

Policies

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OPTN Policies: Contents

Policy 1:	Administrative Rules and Definitions	1
Policy 2:	Organ Procurement.....	22
Policy 3:	Candidate Registrations, Modifications, and Removals.....	37
Policy 4:	Histocompatibility.....	46
Policy 5:	Organ Offer and Acceptance.....	70
Policy 6:	Multi-Organ Allocation	77
Policy 7:	Allocation of Hearts.....	82
Policy 8:	Allocation of Intestines.....	97
Policy 9:	Allocation of Kidneys.....	100
Policy 10:	Allocation of Livers.....	117
Policy 11:	Allocation of Lungs.....	142
Policy 12:	Allocation of Pancreas and Pancreas Islets.....	172
Policy 13:	Living Donation	180
Policy 14:	Kidney Paired Donation	181
Policy 15:	Identification of Transmissible Diseases in Organ Recipients.....	182
Policy 16:	Packaging, Labeling, Shipping, and Storage.....	187
Policy 17:	International Organ Transplantation	194
Policy 18:	Data Submission Requirements.....	197
Policy 19:	Release of Data.....	202
Policy 20:	Travel Expense and Reimbursement.....	205

Policy 1: Administrative Rules and Definitions

1.1	Rules of Construction	1
1.2	Definitions	2
1.3	Variances	18
1.4	Allocation of Organs During Emergencies	20
1.5	Department of Defense Directive	21

Introduction

This policy sets the rules and definitions used in construction of the OPTN Policies. This policy also addresses when and how Members may follow alternatives to the OPTN policies. The three reasons for deviating from policy include 1) Board approved variances, 2) emergencies, and 3) conflicts with Department of Defense (DOD) directives.

Policy Statement

1.1 Rules of Construction

The rules and definitions set forth in this Policy will be used in construction of the OPTN Policies.

1.1(A) Computation of Time

Days end at midnight in the time zone of the city of the OPTN Contractor's headquarters.

1.1(B) Gender

A word used in the masculine includes the feminine and neuter.

1.1(C) Headings

The headings of the sections are intended as mere catchwords to indicate the contents of the sections, do not constitute part of the OPTN Policies, and may not be used to indicate or infer the intent of the Policy. Similarly, the introductions preceding each Policy and the notes and histories subsequent to each Policy are nonbinding and may not be used to indicate or infer the intent of the Policy.

1.1(D) Lists

The use of "and" means that all of the elements in the list are mandatory to satisfy the rule.

The use of "either... or" indicates an exclusive disjunction. The use of "or" without the use of "either" indicates an inclusive disjunction such that a combination of the elements in the list may be used to satisfy the rule.

1.1(E) Reporting of Information to the OPTN Contractor

The OPTN Contractor may set acceptable methods for the reporting of information required by these policies.

1.2 Definitions

A

Active candidate

A candidate eligible to be considered for organ offers at a given point in time.

Agent

An agent as defined by all laws where the patient is located.

Allocating OPO

The OPO that runs the final match list and allocates the organ to the recipient.

Alternative allocation system

A type of variance that allows Members to allocate organs differently than the standard allocation system requires for that organ.

Alternative Local Unit (ALU)

A type of variance that creates distinct geographic areas that function as distinct areas for organ procurement and distribution.

Alternative Point Assignment System

A type of variance that permits Members to assign points differently than the OPTN policies.

Antigen

Genetically controlled areas found on all cell types except for erythrocytes and trophoblasts.

Antigen mismatch

An antigen mismatch occurs when a donor antigen would be recognized by the recipient as being different from the recipient's own antigens. In cases where a donor only has one antigen identified at an 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 after a Transplant Hospital accepts an organ but before the organ is transplanted.

Bridge Donor

A donor who does not have a match identified during the same match run as his paired candidate.

Business Days

Calendar days excluding weekends and federal holidays.

C

Calculated Panel Reactive Antibody (CPRA)

The percentage of 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 racial/ethnic groups in proportion to their representation in the national deceased donor population.

Candidate

A person registered on the organ transplant waiting list. When an organ is offered to the candidate, the candidate is then referred to as a Potential Transplant Recipient (PTR). References in these Policies to candidates include potential candidates if and as applicable.

Chain

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

Circulatory death

The irreversible cessation of circulatory and respiratory functions

Classification

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

Closed variance

A variance not open for other Members to join it.

Confidential Information

Includes, but is not limited to, all of the following:

1. Financial data and information of the OPTN Contractor
2. Confidential medical peer review information and related materials
3. Data and information subject to federal or state confidentiality statutes and regulations
4. Proprietary information of the OPTN Contractor
5. Health information regarding any individuals
6. Any person-level or institution-level data regarding patient safety incidents that are submitted to the OPTN Contractor

Confidential Medical Peer Review Information

All documents or statements initiated, created or generated by or at the request of the OPTN or the OPTN Contractor as part of its peer review function.

D

Data

Information submitted by Members to the OPTN Contractor about candidates, recipients, potential donors, and donors and information derived from such data

Data Use Agreement

An agreement between a data requestor and the OPTN Contractor stating the permissible use of data received from the OPTN Contractor.

Day

Calendar day

DCD Donor

Also known as a non-heartbeating or asystolic donor.

Decedent

A deceased individual whose body is or may become the source of a donated organ.

Directed donation

The allocation of an organ to a specific candidate named by the person who authorized the donation

Donation after Circulatory Death (DCD)

The organ recovery process that may occur after circulatory death.

Donation Service Area (DSA)

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

Donor

Someone from whom an organ or tissue is removed for transplantation. Unless otherwise specified, the term donor is synonymous with *deceased donor* and does not include *living donors*.

Donor Hospital

The hospital where the donor is admitted.

Donor ID

A unique identification assigned to each donor by the OPTN Contractor.

Donor Record

The record maintained by the OPO regarding an individual donor.

E

Eligible death

For the purposes of DSA performance assessments, patients are deemed an eligible death if the patient meets *all* of the following criteria:

- Is no greater than 70 years of age
- Is legally declared brain dead by neurologic criteria in accordance with current standards of accepted medical practice and state or local law
- Has a body weight of at least 5 kg
- Has a Body Mass Index (BMI) no greater than 50 kg/m²
- Has at least one kidney, liver, heart, or lung that is deemed suitable for transplant
- Exhibits *none* of the following:
 - Agranulocytosis
 - Aplastic anemia
 - Bacterial infection: gangrenous bowel, intra-abdominal sepsis, perforated bowel, or tuberculosis
 - Fungal infection: aspergillus, candidemia, cryptococcus, coccidioides, histoplasma, or invasive yeast infection
 - Hematologic malignancies: hodgkin's disease, leukemia, lymphoma, or multiple myeloma
 - Meningitis (bacterial, fungal, parasitic, or viral) or encephalitis
 - Parasitic infection: leishmania, malaria (plasmodium sp.), strongyloides, or trypanosoma cruzi (chagas')
 - Prion infection: Creutzfeldt-Jakob disease

- Retroviral infections: cytomegalovirus viremia, acute Epstein Barr Virus (EBV) (mononucleosis), active herpes simplex, HTLV I/II, meningitis, pneumonia, varicella zoster, SARS, viral encephalitis, or West Nile Virus
- Viral infection: HIV (detected by serological or molecular detection), rabies, or reactive hepatitis B surface antigen
- Does not exhibit current malignant neoplasms except for non-melanoma skin cancers without evident metastatic disease
- With no melanoma or any history of melanoma
- With no previous malignant neoplasms that have current evident metastatic disease
- Where all Transplant Hospitals on a match run do not decline the organ offer preoperatively
- Where the organ recovery team, upon visualization in the organ recovery operating room, does not determine the no organs are suitable for transplantation.

Emergency

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

Exchange

A set of 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.

G

Geographical Area

A physical area used to group potential recipients in a *classification*. OPTN Policy uses the following geographical areas for organ allocation: *local unit, 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

Hemodilution

A sample with plasma dilution sufficient to affect the results of communicable disease testing.

Host Organ Procurement Organization (Host OPO)

The OPO responding to an organ donor call from a hospital.

I

Imminent Neurological Death

A patient who, upon clinical evaluation documented in the OPO record or donor hospital chart, meets *all* of the following criteria:

1. Is 70 years old or younger
2. Has severe neurological injury
3. Requires ventilator support
4. Has not yet been legally declared brain dead according to hospital policy
5. Does not exhibit any of the conditions that would exclude the person from being reported as an eligible death
6. Has an absence of *at least three* of the following brain stem reflexes:
 - Corneal Reflex
 - Cough Reflex
 - Doll's eyes reflex
 - Gag Reflex
 - Pupillary reaction
 - Response to iced caloric
 - Response to painful stimuli

Importing Organ Procurement Organization (Importing OPO)

An OPO receiving a donor organ from an OPO outside of their donation service area.

Inactive Candidate

A candidate that is temporarily unsuitable for transplantation.

Independent Donor Advocate

A person available to assist potential living donors.

Initial Primary Hospital

The first Transplant Hospital where a candidate registers for an organ transplant.

Institution Level Data

Data about a Member or Transplant Program

Intestine

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

L

Living Donor

A living person who donates an organ for the intent of transplantation.

Living Donor Recipient

A transplant recipient that receives a living donor organ.

Living Donor Organ

An organ from a living donor.

Local Unit

The geographic area for organ procurement and distribution. This is the *donation service area* (DSA) for an Organ Procurement Organization (OPO) unless there is an applicable variance.

M

Match

A donor and his matched candidate.

Match Run

A procedure that ranks candidates based on donor and candidate medical compatibility and criteria. A match run will also be used to generate a set of exchanges for a KPD.

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 recipient of a donor's kidney.

Matched Donor

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

Matched Recipient

A matched candidate that has received a transplant.

Medical Chart

The record maintain by a physician at their hospital.

Model for End Stage Liver Disease (MELD)

The scoring system used to measure illness severity in the allocation of livers to adults.

Member

Members of the OPTN in all seven OPTN membership categories. The OPTN Membership categories are Transplant Hospital Members, Organ Procurement Organization (OPO) Members, Histocompatibility Laboratory Members, Medical/Scientific Members, Public Organization Members, Business Members, and Individual Members.

Month

Calendar month.

Multiple Hospital Registration

Being on the waiting list for the same organ at more than one Transplant Hospital.

Multi-organ Candidate

A candidate registered for more than one organ at one or more Transplant Hospitals.

N

Non-Directed Donor (NDD)

A donor that enters KPD without a paired candidate.

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.



Open Variance

A variance that allows other Members to join it.

OPTN Computer Match Program

A set of computer-based instructions which compares data on a cadaveric 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 donor organs.

OPTN Contractor

The corporation currently operating the OPTN under contract with HHS. In 1984 the National Organ Transplantation Act (NOTA) directed the Secretary of HHS to establish by contract an Organ Procurement and Transplantation Network (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 the National Organ Transplant Act (NOTA), OPTN Final Rule, OPTN Charter, OPTN Bylaws, and OPTN Policies.

Organ

A human kidney, liver, heart, lung, pancreas, and any other human organ (other than corneas and eyes) specified by the Secretary of the United States Health and Human Services by regulation.

Organ Allocation Policies

OPTN Policies: Policy 6: *Multi-Organ Allocation*; Policy 7: *Allocation of Hearts*; Policy 8: *Allocation of Intestines*; Policy 9: *Allocation of Kidneys*; Policy 10: *Allocation of Livers*; Policy 11: *Allocation of Lungs*; and Policy 12: *Allocation of Pancreas and Pancreas Islets*.

Organ Center

The office within the OPTN responsible for facilitating organ sharing among transplant hospitals, organ procurement organizations, and histocompatibility laboratories across the U.S.

Organ Procurement Organization (OPO)

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

Organ Procurement and Transplantation Network (OPTN)

The network established pursuant to section 372 of the Social Security Act.

Organ Recovery

Occurs once cross clamp of the donor aorta has occurred.

Organ Transplant

Occurs once any initiation of anastomosis has taken place during the intended transplant or the initiation of an islet cell infusion has occurred. The transplant procedure is complete when either (1) the chest or abdominal cavity is closed and the final skin stitch or staple is applied or (2) the islet cell infusion is complete. Organ transplants include solid organ transplants and islet cell infusions but not extracorporeal transplants.

Other Antibody Specificities

Antigens that may result in a positive or negative crossmatch. The rate of positive crossmatches would be expected to be higher against donors who express these antigens.

P

Pair

A donor and his paired candidate.

