.B: Infectious Disease Screening Criteria, Policy 5.4.C: Liver Offers,* and *Policy 5.5: Re-execution of the Match Run Due to New Information:* 6/2/2015 (11/19/2015); *Policy 5.3.C: Liver Acceptance Criteria* and *Policy 5.4.F: Allocation to Candidates Not on the Match Run*: 6/2/2015 (11/21/2015); *Policies 5.4.B: Order of Allocation, 5.6: Blood Type Verification Upon Receipt,* and *5.7: Pre-transplant Verification*: 6/2/2015; (6/23/2016); *Policy 5.3.C: Pediatric Heart Acceptance Criteria*: 6/23/2014 (7/7/2016); *Policy 5.3.E: Pediatric Heart Acceptance Criteria to Receive Intended Blood Group Incompatible Hearts*: 12/1/2015 (7/7/2016); *5.3.C: Informed Consent for Kidneys Based on KDPI Greater than 85%*: 6/6/2016 (9/1/2016); *Policy 5.8: Pre-Transplant Verification*: 12/5/2016 (3/1/2017); Policy 5.3.E: Pediatric Heart Acceptance Criteria to Receive Hearts from Donors of Any Blood Type: 12/1/2015 (3/30/2017)

Pending Implementation

Policy 5.10: Allocation of Multi-Organ Combinations: 6/6/2016 (TBD)

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 2.16: Requirements for Controlled Donation after Circulatory Death (DCD) Protocols.*

Policy 6: Allocation of Hearts and Heart-Lungs

6.1 Status Assignments

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

6.1.A Adult Heart Status 1A Requirements

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 devices in place:	14 days, and must be recertified by an attending physician every 14 days from the date of the

If the candidate meets this condition:	Then adult status 1A is valid for:
• Total artificial heart (TAH) • Intra-aortic balloon pump • Extracorporeal membrane oxygenation (ECMO)	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

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

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

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

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

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

6.1.E Pediatric Heart Status 1B Requirements

To assign a candidate pediatric heart status 1B, the candidate's transplant program must submit a *Heart Status 1B Justification Form* to the OPTN 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 one or more inotropic agents but does not qualify for pediatric status 1A. The OPTN Contractor maintains a list of the OPTN-approved status 1B inotropic agents and doses.
2. Is less than one year old at the time of the candidate's initial registration and has a diagnosis of hypertrophic or restrictive cardiomyopathy.

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

6.1.F Pediatric Heart Status 2 Requirements

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

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

6.1.G Inactive Adult and Pediatric Candidates

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

6.2 Status Updates

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

6.3 Status Exceptions

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

Table 6-3: Exception Qualification and Periods

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

The candidate's transplant physician must submit a justification form 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. If an adult status 1A exception request is not approved by the RRB, the candidate's transplant program may override the decision and list the candidate at the requested status. If a pediatric status 1A or status 1B exception request 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 automatic 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

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

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

If a candidate's status is upgraded, waiting time accrued while 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.

6.5 Heart Allocation Classifications and Rankings

6.5.A Allocation of Hearts by Blood Type

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

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

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

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

Pediatric candidates that are at least one year of age at the time of the match run but registered before their second birthday and are eligible to receive a heart from an intended blood group incompatible deceased donor will be classified as a secondary blood type match candidate, unless they are a primary blood type match candidate according to *Table 6-4*.

6.5.B Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Hearts

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

1. Candidate is less than one year old at the time of the match run, and meets *both* of the following:
   a. Is registered as status 1A or 1B.
   b. Has reported isohemagglutinin titer information for A or B blood type antigens to the OPTN Contractor within the last 30 days.
2. Candidate is at least one year old at the time of the match run, and meets all of the following:
   a. Is registered prior to turning two years old.
   b. Is registered as status 1A or 1B.
   c. Has reported to the OPTN Contractor isohemagglutinin titers less than or equal to 1:16 for A or B blood type antigens from a blood sample collected within the last 30 days. The candidate must not have received treatments that may have reduced isohemagglutinin titers to 1:16 or less within 30 days of when this blood sample was collected.

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

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

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

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

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

1. At transplant from a blood sample taken within 24 hours prior to transplant.
2. If graft loss occurs within one year after transplant from the most recent blood sample, if available.
3. If recipient death occurs within one year after transplant from the most recent blood sample, if available.

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

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

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

6.5.C Sorting Within Each Classification

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

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

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

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

Classification	Candidates that are within the:	And 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

Classification	Candidates that are within the:	And are:
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

Classification	Candidates that are within the:	And are:
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

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

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

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

Classification	Candidates that are 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

Classification	Candidates that are within the:	And are:
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
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

Classification	Candidates that are within the:	And are:
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
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

Classification	Candidates that are within the:	And are:
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
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

6.5.F Allocation of Heart-Lungs

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.

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: 11/12/2013 (2/1/2014); *6.4: Waiting Time*: 6/2/2015 (9/1/2015); *Policies 6.1: Status Assignments, 6.3: Status Exceptions*, and *6.4: Waiting Time*: 6/23/2014 (3/22/2016) *Policy 6.5: Heart Allocation Classifications and Rankings*: 6/23/2014 (7/7/2016); *Policy 6.5: Heart Allocation Classifications and Rankings*: 12/1/2015 (7/7/2016); *Policy 6.5.G: Allocation of Domino Donor Hearts:* 12/1/2015 (11/10/2016); *Policy 6.5: Heart Allocation Classifications and Rankings:* 12/1/2015 (3/30/2017)

Pending Implementation

Policy 6: Allocation of Hearts and Heart-Lungs: 12/5/2016 (TBD)

Notes

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

Policy 7: Allocation of Intestines

7.1 Status Assignments

Each intestine candidate is assigned a status that reflects the candidate's medical condition. Candidates may be assigned *any* of the following:

- Status 1
- Status 2
- Inactive status

7.1.A Status 1 Requirements

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

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

7.1.C Inactive Status

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

7.2 Waiting Time

Inactive candidates will accrue waiting time while inactive for up to a maximum of 30 cumulative days.

7.3 Intestine Allocation Classifications and Rankings

7.3.A Sorting Within Each Classification

Within each allocation classification, candidates are sorted by waiting time (longest to shortest).

7.3.B Allocation of Intestines

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

Table 7-1: Allocation of Intestines

Classification	Candidates 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: 11/12/2013 (2/1/2014)

Notes

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

Policy 8: Allocation of Kidneys

8.1 Calculated Panel Reactive Antibody (CPRA)

CPRA is the percentage of donors expected to have one or more of a candidate's indicated unacceptable antigens. CPRA will be calculated automatically when a transplant hospital reports unacceptable antigens to the OPTN 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

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

Allocation of deceased donor kidneys is based on the HLA typing identified by the donor histocompatibility laboratory. If the recipient HLA laboratory identifies a different HLA type for the deceased donor and the intended recipient cannot be transplanted, the kidney must be allocated according to *Policy 5.9: Released Organs.* When reallocating the kidney, the OPO has the discretion to use either the HLA typing identified by the donor histocompatibility laboratory or the recipient HLA laboratory.

8.3 Kidney Allocation Points

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

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.G, 8.5.H, 8.5.I, or 8.5.J	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.G, 8.5.H, or 8.5.I	4 points
Aged 11-17 at time of match and a 0-ABDR mismatch with the donor	8.5.G, 8.5.H, or 8.5.I	3 points
Aged 0-10 at time of match and donor has a KDPI score <35%	8.5.G, 8.5.H	1 point
A prior living donor	8.5.G, 8.5.H, or 8.5.I	4 points
Sensitized (CPRA at least 20%)	8.5.G, 8.5.H, or 8.5.I	*See Table 8-2: Points for CPRA*
A single HLA-DR mismatch with the donor*	8.5.G, 8.5.H, or 8.5.I	1 point
A zero HLA-DR mismatch with the donor*	8.5.G, 8.5H, or 8.5.I	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

If the candidate's CPRA score is:	Then the candidate receives this many points:
98	24.40
99	50.09
100	202.10

8.4 Waiting Time

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

If a kidney candidate is 18 years or older on the date the candidate is registered for a kidney, then the candidate's waiting time is based on the earliest of the following:

1. The candidate's registration date with a measured or calculated creatinine clearance or glomerular filtration rate (GFR) less than or equal to 20 mL/min.
2. The date after registration that a candidate's measured or calculated creatinine clearance or GFR becomes less than or equal to 20 mL/min.
3. The date that the candidate began regularly administered dialysis as an End Stage Renal Disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting.

8.4.B Waiting Time for Candidates Registered prior to Age 18

If a kidney candidate is less than 18 years old at the time of registration on the waiting list, then the candidate's waiting time is based on the earlier of the following:

1. The date that the candidate registered on the waiting list regardless of clinical criteria.
2. The date that the candidate began regularly administered dialysis as an ESRD patient in a hospital based, independent non-hospital based, or home setting.

8.4.C Waiting Time for Kidney Recipients

If a kidney recipient returns to the kidney waiting list, waiting time will be based only on the dates after the most recent kidney transplant, unless the candidate qualifies for reinstatement of waiting time according to *Policy 3.6.B.i: Non-function of a Transplanted Kidney*.

8.5 Kidney Allocation Classifications and Rankings

8.5.A Candidate Classifications

Each candidate on the kidney waiting list after turning 18 years old receives an Estimated Post Transplant Survival (EPTS) score. A candidate's EPTS score represents the percentage of kidney candidates in the nation with a longer expected post-transplant survival time. EPTS is based on *all* of the following:

1. Candidate time on dialysis
2. Whether or not the candidate has a current diagnosis of diabetes
3. Whether or not the candidate has had any prior solid organ transplant
4. Candidate age

If a kidney recipient returns to the kidney waiting list, only time on dialysis after the most recent kidney transplant applies for number 1 above, candidate time on dialysis, as defined in *Policy 8.4: Waiting Time*.

Each candidate's EPTS score is calculated when the candidate is registered on the waiting list. The OPTN 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

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
Creatinine (mg/dL)	All donors	0.2200*(creatinine - 1)

This deceased donor characteristic:	Applies to:	KDRI score component:
	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 KDPI score is rounded to the nearest integer.

The KDPI used for allocation is based on the most recent values of donor characteristics reported to the OPTN 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 Sorting Within Each Classification

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.D Allocation of Kidneys by Blood Type

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

Table 8-4: Allocation of Kidneys by Blood Type

Kidneys from Donors with:	Are Allocated to Candidates with:
Blood Type O	Blood type O. For offers made to candidates in 0-ABDR mismatch categories, blood type O kidneys may be transplanted into

Kidneys from Donors with:	Are Allocated to Candidates with:
	candidates who have blood types other than O.
Blood Type A	Blood type A or blood type AB.
Blood Type B	Blood type B. For offers made to candidates in 0-ABDR mismatch categories, blood type B kidneys may be transplanted into candidates who have blood types other than B.
Blood Type AB	Blood type AB.
Blood Types A, non-A_1 and AB, non-A_1B	Kidneys may be transplanted into candidates with blood type B who meet *all* of the following criteria: 1. The transplant program obtains written informed consent from each blood type B candidate regarding their willingness to accept a blood type A, non-A_1 or blood type AB, non-A_1B blood type kidney. 2. The transplant program establishes a written policy regarding its program's titer threshold for transplanting blood type A, non-A_1 and blood type AB, non-A_1B kidneys into candidates with blood type B. The transplant program must confirm the candidate's eligibility every 90 days (+/- 20 days).

8.5.E Prior Living Organ Donors

A kidney candidate will be classified as a prior living donor if *all* of the following conditions are met:

1. The candidate donated for transplantation, within the United States or its territories, at least *one* of the following:

   - Kidney
   - Liver segment
   - Lung segment
   - Partial pancreas
   - Small bowel segment.

2. The candidate's physician reports *all* of the following information to the OPTN 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.F Highly Sensitized Candidates

Before a candidate with a CPRA score of 99% or 100% can receive offers in allocation classifications 1 through 10 in allocation sequences according to *Policy 8.5: Kidney Allocation Classifications and Rankings*, the transplant program's HLA laboratory director and the

candidate's transplant physician or surgeon must review and sign a written approval of the unacceptable antigens listed for the candidate. The transplant hospital must document this approval in the candidate's medical record.

8.5.G Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%

Kidneys from deceased donors with a kidney donor profile index (KDPI) score of less than or equal to 20% are allocated to candidates according to *Table 8-5* 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%, and blood type identical	Any
15	Nation	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run,	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
		CPRA greater than or equal to 80%, and blood type identical	
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%, 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%, 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	O

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
		21% but no greater than 79%, and blood type B	
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%, 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%, 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,	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
		CPRA greater than or equal to 21% but no 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%, and blood type identical	Any
46	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, 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%, and blood type B	O
51	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, 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
53	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21%	O

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
		but no greater than 79%, and blood type B	
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%, and blood type permissible	Any
56	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, 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	A2 or A2B
68	Nation	Top 20% EPTS, blood type permissible or identical	Any
69	Nation	All remaining candidates, blood type permissible or identical	Any

8.5.H Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%

Kidneys from deceased donors with KDPI scores greater than 20% but less than 35% are allocated to candidates according to *Table 8-6* 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%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, 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

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
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%, and blood type B	O
24	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, 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
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

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
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%, and blood type permissible	Any
33	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, 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 permissible or identical	Any
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

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
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.I Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%

Kidneys from donors with KDPI scores greater than or equal to 35% but less than or equal to 85% are allocated to candidates according to *Table 8-7* 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
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

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
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%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, 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%, and blood type B	O
24	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, 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
28	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to	O

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
		20%, less than 18 at time of match, and blood type B	
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%, and blood type permissible	Any
33	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, 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
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.J Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%

With the exception of 0-ABDR mismatches, kidneys from deceased donors with KDPI scores greater than 85% 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	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 permissible or identical	Any
14	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, 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%, and blood type B	O

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
20	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, 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%, and blood type permissible	Any
25	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% , 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

An OPO must offer kidneys individually through one of the allocation sequences in *Policy 8.5: Kidney Allocation Classifications and Rankings* 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

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

If both kidneys from a deceased donor are able to be transplanted, the transplant hospital that received the offer for the candidate with higher priority on the waiting list will get to choose first which of the two kidneys it will receive.

However, when a kidney is offered to a 0-ABDR mismatched candidate, a candidate with a CPRA greater than or equal to 99% 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

The host OPO must allocate deceased donor kidneys according to *Table 8-10* below.

Table 8-10: National Kidney Offers

If the organ offer is for:	Then the host OPO must:
A national 0-ABDR mismatch candidate	Allocate the kidney or contact the Organ Center for assistance allocating the kidney
A national 100% CPRA candidate in match classifications 1 through 10 in allocation sequences according to *Tables 8-5* through *8-8*	Allocate the kidney or contact the Organ Center for assistance allocating the kidney
Any other national candidates	Contact the Organ Center for assistance allocating the kidney

8.7.D Multi-Organ Combinations Allocated but Not Transplanted

If a multi-organ combination that includes a kidney is allocated but the kidney transplant is not performed, the kidney must be reallocated according to *Policy 5.9: Released Organs*.

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: 11/12/2013 (2/1/2014); 3/7/14; 9/15/2014 (10/30/14); 6/24/2013 (12/4/2014); 11/12/2014 (5/1/2015); 6/2/2015 (9/1/2015); 6/6/2016 (9/1/2016)

Pending Implementation

Policy 8.5 Kidney Allocation Classifications and Rankings: 6/6/2016 (TBD); *Policy 8.5.G: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or Equal to 20%* and *8.7.A: Mandatory Sharing:* 6/6/2016 (TBD)

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

9.1 Status and Score Assignments

Each liver transplant candidate is assigned a score that reflects the probability of death within a 3-month period as determined by the Model for End-Stage Liver Disease (MELD) scoring system or the Pediatric End Stage Liver Disease (PELD) scoring system. Liver candidates can also be assigned a priority status if the candidate meets the requirements for that status.

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

- Adult status 1A
- Calculated MELD score
- Exception MELD score
- Inactive status

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

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

Liver candidates less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, will be classified as a 12 to 17 year old for the purposes of allocation in:

Policy 9.6.F: Allocation of Livers from Deceased Donors 11 to 17 Years Old
Policy 9.6.G: Allocation of Livers from Deceased Donors Less than 11 Years Old
Policy 9.6.H: Allocation of Liver-Intestines from Deceased Donors at Least 18 Years Old

If the candidate is removed from the waiting list at any time and returns to the waiting list after turning 18 years old, the candidate must then be registered as an adult.

9.1.A Adult Status 1A Requirements

To assign a candidate adult status 1A, the candidate's transplant hospital must submit a *Liver Status 1A Justification Form* to the OPTN 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:

    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 56 days of the first signs or 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. Anhepatic

    c. Primary non-function of a transplanted whole liver within 7 days of transplant, with aspartate aminotransferase (AST) greater than or equal to 3,000 U/L and at least *one* of the following:
        - International normalized ratio (INR) greater than or equal to 2.5
        - Arterial pH less than or equal to 7.30
        - Venous pH less than or equal to 7.25
        - Lactate greater than or equal to 4 mmol/L

        All laboratory results reported for the tests required above must be from the same blood draw taken 24 hours to 7 days after the transplant.

    d. Primary non-function within 7-days of transplant of a transplanted liver segment from a deceased or living donor, evidenced by at least *one* of the following:
        i. INR greater than or equal to 2.5
        ii. Arterial pH less than or equal to 7.30
        iii. Venous pH less than or equal to 7.25
        iv. Lactate greater than or equal to 4 mmol/L

    e. Hepatic artery thrombosis (HAT) within 7-days of transplant, with AST greater than or equal to 3,000 U/L and at least *one* of the following:
        - INR greater than or equal to 2.5
        - Arterial pH less than or equal to 7.30
        - Venous pH less than or equal to 7.25
        - Lactate greater than or equal to 4 mmol/L

        All laboratory results reported for the tests required above must be from the same blood draw taken 24 hours to 7 days after the transplant.

        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.

    f. Acute decompensated Wilson's disease

9.1.B Pediatric Status 1A Requirements

To assign a candidate pediatric status 1A, the candidate's transplant hospital must submit a *Liver Status 1A Justification Form* to the OPTN 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 registration. This includes candidates less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, but does not include candidates removed from the waiting list at any time who then return to the waiting list after turning 18 years old.
2. The candidate has at least *one* of the following conditions:

    a. Fulminant liver failure without pre-existing liver disease, defined as the onset of hepatic encephalopathy within 56 days of the first signs and 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. Acidosis, defined as *one* of the following:
            - Arterial pH less than or equal to 7.30
            - Venous pH less than or equal to 7.25
            - Lactate greater than or equal to 4 mmol/L

        All laboratory results reported for any tests required for the primary non-function of a transplanted liver diagnosis above must be from the same blood draw taken between 24 hours and 7 days after the transplant.

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

    d. Acute decompensated Wilson's disease

9.1.C Pediatric Status 1B

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 registration. This includes candidates less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, but does not include candidates removed from the waiting list at any time who then return to the waiting list after turning 18 years old.