Paired Candidate

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

Paired Donation of Human Kidneys (KPD)

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

- An individual (the first donor) desires to make a living donation of a kidney specifically to a particular patient (the first patient), but such donor is biologically incompatible as a donor for such patient.
- A second individual (the second donor) desires to make a living donation of a kidney specifically to a second particular patient (the second patient), but such donor is biologically incompatible as a donor for such patient.
- The first donor is biologically compatible as a donor of a kidney for the second patient, and the second 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 donor in the group of donor-patient pairs is biologically compatible as a donor of a kidney for a patient in such group.
- All donors and patients in the group of donor-patient pairs enter into a single agreement to donate and receive such kidneys, respectively, according to such biological compatibility in the group.
- Other than described as above, no valuable consideration is knowingly acquired, received, or otherwise transferred with respect to the kidneys referred to.

Paired Donor

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

Paired Recipient

A paired candidate that has received a transplant.

Patient

Includes *all* of the following:

- Potential donors undergoing an OPO's potential donor evaluation, and donor management and procurement processes.
- Potential candidates and potential living donors undergoing a Transplant Program's evaluation process.
- Candidates
- Living donors being followed by a Transplant Program
- 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.

Person Level Data

Person level data – Data about an individual candidate, recipient, donor, or potential donor that does not contain personally identifiable information.

Person Identified Data

Person level data that contain personally identifiable information.

Potential donor's Transplant Hospital

The Transplant Hospital that enters the potential donor in a KPD program.

Potential Recipient

A candidate that appears on a match run.

Primary Waiting Time

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

Prior Living Organ Donor

A candidate is a prior living organ donor if the candidate has donated for transplantation within the United States or its territories one or more of the following: kidney, liver segment, lung segment, partial pancreas, or small bowel segment.

Proprietary Information

Information including business practices, programming code, trade secrets, internal procedures and any other proprietary information that is not public.

Q

Qualified Specimen

A specimen without evidence of hemodilution.

Qualifying Date

The date that a candidate began accruing waiting time.

R

Receiving Transplant Program

A Transplant Program getting a donor organ from a Host OPO.

Recipient

A candidate that has received an organ transplant.

Recipient Transplant Hospitals

Transplant Hospitals that perform living donor transplants.

Recovery Hospital

Hospitals that recover living donor organs.

Released Organ

An organ that was allocated to a candidate but rejected before transplantation and offered for transplantation to another .

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, Eastern Vermont

Region 2 Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Northern Virginia, West Virginia

Region 3	Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico
Region 4	Oklahoma, Texas
Region 5	Arizona, California, Nevada, New Mexico, Utah
Region 6	Alaska, Hawaii, Idaho, Montana, Oregon, Washington
Region 7	Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
Region 8	Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming
Region 9	New York, West Vermont
Region 10	Indiana, Michigan, Ohio
Region 11	Kentucky, North Carolina, South Carolina, Tennessee, Virginia

Register

To add a candidate to the waiting list.

Registration Date

The date that the candidate was registered on the waiting list.

S

Sharing Arrangements

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

Suitable for Transplant

For the purposes of DSA performance assessments, organs are deemed suitable for transplant unless they meet any of the following criteria:

1. Heart:

- Has a history of Coronary Artery Bypass Graft (CABG)
- Has a history of coronary stent or intervention
- Has current or past medical history of myocardial infarction (MI)
- Has severe vessel diagnosis as supported by cardiac catheterization
- Has acute myocarditis or endocarditis
- Has heart failure due to cardiomyopathy
- Has an internal defibrillator or pacemaker
- Has moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization
- Had a valve repair
- Has serial echo results showing severe global hypokinesia
- Has myxoma
- Has congenital heart defects

2. Kidney:

- Has polycystic kidney disease

- Has glomerulosclerosis $\geq 30\%$ by kidney biopsy
- Has chronic renal failure
- Has no urine output for at least 24 hours
- 3. Liver:
 - Has cirrhosis
 - Has direct bilirubin divided by total bilirubin greater than or equal to 15 mg/dl over 24 hours with no trauma or transfusion
 - Has portal hypertension
 - Has macrosteatosis greater than or equal to 60%
 - Has bridging fibrosis greater than or equal to stage III
 - Has terminal AST/ALT greater than 5,000 U/L
- 4. Lung:
 - Has diagnosed Chronic Obstructive Pulmonary Disease (COPD)
 - Has terminal PaO₂/FiO₂ less than 250 mmHg
 - Has asthma, with a daily prescription, and the cause of death is due to asthma
 - Has pulmonary fibrosis
 - Had a lobectomy
 - Has multiple blebs documented on Computed Axial Tomography (CAT) scan
 - Has pneumonia as indicated on Computed Tomography (CT), x-ray, bronchoscopy, or cultures
 - Has bilateral severe pulmonary contusions indicated on a CT.

Summarized data

Facts or numbers which are based on person-level data but are not specific to an individual candidate, recipient, or donor.

T

Three-way Exchange

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

Time-out

A brief period time whereby action stops until some information is verified or action is completed.

Transmissible Disease

Any disease, malignancy, or medical condition that can be transmitted from a donor to a recipient through an organ or extra vessel transplant.

Transplant Date

Determined by the beginning of the first anastomosis. In the event of a multi-organ transplant procedure, each organ shall be reported with the transplant date as determined by the first organ.

Transplant Hospital

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

Transplant Program

A component within a Transplant Hospital that provides transplantation of a particular type of organ.

Two-way Exchange

A set of matches that includes two donor-candidate pairs where each 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 at the candidate's center with a donor having any one of those antigens.

United States Public Health Service Guidelines

The U.S. Public Health Service Guidelines for Preventing Transmission of Human Immunodeficiency Virus through Transplantation of Human Tissue and Organs, as adopted on May 20, 1994.

V

Variance

An experimental policy that tests methods of improving allocation.

W

Waiting List

The computerized list of candidates who are waiting to be matched with specific donor organs in hopes of receiving transplants.

Y

Year

Calendar year.

Z

Zero Antigen Mismatches

A candidate is considered a zero mismatch candidate if the candidate meets *one* of the following conditions:

1. At least one donor antigen is identified for the A, B, and DR loci identified
2. At least one candidate antigen is identified for the A, B, and DR loci identified
3. None of the A, B, or DR antigens identified are different between the donor and candidate
4. The donor and the candidate are blood type compatible.

In cases where a candidate has only one antigen identified at an HLA locus (A, B, or DR), the antigens are considered to be identical at that locus.

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 local unit.
- Zone B** All Transplant Hospitals within 1,000 nautical miles of the donor hospital but outside of Zone A
- Zone C** All Transplant Hospitals within 1,500 nautical miles of the donor hospital but outside of Zone B
- 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:

1. Alternative allocation systems
2. Alternative local units
3. Sharing arrangements
4. Alternative point assignment systems.

The following principles apply to *all* variances:

1. Variances must comply with the National Organ Transplant Act 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 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 local unit.
5. Where the local unit created by a variance is a subdivision of the OPO's Donation Service Area (DSA), and the geographic unit for an organ allocation classification is the donor hospital's local unit, the OPO will allocate organs to the remainder of the DSA after allocating organs to the 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. Committees will not review a variance application unless the applicant receives affirmative support from at least 75% of the Members required to join by the application.
7. The Board of Directors may extend, amend, or terminate a variance at any time.

1.3(B) Application

Members wishing to create or amend a variance must submit an application to OPTN Contractor. Completed applications will be considered through the policy development process described in Article XI of the OPTN Bylaws. The application must address *all* of the following:

1. The purpose for which the variance is proposed and how the variance will further this purpose.
2. Whether each Member affected by the variance supports it. If unanimous support does not exist, the application must include statements explaining the opposition from each participating Member.
3. A defined expiration date or period of time after which the variance will conclude, 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.

Members wishing to join an open variance must submit an application as dictated by the specific variance. If a Member’s application will require other Members to join the variance, the applicant must solicit support from them. Table 1-1: *Open Variance Applications* states who may review and approve an application to join an open variance.

Table 1-1: Open Variance Applications

If the application...	Then...
Receives affirmative support from 100% of the Members required to join by the application	The OPTN Contractor will approve the application.
Receives affirmative support from 75-100% of the Members required to join by the application	The sponsoring Committee may approve the application.
Receives affirmative support from less than 75% of the Members required to join by the application	The application will not be approved.

1.3(C) Reporting Requirements

Members participating in a variance must submit data and status reports to the sponsoring Committee at least annually, that:

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

Participating Members must also submit 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 review the variance’s achievements toward its stated purpose.

1.3(D) Final evaluation

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* combination 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(E) 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(F) Appeals

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 meet to consider the appeal. The Member submitting the appeal may participate in this meeting of the sponsoring Committee. The sponsoring Committee will recommend action on the variance to the Board of Directors.

Once the sponsoring Committee recommends action on the variance to the Board of Directors, a Member cannot request another appeal until the Policy Oversight Committee (POC) and Board of Directors decide on the variance. While evaluating the variance, 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 Emergency Situations

In the event of a regional or national emergency, the OPTN Contractor will attempt to distribute instructions to all Members 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. Should contact the OPTN Contractor by e-mail to determine operating procedures and to obtain assistance
2. Should continue to use the OPTN computer match program for organ allocation and distribution
3. Must document and submit 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. Should refer to recent matches of similar blood type and body size for ranking local transplant candidates
2. Should use local transplant program waiting lists to match the best organ with waiting transplant candidates
3. Must document and submit to the OPTN Contractor their process for allocation during the combined 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 6/23/2003; 11/20/2003; 6/24/2004; 11/18/2004; 6/29/2006; 6/26/2007; 2/20/2008; 3/2/2009; *Policy 3.4: Organ Procurement, Distribution, and Allocation:* 6/27/2002; 11/20/2003; 6/24/2004; 11/18/2004; 6/23/2005; 11/17/2005/ 9/20/2006; 12/13/2006; 11/16/2009; 6/21/2010; *Policy 1: Administrative Rules and Definitions:* 11/2012 (eff. 2/1/2013)

Notes

- For patient notification requirements for inactive programs due to natural disasters, see Bylaws, appendix B, § II(C)(2)(b)(ii).
- For the policy development process, see 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: Organ Procurement

2.1	OPO Responsibilities	22
2.2	Evaluating Potential Donors	23
2.3	Hemodilution Assessment	23
2.4	Potential Donors Information	24
2.5	HIV Screening of Potential Donors	31
2.6	Donor Maintenance	32
2.7	Organ Procurement	32
2.8	Organ Procurement Sequence	33
2.9	Controlled Donation after Circulatory Death	33

Introduction

This Policy sets minimum standards for the selection, evaluation, and maintenance of donors and the procurement of organs.

Policy Statement

2.1 OPO Responsibilities

The Host Organ Procurement Organization (Host OPO) is responsible for *all* of the following and must maintain the corresponding documentation for seven years from the date that the donor record is completed:

1. Identifying potential donors
2. Obtaining authorization for the removal of organs
3. Evaluating and screening donors
4. Submitting the donor's human leukocyte antigen (HLA) type to the OPTN Contractor
5. Executing the approved OPTN automated organ allocation computer algorithm for each donated organ
6. Maintaining donors
7. Procuring organs
8. Packaging and transporting organs
9. Procuring, dividing, and packaging adequate tissue typing material
10. Preserving and packaging organs.

Additionally, the Host OPO is responsible for documenting and maintaining the corresponding documentation for seven years from the date that the donor record is complete *all* of the following:

1. Death pronouncement
2. Authorization for donation
3. Donor evaluation

4. Donor maintenance
5. Organ recovery quality.

Every Organ Procurement Organization (OPO) must define what constitutes an acceptable deceased donor or organ for the Transplant Programs in its local unit.

Each OPO must establish and implement a plan to address organ donations for diverse cultural and ethnic populations.

2.2 Evaluating Potential Donors

The Host OPO must:

1. Determine that death was pronounced according to applicable laws
2. Obtain the donor's medical and behavioral history from one or more individuals familiar with the donor
3. Review the donor's medical chart
4. Perform a physical examination of the donor
5. Obtain the donor's vital signs.

After performing all of the above activities, the Host OPO must report this information to all receiving OPOs and Transplant Hospitals. However, if any of this information is not available, the Host OPO must document in the donor record the reason it is not available.