2. The candidate has *one* of the following conditions:

   a. The candidate has a biopsy-proven hepatoblastoma without evidence of metastatic disease.

   b. The candidate has an organic acidemia or urea cycle defect and a MELD or PELD exception score of 30 points for at least 30 days.

   c. Chronic liver disease with a calculated MELD greater than 25 for adolescent candidates 12 to 17 years old, or a calculated 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: Liver-Intestine Candidates* and has at least *one* of the following criteria:
      i. Is on a mechanical ventilator
      ii. Has gastrointestinal bleeding requiring at least 10 mL/kg of red blood cell replacement within the previous 24 hours
      iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
      iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension.

9.1.D MELD Score

Candidates who are at least 12 years old receive an initial $MELD_{(i)}$ score equal to:

$$0.957 \times Loge(creatinine\ mg/dL) + 0.378 \times Log_e(bilirubin\ mg/dL) + 1.120 \times Loge\ (INR) + 0.643$$

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

The following candidates will receive a creatinine value of 4.0 mg/dL:

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

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

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

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

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

If a candidate's recalculated MELD score requires recertification within 7 days of implementation based on *Table 9-1: Liver Status Update Schedule*, the transplant hospital will have 7 days to update laboratory values. If after 7 days the laboratory values are not updated, the candidate will be re-assigned to the previous lower MELD score.

9.1.E PELD Score

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

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

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

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

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

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

9.1.F Liver-Intestine Candidates

Candidates awaiting a 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 23 additional points to their calculated MELD or PELD score instead of the 10 percentage point increase. The transplant hospital must document in the candidate's medical record the medical justification for the combined liver-intestine transplant and that the transplant was completed.

9.2 Status and Laboratory Values Update Schedule

The OPTN 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 when reported, the new laboratory values must be no older than:
Status 1A or 1B	7 days	48 hours

If the candidate is:	The new laboratory values must be reported every:	And when reported, the new laboratory values must be no older than:
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.D: Pediatric Liver Candidates with Metabolic Diseases*.

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

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

9.3 Score and Status Exceptions

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 MELD/PELD Exception Applications

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.B Review of Exceptions by the RRB and Committees

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.C Specific MELD/PELD Exceptions

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.E: 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.
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: 1. Clear diagnosis of FAP. 2. Echocardiogram showing the candidate has an ejection fraction greater than 40 percent. 3. Ambulatory status. 4. Identification of transthyretin (TTR gene) mutation (Val30Met vs. non-Val30Met). 5. 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.F: Candidates with Hepatocellular Carcinoma (HCC).*	*See Policy 9.3.F: Candidates with Hepatocellular Carcinoma (HCC).*
Hepatopulmonary Syndrome (HPS)	*All* of the following: 1. Clinical evidence of portal hypertension. 2. Evidence of a shunt. 3. PaO_2 less than 60 mmHg on room air. 4. 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.D: Pediatric Liver Candidates with Metabolic Diseases.*	See *Policy 9.3.D: Pediatric Liver Candidates with Metabolic Diseases.*

If the candidate has:	And submits to the OPTN Contractor evidence that includes:	Then the candidate:
Portopulmonary Hypertension	The candidate has a mean pulmonary arterial pressure (MPAP) below 35 mmHg following intervention. The diagnosis must also include *all* of the following: 1. Initial mean pulmonary arterial pressure (MPAP) level. 2. Initial pulmonary vascular resistance (PVR) level. 3. Initial transpulmonary gradient to correct for volume overload. 4. Documentation of treatment. 5. Post-treatment MPAP less than 35 mmHg. 6. 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: 1. Is registered for a combined liver-kidney transplant. 2. Alanine glyoxylate aminotransferase (AGT) deficiency proven by liver biopsy using sample analysis or genetic analysis. 3. Glomerular filtration rate (GFR) less than or equal to 25 mL/min, by six variable Modification of Diet in Renal Disease formula (MDRD6) or direct measurement of iothalamate or iohexol, for 42 or more days.	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.D Pediatric Liver Candidates with Metabolic Diseases

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.E Candidates with Cholangiocarcinoma

A candidate will receive the MELD/PELD exception in *Table 9-2: Specific Standardized 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 must 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 must be considered un-resectable because of technical considerations or underlying liver disease.

3. If cross-sectional imaging studies demonstrate a mass, the mass must be less than three cm.
4. Intrahepatic and extrahepatic metastases must 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 must 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) must be avoided because of the high risk of tumor seeding associated with these procedures.

9.3.F Candidates with Hepatocellular Carcinoma (HCC)

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.F.i through vi below will be listed at their calculated MELD or PELD score.

9.3.F.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.F.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 or MRI to rule out any extrahepatic spread or macrovascular involvement
3. A CT of the chest to rule out metastatic disease
4. An indication that the candidate is not eligible for resection
5. The candidate's alpha-fetoprotein level

9.3.F.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; thinner slices are preferable especially if multiplanar reconstructions are performed
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 MDCT	1. Late arterial phase: artery fully enhanced, beginning contrast enhancement of portal vein 2. Portal venous phase: portal vein enhanced, peak liver parenchymal enhancement, beginning contrast enhancement of hepatic veins 3. 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 MRI	1. Pre-contrast T1W: do not change scan parameters for post contrast imaging. 2. Late arterial phase: artery fully enhanced, beginning contrast enhancement of portal vein. 3. Portal venous phase: portal vein enhanced, peak liver parenchymal enhancement, beginning contrast enhancement of hepatic veins. 4. 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.F.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: 1. Single nodule ≥ 1 cm and < 2 cm. The maximum diameter of lesions should be measured on late arterial or portal phase images. 2. Increased contrast enhancement on late arterial phase (relative to hepatic parenchyma). 3. 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: 1. Single nodule ≥ 1 cm and < 2 cm. The maximum diameter of lesions should be measured on late arterial or portal phase images. 2. Increased contrast enhancement on late arterial phase (relative to hepatic parenchyma). 3. Growth (maximum diameter increase) by 50% or more documented on serial MRI or CT obtained ≤ 6 months apart. Growth criteria do not apply to ablated lesions.
5B	Must meet *all* of the following:

Class	Description
	1. Single nodule diameter ≥ 2 cm. and ≤ 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: a. Washout on portal venous/delayed phase. b. Late capsule or pseudocapsule enhancement. c. 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. d. 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.F.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.F.vi Extensions of HCC Exceptions

In order for a candidate to maintain an HCC approved exception, the transplant program must submit an updated MELD/PELD exception application every three months. The candidate will receive the additional priority until transplanted or is found unsuitable for transplantation based on the HCC progression. Upon submission of the first extension, the candidate will be listed at the calculated MELD/PELD score. Upon submission of the second extension, the candidate will be assigned a MELD/PELD score equivalent to a 35 percent risk of 3-month mortality (MELD 28/PELD 41). For each subsequent extension, the candidate will receive additional MELD or PELD points equivalent to a 10 percentage point increase in the candidate's mortality risk every three months.

The HCC exception score will be capped at 34. Upon implementation, candidates with HCC exception scores greater than 34 will receive a score of 34 for their remaining HCC exception extensions. Candidates with scores greater than 34 at the time of implementation may be referred to the RRB if they demonstrate the need for higher priority.

To receive the extension, the transplant program must submit an updated MELD exception 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 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.F.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.F.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.F.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 Explant 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.G MELD/PELD Score Exception Extensions

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 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

9.4.A Waiting Time for Liver Candidates

Liver transplant candidates on the waiting list accrue waiting time within status 1A or 1B or any assigned MELD or PELD score.

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

1. Waiting time at current MELD or PELD score
2. Previous waiting time accrued during an earlier period at current MELD or PELD score
3. Previous total waiting time accrued at any MELD or PELD score higher than the current MELD or PELD score
4. Previous total waiting time accrued at status 1A and status 1B

Status 1A or 1B candidates will receive waiting time points based on their waiting time in that status, according to *Policy 9.5.A: Points for Waiting Time*.

9.4.B Waiting Time for Liver-Intestine Candidates

Waiting time accrued by a candidate for an isolated intestinal organ transplant while waiting on the waiting list may also be applied for a combine liver-intestine transplant, when it is determined that the candidate requires both organs.

9.5 Liver Allocation 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

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

For status 1A and 1B transplant candidates, those with the same blood type as the deceased liver donor will receive 10 points. Candidates with compatible but not identical blood types will receive 5 points, and candidates with incompatible types will receive 0 points.

Blood type O candidates who will accept a liver from a blood type A, non-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

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

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

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

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 ≥ 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 ≥ 30, transplant hospitals may specify on the waiting list if those candidates will accept a liver from a deceased donor of any blood type. Candidates are given points depending on their blood type according to *Policy 9.5.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 ≤ 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 ≤ 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
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

Classification	Candidates that are within the:	And are:
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 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
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 at 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

Classification	Candidates that are within the:	And are:
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 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	OPO's Region	Adult status 1A
5	OPO's Region	Pediatric status 1B
6	OPO's 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

Classification	Candidates that are within the...	And are...
9	OPO's Region	MELD of at least 15 and at least 12 to 17 years old
10	OPO's 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	OPO's Region	MELD less than 15 and 12 to 17 years old
14	OPO's 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
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	OPO's 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	OPO's Region	MELD of at least 15, 12 to 17 years old, and compatible blood type
25	OPO's 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

Classification	Candidates that are within the...	And are...
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 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 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, MELD/PELD of 36
12	OPO's region	Liver or liver-intestine, MELD/PELD of 36

Classification	Candidates that are within the:	And are:
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
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

Classification	Candidates that are within the:	And are:
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

Classification	Candidates that are within the:	And are:
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.I Allocation of Liver-Intestines from Donors less than 11 Years Old

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	OPO's region	Liver or liver-intestine, Pediatric Status 1B
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

Classification	Candidates that are within the:	And are:
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 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

Classification	Candidates that are within the:	And are:
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
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

Classification	Candidates that are within the:	And are:
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.J Allocation of Liver-Intestine from Donors at Least 11 Years of age

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

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

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.

9.8 Variances

9.8.A Open Variance for Segmental Liver Transplantation

This variance only applies when a transplant program transplants a right lobe or right tri-segment of the liver.

Under this variance, a transplant program may offer the remaining left lobe or left-lateral segment into a different, medically suitable, potential recipient registered at the same transplant hospital or an affiliated pediatric institution instead of offering the remaining segment to potential recipients at other transplant programs. The transplant program must determine potential recipient for the

second segment by using the same match run used to allocate the right lobe or tri-segment. Additionally, the transplant program must document all refusals of potential transplant recipients that are prioritized ahead of the potential transplant recipient that received the second segment.

Each participating region or DSA must meet to review the results of the first ten segmental liver transplants performed as a result of this variance, and each ten thereafter. If the re-transplant rate for segmental liver transplant recipients at any liver transplant program participating in the variance exceeds three within any sequential twenty transplants, the variance at that transplant program will be put on hold until the transplant program can review results and surgical practices.

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: 11/12/2013 (2/1/2014); 11/12/2014 (5/1/2015); 6/2/2015 (9/1/2015); *Policy 9.3.G: Candidate with Hepatocellular Carcinoma*: 11/12/14 (10/8/2015); *Policy 9.1.D: Meld Score*: 6/23/2014 (1/11/2016); *Policy 9.1.D: Meld Score*: 7/20/2015 (1/11/2016)

Pending Implementation

Policy 9.1: Status Scores and Assignments: 6/2/2015 (TBD); *Policy 9.7: Liver-Kidney Allocation*: 6/6/2016 (TBD); *9.3.F: Candidates with Hepatocellular Carcinoma (HCC)*: 12/5/2016 (TBD)

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.
- For descriptions of Classes 1-4 for cirrhotic liver nodules imaging, which are not applicable to OPTN Policy, please see http://www.acr.org/SecondaryMainMenuCategories/quality_safety/LI-RADS.aspx.
- For *Guidance to Liver Transplant Programs and Regional Review Boards for MELD/PELD Exceptions submitted for Neuroendocrine Tumors and Polycystic Liver Diseases* see http://optn.transplant.hrsa.gov/ContentDocuments/Guidance_Liver_Exceptions.pdf

Policy 10: Allocation of Lungs

10.1 Priorities and Score Assignments for Lung Candidates

Lung candidates:

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

10.1.A Candidates Less than 12 Years Old - Priority 1

A lung candidate less than 12 years old may be assigned priority 1 if at least *one* of the following requirements is met:

1. Candidate has respiratory failure, evidenced by at least *one* of the following:
   - Requires continuous mechanical ventilation
   - Requires supplemental oxygen delivered by any means to achieve FiO_2 greater than 50% in order to maintain oxygen saturation levels greater than 90%
   - Has an arterial or capillary PCO_2 greater than 50 mm Hg
   - Has a venous PCO_2 greater than 56 mm Hg
2. Pulmonary hypertension, evidenced by at least *one* of the following:
   - Has pulmonary vein stenosis involving 3 or more vessels
   - Exhibits *any* of the following, in spite of medical therapy:
     - Cardiac index less than 2 L/min/M^2
     - Syncope
     - Hemoptysis
     - Suprasystemic PA pressure on cardiac catheterization or by echocardiogram estimate

The OPTN 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

If a lung candidate less than 12 years old does not meet any of the above criteria to qualify for priority level 1, then the candidate is priority 2.

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

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

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

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

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

10.1.D Candidates at Least 12 Years Old - LAS

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

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

When registering a candidate who is at least 12 years old for a lung transplant, or when registering a candidate with an approved adolescent classification exception according to *Policy 10.2.B: Lung Candidates with Exceptional Cases*, transplant programs must report to the OPTN 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 or the LRB's approval of an adolescent classification exception. The first six-month period begins six months from the date of the candidate's initial registration, or, in the case of adolescent classification exceptions, six months from the date of LRB approval, with a new six-month period occurring every six months thereafter.

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

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

LAS covariate data obtained by heart catheterization does not need to be reported to the OPTN 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:	Then the LAS calculation will use this substituted value:
Bilirubin	Missing, expired, or less than 0.7 mg/dL	0.7 mg/dL
Body mass index (BMI)	Missing or expired	100 kg/m^2
Cardiac index	Missing	3.0 L/min/m^2
Central venous pressure (CVP)	Missing or less than 5 mm Hg	5 mm Hg
Continuous mechanical ventilation	Missing or expired	No mechanical ventilation in the waiting list model Continuous mechanical ventilation while hospitalized in the post-transplant survival measure
Creatinine: serum	Missing or expired	0.1 mg/dL in the waiting list model 40 mg/dL in the post-transplant survival measure for candidates at least 18 years old 0 mg/dL in the post-transplant survival measure for candidates less than 18 years old
Diabetes	Missing or expired	No diabetes
Forced vital capacity (FVC)	Missing or expired	150% for Diagnosis Group D

If this covariate's value:	Is:	Then the LAS calculation will use this substituted value:
Functional status	Missing or expired	No assistance needed in the waiting list model Some or total assistance needed in the post-transplant survival measure
Oxygen needed at rest	Missing or expired	No supplemental oxygen needed in the waiting list model 26.33 L/min in the post-transplant survival measure
PCO_2	Missing, expired, or less than 40 mm Hg	40 mm Hg
Pulmonary artery (PA) systolic pressure	Missing or less than 20 mm Hg	20 mm Hg
Six-minute-walk distance	Missing or expired	4,000 feet in the waiting list urgency measure 0 feet in the post-transplant survival measure

10.1.F The LAS Calculation

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

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

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

The equation for the LAS calculation is:

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

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

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

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

For this covariate:	The following coefficient is used in the LAS calculation:
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

For this covariate:	The following coefficient is used in the LAS calculation:
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
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

For this covariate:	The following coefficient is used in the LAS calculation:
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
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 (88% or greater) at rest (L/min)	0.0213187586203456*O_2 for Diagnosis Group B 0.1188479817592500*O_2 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.

Table 10-4: 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
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 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%
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

For this variable:	The following is used in the LAS calculation:
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
17. Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)	0.0747978926517300*O_2 for Diagnosis Group A 0.0164276945879309*O_2 for Diagnosis Groups B, C, and D
18. Functional Status	-0.1900086366785100 if no assistance needed with activities of daily living 0 if some or total assistance needed with activities of 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-Six-minute-walk distance) 0 if six-minute-distance-walked is at least 1,200 feet

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

10.1.F.i Lung Disease Diagnosis Groups

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

Group A

A candidate is in Group A if the candidate has *any* of the following diagnoses:

- Allergic bronchopulmonary aspergillosis
- Alpha-1 antitrypsin deficiency
- Bronchiectasis
- Bronchopulmonary dysplasia
- Chronic obstructive pulmonary disease/emphysema
- Ehlers-Danlos syndrome
- Granulomatous lung disease
- Inhalation burns/trauma
- Kartagener's syndrome
- Lymphangioleiomyomatosis
- Obstructive lung disease
- Primary ciliary dyskinesia;
- Sarcoidosis with 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
- Bronchioloalveolar 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 lymphangiectasia (PL)
- 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 PCO2 in the LAS

The LAS calculation uses two measures of PCO_2:

1. Current PCO_2
2. PCO_2 Threshold Change

Current PCO_2

Current PCO_2 is the PCO_2 value reported to the OPTN Contractor with the most recent test date and time. A program may report a PCO_2 value from an arterial,

venous, or capillary blood gas test. All blood gas values will be converted to an arterial value as follows:

- A capillary value will equal an arterial value.
- A venous value minus 6 mmHg equals an arterial value.

PCO_2 Threshold Change

There are two PCO_2 threshold change calculations:

- The PCO_2 Threshold Change Calculation
- The Threshold Change Maintenance Calculation

The PCO_2 Threshold Change Calculation

An increase in PCO_2 that is at least 15% will impact a candidate's LAS. If a value is less than 40 mmHg, the system will substitute the normal clinical value of 40 mmHg before calculating change. The PCO_2 threshold change calculation uses the highest and lowest values of PCO_2 as follows:

- The test date and time of the lowest value reported to the OPTN Contractor used in the PCO_2 threshold change calculation must be earlier than the test date and time of the highest value used in the PCO_2 threshold change calculation.
- Test dates of these highest and lowest values cannot be more than six months apart.
- The PCO_2 threshold change calculation can use an expired lowest value, but cannot use an expired highest value.

If a current PCO_2 value expires according *to Policy 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old*, the candidate's LAS will lose the impact from the PCO_2 threshold change calculation. The equation for the PCO_2 threshold change calculation is:

$$\frac{\text{Highest } PCO_2 - \text{Lowest } PCO_2}{\text{Lowest } PCO_2}$$

The Threshold Change Maintenance Calculation

When a 15% or greater PCO_2 threshold change calculation impacts a candidate's LAS, the LAS threshold change maintenance calculation assesses whether to maintain that impact. To maintain the impact of the PCO_2 increase, the candidate's current PCO_2 value must be at least 15% higher than the lowest value used in the PCO_2 threshold change calculation. The equation for this threshold change maintenance calculation is:

$$\frac{\text{Current } PCO_2 - \text{Lowest } PCO_2}{\text{Lowest } PCO_2}$$

The threshold change maintenance calculation occurs either when the current PCO_2 value expires, according to *Policy 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old*, or a new current PCO_2 value is entered. For this calculation, the lowest and highest values that were used in the PCO_2 threshold change calculation can be expired. The current PCO_2 value can be the highest one that was used in the PCO_2 threshold change calculation. If a current PCO_2 value expires, the candidate's LAS will no longer be affected by the PCO_2 threshold change.

If a transplant hospital reports a new current PCO_2 value for a candidate who has lost the impact from the PCO_2 threshold change calculation, the LAS will perform the threshold change maintenance calculation. If the new current PCO_2 value is at least 15% higher than the lowest value used in the PCO_2 threshold change calculation, the candidate's LAS will again be affected by the PCO_2 threshold change calculation.