The medical and behavioral history on each potential donor should include *all* of the following:

1. Medical conditions communicated by medical and behavioral historian, or identified in the donor medical record
2. The presence of potentially transmissible diseases, malignancies, or other conditions that the donor organ could transmit and reasonably impact the transplant recipient
3. Any testing and laboratory assessments used to identify malignant and infectious conditions communicated by medical and behavioral historian, or identified in the donor medical record
4. Any factors associated with increased risk for disease transmission, including blood borne pathogens, human immunodeficiency virus (HIV), hepatitis B (HBV), and hepatitis C (HCV)
5. Whether the donor meets the increased-risk for disease transmission as specified in the U.S. Public Health Service Guidelines
6. If the donor has prior exposure to or is a recipient of non-recombinant Human Pituitary Derived Growth Hormone (HPDGH)
7. Information indicated in Table 2-1: *Donor Information*.

2.3 Hemodilution Assessment

Prior to screening, the Host OPO must assess all potential donor blood samples, that were obtained for screening tests, for hemodilution using an U.S. Food and Drug Administration (FDA) approved hemodilution calculation. The Host OPO must document in the donor medical chart a complete history of all blood products and intravenous fluid transfusions the donor received since admission to the Donor Hospital.

However, if a qualified specimen is not available and testing occurs on a hemodiluted specimen, the Host OPO must treat the donor as presenting an increased risk for disease transmission as specified in the U.S. Public Health Service guidelines. Additionally, the Host OPO must report *all* of the following to the accepting Transplant Programs:

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).

2.4 Potential Donors Information

2.4(A) Blood Typing and Subtyping

The Host OPO is responsible for determining each donor's blood type and sub-type of blood type A donors. For the purposes of determining a donor's blood type and sub-type, the Host OPO must send *one* of the following:

1. Two blood samples to two different labs
2. Two blood samples from separate draws to the same lab

The Host OPO must report the donor's blood type to the OPTN Contractor. Afterwards, the Host OPO must have someone, other than the person who reported the donor's blood type to the OPTN Contractor, determine that the donor's blood type matches the reported blood type. The Host OPO must document that such separate verification occurred.

When a donor with blood type A or AB is subtyped and found to be non-A₁ (negative for A₁) or non-A₁B (negative for A₁B), the OPO must complete a second determination subtype test to assess the accuracy of the result. Blood samples for the initial and second determination subtype tests must be either of the following:

1. Two blood samples to two different labs
2. Two blood samples from separate draws to the same lab

Subtype testing must be performed only on pre-transfusion specimens. The two test results must indicate the same subtype before a match can be run using the subtype to allocate organs. When two pre-transfusion samples are not available, or the initial and second determination test results do not indicate the same subtype, the donor must be allocated based on the primary blood type, and the subtype should not be reported to the OPTN Contractor.

The OPO must document that the initial and second determination tests have taken place. Each OPO must establish and implement a procedure for two individuals to verify the accuracy of the initial and second determination subtyping test results by using both ABO subtyping source documents and document that this process has taken place.

2.4(B) Donor Tests

The Host OPO is responsible for evaluating donors according to this section. Information requiring laboratory testing must occur in an appropriately accredited laboratory using an FDA licensed, approved, or cleared serological screening test. The Host OPO must report to all receiving Transplant Programs the results of any tests performed.

Table 2-1: *Donor Information* shows the information and tests that the Host OPO must report for each organ type. Fields with a “●” indicate that the information is required for that organ. Fields with a “○” indicate that the information is not required for that organ.

Fields with a “◐” indicate that the information is required with certain conditions.

If a required screenings test is not commercially available prior to transplant, then:

1. The Host OPO may use an FDA-licensed, approved, or cleared diagnostic test for all tests except Anti-HIV
2. The Host OPO must document the utilized test in the donor record.

Table 2-1: Donor Information

	Is this information required for that organ?	Heart	Kidney	Liver	Lung	Pancreas	All Other Organs
Crossmatch	HLA A, B, Bw4, Bw6, C, DR, & DQB antigens	○	●	○	○	●	○
	Abdominal injuries and operations, history of	○	●	○	○	●	○
Details	Age	●	●	●	●	●	○
	Alcohol use, if known	○	○	○	○	●	○
	Blood type	●	●	●	●	●	●
	Brain death, cause of	●	○	●	●	○	○
	Cardiac arrest, history of	●	○	○	●	●	○
	Cardiopulmonary history	●	○	○	●	○	○
	Date of admission	○	●	○	○	●	○
	Diabetes, family history of	○	○	○	○	●	○
	Diagnosis	○	●	●	○	●	○
	Donor ID number	●	●	●	●	●	●
	Drug use, history of	●	○	●	●	○	○
	Height	●	○	●	●	○	○

Organ Procurement and Transplantation Network (OPTN) Policies
 Policy 2: Organ Procurement

	Is this information required for that organ?	Heart	Kidney	Liver	Lung	Pancreas	All Other Organs
	History of treatment in hospital	●	○	●	●	●	○
	Medical history	●	●	●	●	●	○
	Name	○	●	●	○	●	○
	Race	○	●	●	○	●	○
	Sex	●	●	●	●	●	○
	Smoking, history of	○	○	○	●	○	○
	Social history	●	●	●	●	●	○
	Weight	●	○	●	●	●	○
Labs	Alanine aminotransferase (ALT)	○	○	●	○	○	○
	Alkaline phosphatase, within the past 12 hours	○	○	●	○	○	○
	Arterial blood gas results	●	●	●	●	●	●
	Aspartate aminotransferase (AST)	○	○	●	○	○	○
	Bilirubin, direct	○	○	●	○	○	○
	Bilirubin, total, within the past 12 hours	○	○	●	○	○	○
	Blood and urine cultures	●	●	●	●	●	●
	Blood urea nitrogen (BUN), final	○	●	○	○	○	○
	Blood glucose	○	○	○	○	●	○
	Complete blood count (CBC)	●	●	●	●	●	●
	Creatinine	○	●, final reading	● within past 12 hours	○	○	○
	Electrolytes	●	●	●	●	●	●
	Hemoglobin (hgb) and Hematocrit (hct) (H&H), within the past 12 hours	○	○	●	○	○	○
	International normalized ration (INR) or prothrombin time (PT) if INR is not available. It must be within the past 12 hours	○	○	●	○	○	○

Organ Procurement and Transplantation Network (OPTN) Policies
 Policy 2: Organ Procurement

	Is this information required for that organ?	Heart	Kidney	Liver	Lung	Pancreas	All Other Organs
	Partial thromboplastin time (PTT)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Serum amylase	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
	Serum glucose	<input checked="" type="radio"/>					
	Sputum gram stain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Urinalysis, final	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Urinalysis, within 24 hours prior to cross clamp	<input checked="" type="radio"/>					
	Ventilator settings	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
	White blood cell (WBC) count, within the past 12 hours	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Medications & Fluids	Current medication	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
	Hydration, history of treatment	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Insulin protocol	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
	Oliguria, history of	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
	Transfusion, history of	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
	Vasopressors, current treatment	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Organ Data	Anatomical description, including number of blood vessels, ureters, and approximate length of each, injuries to or abnormalities of the blood	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Recovery blood pressure & urine output information	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Recovery medications	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Type of recovery procedure, flush solution, flush method, and flush storage solution	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Typing material, description of	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Warm ischemia time and organ flush characteristics	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ser	Anti-cytomegalovirus (CMV) assay	<input checked="" type="radio"/>					

Organ Procurement and Transplantation Network (OPTN) Policies
 Policy 2: Organ Procurement

	Is this information required for that organ?	Heart	Kidney	Liver	Lung	Pancreas	All Other Organs
	Anti-Human immunodeficiency virus (HIV) I & II screening	●	●	●	●	●	●
	Epstein-barr virus (EBV) serological testing	●	●	●	●	●	●
	Hepatitis, including hepatitis B surface antigen (HBsAg), hepatitis B core antibody (HBcAb), and anti-hepatitis C (HCV)	●	●	●	●	●	●
	Sepsis, indication of	○	●	●	○	●	○
	Venereal disease research laboratory (VDRL) or rapid plasma regain (RPR)	●	●	●	●	●	●
Tests	Bronchoscopy	○	○	○	●	○	○
	Chest x-ray	●	●	●	○, interpret ed by a radiologi st or qualified physicia n within 3 hours prior to the offer	●	●
	Echocardiogram or cardiology consult	●	○	○	●	○	○
	Electrocardiogram, interpreted	○, 12 lead	○	○	●	○	○
Vital Signs	Blood pressure, history of average	○	●	○	○	●	○
	Hypotensive episodes, history of	●	●	●	●	●	○
	Urine output, history of average	○	●	●	○	●	○
	Vital signs	●	●	●	●	●	○

If the Host OPO or Donor Hospital lacks the personnel or technical capability to perform a bronchoscopy, the receiving Transplant Hospital may perform it. The lung recovery team may perform a confirmatory bronchoscopy provided unreasonable delays are avoided and

subject to donor stability and the time limitations in Policy 5.3(B) *Time Limit For Acceptance*.

2.4(C) Requested Organ Specific Information

2.4(C)(I) Kidney

If requested, the Host OPO should provide the Transplant Hospital receiving the kidney with biopsy information as follows:

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

2.4(C)(II) Heart

The heart recovery team must have the opportunity to speak directly with the Donor Hospital's responsible ICU personnel or the on-site donor coordinator in order to obtain current information about the donor hemodynamics.

If requested by the potential recipient's Transplant Hospital, the Host OPO or Donor Hospital must provide the donor's human leukocyte antigen (HLA) type.

If the potential recipient's Transplant Hospital requires donor HLA type prior to submitting a final organ acceptance, it must communicate this request to the OPO and document this request. If a Transplant Hospital requests donor HLA type prior to submitting a final organ acceptance, the Host OPO must provide the following, identified splits before the organ's final acceptance:

- HLA-A,
- HLA-B,
- HLA-Bw4,
- HLA-Bw6,
- HLA-Cw,
- HLA-DR, and
- HLA-DQ antigens.

The Transplant Hospital may request HLA-DP type, but the Host OPO need only provide it if its affiliated laboratory performs related testing. The Host OPO must document provision of HLA type to the requesting Transplant Hospital.

If requested, the Donor Hospital should report *all* of the following information to the receiving Transplant Hospital:

1. Coronary angiography for male donors over 40 years old and female donors over 45 years old
2. Central venous pressure (CVP) or Swan Ganz instrumentation

3. Cardiac enzymes, including creatine phosphokinase (CPK) isoenzymes.

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

1. Male over 40 years old or female over 45 years old
2. Segmental wall motion abnormality on echo
3. Troponin elevation
4. History of chest pain
5. Abnormal electrocardiogram (ECG) consistent with ischemia or myocardial infarction
6. *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.

2.4(C)(III) Lung

The lung recovery team must have the opportunity to speak directly with responsible ICU personnel or the on-site donor coordinator in order to obtain current information about the donor hemodynamics.

If requested by the potential recipient's Transplant Hospital, the Host OPO or Donor Hospital must provide the donor's human leukocyte antigen (HLA) type.

If the potential recipient's Transplant Hospital requires donor HLA type prior to submitting a final organ acceptance, it must communicate this request to the OPO and document this request. If a Transplant Hospital requests donor HLA type prior to submitting a final organ acceptance, the Host OPO must provide the following, identified splits before the organ's final acceptance:

- HLA-A,
- HLA-B,
- HLA-Bw4,
- HLA-Bw6,
- HLA-Cw,
- HLA-DR, and
- HLA-DQ antigens.

The Transplant Hospital may request HLA-DP type, but the Host OPO need only provide it if its affiliated laboratory performs related testing. The Host OPO must document provision of HLA type to the requesting Transplant Hospital.

If requested, the Host OPO should report *all* of the following information to the receiving Transplant Hospital:

1. Measurement of chest circumference at the level of nipples

2. Mycology sputum smear
3. Chest x-ray measurement vertically from the apex of the chest to the apex of the diaphragm and transverse at the level of the diaphragm.

An arterial blood gas measurement, must be performed preferably with a positive end expiratory pressure (PEEP) of 5 cm of water. The measurement should be obtained while the donor is on 100% inspired oxygen concentration (FiO₂) and within 2 hours of the lung offer.

2.4(D) Follow-up Testing

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

1. Obtain post-recovery donor testing results
2. Report all positive screening or diagnostic test to the Transplant Hospital's patient safety contact, within 24 hours of receipt.

The Host OPO must report to the Transplant Programs *all* of the following:

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

The Host OPO must report to the OPTN Contractor, any new disease or malignancy in the donor that may be transmitted to transplant recipients.

2.5 HIV Screening of Potential Donors

2.5(A) HIV Screening

The Host OPO must screen all potential donors for anti-HIV-1 and anti-HIV-2 using an FDA-licensed, serological antibody test. To proceed, *all* of the following must occur:

1. The sample is qualified.
2. The HIV screening test is negative.
3. Blood for the subsequent transfusion is negative for HIV.