Normal PCO_2 Value

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

10.1.F.iii Bilirubin in the LAS

The LAS calculation uses two measures of total bilirubin:

- Current bilirubin (for all candidates)
- Bilirubin Threshold Change (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 greater than 1.0 mg/dL will impact candidate's LAS.

Bilirubin Threshold Change (Diagnosis Group B Only)

There are two Bilirubin threshold change calculations:

- Bilirubin Threshold Change Calculation
- Threshold Change Maintenance Calculation

Bilirubin Threshold Change Calculation

For candidates in diagnosis Group B, an increase-in-bilirubin that is at least 50% impacts the candidate's LAS. The bilirubin threshold change calculation uses the highest and lowest values of bilirubin as follows:

- The test date and time of the lowest bilirubin value reported to the OPTN Contractor used in the bilirubin threshold change calculation must be earlier than the test date and time of the highest bilirubin value used in the bilirubin threshold change calculation.
- The highest value must be at least 1.0 mg/dL.
- Test dates of these highest and lowest values cannot be more than six months apart.
- The bilirubin threshold calculation can use an expired lowest value, but cannot use an expired highest value.
- If a value is less than 0.7 mg/dL, the bilirubin threshold change calculation will use the normal clinical value of 0.7 mg/dL.

The equation for this bilirubin threshold change 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 1.0 mg/dL and at least 50% higher than the lowest value used in the bilirubin threshold change calculation. The equation for the threshold change maintenance calculation is:

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

The threshold change 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 bilirubin threshold change calculation can be expired. The current bilirubin value can be the highest one that was used in the bilirubin threshold change calculation. If a current bilirubin value expires, the candidate's LAS will no longer be affected by the bilirubin threshold change.

If a transplant hospital reports a new current bilirubin value for a candidate who has lost the impact from the bilirubin threshold change 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 bilirubin threshold change calculation, the candidate's LAS will again be affected by the bilirubin threshold change 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

The LAS calculation uses two measures of creatinine:

1. Current creatinine (only for candidates who are at least 18 years old)
2. Creatinine Threshold Change (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.

Creatinine Threshold Change Calculations

There are two creatinine threshold change calculations:

1. Creatinine Threshold Change Calculation
2. Threshold Change Maintenance Calculation

The Creatinine Threshold Change Calculation

An increase in creatinine that is at least 150% will impact a candidate's LAS. The creatinine threshold change calculation uses the highest and lowest values of creatinine as follows:

- The test date and time of the lowest creatinine value reported to the OPTN Contractor used in the creatinine threshold change calculation must be earlier

than the test date and time of the highest creatinine value used in the creatinine threshold change calculation.
- The highest value must be at least 1.0 mg/dL.
- Test dates of these highest and lowest values cannot be more than six months apart.
- The creatinine threshold change calculation can use an expired lowest value, but cannot use an expired highest value.

The equation for this creatinine threshold change calculation is:

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

The Threshold Change Maintenance Calculation

When a creatinine threshold change 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 1.0 mg/dL and at least 150% higher than the lowest value used in the creatinine threshold change 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 threshold change maintenance calculation will occur.

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

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

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

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

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

10.2 Priority and Score Exceptions

10.2.A Allocation Exception for Sensitized Patients

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

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.C: Allocation of Lungs from Deceased Donors at Least 18 Years Old*, and *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, specific LAS, or adolescent classification exceptions 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 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 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 at least 12 years old awaiting a lung transplant on the waiting list at inactive status will not accrue any waiting time while at inactive status. Lung candidates less than 12 years old accrue waiting time when registered at inactive status.

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

10.3.A Lung Candidates at Least 12 Years Old

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

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

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

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

10.4 Lung Allocation Classifications and Rankings

10.4.A Sorting Within Each Classification

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

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

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

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

10.4.B Allocation of Lungs by Blood Type

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

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

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

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

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

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

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

If the candidate is	And meets *all* of the following:
Less than one year old at the time of the match run	1. Is priority 1. 2. Has reported isohemagglutinin titer information for A or B blood type antigens to the OPTN Contractor within the last 30 days.
At least one year old at the time of the match run	1. Is registered prior to turning two years old. 2. Is priority 1. 3. Has reported to the OPTN Contractor isohemagglutinin titers less than or equal to 1:16 for A or B blood type antigens from a blood sample collected within the last 30 days. The candidate must not have received treatments that may have reduced isohemagglutinin titers to 1:16 or less within 30 days of when this blood sample was collected.

10.4.B.ii Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Group Incompatible Lung

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

Accurate isohemagglutinin titers must be reported for candidates eligible for an intended blood group incompatible lung, according to *Table 10-7* below, at *all* of the following times:

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

Table 10-7: Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Group Incompatible Lung

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

Accurate isohemagglutinin titers must be reported for recipients of an intended blood group incompatible lung, according to *Table 10-8*, as follows:

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

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

Table 10-8: Isohemagglutinin Titer Reporting Requirements for a Recipient of an Intended Blood Group Incompatible Lung

If the deceased donor's blood type is:	And the recipient's blood type is:	Then the transplant program must report the following isohemagglutinin titers to the OPTN Contractor:
A	B or O	Anti-A
B	A or O	Anti-B
AB	A	Anti-B
AB	B	Anti-A
AB	O	Anti-A and Anti-B

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

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

Table 10-9: Allocation of Lungs from Deceased Donors at Least 18 Years Old

Classification	Candidates that are 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 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
4	OPO's DSA	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
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 and *one* of the following:

Classification	Candidates that are included within the:	And are:
		• Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
10	Zone A	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
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 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
16	Zone B	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
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
20	Zone C	At least 12 years old, blood type compatible with the donor
21	Zone C	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
22	Zone C	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor

Classification	Candidates that are included within the:	And are:
		• At least 1 year old and eligible for intended blood group incompatible offers
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 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
28	Zone D	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
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 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
34	Zone E	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
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 Less than 18 Years Old

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

Table 10-10: Allocation of Lungs from Deceased Donors Less than 18 Years Old

Classification	Candidates that are included within the:	And are:
1	OPO's DSA, Zone A, or Zone B	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
2	OPO's DSA, Zone A, or Zone B	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
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, Zone A, or Zone B	12 to less than 18 years old, blood type identical to the donor
6	OPO's DSA, Zone A, or Zone B	12 to less than 18 years old, blood type 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	At least 18 years old, blood type identical to the donor
12	Zone B	At least 18 years old, blood type compatible with the donor
13	Zone C	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers

Classification	Candidates that are included within the:	And are:
14	Zone C	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
15	Zone C	Priority 2, blood type identical to the donor
16	Zone C	Priority 2, blood type compatible with the donor
17	Zone C	12 to less than 18 years old, blood type identical to the donor
18	Zone C	12 to less than 18 years old, blood type compatible with the donor
19	Zone C	At least 18 years old, blood type identical to the donor
20	Zone C	At least 18 years old, blood type compatible with the donor
21	Zone D	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
22	Zone D	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
23	Zone D	Priority 2, blood type identical to the donor
24	Zone D	Priority 2, blood type compatible with the donor
25	Zone D	12 to less than 18 years old, blood type identical to the donor
26	Zone D	12 to less than 18 years old, blood type compatible with the donor
27	Zone D	At least 18 years old, blood type identical to the donor
28	Zone D	At least 18 years old, blood type compatible with the donor
29	Zone E	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers

Classification	Candidates that are included within the:	And are:
30	Zone E	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
31	Zone E	Priority 2, blood type identical to the donor
32	Zone E	Priority 2, blood type compatible with the donor
33	Zone E	12 to less than 18 years old, blood type identical to the donor
34	Zone E	12 to less than 18 years old, blood type compatible with the donor
35	Zone E	At least 18 years old, blood type identical to the donor
36	Zone E	At least 18 years old, blood type compatible with the donor

10.5 Probability Data Used in the LAS Calculation

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

t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$
0	1.0000000000	49	0.9966437334	98	0.9931596573	147	0.9905400510	196	0.9872991723
1	0.9999907157	50	0.9965433845	99	0.9930980163	148	0.9905400510	197	0.9872626749
2	0.9999254055	51	0.9965175429	100	0.9930607383	149	0.9905400510	198	0.9871552755
3	0.9998674170	52	0.9963972737	101	0.9930052489	150	0.9905400510	199	0.9871220338
4	0.9997455435	53	0.9963972737	102	0.9930052489	151	0.9905400510	200	0.9865302072
5	0.9995975343	54	0.9963631304	103	0.9929378277	152	0.9903840245	201	0.9865302072
6	0.9994989961	55	0.9963053385	104	0.9929378277	153	0.9903328361	202	0.9864801346
7	0.9993713802	56	0.9961914895	105	0.9928829296	154	0.9903328361	203	0.9859628001
8	0.9993046242	57	0.9961189511	106	0.9928829296	155	0.9903328361	204	0.9859256159
9	0.9992177050	58	0.9959421227	107	0.9928506946	156	0.9902446847	205	0.9859256159
10	0.9990851999	59	0.9959421227	108	0.9927619069	157	0.9902446847	206	0.9858198690
11	0.9989901794	60	0.9959092500	109	0.9927244496	158	0.9902446847	207	0.9858198690
12	0.9988873318	61	0.9959092500	110	0.9926433860	159	0.9901449203	208	0.9857415923
13	0.9988160788	62	0.9958731922	111	0.9926433860	160	0.9896887318	209	0.9857415923
14	0.9987295863	63	0.9958457969	112	0.9925624932	161	0.9896887318	210	0.9857415923
15	0.9986602768	64	0.9958457969	113	0.9920885646	162	0.9896520090	211	0.9857075131
16	0.9985875403	65	0.9956136053	114	0.9920640055	163	0.9895745634	212	0.9857075131
17	0.9984554393	66	0.9955529860	115	0.9920400127	164	0.9895745634	213	0.9855411680
18	0.9983616851	67	0.9955529860	116	0.9919966080	165	0.9889025189	214	0.9855411680
19	0.9982588046	68	0.9955529860	117	0.9919660469	166	0.9888730124	215	0.9855411680
20	0.9982200289	69	0.9955000986	118	0.9919399263	167	0.9888730124	216	0.9854501485
21	0.9980677506	70	0.9954789372	119	0.9919399263	168	0.9887838841	217	0.9854501485
22	0.9980357372	71	0.9953493820	120	0.9919399263	169	0.9887222824	218	0.9854501485
23	0.9979724590	72	0.9952934145	121	0.9915144847	170	0.9886945957	219	0.9853304718
24	0.9978684291	73	0.9951363273	122	0.9915144847	171	0.9886945957	220	0.9852652088
25	0.9977699910	74	0.9949654223	123	0.9915144847	172	0.9886945957	221	0.9852652088
26	0.9977420222	75	0.9948209678	124	0.9915144847	173	0.9886549235	222	0.9852652088
27	0.9976665328	76	0.9947736691	125	0.9914883902	174	0.9886549235	223	0.9852652088
28	0.9976255053	77	0.9947021905	126	0.9914618560	175	0.9886549235	224	0.9852652088
29	0.9975404117	78	0.9947021905	127	0.9913925084	176	0.9886246774	225	0.9846212073
30	0.9974725579	79	0.9946337898	128	0.9913069760	177	0.9885475245	226	0.9845486667
31	0.9973914097	80	0.9945649862	129	0.9913069760	178	0.9885475245	227	0.9845486667
32	0.9973268946	81	0.9945465023	130	0.9912697831	179	0.9885475245	228	0.9845486667
33	0.9972974521	82	0.9944645092	131	0.9912361687	180	0.9880619575	229	0.9845486667
34	0.9972743143	83	0.9944645092	132	0.9912361687	181	0.9880619575	230	0.9844886959
35	0.9972419197	84	0.9942969766	133	0.9910529687	182	0.9880619575	231	0.9844886959
36	0.9972419197	85	0.9942969766	134	0.9910121623	183	0.9880212199	232	0.9843962284
37	0.9971814314	86	0.9942969766	135	0.9910121623	184	0.9879335450	233	0.9843236173
38	0.9971367830	87	0.9942969766	136	0.9909776544	185	0.9878851712	234	0.9842799561
39	0.9971209292	88	0.9941805902	137	0.9909776544	186	0.9878851712	235	0.9840794709
40	0.9971209292	89	0.9940771789	138	0.9909776544	187	0.9878851712	236	0.9840794709
41	0.9970189115	90	0.9940345018	139	0.9909355857	188	0.9878851712	237	0.9840145629
42	0.9969461979	91	0.9940082090	140	0.9909011142	189	0.9878560942	238	0.9840145629
43	0.9969159237	92	0.9938663826	141	0.9909011142	190	0.9878560942	239	0.9840145629
44	0.9968488001	93	0.9938313146	142	0.9908111395	191	0.9878560942	240	0.9840145629
45	0.9968488001	94	0.9938070978	143	0.9907387924	192	0.9878560942	241	0.9838347625
46	0.9968199961	95	0.9937145919	144	0.9905945464	193	0.9878560942	242	0.9838347625
47	0.9967799694	96	0.9933077154	145	0.9905945464	194	0.9876077782	243	0.9837917116
48	0.9967313053	97	0.9932199214	146	0.9905400510	195	0.9873585581	244	0.9837534417

(Continued on next page)

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

t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$
245	0.9837534417	269	0.9829597020	293	0.9818267812	317	0.9802178676	341	0.9785965606
246	0.9837534417	270	0.9829597020	294	0.9818267812	318	0.9801289145	342	0.9785965606
247	0.9836972199	271	0.9827972342	295	0.9815730256	319	0.9801289145	343	0.9783012252
248	0.9836363251	272	0.9827972342	296	0.9813194319	320	0.9800157994	344	0.9782502701
249	0.9836363251	273	0.9827972342	297	0.9807747475	321	0.9800157994	345	0.9782502701
250	0.9836363251	274	0.9827972342	298	0.9807747475	322	0.9800157994	346	0.9782502701
251	0.9836363251	275	0.9827004206	299	0.9805186284	323	0.9797725024	347	0.9781167565
252	0.9832432776	276	0.9826027019	300	0.9803970706	324	0.9797725024	348	0.9780370471
253	0.9832432776	277	0.9826027019	301	0.9803970706	325	0.9796706377	349	0.9780370471
254	0.9832432776	278	0.9825107450	302	0.9803970706	326	0.9796706377	350	0.9780370471
255	0.9830967678	279	0.9824570403	303	0.9803970706	327	0.9791639481	351	0.9780370471
256	0.9830967678	280	0.9824570403	304	0.9803970706	328	0.9791639481	352	0.9779370209
257	0.9830967678	281	0.9824570403	305	0.9803970706	329	0.9791639481	353	0.9779370209
258	0.9830967678	282	0.9824128485	306	0.9803970706	330	0.9791639481	354	0.9779370209
259	0.9830967678	283	0.9823232942	307	0.9803390799	331	0.9791001516	355	0.9778553245
260	0.9830967678	284	0.9823232942	308	0.9803390799	332	0.9791001516	356	0.9778553245
261	0.9830967678	285	0.9823232942	309	0.9803390799	333	0.9789346942	357	0.9778553245
262	0.9830516708	286	0.9823232942	310	0.9803390799	334	0.9789346942	358	0.9777099092
263	0.9830516708	287	0.9823232942	311	0.9803390799	335	0.9788174060	359	0.9777099092
264	0.9830516708	288	0.9823232942	312	0.9803390799	336	0.9788174060	360	0.9768812539
265	0.9830516708	289	0.9823232942	313	0.9803390799	337	0.9788174060	361	0.9768812539
266	0.9830516708	290	0.9823232942	314	0.9803390799	338	0.9788174060	362	0.9768812539
267	0.9830516708	291	0.9819156574	315	0.9802178676	339	0.9788174060	363	0.9767085255
268	0.9829597020	292	0.9818779459	316	0.9802178676	340	0.9788174060	364	0.9767085255

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

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
0	1.0000000000	48	0.9818819454	97	0.9724145650	146	0.9651646731	195	0.9585852831
0	0.9989463518	49	0.9813940581	98	0.9724145650	147	0.9650179741	196	0.9585852831
1	0.9975582572	50	0.9811149797	99	0.9721278916	148	0.9650179741	197	0.9585106153
2	0.9968950221	51	0.9808357071	100	0.9719843820	149	0.9647244778	198	0.9583612369
3	0.9963635815	52	0.9804163818	101	0.9717688365	150	0.9646510762	199	0.9580621750
4	0.9954983869	53	0.9802065044	102	0.9716969486	151	0.9645042403	200	0.9580621750
5	0.9951651492	54	0.9801365116	103	0.9715531365	152	0.9643573707	201	0.9579873451
6	0.9945645668	55	0.9799264755	104	0.9713373330	153	0.9640634927	202	0.9579873451
7	0.9941636334	56	0.9796462096	105	0.9712653813	154	0.9638429283	203	0.9579125074
8	0.9939630137	57	0.9794358024	106	0.9711934225	155	0.9636958085	204	0.9577628083
9	0.9933601591	58	0.9790847785	107	0.9711214419	156	0.9634750547	205	0.9576130592
10	0.9931589002	59	0.9788739877	108	0.9710494372	157	0.9633278327	206	0.9575381540
11	0.9924871748	60	0.9787334069	109	0.9709774209	158	0.9631069028	207	0.9573882873
12	0.9923526429	61	0.9784520623	110	0.9707613132	159	0.9627384081	208	0.9573133332
13	0.9919487360	62	0.9783816832	111	0.9706892585	160	0.9625171483	209	0.9572383663
14	0.9916792045	63	0.9781704820	112	0.9706171946	161	0.9624433701	210	0.9571633895
15	0.9912068471	64	0.9781000588	113	0.9705451162	162	0.9622957853	211	0.9571633895
16	0.9905308509	65	0.9779591798	114	0.9704730247	163	0.9620743353	212	0.9569383725
17	0.9902600814	66	0.9778182436	115	0.9703288079	164	0.9619266457	213	0.9568633391
18	0.9899212765	67	0.9778182436	116	0.9699680182	165	0.9617049921	214	0.9567883006
19	0.9895819543	68	0.9775361418	117	0.9698236079	166	0.9616310727	215	0.9567132550
20	0.9895140131	69	0.9772537901	118	0.9696791597	167	0.9615571395	216	0.9566381918
21	0.9889017936	70	0.9770418835	119	0.9696069224	168	0.9614831983	217	0.9564880147
22	0.9882201168	71	0.9769712231	120	0.9693901236	169	0.9614831983	218	0.9562625865
23	0.9878104319	72	0.9769005466	121	0.9691008601	170	0.9614092449	219	0.9562625865
24	0.9874685977	73	0.9767590709	122	0.9689561390	171	0.9611132339	220	0.9561873965
25	0.9872633504	74	0.9765466782	123	0.9686665562	172	0.9611132339	221	0.9561121949
26	0.9870579950	75	0.9764758630	124	0.9685941382	173	0.9610391867	222	0.9560369867
27	0.9865784176	76	0.9761925132	125	0.9683767411	174	0.9609651281	223	0.9558865533
28	0.9863040866	77	0.9759089522	126	0.9681590825	175	0.9608910582	224	0.9557360679
29	0.9860295071	78	0.9757670435	127	0.9680864781	176	0.9607428635	225	0.9557360679
30	0.9859608276	79	0.9756250284	128	0.9678684348	177	0.9605945954	226	0.9557360679
31	0.9857547158	80	0.9754829371	129	0.9677956729	178	0.9604462255	227	0.9556608016
32	0.9854796626	81	0.9754829371	130	0.9675043666	179	0.9604462255	228	0.9556608016
33	0.9851355094	82	0.9754829371	131	0.9673585766	180	0.9603719931	229	0.9555102388
34	0.9849288641	83	0.9749850268	132	0.9671398110	181	0.9602977341	230	0.9555102388
35	0.9845152420	84	0.9749850268	133	0.9671398110	182	0.9601491697	231	0.9552089409
36	0.9844462708	85	0.9747001806	134	0.9669939177	183	0.9600748710	232	0.9552089409
37	0.9841701925	86	0.9747001806	135	0.9667019115	184	0.9598519074	233	0.9551335669
38	0.9838247337	87	0.9744152006	136	0.9664827327	185	0.9597775675	234	0.9549827718
39	0.9834789109	88	0.9739873157	137	0.9664827327	186	0.9597032090	235	0.9548319320
40	0.9832019349	89	0.9738445742	138	0.9664096522	187	0.9596288106	236	0.9546810412
41	0.9830633211	90	0.9736303735	139	0.9662634193	188	0.9595543795	237	0.9545300840
42	0.9828552725	91	0.9734160812	140	0.9661902639	189	0.9594799325	238	0.9544545732
43	0.9827164882	92	0.9734160812	141	0.9661902639	190	0.9592564778	239	0.9542279182
44	0.9825775890	93	0.9732016972	142	0.9659707159	191	0.9591074222	240	0.9542279182
45	0.9822995280	94	0.9730587142	143	0.9657510525	192	0.9590328768	241	0.9540767061
46	0.9821604041	95	0.9729156920	144	0.9656778054	193	0.9590328768	242	0.9540767061
47	0.9819515885	96	0.9726294362	145	0.9653113457	194	0.9587345577	243	0.9539254009