If the Host OPO performs multiple HIV tests, it must report the results of all HIV tests directly to all receiving Transplant Programs. However, the OPO may proceed if *all* of the following occur:

1. The Host OPO initiated an HIV screening
2. The organs to be donated without final HIV screening results are not kidneys
3. The Host OPO and receiving institution find that an extreme medical emergency warrants the transplantation of an organ not tested for HIV
4. The Host OPO reports all available information regarding donor medical and behavioral history to the Transplant Program

5. The Host OPO treats this donor as presenting an increased risk for disease transmission as described in the U.S. Public Health Service Guidelines
6. The Transplant Program obtains and documents informed authorization from the potential transplant recipient or his authorized agent before transplantation.

2.5(B) Prohibition on Use of HIV Positive Organs

Members may not knowingly participate in the recovery or transplantation of organs from donors infected with HIV. Therefore, Members may only recover organs if the laboratory data, medical history, and behavioral history indicate that the donor is not HIV infected.

2.5(C) Informing Personnel

The Host OPO should inform health care personnel, who care for potential donors or donors who test positive for HIV, only when it is necessary for medical decision-making purposes.

2.6 Donor Maintenance

The Host OPO must make reasonable efforts to maintain the donor. They must document these efforts and report this information to the receiving OPOs or Transplant Hospitals as follows:

1. Maintain adequate blood pressure to maintain perfusion of vital organs
2. Monitor vital signs
3. Administer IV therapy or drugs, as required
4. Administer antibiotic therapy, as required
5. Administer and monitor fluid intake and output.

2.7 Organ Procurement

2.7(A) Conflicts of Interest

Neither the attending physician of the decedent at death nor the physician who determines the time of the decedent's death may participate in the operative procedure for removing or transplanting an organ from the decedent.

2.7(B) Procedures

The Host OPO must:

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

The Host OPO and histocompatibility laboratory must establish the minimum tissue typing material, type of specimen, medium, and shipping requirements required to generate match runs for placement of organs. Table 2-2: *Minimum Typing Materials* shows the requirements for each organ as follows:

Table 2-2: Minimum Typing Materials

The Host OPO must provide...	If the organ is a...
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	Kidney or pancreas. They are also required for all other organs if the receiving Transplant Hospital requests and they are available.

2.7(C) Maintenance of Serum Samples

The Host OPO must maintain a serum sample for each donor for at least 10 years after the date of organ recovery. This serum sample must be available for retrospective testing. The Host OPO must document the type of specimen in the donor medical chart and, if possible, should use qualified specimens.

2.8 Organ Procurement Sequence

After a Member indicates its initial acceptance of an organ, the Transplant Hospitals or OPOs involved must agree upon the time that multiple organ procurement will begin. If the Members cannot agree upon the procurement time, the Host OPO may withdraw the offer from the Transplant Hospital or OPO unable to agree upon a time for procurement to begin.

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.

Organ recovery teams may only recover organs for which they have received authorization. An authorized organ should be recovered if it is transplantable or a transplant recipient is identified for the organ. The Host OPO must document the specific reason for non-recovery of an authorized organ.

2.9 Controlled Donation after Circulatory Death

2.9(A) Agreement

In order to recover organs from a Donation after Circulatory Death (DCD) donor, a Host OPO and Transplant Hospital must establish and follow a protocol that contains the standards in Policies 2.9(B) through 2.9(E) below.

The OPO must have a written agreement with hospitals that participate in DCD recovery. The participating hospital must be a Medicare or Medicaid participating hospital or Critical Access Hospital as certified by Medicare. The participating hospital must also have a ventilator and a functional operating room.

Members that experience difficulty adopting a DCD protocol may consult with the joint OPO Committee and Membership and Professional Standards Committee (MPSC) working group.

2.9(B) Donor Selection

The Host OPO and the patient's primary health care team must collaboratively determine if a patient has a permanent and irreversible neurological injury or disease which may allow for a planned withdrawal of life-sustaining medical treatment or ventilated support. In making the decision, they may also collaborate with the OPO medical director and Transplant Hospital teams that may receive these organs.

2.9(C) Authorization

The hospital's patient care team and legal next of kin must make the decision to withdraw life-sustaining measures. They must document this decision in the patient medical chart. Also, they must create a plan for patient care where death does not occur within the established time period after the withdrawal of life-sustaining medical treatment or ventilated support. This plan should include provisions for end of life care and the immediate notification of the patient's next of kin.

One of the following persons must give authorization before administering drugs or procedures for the purposes of organ donation:

- The patient who authorizes being an organ donor candidate
- The patient's next of kin as defined by state or local law
- The patient's designated health care agent.

A medical examiner or coroner must give clearance to recover organs, when applicable.

Authorization must include, but not be limited to, details of the following:

1. Anticoagulants
2. Bronchoscopy
3. Extracorporeal Membrane Oxygenation (ECMO) circuit cannulation
4. Femoral line placements
5. Lymph node excision
6. Vasodilators.

2.9(D) Withdrawal of Life Sustaining Measures

Before the hospital's patient's care team withdraws life-sustaining medical treatment or ventilated support, the Host OPO must conduct a timeout to:

1. Verify the patient's identification

2. Determine the process and location for withdrawing life-sustaining treatment or ventilated support. Items to consider may include, but are not limited to, endotracheal tube (ETT) removal or termination of blood pressure management medications
3. Review the roles and responsibilities of the primary patient care team, the OPO team, and the organ recovery team
4. Review the plan for patient care if death does not occur within the established time after the withdrawal of life-sustaining medical treatment or ventilated support.

No member of the organ recovery team may be present for the withdrawal of life sustaining medical treatment or ventilated support.

No member of the organ recovery team may participate in the guidance or administration of palliative care or the declaration of death.

2.9(E) Declaration of Death

The patient care team member that declares the death must not be a member of the Host OPO or organ recovery team.

Death is declared following hospital policy and applicable state and local laws.

Declaration of death must not occur until after *both* of the following:

1. The patient has an irreversible cessation of circulatory and respiratory functions
2. A sufficient time has passed, as defined by hospital policy.

Organ recovery must not begin until after the declaration of death by the hospital patient care team.

2.9(F) 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 5.2(C) *Liver* 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 circumstances:

- Donor instability
- Lack of donor family approval and authorization
- 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 upon request.

History

Policy 2: Minimum Procurement Standards for an Organ Procurement Organization 6/27/2002; 6/26/2003; 1/20/2003; 11/18/2004; 5/23/2005; 11/17/2005; 12/13/2006; 2/20/2008; 3/2/2009; 11/18/2010; *Policy 2: Organ Procurement*: 11/2012 (eff. 2/1/2013)

Notes

- For record maintenance and reporting requirements, see 42 C.F.R. § 121.11.
- 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 15.1: *Patient Safety Contact*.
- For Host OPO's responsibilities concerning the identification of transmissible diseases in organ recipients, see Policy 15.5(B): *Recovery Hospital and Host OPO's Notifications*.
- For Host OPO's responsibilities concerning packaging, labeling and transporting of organs, vessels, and tissue typing materials, see Policy 16: *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	37
3.2	Waiting List Registration	38
3.3	Patient Notification	39
3.4	Waiting Time for Inactive Candidates	39
3.5	Waiting Time Modifications	40
3.6	Waiting Time Assignments for Multi-Organ Candidates	42
3.7	Waiting Time Reinstatement for Non-Function of Transplanted Organ	43
3.8	Transfers and Multiple Registrations	44
3.9	Removing Candidates from the Waiting List	45

Introduction

This Policy sets the requirements associated with candidate registrations, modifications, and removals.

Policy Statement

3.1 Access to Computer Systems

Only the following categories of Members may access the waiting list:

1. Transplant Hospitals
2. Organ Procurement Organizations (OPO)
3. Histocompatibility Laboratories

Members may not allow non-members to access or use the waiting list on behalf of non-members unless the member has a data use agreement with the non-member according to Policy 19: *Release of Data*. Additionally, the non-member must be a third party assisting the member with *one* of the following:

- Facilitating transplants
- Placing organs for purposes other than transplantation
- Reporting data to the OPTN.

Members may not register a candidate on the waiting list for a transplant at a Transplant Program that is not approved for that organ type.

3.2 Waiting List Registration

3.2(A) Registration Fee

The registration fee, authorized by 42 C.F.R. § 121.5(c) and OPTN Bylaws Section 1.2(D): *Registration Fees*, for the registration of a candidate is \$603.

3.2(B) General Candidate Registrations and Blood Typing

The candidate's Transplant Program must do *all* of the following:

1. Register on the waiting list all candidates for deceased donor organ transplants, including directed donations from deceased donors
2. Complete all candidate additions, modifications, and removals in the waiting list
3. Determine the candidate's blood type using two blood samples that are taken at different times
4. Report the candidate's actual blood type to the OPTN Contractor
5. Have someone, other than the person who reported the candidate's blood type to the OPTN Contractor, compare the candidate's blood type on the waiting list against the source documents. A candidate is not eligible to match with a donor until after this comparison occurs.

3.2(C) Multiple Organ Candidate Registration

If a multi-organ candidate requires a heart, lung, or liver, then the candidate's Transplant Program must register the candidate on the waiting list for each organ.

3.2(D) HLA Requirements

The candidate's Transplant Program must report to the OPTN Contractor HLA information (at least 1A, 1B, and 1DR antigen) according to Table 3-1: *HLA Requirements*.

Table 3-1: HLA Requirements

<i>If candidate is registered for a:</i>	<i>Then, HLA information is:</i>
Kidney alone	Required
Kidney-pancreas	Required
Kidney with any other non-renal organ	Not required
Pancreas	Required

Transplant Programs must report HLA information using current World Health Organization (WHO) nomenclature.

3.2(E) Registration of *In Utero* Candidates

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

Transplant Programs must identify *in utero* candidates when registering them on the waiting list. If an *in utero* thoracic candidate is born, then the candidate will lose their *in utero* status and have their start date for accumulating waiting time reset to the time of birth.

3.3 Patient Notification

Transplant Hospitals must notify patients in writing within ten business days according to Table 3-2: *Patient Notification*.

Table 3-2: Patient Notification

After this event...	The Transplant Hospital must send a notification with the following information...
The patient's evaluation finishes	That the evaluation is finished and whether the patient will be placed on the waiting list at this time
Patient is placed on waiting list	The date the patient was registered
Patient is removed from the waiting list for reasons other than transplantation or death	That the patient has been removed from the waiting list

Each written notification must reference and include the OPTN Contractor's *Patient Information Letter* that provides the telephone number available to patients and others to report concerns or grievances through the OPTN.

3.4 Waiting Time for Inactive Candidates

Candidates accrue waiting time while inactive according to Table 3-3: *Waiting Time for Inactive Candidates*.

Table 3-3: Waiting Time for Inactive Candidates

If the candidate is registered for the following organ:	Then the candidate accrues the following waiting time while inactive:
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 of age	No time
Lung and is less than 12 years of age	Unlimited time
Pancreas	Unlimited time
Pancreas islet	Unlimited time
All other organs	Up to 30 days

3.5 Waiting Time Modifications

3.5(A) Types of Applications

Applications for waiting time modifications that meet *any* of the following qualifications must follow the procedures for expedited modifications of waiting time in Policy 3.5(C): *Expedited Modifications of Waiting Time*.

1. An error occurred in modifying, removing, or renewing the candidate's waiting list record and the Transplant Program requests a modified waiting time to include time accrued under the previous registration, in addition to any time lost by the error.
2. The candidate was removed from the waiting list for medical reasons, other than receiving a transplant, was subsequently reregistered for the same organ with the same diagnosis, and the Transplant Program requests a modified waiting time to only include the time accrued under the previous registration without the time interval when the candidate was removed from the waiting list.
3. The candidate is waiting for a heart, liver, or lung, needs a second organ, and the Transplant Program requests a modified waiting time for the second organ that includes the waiting time accrued for the first organ.

Applications to modify a candidate's registration date and all other applications for waiting time modifications must follow the procedures for modifications of waiting time in 3.5(C) *Expedited Modifications of Waiting Time* below.

3.5(B) Application

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

1. The requested registration date and documentation showing an intent to register the candidate at the requested registration date
2. That the candidate met applicable waiting time qualifying criteria in the organ allocation policies
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.

3.5(C) Expedited Modifications of Waiting Time

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

1. Upon receipt of a complete application, 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.

3.5(D) Modifications of Waiting Time

All other applications for waiting time modifications must use the following process:

Upon receipt of a complete application and approval or explanation of disagreements from all applicable Transplant Programs within the local unit where the candidate is registered, the OPTN Contractor will forward the application, without person-identified data, according to Table 3-4: *Review of Waiting Time Modification Applications*.

Table 3-4: Review of Waiting Time Modification Applications

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

1. The reviewer will determine if it is appropriate to modify the candidate’s waiting time as requested in the application and notify the OPTN Contractor of the decision.
2. Upon notice from the reviewer, 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.

3.5(E) Modifications Following Removals

Transplant Hospitals may request a waiting time modification for a candidate removed from the waiting list as permitted by Table 3-5: *Standard Waiting Time Modifications*.

Table 3-5: Standard Waiting Time Modifications

If the reason for removal from the waiting list is...	Then the reinstated waiting time will include...
Errors or miscommunication between clinical or clerical personnel.	Time accrued under the previous registration and the time interval since the erroneous removal.
Medical reasons other than having received a transplant and registered again for the same organ with the same diagnosis.	Time accrued under the previous registration but not time since the candidate was removed from the waiting list.

To reinstate waiting time accrued under a previous registration, the Transplant Program must submit a *waiting time modification form* to the OPTN Contractor. The OPTN Contractor will modify the candidate’s waiting time after they verify the information.

3.6 Waiting Time Assignments for Multi-Organ Candidates

Multi-organ candidate may assign waiting time from one waiting list to another waiting list according to Table 3-6: *Waiting Time Assignments for Multi-Organ Candidates*. Fields with a “●” indicate that the assignment is automatic and does not require an application. Fields with a “○” indicate impermissible assignments of waiting time. Fields with a “◐” indicate that the candidate’s Transplant Program must submit an application pursuant to Policy 3.5: *Waiting Time Modifications* with the following modification: instead of providing documentation showing an intent to register the candidate at the requested registration date, the application must explain why the transfer is reasonable and is in the candidate’s best interest.

Table 3-6: Waiting Time Assignments for Multi-Organ Candidates

From this registration:	To this registration						
	Kidney	Kidney-Pancreas	Pancreas	Pancreas Islet	Heart	Lung	Heart-lung
Kidney	n/a	●	●	○	○	○	○
Kidney-Pancreas	●	n/a	●	○	○	○	○
Pancreas	○	○	n/a	◐	○	○	○
Pancreas Islet	○	○	◐	n/a	○	○	○
Heart	○	○	○	○	n/a	●	●
Lung	○	○	○	○	●	n/a	●
Heart-Lung	○	○	○	○	●	●	n/a

Notwithstanding the above, a candidate may only assign their waiting time from the kidney waiting list to the kidney-pancreas waiting list if the candidate meets the criteria in Policy 12.3: *Waiting Time*.

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:

- The date the candidate registered for a pancreas transplant
- The date the candidate registered for a kidney-pancreas transplant
- The date the candidate began accruing waiting time for a kidney pancreas transplant.

3.7 Waiting Time Reinstatement for Non-Function of Transplanted Organ

The OPTN Contractor will reinstate waiting time, without interruption, to candidates when immediate and permanent non-function of any transplanted organs occurs only as permitted by Table 3-7: *Waiting Time Reinstatements*.

Table 3-7: Waiting Time Reinstatements

	Kidney	Pancreas	Intestine
Graft failure occurs within	90 days of transplant	14 days of transplant	7 days of transplant
And is evidenced by	One of the following: 1. The removal of the organ 2. Dialysis treatment 90 days after transplant 3. Creatine clearance (CrCl) or calculated Glomerular filtration rate (GFR) less than or equal to 20 ml/min 90 days after transplant	One of the following: 1. The removal of the organ 2. A statement of intent from the Transplant Hospital to perform a pancreatectomy, and a statement that there is documented, radiographic evidence that the transplant pancreas failed	The removal of the organ
The OPTN Contractor will reinstate waiting time after receiving	A completed renal waiting time reinstatement form	A completed pancreas waiting time reinstatement form	A completed intestinal organ waiting time reinstatement form and the operative report
The Organ Center must notify	The Transplant Hospital	The Transplant Hospital	The OPO serving the Transplant Hospital

3.8 Transfers and Multiple Registrations

3.8(A) Accepting Multiple Registered Candidates

Candidates may register at multiple Transplant Programs anywhere. However, Transplant Programs may decide whether or not to accept candidates that have multiple registrations for the same organ.

3.8(B) Notifying Candidate of Their Options

During the evaluation process, Transplant Programs must inform and provide written materials to each of its candidates about *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 the above requirement.

If a Transplant Program does not accept candidates with multiple registrations or does not allow candidates to transfer waiting time, then it must inform the candidate during the evaluation process or sooner.

3.8(C) Transferring Waiting Time

A candidate may transfer his primary waiting time from one Transplant Hospital to another Transplant Hospital as follows:

1. Both Transplant Hospitals must register the individual as a candidate.
2. One of the Transplant Hospitals must submit a *waiting time transfer form* to the OPTN Contractor.
3. The OPTN Contractor will transfer the qualifying date and waiting time accrued from the earlier Transplant Hospital to the new Transplant Hospital.
4. The OPTN Contractor will remove the candidate from the waiting list of the earlier Transplant Hospital.
5. The OPTN Contractor will send a notice of the primary waiting time transfer to each of the Transplant Hospitals involved.

3.8(D) Transferring Waiting Time for Multiple Registered Candidates

A candidate may transfer his primary waiting time from one Transplant Hospital to another Transplant Hospital as follows:

1. Both Transplant Hospitals must register the individual as a candidate.
2. One of the Transplant Hospitals must submit a *waiting time transfer form* to the OPTN Contractor.
3. The OPTN Contractor will exchange the qualifying date and waiting time accrued between the two Transplant Hospitals.

4. The OPTN Contractor will send a notice of the primary waiting time transfer to each of the Transplant Hospitals involved.

3.8(E) Indication of Multiple Registrations

If a candidate registers at more than one Transplant Hospital, then the OPTN Contractor will notify both Transplant Hospitals of the multiple registration but will not identify the names of the Transplant Hospitals where the candidates are registered.

3.9 Removing Candidates from the Waiting List

If a candidate receives a transplant or dies while awaiting a transplant then, within 24 hours of the transplant date or death, the registering Transplant Hospital must remove the candidate from all organ waiting lists for the transplant and submit the *Recipient Feedback Form* to the OPTN Contractor. Candidates that receive pancreatic islets may remain on the waiting list until they receive their third islet infusion. 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 request removal of the candidate from the Transplant Hospital's waiting list.

If the transplant recipient registers again on the waiting list for that transplanted organ, then waiting time must begin as of the date and time the candidate reregisters. The waiting time from the previous registration may be added to the new registration according to Policy 3.5: *Waiting Time Modifications*.

History

Policy 3.2: UNOS Patient Waiting List: 11/15/2001; 6/27/2002; 6/26/2003/ 11/20/2003; 6/24/2004; 11/18/2004; 6/23/2005; 9/20/2006; 3/2/2009; 11/16/2009; Policy 3: Candidate Registrations, Modifications, and Removals: 11/2012 (eff. 2/1/2013)

Notes

- For acceptance and screening criteria, see Policy 5.1: *Acceptance and Screening Criteria*.
- For international exchange of organs, see Policy 17: *International Organ Transplantation*.
- For criteria to accrue waiting time, see Policies 7.3: *Waiting Time*; 8.3: *Waiting Time*; 9.4: *Waiting Time*; 10.4: *Waiting Time*; 11.3: *Waiting Time*; and 12.3: *Waiting Time*.

Policy 4: Histocompatibility

4.1	Guidelines for Written Contracts between Histocompatibility Laboratories and Transplant Programs	46
4.2	HLA Typing	50
4.3	HLA Antigen Values and Split Equivalences	51
4.4	Resolving Discrepant Donor and Recipient HLA Typing Results	52
4.5	Antibody Screening	53
4.6	Kidney and Pancreas Organ Transplantation	54
4.7	Other Organ and Islet Cell Transplantation	55
4.8	Cytotoxicity Methods	56
4.9	Blood Type Determination	56
4.10	Nucleic Acid Analysis	57
4.11	Flow Cytometry	60
4.12	Enzyme Linked Immuno Sorbent Assay (ELISA)	63
4.13	Solid Phase Multi-channel Arrays	63
4.14	Preservation of Zero Mismatch Tissue Typing Materials	64
4.15	Reference Tables of HLA Antigen Values and Split Equivalences	64

Introduction

This Policy sets requirements for histocompatibility testing in organ transplantation.

Policy Statement

4.1 Guidelines for Written Contracts between Histocompatibility Laboratories and Transplant Programs

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

4.1(A) Recommended Elements

Written agreements between Histocompatibility Laboratories and Transplant Programs should include *all* of the following elements:

1. A process to obtain accurate and current sensitization history for each patient.
2. The assay format that will be used for antibody screening and for crossmatching.
3. The frequency of periodic sample collection.
4. The frequency of antibody screenings.
5. The criteria and a process for establishing a risk category for each patient and the crossmatching strategy for each established risk category.
6. The criteria and a process for determining unacceptable antigens or acceptable antigens used during organ allocation.
7. A process for monitoring recipients post-transplant, or for monitoring desensitization protocols.
8. A process for blood type verification compliant with Policy 3.2(B): *General Candidate Registrations and Blood Typing*, if the laboratory registers candidates for the Transplant Program.

4.1(B) Sensitization History

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

Table 4-1: Determining Sensitization

If this event occurred...	Then the laboratory should evaluate...	And note...
Previous graft of solid organ, bone or tendon	Date of transplant and organs transplanted	
	Date of graft loss	Dates of graft removal, re-transplant, and return to dialysis
	Cause of graft loss	
	HLA typing of donors	Used to identify potential unacceptable antigens
	Rejection history, history of delayed function, history of non-compliance, or reduced immune-suppression due to infection	
Pregnancy	Number, year of each occurrence	Gravida/para
Transfusions	Number, type of product, month and year of each occurrence	
Assist device placement	Type of device, date of placement, duration of treatment	Primarily for thoracic transplantation
Disease	Identification of diseases	Auto-immunity may

If this event occurred...	Then the laboratory should evaluate...	And note...
	causing end-stage organ failure	invalidate some laboratory assays
Acute infections	Viral infection or bacterial infection requiring antibiotics	If the infection occurred since last antibody screening test. Induction of cells or antibodies with specificity for HLA or non-specific activation of memory
Chronic infections	Viral infection	Response to tolerance induction protocols
Vaccinations	Type, date of each occurrence	Time passed since last antibody screening test.

4.1(C) Detection of Antibodies

An antibody history is used in the antibody screening and crossmatching of donors and recipients. Laboratories may use the tests in Table 4-2: *Assays to Identify Antibody Screening or Crossmatching* to create an antibody history and assess sensitization in transplant candidates.

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

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

This assay...	Is used ...
autoantibody	
Treatment of serum	
Autologous cells	

Assays should be used to:

1. Identify whether a patient has circulating antibodies to HLA class I and class II antigens:
 - Initial serial screening should include cytotoxicity and more sensitive tests to identify patients with antibodies.
 - Several sera should be evaluated to establish a baseline.
2. Determine antibody specificity in patients with detectable circulating antibodies using some combination of:
 - A panel of representative cells for cytotoxicity.
 - ELISA tests for specificity.
 - Antigen-coated microparticles.
3. Monitor patients who do not currently have antibodies for the development of antibodies using:
 - Periodic screening of unsensitized patients to detect appearance of anti-HLA antibodies.
 - Characterization of antibody specificity.

4.1(D) Periodic Sample Collection

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

4.1(E) Crossmatching Strategies

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

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

Table 4-3: Recommended Elements for Crossmatching Strategies lists elements that laboratories should include in developing crossmatching strategies. Strategies should be tailored to the level of risk.

Table 4-3: Recommended Elements for Crossmatching Strategies

Element	Options
---------	---------

Selection of technique(s)	Refer to Table 4-2: <i>Assays to Identify Antibody Screening or Crossmatching.</i>
Selection of serum	<ol style="list-style-type: none"> 1. Stability of a candidate’s antibody response incorporated into choice of time between serum collection and transplant. 2. Use of historic serum.
Timing	<ol style="list-style-type: none"> 1. Prior to transplant (number of hours or days). 2. Peri-transplant or retrospective (number of hours or days). 3. Timed to limit cold ischemia.