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

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
244	0.9538497172	269	0.9511902217	293	0.9485888127	317	0.9463585089	341	0.9437285938
245	0.9538497172	270	0.9509612738	294	0.9483586281	318	0.9463585089	342	0.9436509982
246	0.9537740199	271	0.9506558210	295	0.9482818803	319	0.9462042511	343	0.9435733917
247	0.9537740199	272	0.9505794198	296	0.9481283428	320	0.9462042511	344	0.9434181618
248	0.9536983112	273	0.9504265693	297	0.9480515582	321	0.9461270863	345	0.9433405390
249	0.9536225901	274	0.9502736813	298	0.9479747621	322	0.9460499065	346	0.9431075841
250	0.9533952367	275	0.9501207590	299	0.9478210865	323	0.9460499065	347	0.9430298440
251	0.9533193886	276	0.9501207590	300	0.9476673351	324	0.9458955253	348	0.9430298440
252	0.9530158831	277	0.9498147874	301	0.9476673351	325	0.9458183199	349	0.9429520371
253	0.9530158831	278	0.9496617253	302	0.9473596856	326	0.9455866228	350	0.9427185272
254	0.9527122194	279	0.9496617253	303	0.9473596856	327	0.9454321012	351	0.9427185272
255	0.9527122194	280	0.9495851653	304	0.9473596856	328	0.9454321012	352	0.9427185272
256	0.9527122194	281	0.9495851653	305	0.9473596856	329	0.9453548209	353	0.9426406582
257	0.9524843651	282	0.9494319939	306	0.9472827362	330	0.9452775175	354	0.9424848995
258	0.9524083896	283	0.9493553886	307	0.9472827362	331	0.9451228653	355	0.9424848995
259	0.9523323977	284	0.9492787721	308	0.9472057776	332	0.9451228653	356	0.9421732641
260	0.9522563886	285	0.9492787721	309	0.9471288083	333	0.9449681796	357	0.9420173651
261	0.9521803676	286	0.9492021461	310	0.9469748345	334	0.9448908227	358	0.9417833903
262	0.9521043365	287	0.9492021461	311	0.9468208245	335	0.9447360580	359	0.9417053586
263	0.9518761834	288	0.9491255112	312	0.9468208245	336	0.9445812189	360	0.9416273052
264	0.9518000820	289	0.9490488687	313	0.9468208245	337	0.9445037758	361	0.9415492338
265	0.9516477499	290	0.9488955575	314	0.9467438071	338	0.9441938892	362	0.9415492338
266	0.9516477499	291	0.9488188902	315	0.9465897325	339	0.9440388525	363	0.9413148953
267	0.9515715365	292	0.9488188902	316	0.9464356005	340	0.9439613054	364	0.9413148953
268	0.9514952979								

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: 11/12/2013 (2/1/2014); 3/7/14; 06/23/14 (7/1/14); 11/12/14 (2/1/2015); 11/12/2012 (02/19/15); 11/12/2014 (02/19/15); *Policy 10: Allocation of Lungs:* 12/1/2015 (3/30/2017)

Notes

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

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

11.1 Calculated Panel Reactive Antibody (CPRA)

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

11.2 Waiting List Registration

11.2.A Pancreas Registration

Each candidate registered on the pancreas waiting list must meet *one* of the following requirements:

- Be diagnosed with diabetes
- Have pancreatic exocrine insufficiency
- Require the procurement or transplantation of a pancreas as part of a multiple organ transplant for technical reasons

11.2.B Combined Kidney-Pancreas Registration

Each candidate registered on the kidney-pancreas waiting list must be diagnosed with diabetes or have pancreatic exocrine insufficiency with renal insufficiency.

11.2.C Islet Registration Status

A transplant hospital may register an islet candidate on the waiting list with an active status if the candidate meets *either* of the following requirements:

1. Is insulin dependent
2. Has a hemoglobin A1c (HbA1c) value greater than 6.5%

An islet candidate that does not meet either of these requirements above must have an inactive status on the waiting list. If the transplant hospital changes a candidate's status from inactive to active, the transplant hospital must document that the candidate met one of the above requirements.

If a candidate's clinical condition changes and the candidate becomes inactive, the transplant hospital must report this to the OPTN 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 in the candidate's medical record the candidate's insulin status and HbA1c value. The transplant hospital must use the most recent HbA1c test performed within the last six months when determining whether the candidate meets the criteria for active status.

11.3 Waiting Time

Waiting time for pancreas and islet candidates begins on the date the candidate is first registered as a pancreas or islet candidate on the waiting list.

Pancreas, kidney-pancreas, and islet candidates continue to accrue waiting time while registered as active or inactive.

11.3.A Kidney-Pancreas Waiting Time Criteria for Candidates Less than 18 Years Old

To accrue waiting time for a kidney-pancreas transplant, a kidney-pancreas candidate who is less than 18 years old at the time of kidney-pancreas registration does not have to meet the qualifying criteria according to *Policy 11.3.B* below.

11.3.B Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old

If a kidney-pancreas candidate is 18 years or older on the date the candidate is registered for a kidney-pancreas, then the candidate begins to accrue waiting time once the candidate has met all of the following conditions:

1. The candidate is registered for a kidney-pancreas.
2. The candidate qualifies for kidney waiting time according to *Policy 8.4: Waiting Time*.
3. The candidate meets *at least 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.

Once a kidney-pancreas candidate begins to accrue waiting time, the candidate will remain qualified for waiting time, unless the candidate was registered for a kidney-pancreas prior to implementation of this policy. A candidate who was registered for a kidney-pancreas, and accrued waiting time prior to implementation of this policy, will remain qualified if the candidate qualifies for kidney waiting time according to *Policy 8.4: Waiting Time*.

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 3.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 3.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 3.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.

11.3.C Islet Waiting Time Criteria

An islet candidate will retain waiting time through three registrations at the registering transplant hospital, including the waiting time from the previous registrations and any intervening time. After a candidate has received a series of three islet infusions at the registering transplant hospital, waiting time will be reset, and the candidate will retain waiting time through another three infusions.

11.3.D Waiting Time Assignments for Kidney, Kidney-pancreas, and Islet Candidates

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 11.3.B: Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old* are met.
Kidney	Pancreas
Kidney-pancreas	Kidney
Kidney-pancreas	Pancreas
Pancreas	Pancreas Islets; if criteria in *Policy 11.3.D.i* below are met.
Pancreas Islets	Pancreas; if criteria in *Policy 11.3.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*.
Waiting time accrued by a pancreas islet candidate while registered on the waiting list will not be assigned to the registration for a combined kidney-pancreas transplant or an isolated kidney transplant except as outlined in *Policy 3.7: Waiting Time Modifications*.

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

11.3.D.i Criteria to assign Pancreas Waiting Time to Islet Waiting Time

Waiting time accrued by an isolated pancreas transplant candidate while registered on the waiting list will be assigned to the registration for 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.

11.3.D.ii Criteria to assign Islet Waiting Time to Pancreas

Waiting time accrued by an 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.

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

11.4.A Kidney-Pancreas Allocation Order

If a host OPO has both a kidney and a pancreas to offer for allocation, then the host OPO 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/m²* 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.

11.4.B Pancreas Allocation When a Kidney is Unavailable

If a host OPO only has a pancreas, but not a kidney to offer for allocation, then the host OPO must offer the pancreas to pancreas and islet candidates but not kidney-pancreas candidates according to *Tables 11-4: Allocation of Kidneys and Pancreas from Deceased Donors 50 Years Old and Less with a BMI less than or equal to 30 kg/m²* and *11-5: Allocation of Kidneys and Pancreas from Deceased Donors more than 50 Years Old or with a BMI Greater than 30 kg/m²*.

OPOs may not allocate a kidney to a potential pancreas recipient who is receiving the pancreas offer due to the match run prioritization of the potential recipient's isolated pancreas registration.

11.4.C Organ Offer Limits

Any pancreas that will be 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 11.4: Pancreas, Kidney-Pancreas, and Islet Allocation Classifications and Rankings*.
- Allocate the organ for the remaining zero antigen mismatched potential recipients.

11.4.D Blood Type for Kidney-Pancreas Allocation

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

11.4.E Sorting Within Each Classification

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

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

Pancreas, kidney-pancreas, and islets from donors 50 years old or less and who have a BMI less than or equal to 30 kg/m^2 will be allocated to candidates according to *Table 11-4* 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

11.4.G Deceased Donors More than 50 Years Old or with a BMI Greater Than 30 kg/m^2

Pancreas, kidney-pancreas, and islets from deceased donors more than 50 years old or from deceased donors who have a BMI greater than 30 kg/m^2 are allocated to candidates according to *Table 11-5* 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 to 80%, and either pancreas or kidney-

Classification	Candidates that are within the:	And are:
		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

11.5 Reallocation of Unsuitable Islets

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.

11.6 Facilitated Pancreas Allocation

11.6.A Transplant Program Qualifications

A transplant program qualifies to receive facilitated pancreas offers if within the two previous years it has transplanted a minimum of five pancreas recovered from deceased donors outside its DSA. This includes pancreas transplanted as part of a multi-organ transplant.

Transplant programs that qualify for facilitated pancreas allocation must notify the OPTN Contractor in writing if they do not wish to participate.

11.6.B Facilitated Pancreas Offers

OPOs and the Organ Center are permitted to make facilitated pancreas offers if no pancreas offer has been accepted three hours prior to the scheduled donor organ recovery. The OPO or Organ Center must offer the pancreas only to potential transplant recipients registered at a transplant program that participates in facilitated pancreas allocation. Facilitated pancreas offers must be made in the order of the match run, and OPOs will only have access to facilitated allocation after all local pancreas and kidney-pancreas offers have been declined.

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: 11/12/2013 (2/1/2014); 11/9/2010 (10/30/2014); 6/24/2013 (12/4/2014); 6/2/2015 (9/1/2015); *Policy 11.6 Facilitated Pancreas Allocation:* 12/1/2015 (8/18/2016)

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: Allocation of Vascularized Composite Allografts (VCA)

12.1 Waiting Time

Waiting time for VCA candidates begins when the candidate is registered on the waiting list. For those candidates registered prior to September 1, 2014, waiting time will begin when the transplant hospital requests that the OPO actively seek a donor for an identified VCA candidate.

12.2 VCA Allocation

The host OPO will offer VCAs to candidates with compatible blood type willing to accept a VCA with similar physical characteristics to the donor. The OPO will offer VCAs to candidates in the following order:

1. Candidates that are within the OPO's region.
2. Candidates that are beyond the OPO's region.

Within each classification, candidates are sorted by waiting time (longest to shortest).

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

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

History

Policy 12: Vascularized Composite Allografts (VCA): 06/23/14 (7/3/14); 6/2/2015 (9/1/2015)

Notes

- For membership requirements for VCA transplant programs, see *OPTN Bylaws Appendix J.*

Policy 13: Kidney Paired Donation (KPD)

13.1 Candidate Requirements for Participation

In order to participate in the OPTN Kidney Paired Donation (KPD) program, candidates must be registered on the deceased donor kidney waiting list at the transplant hospital that wishes to enroll the candidate in the OPTN KPD program.

13.2 Potential KPD Donor Requirements for Participation

In order to participate in the OPTN KPD program, potential KPD donors must comply with *both* of the following requirements:

1. Be at least 18 years old
2. Not be currently registered as a potential KPD donor for any other candidate registered in the OPTN KPD program

13.3 Informed Consent for KPD Candidates

13.3.A Release of Protected Health Information

For any KPD exchange, a paired candidate will not be eligible for a KPD match run until the paired candidate's transplant hospital obtains written consent from the paired candidate to share protected health information (PHI) with all other transplant hospitals in the KPD exchange. The paired candidate's transplant hospital must maintain documentation of this consent in the paired candidate's medical record.

13.3.B Agreement to Accept a Shipped Kidney

The OPTN KPD program will only match a paired candidate with a donor whose recovery will occur at a transplant hospital that is different than the paired candidate's transplant hospital if the paired candidate's transplant hospital has obtained documentation in the candidate's medical record that the candidate is willing to receive a shipped kidney.

For any KPD exchange, the paired candidate's transplant hospital must document in the candidate's medical record that the candidate has been informed of the potentially negative consequences related to shipping a kidney, including that the donor's kidney could be lost in transport.

13.3.C Additional Requirements for KPD Candidates

For any KPD exchange, the paired candidate's transplant hospital must document in the candidate's medical record that it has informed the paired candidate of all the following elements of the KPD program:

1. The KPD program's matching requirements
2. KPD donors and candidates do not choose their match
3. A KPD donor or a candidate may decline a match
4. The KPD program's rules for when members are allowed to facilitate meetings between matched donors and recipients
5. That even if the candidate's paired donor donates, the paired candidate might not be transplanted.
6. The KPD program's remedy for failed KPD exchanges and that the remedy does not include any additional priority for the paired candidate on the deceased donor waiting list

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

13.4 Informed Consent for KPD Donors

13.4.A Release of Protected Health Information (PHI)

For any KPD exchange, a paired donor will not be eligible for a KPD match run until the paired donor's transplant hospital obtains written consent from the paired donor to share protected health information (PHI) with all other transplant hospitals in the KPD exchange. The paired donor's transplant hospital must maintain documentation of this consent in the paired donor's medical record.

13.4.B General KPD Donor Informed Consent

For any KPD exchange, the paired donor's transplant hospital is responsible for obtaining and documenting informed consent from the paired donor according to *Policy 14.3: Informed Consent Requirements*. If a different transplant hospital performs the organ recovery, the recovery hospital must also obtain and document informed consent according to *Policy 14*.

13.4.C Additional Requirements for KPD Donors

For any KPD exchange, the paired donor's transplant hospital must maintain documentation in the paired donor's medical record that it has informed the paired donor of *all* of the following:

1. The KPD program's matching requirements
2. KPD donors and candidates do not choose their match
3. A KPD donor or a candidate may decline a match
4. The possibility of helping more than one candidate receive a transplant
5. The possibility that the paired donor may have to wait to find a match
6. The possibility that the paired donor might have to wait longer to donate after a match has been identified because of logistical issues
7. The possibility that the paired candidate might not receive a transplant because of an unexpected issue with the matched donor's kidney found during or after surgery

8. The possibility that the paired donor's kidney might not be transplanted or the paired donor's matched candidate might not receive a transplant because of unexpected events
9. The KPD program's remedy for failed KPD exchanges and that the remedy does not include any additional priority for the paired candidate on the deceased donor waiting list
10. The possibility that the matched candidate's insurance might not cover travel costs if the paired donor travels to the matched recipient transplant hospital
11. The possibility that the paired donor's paired recipient and the paired donor's matched recipient might not have equal outcomes
12. The possibility of the paired donor's name appearing on the matched candidate's insurance estimation of benefits
13. That the donor's kidney could be lost in transport, and other potentially negative consequences related to shipping a kidney
14. That the paired donor may require additional testing, including multiple blood draws for crossmatching
15. The KPD program's rules for when members are allowed to facilitate meetings between matched donors and recipients

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

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

For any KPD exchange, before a NDD can participate in the KPD program, the NDD's transplant hospital must document in the NDD's medical record that it has informed the NDD of *all* their donation options including:

1. Participating in KPD
2. Donating to a candidate waiting for a deceased donor kidney according to *Policy 14.6.B: Placement of Non-directed Living Donor Kidneys*
3. Any other options available in the NDD's donation service area

13.4.E Additional Requirements for Bridge Donors

For any KPD exchange, before a bridge donor is entered into a KPD match run, the bridge donor's transplant hospital is responsible for obtaining and maintaining documentation in the donor's medical record that it has informed the bridge donor of *all* of the following:

1. The bridge donor may need to have another medical evaluation at a future time.
2. The bridge donor may need to be available to provide blood on multiple occasions for crossmatching.
3. How the KPD program determines whether a chain ends with a bridge donor
4. Approximately how long the bridge donor can expect to wait before undergoing surgery to recover the bridge donor's kidney, based on the experience of the bridge donor's transplant hospital. The bridge donor will have the option to revise the estimated amount of time the donor is willing be a bridge donor based on this information. The bridge donor's transplant hospital will document in the donor's medical record how long the donor is willing to be a bridge donor.

The bridge donor's transplant hospital must maintain documentation in the donor's medical record that the donor has verbally consented to remain a bridge donor each time the donor is identified as a bridge donor in an accepted KPD exchange.