4.2 HLA Typing

Table 4-4: *Requirements for HLA Typing* provides the requirements of HLA typing of HLA A, B, Bw4, Bw6, C, DR, DR51, DR52, Dr53, and DQB Antigens. Laboratories should report splits for all loci shown in Policy 4.15: *Reference Tables of HLA Antigen Values and Split Equivalences.*

Table 4-4: Requirements for HLA Typing

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

4.2(A) Typing Assignment

Laboratories must do *all* of the following:

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

4.2(B) Reagent Validation

Laboratories must do *all* of the following:

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

4.2(C) HLA Typing by Nucleic Acid Analysis

Laboratories must do *all* of the following:

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

4.2(D) Typing by Sequenced Based Typing (SBT)

Laboratories must do *all* of the following:

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

4.3 HLA Antigen Values and Split Equivalences

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

Refer to Tables Table 4-6, Table 4-7,
Table 4-8, Table 4-9, Table 4-10,
Table 4-11,
Table 4-12, and
Table 4-13 that follow to determine the candidate-donor antigen combinations reported
and whether they are mismatched.

HLA matching of A, B, and DR locus antigens is based on the antigens which are listed in
Policy 4.15 *Reference Tables of HLA Antigen Values and Split Equivalences*. These tables will
be updated annually by the Histocompatibility Committee. For matching purposes, split
antigens not on this list will be indicated on the waiting list as the parent antigens and will
match only with the corresponding parent antigens. Laboratories are encouraged to assign
all splits.

4.4 Resolving Discrepant Donor and Recipient HLA Typing Results

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. Laboratories must try to resolve these discrepancies.

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

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

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

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

The Laboratory Director or designated staff must contact the other Laboratory Director or
designated staff to resolve the discrepancies. If a resolution is reached, the laboratory with
the correct typing results should submit the corrected HLA typing to the OPTN Contractor
as resolved. The laboratory must also identify the specific reason for the discrepant typing.

The OPTN Contractor will remove all discrepant flags from HLA typing results that have been resolved. Discrepancies that have not been resolved will remain flagged, and will be reviewed by the Histocompatibility Committee. The Histocompatibility Committee will review, at least annually, any outstanding discrepant typings recorded during the previous 12 months.

4.5 Antibody Screening

Table 4-5: *Requirements for Antibody Screening* summarizes the requirements of antibody screening.

Table 4-5: Requirements for Antibody Screening

Laboratories performing assays using...	Must conform to standards in...
Cytotoxicity	Policy 4.8: <i>Cytotoxicity Methods</i>
Flow cytometry	Policy 4.11(A): <i>Instrument Standardization and Calibration</i> and Policy 4.11(B): <i>Flow Cytometric Crossmatch Technique</i>
ELISA techniques	Policy 4.12: <i>Enzyme-Linked Immuno Sorbent Assay (ELISA)</i>
Solid phase multichannel arrays	Policy 4.13: <i>Solid Phase Multi-channel Arrays</i>

4.5(A) Techniques

Laboratories must do *all* of the following:

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

4.5(B) Sera

Laboratories must do *all* of the following:

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

4.5(C) Panel and Target Selection

Laboratories must do *all* of the following:

1. Use a sufficient number of antigen panels that are in phenotypic distribution with respect to individual antigens or cross-reactive groups (CREGs) for the population served and for the intended use of the test results.
2. Maintain documentation of the HLA class I or class II phenotypes of the panel.
3. Have appropriate target cells or purified HLA molecules for all assays intended to provide information on HLA antibody specificity.
4. Have sufficient concentration, condition, and phenotype of target cells or purified HLA molecules to ensure that the antibodies being tested for (either HLA class I or class II) can be detected.

4.6 Kidney and Pancreas Organ Transplantation

4.6(A) Personnel Requirements

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

4.6(B) HLA Typing

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

4.6(C) Antibody Screening

Laboratories must have *all* of the following:

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

Laboratories should do *all* of the following:

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

4.6(D) Crossmatching

Laboratories must do *both*:

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

4.6(E) Techniques

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

Laboratories must also:

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

4.6(F) Samples

Laboratories must do *both*:

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

4.7 Other Organ and Islet Cell Transplantation

Laboratories must do *all* of the following:

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

4.8 Cytotoxicity Methods

4.8(A) Percentage of Cell Killed

Laboratories must do *both*:

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

4.8(B) Controls

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

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

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

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

4.8(C) Target Cells

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

4.8(D) Complement

Laboratories must do *all* of the following:

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

4.9 Blood Type Determination

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

If testing for the A₁ subgroup of type A blood is performed, the extract of *Dolichos biflorus* must be used at a dilution and with a technique documented not to agglutinate A₂ cells. Each assay or batch test run must include known A₁ and A₂ cells as controls.

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

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

4.10 Nucleic Acid Analysis

4.10(A) Nucleic Acid Extraction

Laboratories must do *all* of the following:

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

4.10(B) Electrophoresis

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

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

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

4.10(C) Analysis

Laboratories must do *all* of the following:

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

4. Test automated systems and computer programs routinely for accuracy and reproducibility of manipulations.

4.10(D) Template Amplification

4.10(D)(I) Facilities and Equipment

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

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

4.10(D)(II) Reagents

All reagents used in the amplification assay must:

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

4.10(E) Primers

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

Laboratories must also do *all* of the following:

1. Have a policy for quality control of each lot and shipment of primers using reference or well-characterized material.
2. Validate the specificity and robustness of the detection method for labeled primers.

3. Confirm periodically the performance of reagents stored for extended periods.

4.10(F) Amplification Templates

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

4.10(G) Contamination

Nucleic acid contamination must be monitored for the most common amplification products that are produced in the laboratory. Routine wipe tests of pre-amplification work areas must be performed. Monitoring must be performed using a method that is at least as sensitive as routine test methods. If amplified product is detected, the area must be cleaned to eliminate the contamination and retested. Corrective measures must be taken to prevent future contamination.

At least one negative control (no nucleic acid) must be included in each amplification assay. Testing of open tubes in the work area is recommended.

4.10(H) Controls and Quality Assurance

Laboratories must also do *all* of the following:

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

4.10(I) Technique-Specific Standards

4.10(I)(I) Oligonucleotide Probe Assays

Laboratories must also do *all* of the following:

1. Define the specificity and target sequence of oligonucleotide probes.
2. Store oligonucleotide probes under conditions that maintain specificity and sensitivity.
3. Use oligonucleotide probes under empirically determined conditions that achieve the defined specificity.

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

4.10(I)(II) Sequence Specific Amplification

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

4.10(J) Other Techniques

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

4.11 Flow Cytometry

4.11(A) Instrument Standardization and Calibration

Laboratories must also do *all* of the following:

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

4.11(B) Flow Cytometric Crossmatch Technique

Laboratories must also do *all* of the following:

1. Ensure the appropriate definition and purity of cell populations by the use of either a multi-color technique or other documented method.
2. Assess the binding of human immunoglobulin using a fluorochrome labeled reagent such as either an F(ab')₂ anti-human IgG that is specific for the Fc region of the heavy chain or other documented method.
3. Base crossmatch results for a specific cell population (e.g., T-cells, B-cells or monocytes) on the use of a monoclonal antibody that detects an appropriate cluster designated antigen (e.g., CD3 for T cells, CD19 or CD20 for B cells, and CD14 for monocytes).
4. Establish and document the optimum serum-to-cell ratio.

4.11(C) Controls

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

The positive control must be human antibody of the appropriate isotype for the assays and specific for the antigens that are targeted in the crossmatch. Positive controls must be used at a dilution appropriate for the assay (i.e., a dilution at which moderate changes in assay sensitivity are likely to be detected), and must react with appropriate target cells from all humans.

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

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

4.11(D) Interpretation

Laboratories must also do *both*:

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

4.11(E) Immunophenotyping By Flow Cytometry

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

4.11(F) Cell Preparation

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

4.11(G) Quality Control

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

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

Laboratories must also do *all* of the following:

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

4.11(H) Reagents

Laboratories must also do *all* of the following:

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

4.12 Enzyme Linked Immuno Sorbent Assay (ELISA)

4.12(A) The ELISA Reader

Laboratories must also do *all* of the following:

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

4.12(B) ELISA Technique

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

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

4.13 Solid Phase Multi-channel Arrays

4.13(A) Instrument Standardization/Calibration

Instruments must be standardized or calibrated as described Policy 4.11(A) *Instrument Standardization and Calibration*. Calibration and verification of plate alignment and instrument linearity must be performed according to the manufacturer's instructions or at least once every 6 months. The precise movement of the tray and plate must be documented.

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

4.13(B) Reagents

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

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

4.13(C) Technique

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

4.13(D) PRA Determination

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

4.13(E) Histocompatibility Typing

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

4.14 Preservation of Zero Mismatch Tissue Typing Materials

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

4.15 Reference Tables of HLA Antigen Values and Split Equivalences

Tables Table 4-6, Table 4-7, and

Table 4-8 show patient-donor antigen combination and whether they are mismatches. For each candidate antigen, the donor antigens that are not mismatched are listed. All other combinations are considered mismatches. Antigens with an * indicate an allele that may not have a World Health Organization (WHO)-approved serologic specificity. Antigens given **99 means the patient locus was not tested

Table 4-6: HLA A Matching Antigen Equivalences

Patient A Locus Antigen	Equivalent Donor Antigens	Patient A Locus Antigen	Equivalent Donor Antigens	Patient A Locus Antigen	Equivalent Donor Antigens
1	1	11	11	26	26
2	2, 203	19	19	28	28, 69
3	3	23	23	29	29
9	9	24	24, 2403	30	30
10	10	25	25	31	31

Organ Procurement and Transplantation Network (OPTN) Policies
 Policy 4: Histocompatibility

Patient A Locus Antigen	Equivalent Donor Antigens
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, 28
74	74
80	80
203	203, 2
210	210, 2
2403	2403, 24

Patient A Locus Antigen	Equivalent Donor Antigens
*6601	*6601, 66
*6602	*6602, 66
** 99	(No equivalent)

Table 4-7: HLA B Matching Antigen Equivalences

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

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

Patient B Locus Antigen	Equivalent Donor Antigens
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, 7
3901	3901, 39
3902	3902, 39
*3905	*3905, 39
4005	4005, 50
5102	5102, 51, 53
5103	5103, 51
7801	7801
*8201	*8201, 82
** 99	(No equivalent)

Table 4-8: HLA DR Matching Antigen Equivalences

Organ Procurement and Transplantation Network (OPTN) Policies
 Policy 4: Histocompatibility

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

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

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

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

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

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

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

Table 4-9: HLA A Unacceptable Antigen Equivalences

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

Patient's Unacceptable A Locus Antigen	Donor Equivalent Antigens
19	19, 29, 30, 31, 32, 33, 74
23	23, 9
24	24, 2403, 9
25	25, 10
26	26, 10
28	28, 68, 69
29	29
30	30
31	31
32	32

Patient's Unacceptable A Locus Antigen	Donor Equivalent Antigens
33	33
34	34
36	36
43	43
66	66, *6601, *6602, 10
68	68, 28
69	69, 28
74	74
80	80
203	203
210	210

Organ Procurement and Transplantation Network (OPTN) Policies
 Policy 4: Histocompatibility

2403	2403
*6601	*6601, 66

*6602	*6602, 66
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Table 4-10: HLA B Unacceptable Antigen Equivalences

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

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

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

Table 4-11: HLA C Unacceptable Antigen Equivalences

Patient's Unacceptable C Locus Antigen	Donor Equivalent Antigens
w1	w1
w2	w2

Patient's Unacceptable C Locus Antigen	Donor Equivalent Antigens
w3	w3, w9, w10
w4	w4

Patient's Unacceptable C Locus Antigen	Donor Equivalent Antigens
w5	w5
w6	w6

Organ Procurement and Transplantation Network (OPTN) Policies
 Policy 4: Histocompatibility

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

Patient's Unacceptable C Locus Antigen	Donor Equivalent Antigens
*12	*12
*13	*13
*14	*14
*15	*15

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

Table 4-12: HLA DR Unacceptable Antigen Equivalences

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

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

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

Table 4-13: HLA DQ Unacceptable Antigen Equivalences

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

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

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

History

Appendix 3A: HLA Antigen Values and Split Equivalence: 11/15/2001; 6/26/2002; Appendix 3D: Guidelines for the Development of Joint Written Agreements Between Histocompatibility Laboratories and Transplant Programs: 6/24/2004; 11/17/2008; Policy 4: Histocompatibility: 11/2012 (eff. 2/1/2013)

Notes

- For donor crossmatching requirements, see *Policy 2.4: Potential Donors Information*
- For heart donor HLA requirements, see *Policy 2.4(C)(II): Heart*
- For candidate HLA requirements, see *Policy 3.2(D): HLA Requirements*.
- For histocompatibility reporting requirements see *Policy 18.1: Data Submission Requirements*.
- For the release of HLA information, see *Policy 19.3: Requests for Person Identified Data*.