13.5 OPTN KPD Histocompatibility Testing

13.5.A HLA Typing Requirements for OPTN KPD Candidates

Before a candidate can appear on an OPTN KPD match run, the paired candidate's transplant hospital is responsible for reporting to the OPTN Contractor serological split level molecular typing results for *all* of the following:

- HLA-A
- HLA-B
- HLA-Bw4
- HLA-Bw6
- HLA-DR

If the candidate has unacceptable antigens listed for any of the following HLA types, then the paired candidate's transplant hospital is responsible for reporting to the OPTN Contractor serological split level molecular typing results for the corresponding HLA type before the candidate can appear on an OPTN KPD match run:

- HLA-C
- HLA-DR51
- HLA-DR52
- HLA-DR53
- HLA-DPB1
- HLA-DQA1
- HLA-DQB1

13.5.B Antibody Screening Requirements for OPTN KPD Candidates

The paired candidate's transplant hospital must complete antibody screening tests and report to the OPTN Contractor as follows:

1. Use an antibody testing method that is at least as sensitive as the crossmatch method. If antibodies are detected, then identify unacceptable antigens using a solid-phase single phenotype or solid-phase single-antigen test.
2. If no HLA antibodies or unacceptable antigens are detected, then report the paired candidate as unsensitized.
3. Report donor antigens that are considered absolute contraindications to transplant with the paired candidate as unacceptable antigens.
4. Before candidates can appear on their first OPTN KPD match run, each paired candidate's physician or surgeon or their designee and the histocompatibility laboratory director or the director's designee must review and sign a written approval of the unacceptable antigens listed for the paired candidate. The paired candidate's transplant hospital must document this review in the paired candidate's medical record.
5. Retest active candidates for antibodies according to #1 above at all of the following times:

    - Within 110 days from the date of the most recent antibody test
    - When any potentially sensitizing event occurs
    - When a paired candidate who has been inactive for more than 90 days has been reactivated
    - When an unacceptable and positive physical crossmatch occurs that precludes transplantation of the matched candidate

If any new unacceptable antigens are identified, then the paired candidate's transplant hospital must report these antigens using the process outlined in #3 and #4 above. If no new unacceptable antigens are identified, the paired candidate's transplant hospital must document the antibody screening results in the paired candidate's medical record.

13.5.C HLA Typing Requirements for OPTN KPD Donors

Before a donor can appear on an OPTN KPD match run, the donor's transplant hospital is responsible for reporting to the OPTN Contractor serological split level molecular typing results for *all* of the following:

- HLA-A
- HLA-B
- HLA-Bw4
- HLA-Bw6
- HLA-C
- HLA-DR
- HLA-DR51
- HLA-DR52
- HLA-DR53
- HLA-DQA1
- HLA-DQB1
- HLA-DPB1

13.5.D Responding to OPTN KPD Match Offers

1. Before declining an OPTN KPD match offer due to unacceptable antigens, the matched candidate's physician or surgeon or their designee must review the matched donor's antigens and their matched candidate's unacceptable antigens with the histocompatibility laboratory director or the director's designee. This joint review must be documented in the matched candidate's medical record.
2. When an OPTN KPD match offer is declined due to either a positive crossmatch or unacceptable antigens prior to crossmatch, the transplant hospital declining the offer must submit a written explanation to the OPTN Contractor within 7 days after declining the offer.
3. The matched candidate's transplant hospital is responsible for performing HLA typing on the matched donor and verifying the HLA information reported prior to transplant.

13.6 Matching within the OPTN KPD Program

13.6.A Requirements for Match Run Eligibility for Candidates

The OPTN KPD program will only match candidates who comply with *all* of the following requirements:

1. The candidate's transplant hospital must comply with *Policies 5.6.A: Receiving and Reviewing Organ Offers, 5.7: Organ Check-In, and 5.8: Pre-Transplant Verification*
2. The candidate's transplant hospital must complete the informed consent process according to *Policy 13.3: Informed Consent for KPD Candidates*
3. The candidate's transplant hospital must submit *all* the information for these required fields to the OPTN Contractor:

    a. Candidate details, including *all* of the following:
        - Last name
        - First name

- SSN
- Date of birth
- Gender
- Ethnicity
- ABO
- Whether the candidate has signed an agreement to participate in the OPTN KPD program
- Whether the candidate has signed a release of protected health information
- Whether the candidate is a prior living donor
- KPD status: active, inactive or removed. A candidate must have current active status in the OPTN KPD program to be eligible for a match run.

b. Candidate choices, including *all* of the following
   - Whether the candidate would be willing to travel, and, if so, the transplant hospitals to which a candidate would be willing to travel or the distance the candidate is willing to travel
   - Whether the candidate is willing to accept a shipped kidney, and, if so, from which transplant hospitals the candidate would be willing to accept a shipped kidney
   - Minimum and maximum acceptable donor age
   - Minimum acceptable donor creatinine clearance or glomerular filtration rate (GFR)
   - Maximum acceptable donor BMI
   - Maximum acceptable systolic and diastolic blood pressure
   - Whether the candidate is willing to accept a hepatitis B core antibody positive KPD donor, a CMV positive KPD donor, and an EBV positive KPD donor
   - Whether the candidate would be willing to accept a left kidney, right kidney, or either kidney

c. Candidate HLA as defined in *Policy 13.5.A: Histocompatibility Requirements for KPD Candidates*

4. The candidate must have at least one active and eligible potential KPD donor registered in the OPTN KPD program
5. The candidate's transplant hospital must submit a response for **all** previous match offers for the candidate in the OPTN KPD program, including reasons for refusing offers
6. The candidate must not be in a pending exchange in the OPTN KPD program

13.6.B Requirements for Match Run Eligibility for Potential KPD Donors

The OPTN KPD program will only match potential KPD donors that comply with *all* of the following requirements:

1. The transplant hospital registering the potential KPD donor must perform blood typing and subtyping as required by *Policy 14.5: Living Donor Blood Type Determination and Reporting* with the following modifications:

   a. The transplant hospital registering the potential KPD donor must report the potential KPD donor's actual blood type to the OPTN Contractor
   b. A qualified health care professional, other than the qualified health care professional who initially reported the potential KPD donor's blood type to the OPTN Contractor,

must compare the blood type from the two source documents, and separately report the potential KPD donor's blood type to the OPTN Contractor

c. The potential KPD donor is not eligible for a KPD match run until the transplant hospital verifies and reports two identical blood types

2. The transplant hospital registering the potential KPD donor must complete the informed consent process according to *Policy 13.4: Informed Consent for KPD Donors.*
3. The transplant hospital registering the potential KPD donor must complete the 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
      - 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: active, inactive or removed. A donor must have current active status in the OPTN KPD program to be eligible for a match run.

   b. Clinical information, including *all* of the following:
      - The number of anti-hypertensive medications the potential KPD donor is currently taking
      - Systolic and diastolic blood pressure with date (either 24-hour monitoring or two measurements)
      - Creatinine clearance or glomerular filtration rate (GFR), date, and method
      - Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results

   c. Donor choices, including *all* of the following:

- Whether the potential KPD donor would be willing to travel, and, if so, the transplant hospitals to which the potential KPD donor would be willing to travel or the distance the donor is willing to travel
- Whether the potential KPD donor is willing to ship a kidney
- Whether the potential KPD donor is willing to donate a left kidney, right kidney, or either kidney
- Whether the KPD candidate-donor pair and the transplant hospital are willing to participate in a three-way exchange or a donor chain
- Whether the potential KPD donor and the transplant hospital are willing for the potential KPD donor to be a bridge donor

d. Donor HLA as defined in *Policy 13.5.C HLA Typing Requirements for OPTN KPD Donors*

5. The potential KPD donor must be paired to an active and eligible candidate registered in the OPTN KPD program or be a non-directed donor
6. The transplant hospital registering the potential KPD donor must submit a response for all previous match offers for the potential KPD donor in the OPTN KPD program, including reason for refusing offers
7. The potential KPD donor must not be in a pending exchange in the OPTN KPD program

13.7 OPTN KPD Screening Criteria

13.7.A Blood Type

The OPTN Contractor will only match candidates and potential donors who have identical or compatible blood types as defined in *Table 13-1* below.

Table 13-1: Allocation by Blood Type

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

Donors with:	Are Matched to Candidates with:
	A, non-A_1 and Blood Type AB, non-A_1B Matching.

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

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

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

13.7.C Unacceptable Antigens

A transplant hospital must specify any unacceptable antigens it will not accept for its paired candidates using the process outlined in Policy 13.5.B: Antibody Screening Requirements for OPTN KPD Candidates. The OPTN Contractor will not match the paired candidate with any potential KPD donor who has one of the candidate's unacceptable antigens entered as a human leukocyte antigen (HLA) value.

13.7.D Candidate and Potential Donor Choices

A transplant hospital may specify criteria it will not accept for any of its KPD candidates as outlined in *Policy 13.6.A: Requirements for Match Run Eligibility for Candidates* or potential KPD donors as outlined in *Policy 13.6.B: Requirements for Match Run Eligibility for Potential KPD Donors.* The OPTN Contractor will not match the KPD candidates with potential KPD donors who fall outside the specified criteria or potential KPD donors with KPD candidates who fall outside the specified criteria.

13.7.E Donor Pre-Acceptance and Pre-Refusal

If an OPTN KPD candidate has a CPRA greater than or equal to 90%, then the candidate's transplant hospital must pre-accept or pre-refuse potential donors. The OPTN KPD candidate will only be matched with donors that are pre-accepted. If a donor is not pre-accepted, the donor will automatically be treated as pre-refused and will not be matched with the candidate.

If an OPTN KPD candidate has a CPRA less than 90%, then the candidate's transplant hospital has the option to pre-accept or pre-refuse potential donors. These candidates will automatically be matched with all potential donors, unless the candidate's transplant hospital exercises the option to pre-refuse a potential donor.

13.7.F OPTN KPD Prioritization Points

All OPTN KPD matches receive 100 base points. KPD matches will receive additional points according to *Table 13-2: OPTN KPD Prioritization Points* when the OPTN Contractor identifies all possible matches and exchanges from the list of eligible KPD donors and candidates. The OPTN Contractor will then prioritize the set of exchanges with the highest total point value.

Table 13-2: OPTN KPD Prioritization Points

If the:	Then the match will receive:
Candidate is a 0-ABDR mismatch with the potential donor	200 points
Candidate has a CPRA greater than or equal to 80%	125 points
Candidate is a prior living organ donor	150 points
Candidate was less than 18 years old at the time the candidate was registered in the OPTN KPD program	100 points
Candidate and potential donor are registered for the OPTN KPD program in the same region	25 points
Candidate and potential donor are registered for the OPTN KPD program in the same DSA	25 points
Transplant hospital that registered both the candidate and potential donor in the OPTN KPD program is the same	25 points
Potential donor has at least one of the other antibody specificities reported for the candidate	- 5 points

13.7.G OPTN KPD Waiting Time Reinstatement

KPD waiting time begins on the day the candidate's transplant hospital registers the candidate in the OPTN KPD program. Candidates accrue 0.07 points per day from the date the candidate is registered in the OPTN KPD program. A candidate will accrue KPD waiting time at both active and inactive status in the OPTN KPD program.

The OPTN Contractor will reinstate OPTN KPD waiting time to recipients, without interruption, if the OPTN KPD candidate experiences immediate and permanent non-function of any transplanted kidney and the KPD candidate is re-registered in the OPTN KPD program. Immediate and permanent non-function of a transplanted kidney is defined as *either*:

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

KPD waiting time will be reinstated when the OPTN Contractor receives a request for reinstatement of KPD waiting time and the required supporting documentation from the KPD candidate's transplant hospital.

13.8 Two- and Three-Way Matches

13.8.A Match Size

The OPTN Contractor will match KPD donor-candidate pairs only in two-way or three-way exchanges unless the exchange includes a non-directed donor (NDD) according to *Policy 13.9: Donor Chains.*

13.8.B Logistical Requirements

In two-way or three-way exchanges in the OPTN KPD program, all KPD donor surgeries involved in the exchange must begin within 24 hours and only after all donor surgeons involved in the exchange agree to proceed.

13.9 Donor Chains

13.9.A Chain Size

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

13.9.B Logistical Requirements

In KPD donor chains in the OPTN KPD program, surgeries may or may not occur simultaneously. A KPD candidate must receive a kidney within 24 hours of 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 candidate on the deceased donor waiting list at the transplant hospital that entered the non-directed donor that started that chain.

13.9.C What to Do When a Chain Breaks

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 OPTN KPD Crossmatching Requirements

The matched candidate's transplant hospital must do *all* of the following:

1. Perform a physical crossmatch between the matched candidate and the matched donor before the matched donor's recovery is scheduled.
2. Perform a final crossmatch prior to transplant.
3. Report all crossmatching results to the OPTN Contractor and the matched donor's transplant hospital.

If, at any time, the matched candidate's transplant hospital refuses a match offer due to an unacceptable

positive crossmatch between the candidate and the matched donor, then the matched candidate is ineligible for subsequent match runs. The candidate will remain ineligible until *all* of the following are completed:

1. The matched candidate's physician or surgeon or their designee and the histocompatibility laboratory director or the director's designee review the unacceptable antigens reported for the candidate.
2. The matched candidate's transplant hospital reports to the OPTN Contractor that the review has occurred.

13.11 Receiving and Accepting KPD Match Offers

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

Table 13-3: Deadlines for Performing Responsibilities upon Receiving a KPD Match Offer

The following members:	Must:	Within:
Each transplant hospital receiving a match offer	Report to the OPTN Contractor a preliminary response	2 business days of receiving the match offer.
The matched candidate's transplant hospital and the matched donor's transplant hospital	Agree in writing upon all of the following: • Contents required in the crossmatch kit • Instructions for the donor • Address at which to send the completed blood samples	4 business days of receiving the match offer.
The matched donor's transplant hospital	Report to the OPTN Contractor the agreed upon date of the crossmatch	4 business days of receiving the match offer.
The matched donor's transplant hospital	Make all of the following matched donor's records accessible to the matched candidate's transplant hospital: • Any serologic and nucleic acid testing (NAT) results that have not already been shared with the matched candidate's transplant hospital • Whether the matched donor is increased risk according to the *U.S Public Health Services (PHS) Guideline* • Additional records requested by the matched candidate's transplant hospital	4 business days of receiving the match offer.
The matched candidate's transplant hospital	Report to the OPTN Contractor the results of the crossmatch	15 business days of receiving the match offer.
The matched candidate's transplant hospital	Review the matched donor's records and confirm acceptance or report a refusal of the match offer to the OPTN Contractor	15 business days of the match offer.

If the matched candidate's and matched donor's transplant hospitals do not meet any of the deadlines above, then the exchange will be terminated unless a transplant hospital requests an extension. If a transplant hospital submits an extension request before the deadline, the exchange will not terminate until the resolution of the extension request or the deadline is reached, whichever comes last.

13.11.A Requesting a Deadline Extension for a KPD Exchange

The transplant hospital may request an extension for any of the deadlines in *Table 13-3* by submitting a request in writing to the OPTN Contractor. This written request must include the reason for the request and the new requested deadline date. Upon receipt of the request for extension, the OPTN Contractor will notify all of the transplant hospitals in the exchange. Upon notification, the transplant hospitals in the exchange must respond to the request for extension within 2 business days. If all other transplant hospitals in the exchange agree to the extension, it will be granted. If any of the transplant hospitals in the exchange refuse the extension request, the extension will not be granted.

The transplant hospitals will have two business days to respond to the extension request. At the end of the first business day, the OPTN Contractor will send a second notification to any transplant hospital that has not yet responded. If any of the transplant hospitals fail to respond to the extension request at the end of the second business day, the extension will not be granted and the exchange will be terminated.

13.12 Transportation of Kidneys

For any KPD exchange, the recovery hospital is responsible for packaging, labeling, and transporting kidneys from donors according to *Policy 16.1: Organs Recovered by Living Donor Recovery Hospitals.*

In the OPTN KPD program, the recovery hospital must specify *both* of the following:

1. The location where the recovered kidney must be picked up for transport to the recipient's transplant hospital.
2. The name and telephone number of the person or company who will package and label the kidney.

The recipient's transplant hospital must document *both* of the following:

1. The location where the recovered kidney must be delivered.
2. The name and telephone number of the person or company who will be transporting the kidney from the time that the kidney is recovered until the kidney is delivered to the location specified by the KPD recipient's transplant hospital.

The recovery and recipient hospitals must complete this documentation, along with the date and time it was documented, before the potential KPD donor enters the operating room for the kidney recovery surgery and must maintain this documentation in the donor's medical record.

13.13 Communication between KPD Donors and Recipients

The following rules apply to communication between KPD donors and matched KPD recipients that participated in an OPTN KPD program exchange. These rules do not apply to meetings between potential KPD donors and paired KPD candidates.

Members can facilitate communication such as meetings or other correspondence between KPD donors and their matched recipients that participated in an OPTN KPD program exchange only if *all* of the follow conditions are met:

1. All the KPD donors and recipients participating in the communication agree on conditions of the meeting or correspondence.

2. The meeting or communication occurs after the donor kidney recovery and transplant surgeries have been completed.
3. The transplant hospital establishes and complies with a written protocol for when KPD donors and their matched recipients can communicate. This protocol must include, at a minimum, the timing of the meeting or correspondence and what staff must be involved.
4. The transplant hospital complies with the written protocol for when KPD donors and recipients can communicate. The transplant hospital must maintain documentation of compliance in the KPD donor's or matched recipient's medical record.

History

Policy 13: Kidney Paired Donation: 11/13/2012 (3/13/2013); 11/13/2012 (1/30/2014); 11/12/2013 (2/1/2014); *Policy 13: Kidney Paired Donation*: 6/23/2014 (9/1/2014); 11/12/2014 (5/1/2015); 6/2/2015 (9/1/2015); 6/2/2015 (12/1/2015); 11/12/2014 (1/21/2016); *Policy 13.5: OPTN KPD Histocompatibility Testing:* 12/1/2015 (3/1/2016); *Policy 13.6: Matching within the OPTN KPD Program*: 6/2/2015 (6/23/2016); *Policy 13.11: Receiving and Accepting KPD Match Offers*: 6/2/2015 (3/30/2017)

Pending Implementation

Policies 13.7: OPTN KPD Screening Criteria, 13.8: Two- and Three-Way Matches, and 13.9: Donor Chains: 12/1/2015 (TBD); Policy 13.6.B: Requirements for Match Run Eligibility for Potential KPD Donors: 12/5/2016 (TBD)

Policy 14: Living Donation

14.1 Psychosocial Evaluation Requirements for Living Donors

14.1.A Living Donor Psychosocial Evaluation Requirements

Living donor psychosocial evaluation requirements apply to living kidney, liver, pancreas, lung or intestine donors.

The living donor psychosocial evaluation must be performed by a psychiatrist, psychologist, or masters prepared social worker, or licensed 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 could be identified as risks for poor psychosocial outcome
2. An evaluation for the presence of behaviors that may increase risk for disease transmission as defined by the *U.S. Public Health Service (PHS) Guideline*
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 living donor understands the short and long-term medical and psychosocial risks for both the living donor and recipient associated with living donation
6. An assessment of whether the decision to donate is free of inducement, coercion, and other undue pressure by exploring the reasons for donating and the nature of the relationship, if any, to the transplant candidate
7. An assessment of the living donor's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes evaluating whether the donor has a realistic plan for donation and recovery, with social, emotional and financial support available as recommended

8. A review of the living donor's occupation, employment status, health insurance status, living arrangements, and social support
9. The determination that the living donor understands the potential financial implications of living donation

14.2 Independent Living Donor Advocate (ILDA) Requirements

14.2.A ILDA Requirements for Living Donor Recovery Hospitals

Living donor ILDA requirements apply to living kidney, liver, pancreas, intestine or lung donors.

For any living kidney donor who is undergoing evaluation for donation, the living donor recovery hospital must designate and 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 may be one person or an independent living donor advocate team with multiple members. An ILDA team must designate one person from the team as the key contact for each living donor.