Policy 5: Organ Offer and Acceptance

5.1	Acceptance and Screening Criteria	70
5.2	Organ Offers	72
5.3	Receiving and Accepting Organ Offers	74
5.4	Released Organs	75
5.5	Allocation of Other Organs	75

Introduction

This Policy explains how and when Transplant Hospitals and Programs specify criteria for organs they are willing to accept; how OPOs offer organs; and how organ offers are reviewed and accepted.

Policy Statement

5.1 Acceptance and Screening Criteria

5.1(A) Kidney Acceptance Criteria

A Transplant Hospital may specify the maximum number of mismatched antigens it will accept and any antigens it will not accept for any of its kidney candidates.

Every kidney Transplant Program must establish minimal acceptance criteria for kidneys. Kidney Transplant Programs must report these criteria to the OPTN Contractor annually. Once these criteria are reported, any deceased donor organs offered through the OPTN Contractor will meet these criteria. The kidney acceptance criteria will not apply to imported zero antigen mismatched kidney offers.

5.1(B) Liver Acceptance Criteria

A Transplant Hospital must specify the acceptable donor size for each of its liver candidates.

A Transplant Hospital may specify *any* of the following:

- The maximum number of mismatched antigens it will accept for any of its liver candidates
- Minimal acceptance criteria for livers
- If a blood type O candidate will accept a liver from a donor with non-A₁ blood type
- If a status 1A and 1B candidate will accept a liver from a donor with any blood type
- If a candidate with a MELD or PELD score of at least 30 will accept a liver from a donor with any blood type
- If a candidate will accept a liver for other methods of hepatic support
- If a candidate is willing to accept a segmental graft.

Once the Transplant Hospital reports these criteria to the OPTN Contractor, any deceased donor organs offered through the OPTN Contractor will meet these criteria.

5.1(C) Lung Acceptance Criteria

A Transplant Hospital may specify both:

1. The maximum number of mismatched antigens it will accept for any of its lung candidates
2. Minimal acceptance criteria for lungs.

Once the Transplant Hospital reports these criteria to the OPTN Contractor, any deceased donor organs offered through the OPTN Contractor will meet these criteria.

5.1(D) Heart Acceptance Criteria

A Transplant Hospital may specify both:

1. The maximum number of mismatched antigens it will accept for any of its heart candidates
2. Minimal acceptance criteria for hearts.

Once the Transplant Hospital enters the criteria, any deceased donor organs offered through the OPTN Contractor will meet these criteria.

A Transplant Hospital may specify whether a candidate is willing to accept a heart from any blood type donor if the candidate meets at least *one* of the following conditions:

1. Candidate is *in utero*
2. Candidate is less than 1-year of age, and meets *all* of the following:
 - Classified at Status 1A or 1B
 - Reported current isohemagglutinin titer information for A or B blood type antigens to the OPTN Contractor
3. Candidate is at least 1 year of age, and meets *all* of the following:
 - Is registered prior to two years of age
 - Is classified at Status 1A or 1B
 - Has current isohemagglutinin titer levels less than or equal to 1:4 for A or B blood type antigens reported to the OPTN Contractor
 - Has *not* received treatments within the prior 30 days that may have reduced titer values to 1:4 or less

If a Transplant Hospital indicates that a candidate is willing to accept a heart from any blood type donor, the Transplant Hospital must report Anti-A or Anti-B titers:

1. At the time of registration (all candidates except *in utero* candidates)
2. Every 30 days after registration (all candidates)
3. At transplant (all candidates)
4. Within one year of the transplant if graft loss or death occurs (all candidates transplanted with an incompatible blood type heart).

A subcommittee of the Pediatric Transplant Committee and at least two other persons with analytical or professional expertise in this area of medicine will review these registrations

and outcomes on a quarterly basis. The subcommittee will report their review to the Pediatric Transplantation Committee.

5.1(E) Pancreas Acceptance Criteria

A Transplant Hospital may specify *any* of the following:

1. The maximum number of mismatched antigens it will accept for any of its pancreas and pancreas islet candidates
2. Any unacceptable antigens
3. Minimal acceptance criteria for pancreata and pancreas islets.

Once the Transplant Hospital reports the criteria to the OPTN Contractor, any deceased donor organs offered through the OPTN Contractor will meet these criteria.

5.1(F) Intestine Acceptance Criteria

A Transplant Hospital may specify both:

1. The maximum number of mismatched antigens it will accept for any of its intestinal candidates.
2. Minimal acceptance criteria for intestinal organs.

Once the Transplant Hospital reports the criteria to the OPTN Contractor, any deceased donor organs offered through the OPTN Contractor will meet these criteria.

5.1(G) Acceptance Criteria For All Other Organs

A Transplant Hospital may specify both:

1. The maximum number of mismatched antigens it will accept for any of its transplant candidates.
2. Minimal acceptance criteria for other organs or multi-organ combinations.

Once the Transplant Hospital reports the criteria to the OPTN Contractor, any deceased donor organs offered through the OPTN Contractor will meet these criteria.

5.2 Organ Offers

5.2(A) Nondiscrimination in Organ Allocation

Deceased donor organ allocation to candidates for transplantation shall not differ on the basis of a candidate's citizenship or residency status in the United States. Allocation shall not be influenced by favoritism or discrimination based on political influence, national origin, race, sex, religion, or financial status.

5.2(B) Order of Allocation

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

1. The OPTN Contractor eliminates candidates whose size or blood type is incompatible with the donor.
2. The OPTN Contractor 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 Programs on the initial match run accepts the OPO's offer, the Host OPO may give Transplant Programs the opportunity to update their candidates' data with the OPTN Contractor. The Host OPO may run an updated match run and allocate the organ according to the updated candidate data.
5. If no Transplant Program accepts the OPO's organ offer, the OPTN Contractor may allocate the organ on behalf of the OPO.
6. Transplant Programs may export deceased donor organs to hospitals in foreign countries after offering these organs to all potential recipients. Members must submit the organ export verification form to the OPTN Contractor prior to exporting deceased donor organs.

5.2(C) Liver

The Host OPO must execute a match run for liver allocation within 8 hours prior to the initial liver offer. The Host OPO must use this match run for placement of the donor liver. If a previously accepted liver is subsequently turned down because of a change in specific medical information related to the liver donor, then the Host OPO may re-execute the match run. Any re-execution of the liver match system for the same donor for other reasons must be retrospectively reviewed by the Regional Review Board. This section does not apply to a donor liver that has been recovered and has not been placed within two hours of organ procurement.

5.2(D) Multiple Organs Offer

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

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

5.2(E) Backup Organ Offers

OPOs may make backup offers for all organs. Transplant Hospitals must treat backup offers the same as actual organ offers and must respond within one hour of receiving the donor information required for an organ according to Policy 2.4: *Potential Donors Information*. If a Transplant Hospital refuses to consider or does not respond to a backup offer, the OPO will consider this as a refusal of the offer.

If a Transplant Hospital accepts a backup offer, the Transplant Hospital may later refuse to accept the organ based on medical or logistical criteria. OPOs should promptly notify backup Transplant Hospitals of any change in donor status or organ availability.

5.2(F) Allocating Organs to Candidates Not on Any Match Run

A Transplant Hospital may only transplant organs to candidates who appear on a match run unless the Transplant Hospital deems it necessary to transplant an organ to a candidate who does not appear on any match run for any organ type. Acceptable reasons include, but are not limited to, directed donations or to prevent organ wastage.

In such 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 an organ from an expanded criteria donor (ECD) or donation after circulatory death (DCD) donor
4. That the Transplant Hospital verified the medical suitability between the donor organ and recipient prior to transplant in at least, but not limited to, the following areas as applicable to each organ type:
 - Blood type
 - Donor HLA and candidate's unacceptable antigens
 - Donor height
 - Donor weight
 - Infectious disease test results

5.2(G) Local Conflicts

If any Member has an irresolvable inequity or conflict with an OPO policy regarding the allocation of organs, the Member may submit the issue to the appropriate organ specific committee and Board of Directors for review and adjudication. This section does not apply to issues regarding the allocation of pancreata or pancreas islets.

5.3 Receiving and Accepting Organ Offers

5.3(A) Receiving and Reviewing Organ Offers

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

The transplanting surgeon at the receiving Transplant Hospital must ensure the medical suitability of organs offered for transplantation to potential recipients, including compatibility of donor and candidate blood types.

5.3(B) Time Limit For Acceptance

A Transplant Hospital must access 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 expires and the organ may be offered to the Transplant Hospitals for the candidates ranked next on the match run. Transplant Hospitals must either accept or refuse the organ within one hour of receiving the donor information required for an organ according to Policy 2.4: *Potential Donors Information*, except as stated in Policies 9.7(A): *Mandatory Sharing of Zero Antigen Mismatched Kidneys* and 12.4(C): *Organ Offer Limits*. 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 ranked next on the match run.

5.3(C) Effect of Acceptance

If a Transplant Hospital accepts an OPO’s organ offer, the conditions of their agreement bind the Transplant Hospital and OPO unless they mutually agree upon an alternative allocation of the organ.

5.3(D) Rights Conferred by the Allocation System

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

5.4 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 allocated, deceased donor organs into the originally designated recipient or release the 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 the reason for refusing the organ for that candidate to the OPTN Contractor. 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 the OPO where the candidate’s Transplant Program is located.

5.5 Allocation of Other Organs

5.5(A) Statuses and Scores

For the allocation of organs not specifically addressed in other policies, points are assigned for medical urgency according to Table 5-1: *Medical Urgency Points for Other Organs*.

Table 5-1: Medical Urgency Points for Other Organs

If a candidate meets these criteria...	Then the candidate is this status...	And receives this many points...
At home, functioning normally, and transplant surgery would be an elective procedure	1	4
Homebound and requiring continuous medical care	2	8

If a candidate meets these criteria...	Then the candidate is this status...	And receives this many points...
which can be self administered. Short hospitalizations for intercurrent problems are not considered justification for a change in status.		
Homebound and requiring continuous medical care which requires the assistance of an attendant. Short hospitalizations for intercurrent problems are not considered justification for a change in status.	3	12
Continuously hospitalized because of the candidate's medical condition	4	16
Requires continuous hospitalization as well as intravenous inotropic drug therapy	5	20
Requires continuous hospitalization and a mechanical assist device for survival. Qualifying mechanical assist devices include, but are not limited to, ventilators, total artificial hearts, and intra-aortic balloon pumps.	6	24

5.5(B) Points

For the allocation of organs not specifically addressed in other policies, donors and recipients receive points for the distance between Transplant Hospital and the donor or recipient. The point values are assigned according to *Table 5-2: Distance Points for Other Organs*.

Table 5-2: Distance Points for Other Organs

If the distance from the Transplant Hospital is...	Then the donor receives this many points...	And the recipient receives this many points...
0 – 50 miles	12	6
50 – 500 miles	10	5
500 – 1000 miles	8	4
1000 – 1500 miles	6	3
1500 – 2000 miles	4	2
2000 – 2500 miles	2	1

History

Policy 3.3: Acceptance Criteria: 6/26/2003; 6/23/2005; 6/26/2007; 9/17/2007; 11/17/2008; 3/2/2009; *Policy 5: Organ Offer and Acceptance:* 11/2012 (eff. 2/1/2013)

Notes

Reserved

Policy 6: Multi-Organ Allocation

6.1	Multi-Organ Allocation	77
6.2	Allocation of Heart-Lungs	77
6.3	Allocation of Liver-Intestine from Donors Aged 0 to 10 Years	78
6.4	Allocation of Liver-Intestine from Donors Aged at Least 11 Years	80
6.5	Allocation of Kidney-Pancreas	81

Introduction

This Policy sets rules for the allocation of organs to multi-organ candidates.

Policy Statement

6.1 Multi-Organ Allocation

When allocating multiple organs from the same potential donor, the OPO should consider multi-organ candidates when choosing which organ match run to execute first. If an organ is accepted by a potential recipient who is 1) registered for more than one organ, 2) eligible to receive a heart, lung, or liver from a donor, *and* 3) registered in the same local unit as the donor, then the OPO must offer any second required organ from the same donor to this multi-organ potential recipient.

Otherwise, the OPO should allocate the second required organ, from the same donor, to the multi-organ candidate. If the OPO allocates the second required organ to a multi-organ candidate outside the donor's local unit, then the recipient OPO must pay back an organ of the same type from the next acceptable donor with an identical blood type. However, if the second organ is a kidney, then the recipient OPO must follow the payback rules in Policy 9.7(B):

Payback Requirements.