The ILDA must:

1. Function independently from the transplant candidate's team.
2. Advocate for the rights of the living donor.
3. Fulfill the qualification and training requirements specified in the recovery hospital's protocols regarding knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressure on the living donor's decision about whether to donate. Document that each requirement has been met.
4. Review whether the living donor has received information on each of the following areas and assist the donor in obtaining additional information from other professionals as needed about the:
   a. Informed consent process as described in *Policy 14.3: Informed Consent Requirements*
   b. Evaluation process according to *Policies 14.1.A: Living Donor Psychosocial Evaluation Requirements* and *14.4.A: Living Donor Medical Evaluation Requirements*
   c. Surgical procedure
   d. Medical risks according to *Tables 14-1* through *14-5*
   e. Psychosocial risks according to *Tables 14-1* through *14-5*
   f. Follow-up requirements, and the benefit and need for participating in follow-up according to *Policies 18.1: Data Submission Requirements, 18.5.A: Reporting Requirements after Living Kidney Donation* and *18.5.C: Submission of Living Donor Death and Organ Failure*
5. Document that each topic was reviewed

14.2.B ILDA Protocols for Living Donor Recovery Hospitals

The living donor recovery hospital must develop, and once developed must comply with, written protocols for:

1. The composition of the ILDA team, if the hospital uses a team
2. The qualifications and training (both initial and ongoing) required for the ILDA. Minimum qualifications must include knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressures on the living donor's donation decision.
3. The duties and responsibilities of the ILDA, which must include at least the functions and duties listed throughout *Policy 14.2.A: ILDA Requirements for Living Donor Recovery Hospitals.*

4. The process the living donor recovery hospital will provide for the ILDA to file a grievance when necessary to protect the rights or best interests of the living donor.
5. The process the living donor recovery hospital will use to address any grievance raised by the ILDA concerning the rights or best interests of the living donor.

14.3 Informed Consent Requirements

Living donor informed consent requirements apply to living kidney, liver, pancreas, and intestine or lung donors.

The recovery hospital is responsible for informed consent which must include *all* of the components in *Tables 14-1* through *14-5*.

Documentation of informed consent must be maintained in the donor medical record.

Table 14-1: Requirements for Living Donor Informed Consent

The recovery hospital must:	These elements of informed consent :
Obtain from living donors	The donor's signature on a document that confirms that the donor: • Is willing to donate • Is free from inducement and coercion and • Has been informed that he or she may decline to donate at any time
Provide to living donors	An opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential. The ILDA must be available to assist the donor during the consent process, according to *Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements.* Instruction about all phases of the living donation process, which include: • Consent • Medical and psychosocial evaluations • Pre and post operative care • Required post-operative follow up according to *Policy 18.5: Living Donor Data Submission Requirements.* Teaching or instructional material can include any media, one-on-one or small group interaction. Teaching or instruction must be provided in a language in which the donor is able to engage in meaningful dialogue with recovery hospital's staff.

The recovery hospital must:	These elements of informed consent :
Disclose to living donors	The recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient. 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. The recovery hospital must provide an ILDA. Alternate procedures or courses of treatment for the recipient, including deceased donor transplantation, and that: a. A deceased donor organ may become available for the candidate before the recovery hospital completes the living donor's evaluation or the living donor transplant occurs. b. Any transplant candidate may have risk factors for increased morbidity or mortality that are not disclosed to the donor. Health information obtained during the evaluation is subject to the same regulations as all medical records and could reveal conditions that must be reported to local, state, or federal public health authorities. The recovery hospital is required to: a. Report living donor follow up information, at the time intervals specified in *Policy 18.5: Living Donor Data Submission Requirements.* b. Have the donor commit to post operative follow up testing coordinated by the recovery hospital. Any infectious disease or malignancy pertinent to acute recipient care discovered during the donor's first two years of follow up care: a. May need to be reported to local, state or federal public health authorities b. Will be disclosed to their recipient's transplant center c. Will be reported through the OPTN Improving Patient Safety Portal

The recovery hospital must:	These elements of informed consent :
Disclose to living donors	A living donor must undergo a medical evaluation according to *Policy 14.4: Medical Evaluation Requirements for Living Donors* and a psychosocial evaluation as required by *Policy 14.1: Psychosocial Evaluation Requirements for Living Donors*. The hospital may refuse the donor. In such cases, the recovery hospital must inform the donor that a different recovery hospital may evaluate the donor using different selection criteria. The following are inherent risks associated with evaluation for living donation: a. Allergic reactions to contrast b. Discovery of reportable infections c. Discovery of serious medical conditions d. Discovery of adverse genetic findings unknown to the donor e. Discovery of certain abnormalities that will require more testing at the donor's expense or create the need for unexpected decisions on the part of the transplant team There are surgical, medical, psychosocial, and financial risks associated with living donation, which may be temporary or permanent and include, but are not limited to, *all* of the following: a. Potential medical or surgical risks: i. Death ii. Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure iii. Abdominal symptoms such as bloating, nausea, and developing bowel obstruction iv. That the morbidity and mortality of the donor may be impacted by obesity, hypertension, or other donor-specific pre-existing conditions b. Potential psychosocial risks: i. Problems with body image ii. Post-surgery depression or anxiety iii. Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies iv. Changes to the 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

Table 14-2: Required Recipient Outcome and Transplanted Organ 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 living donor with both national and that hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) hospital-specific reports.	• National 1-year patient and transplanted organ survival • The hospital's 1-year patient and transplanted organ survival • Notification about all Centers for Medicare and Medicaid Services (CMS) outcome requirements not being met by the transplant hospital
Will not be the same and the recipient hospital is known	The recovery hospital must provide the living donor with both national and the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR hospital-specific reports.	• National 1-year patient and transplanted organ survival • The recipient hospital's 1-year patient and transplanted organ survival • Notification about all CMS outcome requirements not being met by the recipient hospital

Table 14-3: Additional Requirements for the Informed Consent of Living Kidney Donors

The recovery program must:	These additional elements as components of informed consent for living kidney donors:
Provide to all living kidney donors	Education about expected post-donation kidney function, and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the living donor in the future, to include: a. On average, living donors may have a 25-35% permanent loss of kidney function after donation. b. Baseline risk of ESRD for 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 living donor cannot predict lifetime risk of CKD or ESRD. d. Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD may be faster with only one kidney. e. Dialysis is required if the donor develops ESRD. f. Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to *Policy 8.3: Kidney Allocation Points*

Disclose to all living kidney donors	Surgical risks may be transient or permanent and include but are not limited to:
	• Potential medical or surgical risks:
	  ○ Decreased kidney function
	  ○ Kidney failure and the need for dialysis or kidney transplant for the donor

Table 14-4: Additional Requirements for the Informed Consent of Living Liver Donors

The recovery program must:	These additional elements as components of informed consent for living liver donors
Disclose to all living liver donors	Surgical risks may be transient or permanent and include but are not limited to: • Acute liver failure with need for liver transplant. • Transient liver dysfunction with recovery. The potential for transient liver dysfunction depends upon the amount of the total liver removed for donation. • Risk of red cell transfusions or other blood products. • Biliary complications, including leak or stricture that may require additional intervention. • Post-donation laboratory tests may result in abnormal or false positive results that may trigger additional tests that have associated risks.

Table 14-5: Additional Required Living Liver Donor Recipient Outcome and Transplanted Living Donor Liver 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 living donor with the hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) program-specific reports.	The hospital's 1-year living donor recipient's survival and recipient's graft survival rates
Will not be the same and the recipient hospital is known	The recovery hospital must provide the living donor with the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR program-specific reports.	The recipient hospital's 1-year living donor recipient's survival and graft survival rates

14.4 Medical Evaluation Requirements for Living Donors

14.4.A Living Donor Medical Evaluation Requirements

Living donor medical evaluation requirements only apply to living kidney, liver, pancreas, lung or intestine donors.

A medical evaluation of the living donor must be performed by the recovery hospital and by a physician or surgeon experienced in living donation. Documentation of the medical evaluation must be maintained in the donor medical record.

The medical evaluation must include *all* of the components in *Tables 14-6* through *14-9* below.

Table 14-6: Requirements for Living Donor Medical Evaluations

This evaluation must be completed:	Including evaluation for and assessment of this information:
General donor history	1. A personal history of significant medical conditions which include but are not limited to: a. Hypertension b. Diabetes c. Lung disease d. Heart disease e. Gastrointestinal disease f. Autoimmune disease g. Neurologic disease h. Genitourinary disease i. Hematologic disorders j. Bleeding or clotting disorders k. History of cancer including melanoma 2. History of infections 3. Active and past medications with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medication 4. Allergies 5. An evaluation for coronary artery disease
General family history	• Coronary artery disease • Cancer
Social history	• Occupation • Employment status • Health insurance status • Living arrangements • Social support • Smoking, alcohol and drug use and abuse • Psychiatric illness, depression, suicide attempts • Increased risk behavior as defined by the *U.S. Public Health Services (PHS) Guideline*
Physical Exam	• Height • Weight • BMI • Vital signs • Examination of all major organ systems
General laboratory and imaging tests	• Complete blood count (CBC) with platelet count • Blood type and subtype as specified in *14.5: Living Donor Blood Type Determination and Reporting* and its subsections • Prothrombin Time (PT) or International Normalized Ratio (INR) • Partial Thromboplastin Time (PTT) • Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin) • HCG quantitative pregnancy test for premenopausal women without surgical sterilization • Chest X-Ray • Electrocardiogram (ECG)

This evaluation must be completed:	Including evaluation for and assessment of this information:
Transmissible disease screening	Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using FDA-licensed, approved, or cleared tests. Testing must include *all* the following: 1. CMV (Cytomegalovirus) antibody 2. EBV (Epstein Barr Virus) antibody 3. HIV antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination test as close as possible, but within 28 days prior to organ recovery 4. Hepatitis B surface antigen (HBsAg) testing as close as possible, but within 28 days prior to organ recovery 5. Hepatitis B core antibody (anti-HBc) testing as close as possible, but within 28 days prior to organ recovery 6. Hepatitis C antibody (anti-HCV) testing as close as possible, but within 28 days prior to organ recovery 7. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 8. Syphilis testing If a living donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to the *U.S. Public Health Services (PHS) Guideline*, testing must also include HIV ribonucleic acid (RNA) by NAT or HIV antigen/antibody (Ag/Ab) combination test. This does not apply to donors whose only increased risk factor is receiving hemodialysis within the preceding 12 months, as they are at risk only for HCV according to the *U.S. Public Health Services (PHS) Guideline.* For tuberculosis (TB), living donor recovery hospitals must determine if the donor is at increased risk for this infection. If TB risk is suspected, testing must include screening for latent infection using *either*: • Intradermal PPD • Interferon Gamma Release Assay (IGRA)
Endemic transmissible diseases	Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation.
Cancer screening	Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) or the U.S. Preventive Services Task Force to screen for: • Cervical cancer • Breast cancer • Prostate cancer • Colon cancer • Lung cancer

14.4.B Additional Requirements for the Medical Evaluation of Living Kidney Donors

Table 14-7: Additional Requirements for the Medical Evaluation of Living Kidney Donors

This evaluation must be completed:	Including evaluation for and assessment of this information:
Kidney - specific donor history	A personal history of significant medical conditions which include, but are not limited to, kidney-specific personal history including: a. Genetic renal diseases b. Kidney disease, proteinuria, hematuria c. Kidney injury d. Diabetes including gestational diabetes e. Nephrolithiasis f. Recurrent urinary tract infections
Kidney-specific family history	• Kidney disease • Diabetes • Hypertension • Kidney Cancer
Physical Exam	• Blood pressure taken on at least two different occasions or 24-hour or overnight blood pressure monitoring
Other metabolic testing	• Fasting blood glucose • Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol) • Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high risk individuals
Kidney-specific tests	• Urinalysis or urine microscopy • Urine culture if clinically indicated • Measurement of urinary protein and albumin excretion • Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection • Hospitals must develop and comply with a written protocol for polycystic kidney disease or other inherited renal disease as indicated by family history • Patients with a history of nephrolithiasis or nephrolithiasis (>3 mm) identified on radiographic imaging must have a 24-hour urine stone panel measuring: o Calcium o Oxalate o Uric acid o Citric acid o Creatinine o Sodium
Anatomic assessment	Determine: • Whether the kidneys are of equal size • If the kidneys have masses, cysts, or stones • If the kidneys have other anatomical defects • Which kidney is more anatomically suited for transplant

14.4.C Additional Requirements for the Medical Evaluation of Living Liver Donors

Table 14-8: Additional Requirements for the Medical Evaluation of Living Liver Donors

This evaluation must be completed:	Including evaluation for and assessment of this information:
Liver-specific family history	• Liver diseases • Bleeding or clotting disorders
General laboratory and imaging tests	• Hospitals must develop and follow a written protocol for hypercoagulable state evaluation
Liver-specific tests	• Hepatic function panel • Ceruloplasmin in a donor with a family history of Wilson's Disease • Iron, iron binding capacity, ferritin • Alpha-1-antitrypsin level: those with a low alpha-1-antitrypsin levels should have a phenotype • must develop and follow a written protocol for testing for genetic diseases • Hospitals must develop and follow a written protocol for screening for autoimmune disease • Hospitals must develop and follow a written protocol for pre-donation liver biopsy
Anatomic assessment	A radiological assessment must be performed to determine if the liver is anatomically suitable for transplantation, and to assess safety of resection for the donor. The evaluation must include at least all of the following: • Assessment of projected graft volume • Donor's remnant volume, • Vascular anatomy • Presence of steatosis

14.4.D Living Donor Exclusion Criteria

Table 14-9: Living Donor Exclusion Criteria

Exclusion criteria for all Living Donors	Living donor recovery hospitals may exclude a donor with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation. Living donor recovery hospitals must exclude all donors who meet any of the following exclusion criteria: • Is both less than 18 years old and mentally incapable of making an informed decision • HIV, unless the requirements for a variance are met, according *to Policy 15.6: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors* • Active malignancy, or incompletely treated malignancy • High suspicion of donor coercion • High suspicion of illegal financial exchange between donor and recipient • Evidence of acute symptomatic infection (until resolved) • Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality
Additional Exclusion Criteria for Living Kidney Donors	Kidney recovery hospitals must exclude all donors who meet *any* of the following additional exclusion criteria: • Uncontrollable hypertension or history of hypertension with evidence of end organ damage • Diabetes
Additional Exclusion Criteria for Living Liver Donors	Liver recovery hospitals must exclude all donors who meet *any* of the following additional exclusion criteria: • HCV RNA positive • HBsAg positive • Donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes • Expected donor remnant volume less than 30% of native liver volume • Prior living liver donor

14.5 Living Donor Blood Type Determination and Reporting

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

14.5.A Living Donor Blood Type Determination

The recovery hospital must ensure that each living donor's blood type is determined by testing at least two donor blood samples prior to generation of the living donor ID. The recovery hospital must develop and comply with a written protocol to resolve conflicting primary blood type results.

Living donor blood samples must:

1. Be drawn on two separate occasions
2. Have different collection times
3. Be submitted as separate samples
4. Have results indicating the same blood type

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

14.5.B Living Donor Blood Subtype Determination

Subtyping is optional for living donors.

If the recovery hospital chooses to subtype *and* pre-red blood cell transfusion samples are available, then subtyping must be completed according to *Table 14-10.*

Table 14-10: Subtyping Requirements by First Subtype Result

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

Living donor blood samples for subtyping must:

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

All subtype results reported to the OPTN Contractor must be from two separate tests indicating the same result. If there are conflicting subtype results, the subtype results must not be reported to the OPTN Contractor and living donor transplant compatibility or allocation must be based on the primary blood type.

If subtype is determined and reported, the recovery hospital must document that subtyping was conducted according to the above requirements.

14.5.C Reporting of Living Donor Blood Type and Subtype

The recovery hospital must report and verify the living donor blood type prior to registration with the OPTN Contractor using the *Living Donor Feedback Form* as required below:

1. Two different qualified health care professionals, as defined in the recovery hospital's protocol, must each make an independent report to the OPTN Contractor for blood type. For VCA recoveries, the blood type verification and reporting must be recorded in the living donor's medical record.
2. If blood subtype is used for ensuring transplant compatibility or allocation, a qualified health care professional must report blood subtype to the OPTN Contractor. This report must be verified by a different qualified health care professional according to the recovery hospital's protocol. For VCA recoveries, the blood subtype verification and reporting must be recorded in the living donor's medical record.

3. Both qualified health care professionals must use all blood type and subtype determination source documents to verify they:
   a. Contain blood type and subtype (if used for ensuring transplant compatibility or allocation) results for the donor
   b. Indicate the same blood type and subtype (if used for ensuring transplant compatibility or allocation) on the two test results
   c. Match the result reported to the OPTN Contractor or VCA donor medical record

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

14.6 Placement of Living Donor Organs

14.6.A Prospective Crossmatching prior to Kidney Placement

A prospective crossmatch is mandatory for all potential kidney living donor recipients. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are outlined in *Policy 4: Histocompatibility*.

14.6.B Placement of Non-directed Living Donor Organs

Prior to determining the placement of a non-directed living donor organ, including non-directed organs from domino donors and non-domino therapeutic organ donors, the recovery hospital must obtain the match run of its waiting list candidates from its local OPO or the Organ Center. When a non-directed living donor organ is placed, the recovery hospital must document how the organ is placed and the rationale for placement.

This requirement does not apply to non-directed living kidney donors who donate a kidney through a Kidney Paired Donation (KPD) arrangement.

14.6.C Transplant Hospital Acceptance of Living Donor Organs

A transplant hospital must only accept and transplant living donor organs according to *Table 14-11* below.

Table 14-11: Transplant Hospital Requirements for Accepting and Transplanting Living Donor Organs

If this type of living donor organ is being recovered:	Then the recovery hospital must:
Kidney	Meet the requirements according to the *OPTN Bylaws E.5: Kidney Transplant Programs that Perform Living Donor Recovery*
Liver	Meet the requirements according to the *OPTN Bylaws F.6: Liver Transplant Programs that Perform Living Donor Recovery*
Other organ types, excluding kidney or liver	Have current designated transplant program approval for that organ type

14.7 Living Donor Pre-Recovery Verification

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

The recovery hospital must conduct a pre-recovery verification that meets *all* of the following requirements:

1. The verification must occur prior to the induction of general anesthesia on the day of the living donor recovery.
2. Recovery hospitals must use at least one of the acceptable sources during the pre-recovery verification to verify all of the following information according to *Table 14-12* below. Recovery hospitals may use the OPTN organ tracking system for assistance in completing these verifications.

Table 14-12: Pre-Recovery Verification Requirements

The recovery hospital must verify *all* of the following information:	Using at least *one* of the following:	By *both* of the following individuals:
Donor ID	• Donor identification band containing the donor ID • Donor identification band and OPTN computer system	1. Recovery surgeon 2. Licensed health care professional
Organ type and laterality (if applicable)	• OPTN computer system	1. Recovery surgeon 2. Licensed health care professional
Donor blood type and subtype (if used for ensuring transplant compatibility or allocation)	• Donor blood type and subtype source documents	1. Recovery surgeon 2. Licensed health care professional
Intended recipient unique identifier	• Recipient medical record • OPTN computer system	1. Recovery surgeon 2. Licensed health care professional
Intended recipient blood type	• Recipient medical record • OPTN computer system	1. Recovery surgeon 2. Licensed health care professional
Donor and intended recipient are blood type compatible (or intended incompatible).	• OPTN computer system • Recipient medical record • Attestation following verification of donor and recipient blood types	1. Recovery surgeon 2. Licensed health care professional
Correct donor organ has been identified for the correct intended recipient	• Donor medical record • OPTN computer system • Attestation following verification of donor ID, organ, and recipient unique identifier	1. Recovery surgeon 2. Licensed health care professional

The recovery hospital must document that the verification was completed according to the hospital's protocol and the above requirements.

14.8 Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials

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
- Living donor organs, tissue typing specimens, or vessels require repackaging by a transplant hospital for transport outside the transplant hospital

14.8.A Living Donor Vessel Recovery and Transplant

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

Any vessels recovered from living donors must be stored according to *Policy 16.6: Vessel Recovery, Transplant, and Storage.*

14.9 Requirements for Domino Donors and Non-Domino Therapeutic Donors

Although domino donors and non-domino therapeutic donors are considered living donors, the requirements in *Policy 14: Living Donation* are limited only to Policies 14.9 A through 14.9 E below for domino donors and non-domino therapeutic donors.

14.9.A Informed Consent Requirements for Domino Donors and Non-Domino Therapeutic Donors

Recovery hospitals must obtain the donor's signature on a document that confirms that the donor:

1. Is willing to donate
2. Is free from inducement and coercion
3. Has been informed that the donor may decline to donate at any time
4. Has received information on treatment options that would not involve organ donation

Recovery hospitals must also provide *all* of the following to domino donors and non-domino therapeutic donors:

1. The disclosure that the recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient
2. The disclosure that it is a federal crime for any person to knowingly acquire, obtain, or otherwise transfer any human organ for anything of value including, but not limited to, cash, property, and vacations.
3. The disclosure that health information obtained during the evaluation for donation is subject to the same regulations as all health records and could reveal conditions that must be reported to local, state, or federal public health authorities.
4. The disclosure that any new information discovered during the domino donor's or non-domino therapeutic donor's first two years of post-donation care that indicates risk of potential transmission of infectious disease or malignancy to the recipient of the domino donor's or non-domino therapeutic donor's native organ:
   a. May need to be reported to local, state, or federal public health authorities
   b. Will be disclosed to the recipient's transplant hospital
   c. Will be reported through the OPTN Improving Patient Safety Portal
5. Information on treatment options that would not involve organ donation.
6. An opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential.

Documentation of the informed consent must be maintained in the donor medical record.

14.9.B Psychosocial and Medical Evaluation Requirements for Domino and Non-Domino Therapeutic Donors

Recovery hospitals must evaluate domino donors and non-domino therapeutic donors according to *all* of the following requirements:

1. Perform an evaluation for the presence of behaviors that may increase risk for disease transmission as defined by the *U.S. Public Health Service (PHS) Guideline*
2. Screen the domino donor or non-domino therapeutic donor for all of the following according to *Policy 14.4: Medical Evaluation Requirements for Living Donors, Table 14-6: Requirements for Living Donor Medical Evaluations*:
   a. Transmissible diseases screening
   b. Endemic transmissible diseases
   c. Cancer screening
3. Develop and comply with written protocols for the domino donor and non-domino therapeutic donor exclusion criteria considering incorporating as appropriate the elements of *Table 14-9: Living Donor Exclusion Criteria*
4. Register and verify the blood type of the domino donor or non-domino therapeutic donor according to *Policy 14.5: Registration and Blood Type Verification of Living Donors before Donation*

Documentation of the psychosocial and medical evaluation must be maintained in the donor medical record.

14.9.C Recovery of Domino Donor and Non-Domino Therapeutic Donor Organs

Transplant hospitals can recover domino donor and non-domino therapeutic donor organs if the hospital has current designated transplant program approval for that organ type.

14.9.D Acceptance of Domino Donor and Non-Domino Therapeutic Donor Organs

Transplant hospitals must only accept domino donor and non-domino therapeutic donor organs recovered at transplant hospitals that have a current designated transplant program approval for that organ type.

14.9.E Reporting and Data Submission Requirements for Domino Donors and Non-Domino Therapeutic Donors

Recovery hospitals must submit the living donor feedback and living donor registration (LDR) forms for the domino donor and non-domino therapeutic donor according to *Policy 18.1: Data Submission Requirements*.

14.10 Living Donor Organ Check-In

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

14.11 Living Donor Pre-Transplant Verification

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

14.12 Reporting Requirements

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

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: 11/12/2013 (2/1/2014); 3/7/14; 06/23/14 (7/3/14); 06/23/14 (9/1/14); 11/12/14 (2/1/15); 11/12/2014 (5/1/2015); 11/12/2014 (8/10/2015); 6/2/2015 (9/1/2015); *Policy 14.4.E: Living Donor Exclusion Criteria*: 6/2/2015 (11/21/2015); *Policy 14.5: Living Donor Blood Type Determination and Reporting, 14.7: Living Donor Pre-Recovery Verification, 14.9: Living Donor Organ Check-In,* and *14.10: Living Donor Pre-Transplant Verification*: 6/2/2015 (6/23/2016); *14.5.B: Living Donor Blood Subtype Determination:* 8/12/2016 (9/1/2016); *Policy 14: Living Donation:* 12/1/2015 (11/10/2016); *Policy 14.7: Living Donor Pre-Recovery Verification:* 12/5/2016 (3/1/2017)

Pending Implementation

Policy 14: Living Donation: 12/5/2016 (TBD)

Notes

- For priority given for prior living kidney donors on the waiting list, see *8.5.F: Prior Living Organ Donor.*
- 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

15.1 Patient Safety Contact

Each OPO and transplant program must identify a patient safety contact and develop and comply with a written protocol for the patient safety contact to fulfill all the following responsibilities:

1. Be available 24 hours a day.
2. Receive notifications of potential disease transmission and related communication from the OPTN 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.

15.2 Potential Candidate Screening Requirements

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 must be offered appropriate counseling.

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

15.3 Informed Consent of Transmissible Disease Risk

Transplant programs must obtain specific informed consent before transplant of any organ when *any* of the following occurs:

- The donor has a known medical condition that may, in the transplant hospital's medical judgment, be transmissible to the recipient, including HIV.
- The donor meets any of the criteria for increased risk of transmitting HIV, hepatitis B, and hepatitis C as specified in the *U.S. Public Health Services (PHS) Guideline.*

- When a hemodiluted specimen is used for 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 evaluated and screened as outlined in *Policy 2.3: Evaluating and Screening Potential Deceased Donors*.
2. Living Donors are required to undergo screening for the diseases listed in *Policy 14.4: Medical Evaluation Requirements for Living Donor*.
3. That there is no comprehensive way to screen 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 Donors with Additional Risk Identified Pre-transplant

If additional 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 or living donor organs for the development of potential donor-derived disease after transplantation.

15.3.B Donors at Increased Risk for Transmission of Blood-borne Pathogens

If a 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 in addition to routine post-transplant care:

1. Additional post-transplant testing for HIV, hepatitis C, and hepatitis B as appropriate based on the recipient's pre-transplant status. Every transplant hospital must develop and implement a written protocol for post-transplant testing for these diseases.
2. Treatment of or prophylaxis for the transmissible disease, when available.

15.4 Host OPO Requirements for Reporting Post-Procurement Test Results and Discovery of Potential Disease Transmissions

Host OPOs must report any test results or information received post-procurement that indicate there may be a possibility for donor-derived disease as follows.

15.4.A Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

The host OPO must report all positive test results and other relevant information received post-procurement for each donor as soon as possible but no later than 24 hours after receipt as follows:

1. All results indicating Pathogens of Special Interest must be reported to the receiving transplant program's patient safety contact and the OPTN Improving Patient Safety Portal. The OPTN Contractor provides a list of Pathogens of Special Interest, including any results that can be excluded from reporting. The OPTN Contractor reviews and updates this list at least annually.
2. All other positive test results and relevant information must be reported according to *Table 15-1 below.*

Table 15-1: Host OPO Reporting Requirements for Positive Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

The host OPO must report *all* of the following *positive* results:		To:
Samples relevant to all recipients	Serologic, NAT, or antigen results indicating presence of parasites, virus, or fungi	The receiving transplant program's patient safety contact
	Cultures from the following specimens: • Ascites • Blood • Cerebrospinal fluid (CSF) • Deep wound • Genital • Pericardial • Pleural fluid	The receiving transplant program's patient safety contact
	Mycobacterial smears and cultures	The receiving transplant program's patient safety contact
	Fungal smears and cultures with the exception of *Candida* species	The receiving transplant program's patient safety contact
Relevant information	Respiratory samples (bacterial or *Candida species*) *only* to transplant programs receiving lungs or head and neck VCAs	The receiving transplant program's patient safety contact
	Urine cultures (bacterial or *Candida species) only* to transplant programs receiving kidneys or genitourinary VCAs	The receiving transplant program's patient safety contact
	Malignancy or other findings highly suggestive of malignancy recognized after procurement	1. The receiving transplant program's patient safety contact 2. The OPTN Improving Patient Safety Portal
	Histopathology results reported post-procurement	The receiving transplant program's patient safety contact

The host OPO must report *all* of the following positive results:		To:
Relevant information	All *final* culture information for any culture results that were reported according to these requirements	The receiving transplant program's patient safety contact
	Other psycho-social history, medical history, autopsy, testing, and laboratory findings identifying infectious conditions that may adversely affect a potential transplant recipient	The receiving transplant program's patient safety contact

15.4.B Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy

If the host OPO is notified that an organ recipient is suspected to have, is confirmed positive for, or dies from a potential transmissible disease, infection, or malignancy and there is substantial concern that it could be from the transplanted organ, then the host OPO must do *all* the following:

1. Communicate the suspected donor's and affected organ recipient's test results and diagnosis that may be relevant to acute patient care, as soon as possible but no more than 24 hours after receipt, to any transplant program patient safety contacts and tissue banks that received organs, vessels, or tissue from the donor. This includes any test results that were not available at the time of procurement or that were performed after procurement. The host OPO must document that this information is shared with all receiving transplant programs and tissue banks.
2. Report the event to the OPTN Improving Patient Safety Portal as soon as possible but no more than 24 hours after notification or receipt of recipient test results or diagnosis.

15.4.C Host OPO Requirements for Post-Reporting Follow Up

If the host OPO reports test results or other relevant information to the OPTN Contractor through the OPTN Improving Patient Safety Portal, then the host OPO must also do *all* the following:

1. Complete and submit the *Potential Disease Transmission Report Form* no later than 24 hours after reporting the event through the OPTN Improving Patient Safety Portal.
2. Contribute to a follow up review of the event, in partnership with OPTN patient safety staff.
3. Provide additional information or specimens related to the deceased donor if requested.

15.5 Transplant Program Requirements for Communicating Post-Transplant Discovery of Disease or Malignancy

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

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

1. If the findings are from transplant program testing of the donor, then the transplant program must notify the host OPO or living donor recovery hospital of the findings.
2. Notify the recipients under care at the transplant program, or the recipient's agents, of the risk or confirmation of transmissible disease or malignancy.

3. Document the new information about the donor and potential risk or confirmation of transmissible disease or malignancy in the recipients' medical records.
4. Follow the notified recipients for the development of the disease or malignancy after transplant.
5. Offer the recipients additional testing, monitoring, and treatment as appropriate, in addition to routine follow up care.

15.5.B Transplant Program Requirements for Reporting Post-Transplant Discovery of Recipient Disease or Malignancy

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

1. Notify host OPO or living donor recovery hospital that procured the organ without waiting for all medical documentation that may eventually become available. The transplant program must notify the host OPO or living donor recovery hospital by phone and provide documentation as soon as possible but no more than 24 hours after learning of the event.
2. Report the event through the OPTN Improving Patient Safety Portal as soon as possible but no more than 24 hours after learning of the event.
3. Provide additional related information or specimens if requested.

15.5.C Transplant Program Requirements for Post-Reporting Follow-Up

If the transplant program has a recipient that is involved in an OPTN Improving Patient Safety Portal report, then the transplant program must also do *all* of the following:

1. Submit any relevant test results including cultures, infectious disease testing results, imaging studies, or autopsy results to OPTN patient safety staff.
2. Respond to host OPO, living donor recovery hospital, and OPTN patient safety staff requests for information regarding the recipient and communicate updated information regarding recipient condition, test results, diagnosis, and plans for treatment and follow up.
3. Contribute to a follow up review of the event in partnership with OPTN patient safety staff.
4. Provide additional related information or specimens if requested.

15.6 Living Donor Recovery Hospital Requirements for Reporting Post-Donation Discovery of Disease or Malignancy

Living donor recovery hospitals must report any post donation test results or information that indicate there may be a possibility for donor-derived disease.

15.6.A Living Donor Recovery Hospital Requirements for Reporting Post-Donation Discovery of Living Donor Disease or Malignancy

If a living donor recovery hospital learns new information about a living donor during the first two years post donation that indicates risk of potential transmission of disease or malignancy, then the living donor recovery hospital must do *all* of the following:

1. Disclose to the living donor that the potential disease transmission or malignancy will be reported to the receiving transplant program and the OPTN Improving Patient Safety Portal.
2. Notify the receiving transplant program.

3. Report the potential transmission through the OPTN Improving Patient Safety Portal as soon as possible but no more than seven days after receipt of the new information.

15.6.B Living Donor Program Requirements for Post Reporting Follow-Up

If the living donor recovery hospital reports test results or other information to the OPTN Contractor through the Improving Patient Safety Portal, then the recovery hospital must also do *all* of the following:

1. Contribute to a follow up review of the event in partnership with OPTN patient safety staff.
2. Provide additional information or specimens related to the living donor if requested.

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

This variance applies to members participating in an institutional review board (IRB) approved research protocol that meets the requirements in the OPTN Final Rule regarding the recovery of organs from donors that test positive for human immunodeficiency virus (HIV) and the transplantation of these organs into HIV positive recipients, including Health and Human Services (HHS) research criteria pertaining to transplantation of organs from HIV positive donors, as applicable.

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

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

15.7.A Requirements for Allocating HIV Positive Deceased Donor Organs

In addition to the requirements of the OPTN Final Rule, the OPO may allocate HIV positive organs only after determining the potential deceased donor is HIV positive and the HIV positive candidate is willing to accept an HIV positive organ as part of a research protocol. The OPO must only allocate HIV positive organs to HIV positive candidates appearing on the match run, except in cases of directed donation. The OPO must verify that the potential recipient is registered as a HIV positive candidate at a transplant hospital that meets the requirements in *Policy 15.6.C: Transplant Hospital Requirements for Transplantation of HIV Positive Organs*.

15.7.B Requirements for Allocating HIV Positive Living Donor Organs

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

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

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

1. The transplant hospital notifies and provides documentation to the OPTN Contractor that it is participating in an institutional review board approved research protocol that meets the requirements in the OPTN Final Rule regarding the recovery and transplantation of organs from HIV positive individuals.

2. The transplant hospital obtains informed consent from the potential transplant recipient to participate in the institutional review board protocol that meets requirements in the OPTN Final Rule.
3. The transplant hospital meets the informed consent requirements according to *Policy 15.3 Informed Consent of Transmissible Disease Risk.*

In order for an HIV positive candidate to appear on a match run for HIV positive donor kidneys or livers, the transplant hospital must complete a two-person reporting and verification process. This process must include two different individuals who each make an independent report to the OPTN Contractor that the candidate is willing to accept an HIV positive organ as part of a research protocol.

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

The OPTN Contractor may release to the public the names of members participating in this variance.

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: 11/12/2013 (2/1/2014); 11/12/2014 (2/1/2015); 6/2/2015 (9/1/2015); *Policies 15.3: Informed Consent of Transmissible Disease Risk, Policy 15.4.A: Transplant Program Requirements,* and *15.6: Open Variance for the Recovery and Transplantation of Organ from HIV Positive Donors*: 6/2/2015 (11/21/2015); 10/19/2015 (11/21/2015); *Policies 15.4: Host OPO Requirements for Reporting Post-Procurement Test Results and Discovery of Potential Disease Transmissions, 15.5: Transplant Program Requirements for Communication Post-Transplant Discovery of Disease or Malignancy,* and *15.6: Living Donor Recovery Hospital Requirements for Reporting Post-Donation Discovery of Disease or Malignancy* 6/6/2016 (9/1/2016); *Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors*: 6/6/2016 (9/1/2016); *Policy 15.6.A: Living Donor Recovery Hospital Requirements for Reporting Post-Donation Discovery of Living Donor Disease or Malignancy*: 8/12/2016 (9/1/2016)

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 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

16.1 Organs Recovered by Living Donor Recovery Hospitals

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. In addition to the list of documents in *Policy 16.4: 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 and tissue typing materials 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 must contain the donor's blood type and subtype, the type of tissue, and the date and time when the sample was obtained. The recovery hospital must document in the donor record all unique identifiers used to label blood samples and tissue typing materials.
5. The recovery hospital will provide specimens for tissue typing if requested. The minimum typing materials for living donor kidneys are: two ACD (yellow top) tubes per kidney.

16.2 Packaging and Labeling Responsibilities

The host OPO or recovery hospital is responsible for packaging and labeling organs, 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.

16.3 Packaging and Labeling

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.

16.3.A Internal Packaging

A triple sterile barrier must protect organs and vessels. A rigid container must be used as one layer when packaging kidneys, pancreas, and vessels that are packaged separately from the organ. If the rigid container is sterile, it can serve as one layer of the required triple sterile barrier. The use of a rigid container is optional for all other organs.

16.3.B Internal Labeling of Organs

The Host OPO must securely attach the completed OPTN internal label, identifying the specific contents, to the outer- most layer of the triple sterile barrier 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.

16.3.C Internal Labeling of Blood and Tissue Typing Materials

Each separate specimen container of blood or tissue typing material must have a label that will remain secured to the container under normal conditions of transport. The label must include the donor ID and at least *one* of the following identifiers:

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

Additionally each specimen should be labeled with *both* of the following:

1. The date and time the sample was procured
2. The type of tissue

The donor blood type and subtype, if used for allocation, should be included on tissue typing material and blood samples if known. If the donor ID or blood type is not available during the preliminary evaluation of a donor, a locally assigned unique ID and one other identifier for the transportation of initial screening specimens may be used. The OPO must document in the OPO donor record all unique identifiers used to label tissue typing specimens.

16.3.D Internal Labeling of Vessels

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 standardized labels that must be used for this purpose. The labels must contain *all* of the following information according to *Table 16-1* below.

Table 16-1: Required Information on Internal Labels for Vessels

This information must be included:	On the rigid container:	On the outermost layer of the triple sterile barrier:
1. Donor ID	●	●
2. Donor blood type	●	●
3. Donor blood subtype, if used for allocation	●	●
4. Recovery date	●	●
5. Description of the container contents	●	●
6. That the vessel is for use in organ transplantation only	●	●
7. All infectious disease testing results		●
8. Whether the vessels are from a donor with a positive result (including NAT) for *any* of the following: • Human Immunodeficiency Virus (HIV), Hepatitis C virus (HCV), or Hepatitis B Virus (HBsAg or NAT) • Hepatitis B virus (HBcAb)	●	
9. Whether the vessels are from a donor that meets the increased risk for disease transmission criteria in the *U.S. Public Health Service (PHS) Guideline*	●	●

16.3.E External Packaging

Only disposable shipping boxes, coolers, or mechanical preservation machines must be used as external transport containers.

16.3.E.i Disposable Shipping Box

If organs, 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.

16.3.E.ii Mechanical Preservation Machine

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.

16.3.E.iii Cooler

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.

16.3.F External Labeling

A label, that under normal conditions of transport will remain secured, must be attached to the outside of the external transport container. Disposable shipping boxes, coolers, and mechanical preservation machines must have the OPTN external label. The OPTN Contractor distributes a standardized label that must be used for this purpose.

The OPTN external label must 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

16.4 Documentation Accompanying the Organ or Vessel

16.4.A Organ Documentation

Each external deceased and living donor transport container holding an organ must be sent with *all* of the following source documentation:

1. Blood type
2. Blood subtype, if used for allocation
3. Infectious disease testing results available at the time of organ packaging

The source documentation must be placed in a watertight container in *either* of the following:

- A location specifically designed for documentation
- Between the inner and external transport containers

16.4.B Vessel Documentation

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.

16.5 Verification of Information before Shipping

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.

16.6 Vessel Recovery, Transplant, and Storage

16.6.A Deceased Donor Vessel Recovery and Transplant Use

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.

16.6.B Vessel Storage

Transplant hospitals must not store a donor's extra vessels if the donor has tested positive for *any* of the following:

- HIV by antibody, antigen, or nucleic acid test (NAT)
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B (HBV) by NAT
- Hepatitis C (HCV) by antibody or NAT

Extra vessels from donors that do not test positive for HIV, HBV, or HCV as above may be stored. When a transplant hospital stores extra vessels it must do *all* of the following:

1. Use stored extra vessels *only* for organ transplantation
2. Designate at least one person to monitor extra vessel storage, use, destruction, and reporting
3. Package and label extra vessels as required by *Policy 16.3: Packaging and Labeling* and *Policy 16.4: Documentation Accompanying the Organ or Vessel*
4. Store extra vessels in a Food and Drug Administration (FDA) approved preservation solution
5. Store extra vessels in a secured refrigerator with a temperature monitor and maintain the temperature no colder than 2 degrees Celsius and no warmer than 8 degrees Celsius
6. Maintain a log of stored extra vessels
7. Maintain all records relating to the monitoring and use of extra vessels
8. Monitor extra vessels daily and log security and refrigerator temperature checks
9. Destroy unused extra vessels within 14 days after the recovery date
10. Report the extra vessel's use or destruction to the OPTN Contractor within seven days of the transplant hospital's use or destruction of the extra vessels

16.6.C Blood Type Verification Prior to Transplant of Deceased Donor Vessels

The transplant hospital must verify the blood type, all infectious disease testing results, container contents, date of expiration, and the Donor ID of the vessels with the blood type and all infectious disease testing results of the recipient prior to transplant. These verifications must be documented and maintained in the recipient medical record.

16.6.D Recovery and Storage of Vessels from Living Donors

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 16.6: Vessel Recovery, Transplant, and Storage*.

16.6.E Blood Type Verification Prior to Transplant of Living Donor Vessels

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 infectious disease testing 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 infectious disease testing results of the recipient prior to transplant. The documentation of these verifications must be maintained in the recipient medical record.

16.7 Transportation Responsibilities

16.7.A Transportation Arrangements

The host OPO is responsible for determining that non-local procurement teams have transportation to and from the local airport.

16.7.B Transportation Costs for Deceased Donor Kidneys

If deceased donor kidneys, and associated tissue typing materials are shipped without any other organs, then the host OPO is responsible for all transportation costs.

16.7.C Transportation Costs for Living Donor Kidneys

The organ recipient's transplant hospital is responsible for transportation costs for living donor kidneys and associated tissue typing material according to CMS regulations.

16.7.D Transportation Costs for all other Organs

For all non-renal organs and tissue typing materials from deceased or living donors, including kidney-pancreas, transportation costs are the responsibility of the member receiving the organ. If an organ or tissue typing material is forwarded to another member for any reason the member

that finally receives the organ or tissue typing material is responsible for transportation costs; unless otherwise agreed upon by the parties involved.

16.7.E Transportation Costs for Tissue Typing Material

The organ recipient's transplant hospital is responsible for payment of transportation costs for tissue typing material sent to crossmatch potential recipients of a living donor kidney. When an organ recipient's transplant hospital requests tissue typing material to crossmatch potential recipients for a non-renal organ, it must pay transportation costs for the tissue typing material.

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: 11/12/2013 (2/1/2014); 3/7/14; 6/23/14 (9/1/2014); 11/12/2014; (2/1/2015); 6/2/2015 (9/1/2015); Policy 16.7.B: Vessel Recovery, Transplant, and Storage 11/12/2013 (10/22/2015); *Policies 16.7.B: Vessel Recovery, Transplant, and Storage, 16.7.C: Blood Type Verification Prior to Transplant of Deceased Donor Vessels,* and *16.7.E: Blood Type Verification Prior to Transplant of Living Donor Vessels*: 6/2/2015 (11/21/2015); *Policies 16.1: Organs Recovered by Living Donor Recovery Hospitals* and *16.4.A: Organ Packaging Documentation Requirements:* 12/1/2015 (3/1/2016); *16.7.B: Vessel Storage*: 3/14/2016 (4/14/2016); *Policy 16.4.C: Internal Labeling of Blood and Tissue Typing Materials:* 6/2/2015 (6/23/2016)

Pending Implementation

Policies 16.1 Packaging and Labeling Requirements for Living Donor Organs and Vessels, 16.2: Packaging and Labeling Responsibilities, 16.3: Packaging and Labeling, 16.4: Documentation Accompanying the Organ or Vessel and *16.5: Verification and Recording or Information before Shipping:* 6/6/2016 (7/1/2017)

Notes

- For tissue typing requirements, see *Policy 4: Histocompatibility*.
- For living donor packaging and labeling requirements, see *Policy 16.1: Organs Recovered by Living Donor Recovery Hospitals*.
- 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

17.1.A Referrals

Members may not enter into contracts with foreign agencies or governments for the transplant of non-US residents/non-US citizens. Members may negotiate the terms and conditions under which any individual candidate would be treated with the understanding that each candidate must be referred on a case-by-case and physician-to-physician basis.

17.1.B Review of Non-US Citizens/Non-US Resident Registrations and Transplants

The Ad Hoc International Relations Committee will review all citizenship data reported to the OPTN 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

The Ad Hoc International Relations Committee will prepare and provide public access to an annual report of transplant hospital activities related to the registration and transplantation of non-US citizens/non-US residents.

17.2 Importation of Deceased Donor Organs from Foreign Sources

Members may import deceased donor organs from foreign sources according to the requirements in the Policies outlined below.

17.2.A Formal Deceased Donor Import Agreement

A member that wishes to enter into a formal, deceased donor organ import agreement with a foreign entity must

1. Submit a proposal to the Ad Hoc International Relations Committee for review
2. Have approval of the agreement by the OPTN Board of Directors

Each formal agreement cannot exceed two years in duration and must include *all* of the following:

1. The basis for the agreement.
2. The expected benefits to the foreign and domestic participants.
3. Credentials of the foreign entity.
4. The number and type of deceased donor organs anticipated for import.
5. An outline of a plan for reporting the results of the agreement.

6. A requirement for the donor organization to submit documentation certifying the authorization of the deceased donor or the deceased donor's agent.
7. A requirement for the donor organization to submit documentation certifying that the deceased donor has met the brain death or donation after circulatory death (DCD) protocols that are in compliance with recognized US standards for domestic organ procurement.
8. A requirement for the donor organization to submit documentation of the deceased donor's ABO.

The Ad Hoc International Relations Committee will review each formal agreement every two years.

17.2.B Requirements for Importing Deceased Donor Organs through a Formal Agreement

The member importing any deceased donor organ from a foreign entity must fulfill *all* the following requirements:

1. Report the event within 72 hours to the Organ Center.
2. Allocate the organ according to the organ allocation policies.
3. Provide the minimum required information about the foreign deceased donor organ, as specified in *Policy 2: Deceased Donor Organ Procurement* and *Policy 5: Organ Offers, Acceptance, and* Verification.
4. Comply with the blood type verification requirements in *Policy 2.6: Deceased Donor Blood Type Determination and Reporting* and *Policy 3.3: Candidate Blood Type Determination and Reporting before Waiting List Registration*.
5. Evaluate the organ for transmissible diseases as specified *in Policy 15: Identification of Transmissible Diseases*.
6. Verify that the foreign entity is authorized as a transplant hospital or organ procurement program by an appropriate agency of its national government.
7. Obtain official documentation from the exporting party that it is a medical center authorized to export organs for transplantation.

17.2.C Deceased Donor Organs Imported from Outside of the United States without a Formal Agreement

A member may import a deceased donor organ recovered outside of the United States without a formal agreement. An imported deceased donor organ must meet all the requirements in *Policy 17.2.B: Requirements for Importing Deceased Donor Organ through a Formal Agreement*. The member must notify the Organ Center immediately so that the OPTN Contractor can allocate the organ according to the match run for that organ.

The member importing the organ must provide *all* of the following to the OPTN 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: 11/12/2013 (2/1/2014)

Notes

- For more information on the role of candidate's citizenship or residency status in allocation, see *Policy 5.4.A Nondiscrimination in Organ Allocation*

Policy 18 Data Submission Requirements

18.1 Data Submission Requirements

Members must report accurate data to the OPTN using standardized forms according to *Table 18-1* below.

Table 18-1: Data Submission Requirements

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For:
Histocompatibility Laboratory	*Donor histocompatibility* (DHS)	30 days after the OPO submits the deceased donor registration	Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory
Histocompatibility Laboratory	*Recipient histocompatibility* (RHS)	*Either* of the following: • 30 days after the transplant hospital removes the candidate from the waiting list because of transplant • 30 days after the transplant hospital submits the *recipient feedback*	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory
OPOs, all	*Death notification records* (DNR)	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	All imminent neurological deaths and eligible deaths in its DSA
OPOs, all	*Monthly Donation Data Report: Reported Deaths*	30 days after the end of the month in which a donor hospital reports a death to the OPO	All deaths reported by a hospital to the OPO

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For:
Allocating OPO	*Potential transplant recipient* (PTR)	30 days after the match run date by the OPO or the OPTN Contractor	Each deceased donor heart, intestine, kidney, liver, lung, or pancreas that is offered to a potential recipient
Allocating OPO	*VCA Candidate List*	30 days after the procurement date	Each deceased donor VCA organ that is offered to a potential VCA recipient
Host OPO	*Donor organ disposition (feedback)*	5 business days after the procurement date	Individuals, except living donors, from whom at least one organ is recovered
Host OPO	*Deceased donor registration* (DDR)	30 days after the *donor organ disposition (feedback)* form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	*Living donor feedback*	The time prior to donation surgery	Each potential living donor organ recovered at the hospital This does not apply to VCA donor organs
Recovery Hospitals	*Living donor feedback* Members must amend the form or contact the OPTN Contractor to amend this form according to *Policy 18.6: Reporting of Liver Donor Adverse Events*	72 hours after the donor organ recovery procedure	Any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient
Recovery Hospitals	*Living donor registration* (LDR)	60 days after the recovery hospital submits the *living donor feedback* form	Each living donor organ recovered at the hospital This does not apply to VCA donor organs

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For:
Recovery Hospitals	*Living donor follow-up* (LDF)	60 days after the six-month, 1-year, and 2-year anniversary of the donation date	Each living donor organ recovered at the hospital This does not apply to VCA, domino donor, and non-domino therapeutic donor organs
Transplant hospitals	*Organ specific transplant recipient follow-up* (TRF)	Either of the following: • 30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure • 14 days from notification of the recipient's death or graft failure	Each recipient followed by the hospital
Transplant hospitals	*Organ specific transplant recipient registration* (TRR)	60 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60 days after transplant hospital submits the *recipient feedback* form	Each liver recipient transplanted by the hospital
Transplant hospitals	*Recipient feedback*	1 day after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital
Transplant hospitals	*Candidate Removal Worksheet*	1 day after the transplant	Each VCA recipient transplanted by the hospital
Transplant hospitals	*Recipient malignancy* (PTM)	30 days after the transplant hospital reports the malignancy on the *transplant recipient follow-up* form	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital

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

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients and living donors is based on recipient or living donor status at a time as close as possible to the specified transplant event anniversary. *Table 18-2: Timely Data Collection* sets standards for when the member must collect the data from the patient.

Table 18-2: Timely Data Collection

Information is timely if this Member	Collects this information for this form:	Within this time period:
Transplant hospital	*Organ specific transplant recipient registration* (TRR)	When the transplant recipient is discharged from the hospital or 42 days following the transplant date, whichever is first
Recovery hospital	*Living donor registration* (LDR)	When the living donor is discharged from the hospital or 42 days following the transplant date, whichever is first This does not apply to VCA transplants.
Recovery hospital	*Living donor follow-up* (LDF)	60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date This does not apply to VCA transplants.

18.3 Recording and Reporting the Outcomes of Organ Offers

The allocating OPO and the transplant hospitals that received organ offers share responsibility for reporting the outcomes of all organ offers. OPOs are responsible for reporting the outcomes of organ offers to the OPTN 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.

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

18.4 Data Submission Standard

18.4.A Timely Data Submission

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

Table 18-3: Data Submission Standard

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

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

18.5 Living Donor Data Submission Requirements

The follow up period for living donors will be a minimum of two years.

The OPTN Contractor will calculate follow-up rates separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.

Living donor follow-up reporting requirements do not apply to any transplant recipient whose replaced or explanted organ is donated to another candidate.

18.5.A Reporting Requirements after Living Kidney Donation

The recovery hospital must report accurate, complete, and timely follow up data for donor status and clinical information using the LDF form for at least:

- 60% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 70% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 80% of their living kidney donors who donate after December 31, 2014

The recovery hospital must report accurate, complete, and timely follow up kidney laboratory data using the LDF form for at least:

- 50% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 60% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 70% of their living kidney donors who donate after December 31, 2014

Required kidney donor status and clinical information includes *all* of the following:

1. Patient status
2. Working for income, and if not working, reason for not working
3. Loss of medical (health, life) insurance due to donation
4. Has the donor been readmitted since last LDR or LDF form was submitted?
5. Kidney complications
6. Maintenance dialysis
7. Donor developed hypertension requiring medication
8. Diabetes
9. Cause of death, if applicable and known

Required kidney laboratory data includes *all* of the following:

1. Serum creatinine
2. Urine protein

18.5.B Reporting Requirements after Living Liver Donation

The recovery hospital must report accurate, complete, and timely follow-up data using the LDF form for living liver donors who donate after September 1, 2014, as follows:

1. Donor status and clinical information for 80% of their living liver donors.
2. Liver laboratory data for at least:
    - 75% of their living liver donors on the 6 month LDF
    - 70% of their living liver donors on the one year LDF

Required liver donor status and clinical information includes *all* of the following:

1. Patient status
2. Cause of death, if applicable and known
3. Working for income, and if not working, reason for not working
4. Loss of medical (health, life) insurance due to donation
5. Hospital readmission since last LDR or LDF was submitted
6. Liver complications, including the specific complications
    - Abscess
    - Bile leak

- Hepatic resection
- Incisional hernias due to donation surgery
- Liver failure
- Registered on the liver candidate waiting list

Required liver laboratory data includes *all* of the following:

1. Alanine aminotransferase
2. Alkaline phosphatase
3. Platelet count
4. Total bilirubin

18.6 Reporting of Living Donor Adverse Events

18.6.A Reporting of Living Donor Adverse Events through the Improving Patient Safety Portal

Recovery hospitals must report these living donor adverse or unanticipated events through the Improving Patient Safety Portal or the OPTN Contractor according to *Table 18-4* below.

Table 18-4: Living Donor Adverse Event Reporting

Recovery hospitals must report:	To the:	Within 72 hours after:
A living donor organ recovery procedure is aborted after the donor has begun to receive general anesthesia.	Improving Patient Safety Portal and the OPTN Contractor	The aborted organ recovery procedure
A living donor dies within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware
A living liver donor is listed on the liver wait list within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware
A living kidney donor is listed on the kidney wait list or begins dialysis within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware
A living donor organ is recovered but not transplanted into any recipient	Improving Patient Safety Portal and the OPTN Contractor	Organ recovery
A living donor organ is recovered and transplanted into someone other than the intended recipient	Improving Patient Safety Portal	Organ recovery

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

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: 11/12/2013 (2/1/2014); 4/10/14; 6/23/2014 (7/3/2014); 6/23/2014 (9/1/2014); *Policy 18.1: Data Submission Requirements:* 11/12/2014 (2/1/2015); *Policy 18.5: Living Donor Data Submission Requirements*: 6/23/2014 (3/31/2015); 6/2/2015 (9/1/2015); *Policy 18.6: Reporting of Living Donor Adverse Events:* 11/12/2014 (11/2/2015); Policy 18.1: Data Submission Requirements: 6/2/2015 (9/1/2015); *Policies 18.1: Data Submission* and *18.6: Reporting of Living Donor Adverse Events:* 6/2/2015 (4/14/2016); *Policy 18.1: Data Submission Requirements:* 12/1/2015 (11/10/2016)

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

The OPTN Contractor will release OPTN data according to the Final Rule and other applicable federal and state laws and regulations. The OPTN Contractor will release all OPTN data requested by the Secretary of the Department of Health and Human Services (HHS).

History

Policy 9: Release of Information to the Public: 6/26/2012
Policy 10: Access to Data:
Policy 19: Data Release: 11/12/2013 (2/1/2014); 6/24/2014 (12/4/2014); 6/2/2015 (9/1/2015); 12/1/2015 (3/1/2016)

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

20.1 Eligibility for Reimbursement

20.1.A General Eligibility Requirements

The OPTN Contractor will reimburse approved travel costs for members, contractors, invited guests, 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

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

20.2.A Booking Travel

OPTN Contractor staff and members must use the approved OPTN Contractor travel agency 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 the approved OPTN travel agency would have paid.

20.2.B Air Travel

If the traveler has an unused airline ticket, the OPTN Contractor will attempt to use the ticket credit on a flight that meets the needs of the traveler.

The OPTN 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.

The approved OPTN Contractor travel agency 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

The OPTN Contractor will approve international travel on a case-by-case basis.

20.3 Hotel Reimbursement

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

20.4.A Mileage

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

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 must 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

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 must 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

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

20.5.A Meal Cost

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

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. However, nothing in this Policy prohibits the OPTN Contractor from using private resources to pay for alcohol.

20.6 Miscellaneous Expenses

20.6.A Telecommunication Charges

The OPTN 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

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

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

20.8.A Expense Reimbursement Form

To request reimbursement from the OPTN Contractor, the traveler must complete and submit an OPTN Contractor expense reimbursement form with original receipts. Off-site OPTN members may submit scanned copies of the original receipts. The traveler must sign the expense reimbursement form and must include *all* of the following information:

1. Dates of travel
2. Reason for travel
3. Meeting location and name of event
4. To whom the reimbursement check will be made payable
5. The address to which the reimbursement will be sent
6. The traveler's phone number

20.8.B Receipts

The expense report must have original receipts for expenses attached. Off-site OPTN members may submit scanned copies of the original receipts. If one traveler has a meal receipt that includes other OPTN Contractor travelers, the receipt must include the names of all travelers.

History

Policy 8: Travel Expense and Reimbursement: 6/23/2009, 11/1/2003; 11/15/2011
Policy 20: Travel Expense and Reimbursement: 11/12/2013 (2/1/2014); 6/2/2015 (9/1/2015)

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