6.2 Allocation of Heart-Lungs

OPOs must use one of the following methods to allocate heart-lungs to candidates:

1. OPOs may use Policy 7: *Allocation of Hearts* to allocate the heart-lungs. A heart-lung candidate that would receive a heart offer under Policy 7: *Allocation of Hearts* will receive a heart-lung offer under this section. If the heart from a heart-lung donor is allocated to a heart candidate, and not to a heart-lung candidate, then the OPO must use Policy 11: *Allocation of Lungs* to allocate the remaining lung or lungs.
2. The OPO may use Policy 11: to allocate the heart-lungs. For each lung classification, the OPO must determine if there is a Status 1A heart candidate within the same geographic area. If there is, then the OPO must use Policy 7: *Allocation of Hearts* to offer the heart to all of the heart candidates through that Status 1A heart candidate's classification. If the heart is

allocated to a Status 1A heart candidate, and not a heart-lung candidate, then the OPO must use Policy 11: *Allocation of Lungs* to allocate the remaining lungs. If there are no Status 1A heart candidates within the lung classification’s geographic area, a heart-lung candidate that would receive a lung offer under Policy 11: *Allocation of Lungs* will receive a heart-lung offer under this section. If the lungs are allocated to a lung candidate, and not a heart-lung candidate, then the OPO must use Policy 7: *Allocation of Hearts* to allocate the remaining heart.

6.3 Allocation of Liver-Intestine from Donors Aged 0 to 10 Years

Livers and intestines from donors aged 10-years or younger are allocated to candidates in the following order:

Table 6-1: Allocation of Combined Liver-Intestines from Donors Aged 0 to 10 Years

Classification	Candidates that are within the...	And are...
The following classifications appear for all blood types		
1.	Donor hospital’s region	Liver or liver-intestine, and Pediatric Status 1A
2.	Nation	Liver or liver-intestine, and Pediatric Status 1A, and 0 to 11 years of age
3.	Nation	Liver-intestine, Pediatric Status 1A, and 12 to 17 years of age
4.	Donor hospital’s local unit	Liver or liver-intestine, Adult Status 1A
5.	Donor hospital’s region	Liver or liver-intestine, Adult Status 1A
6.	Donor hospital’s region	Liver or liver-intestine, Pediatric Status 1B
7.	Donor hospital’s region	Liver or liver-intestine, PELD greater than 20
8.	Nation	Liver-intestine and Pediatric Status 1B
9.	Nation	Liver-intestine and PELD greater than 20
10.	Donor hospital’s region	Liver or liver-intestine, and PELD of 20 or less
11.	Donor hospital’s local unit	Liver or liver-intestine, MELD of at least 15, and 12 to 17 years of age
12.	Donor hospital’s local unit	Liver or liver-intestine, MELD of at least 15, and greater than 17 years of age
13.	Donor hospital’s region	Liver or liver-intestine, MELD of at least 15, and 12 to 17 years of age
14.	Donor hospital’s region	Liver or liver-intestine, MELD of at least 15, and greater than 17 years of age
15.	Donor hospital’s local unit	Liver or liver-intestine, MELD less than 15, and 12 to 17 years of age
16.	Donor hospital’s local unit	Liver or liver-intestine, MELD less than 15, and greater than 17 years of age

Classification	Candidates that are within the...	And are...
17.	Donor hospital's region	Liver or liver-intestine, MELD less than 15, and 12 to 17 years of age
18.	Donor hospital's region	Liver or liver-intestine, MELD less than 15, and greater than 17 years of age
19.	Nation	Liver, Pediatric Status 1A, and 12 to 17 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, and 12 to 17 years of age
24.	Nation	Liver or liver-intestine, with any MELD, and greater than 17 years of age
The following classifications only appear on O blood type donor matches		
25.	Donor hospital's region	Liver or liver-intestine, with any PELD, and compatible blood type match with the donor
26.	Donor hospital's local unit	Liver or liver-intestine, MELD of at least 15, 12 to 17 years of age, and compatible blood type match with the donor
27.	Donor hospital's local unit	Liver or liver-intestine, MELD of at least 15, greater than 17 years of age, and compatible blood type match with the donor
28.	Donor hospital's region	Liver or liver-intestine, MELD of at least 15, 12 to 17 years of age, and compatible blood type match with the donor
29.	Donor hospital's region	Liver or liver-intestine, MELD of at least 15, greater than 17 years of age, and compatible blood type match with the donor
30.	Donor hospital's local unit	Liver or liver-intestine, MELD less than 15, 12 to 17 years of age, and compatible blood type match with the donor
31.	Donor hospital's local unit	Liver or liver-intestine, MELD less than 15, greater than 17 years of age, and compatible blood type match with the donor
32.	Donor hospital's region	Liver or liver-intestine, MELD less than 15, 12 to 17 years of age, and compatible blood type match with the donor
33.	Donor hospital's region	Liver or liver-intestine, MELD less than 15, greater than 17 years of age, and compatible blood type match with the donor
34.	Nation	Liver or liver-intestine, with any PELD, and compatible blood type match with the donor
35.	Nation	Liver or liver-intestine, with any MELD, 12 to 17 years of age, and compatible blood type match with the donor
36.	Nation	Liver or liver-intestine, with any MELD, greater than 17 years of age, and compatible blood type

Classification	Candidates that are within the...	And are...
		match with the donor
The following classifications appear for all blood types		
37.	Donor hospital's local unit	Liver or liver-intestine, Adult or Pediatric Status 1A, and in need of other method of hepatic support
38.	Donor hospital's local unit	Liver or liver-intestine, Pediatric Status 1B, and in need of other method of hepatic support
39.	Donor hospital's local unit	Liver or liver-intestine, with any MELD/PELD, and in need of other method of hepatic support
40.	Donor hospital's region	Liver or liver-intestine, Adult or Pediatric Status 1A, and in need of other method of hepatic support
41.	Donor hospital's region	Liver or liver-intestine, Pediatric Status 1B, and in need of other method of hepatic support
42.	Donor hospital'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.	Donor hospital's local unit	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.	Donor hospital's region	Liver or liver-intestine, with any MELD/PELD, in need of other method of hepatic support, and compatible blood type match with the donor
48.	Nation	Liver or liver-intestine, with any MELD/PELD, in need of other method of hepatic support, and compatible blood type match with the donor

For the purposes of this section, blood type matches are determined according to Policy 10.5(E) *Blood Type and Liver Allocation*.

6.4 Allocation of Liver-Intestine from Donors Aged at Least 11 Years

Liver and intestines from deceased donors older than 10-years must be allocated to liver-intestine candidates in the following order:

1. According to the appropriate liver allocation algorithm in Policy 10.6 *Liver Allocation Classifications and Rankings*

2. According to the appropriate intestine allocation algorithm in Policy 8.5 *Intestine Allocation Classifications and Rankings*.

6.5 Allocation of Kidney-Pancreas

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 either classifications 1 – 5 in Table 12-3: *Allocation of Kidneys and Pancreata from Donors 50 years of age and less with a BMI less than or equal to 30 kg/m²* or classifications 1-5 in Table 12-4: *Allocation of Kidneys and Pancreata from donors greater than 50 years of age or from donors who have a BMI greater than 30 kg/m²*
2. Then, the Host OPO may:
 - a. Continue to offer the kidney and pancreas according to the remaining classifications in Table 12-3: *Allocation of Kidneys and Pancreata from Donors 50 years of age and less with a BMI less than or equal to 30 kg/m²* or
 - b. Offer the pancreas to pancreas and pancreas islet candidates, but not kidney-pancreas candidates, according to the remaining classifications in Table 12-3: *Allocation of Kidneys and Pancreata from Donors 50 years of age and less with a BMI less than or equal to 30 kg/m²* and offer the kidney to kidney candidates according to Policy 9.6 *Kidney Allocation Classifications and Rankings*
3. The Host OPO may switch between options 2a and 2b above at any time after finishing step 1 above.

History

Policy 3.9: Allocation Systems for Organs Not Specifically Addressed: 11/14/2002; 3/2/2009; Policy 6: Multi-Organ Allocation: 11/2012 (eff. 2/1/2013)

Notes

- For multi-organ candidate registrations, see Policy 3.2(C): *Multiple Organ Candidate Registration*.
- For liver-intestine priority points, see Policy 10.3: *Points*.

Policy 7: Allocation of Hearts

7.1	Statuses	82
7.2	Status Exceptions	85
7.3	Waiting Time	86
7.4	Classification Notes	86
7.5	Heart Allocation Classifications and Rankings	88
7.6	Administrative Rules	95
7.7	Variances	96

Introduction

This Policy contains requirements for the allocation of hearts and certain rules regarding heart candidate registrations.

Policy Statement

7.1 Statuses

7.1(A) Adult Heart Status 1A

If the candidate is at least 18 years of age at the time of registration and meets at least *one* of the following conditions, then the candidate's Transplant Program may classify the candidate as Status 1A:

1. Candidate has mechanical circulatory support for acute hemodynamic decompensation that includes at least *one* of the following:
 - Left ventricular assist device (LVAD)
 - Right ventricular assist device (RVAD)
 - Left and right ventricular assist devices (BiVAD)
 - Total artificial heart (TAH)
2. Candidate is admitted to the Transplant Hospital that registered the candidate on the waiting list and has a mechanical circulatory support for acute hemodynamic decompensation with at least *one* of the following:
 - Total artificial heart (TAH)
 - Intra-aortic balloon pump
 - Extracorporeal membrane oxygenation (ECMO)
3. Candidate requires mechanical circulatory support and there is medical evidence of significant device related complications including, but not limited to, thromboembolism, infection, mechanical failure, or life-threatening ventricular arrhythmias. A candidate's sensitization is not an acceptable device related complication to qualify as Status 1A. If a Transplant Program reports a complication that is not listed here, the Transplant Program's Regional Review Board (RRB) will retrospectively review the status.

4. Candidate is admitted to the Transplant Hospital that registered the candidate on the waiting list and requires continuous mechanical ventilation.
5. Candidate is admitted to the Transplant Hospital that registered the candidate on the waiting list, 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 specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.

To classify a candidate as Adult 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 Status 1A until this happens.

7.1(B) Adult Heart Status 1B

If the candidate is at least 18 years of age at the time of registration and has at least *one* of the following devices or therapies in place, then the candidate's Transplant Program may classify the candidate as Status 1B:

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

To classify a candidate as Adult Status 1B, the candidate's Transplant Program must submit a *Heart Status 1B Justification Form* to the OPTN Contractor. A candidate is not classified as Status 1B until this happens. However, this form is not required if the Transplant Program is downgrading the candidate's status from 1A to 1B.

7.1(C) Adult Heart Status 2

If the candidate is at least 18 years of age at the time of registration and does not meet the criteria for Adult Statuses 1A or 1B, then the candidate is Adult Status 2.

7.1(D) Pediatric Heart Status 1A

If the candidate is less than 18 years of age at the time of registration and meets at least *one* of the following criteria, then the candidate's Transplant Program may classify the candidate as Pediatric Status 1A:

1. Requires continuous mechanical ventilation Requires a mechanical circulatory support device
2. Requires a balloon pump
3. Is less than six months of age with congenital or acquired heart disease exhibiting reactive pulmonary hypertension at greater than 50% of systemic level
4. Requires a single high-dose of an intravenous inotrope or multiple intravenous inotropes. The OPTN Contractor will maintain a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.

To classify a candidate as Adult 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 Status 1A until this happens.

A candidate can be Pediatric Status 1A regardless of the candidate's age if the candidate was registered on the waiting list before turning 18 years old.

7.1(E) Pediatric Heart Status 1B

If the candidate is less than 18 years of age at the time of registration and meets at least *one* of the following criteria, then the candidate's Transplant Program may classify the candidate as Pediatric Status 1B:

1. Requires infusion of low dose single inotropes. The OPTN Contractor will maintain a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.
2. Is less than six months of age and does not meet the criteria for Status 1A
3. Is less than the 5th percentile for the candidate's expected height or weight according to the most recent Centers for Disease Control and Prevention's (CDC) clinical growth chart
4. Is 1.5 or more standard deviations below the candidate's expected height growth or weight growth according to the most recent CDC clinical growth chart.

To classify a candidate as 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 classified as Status 1B until this happens. However, this form is not required if the Transplant Program is downgrading the candidate's status from 1A to 1B.

A candidate can be Pediatric Status 1B regardless of the candidate's age if the candidate was registered on the waiting list before turning 18 years old.

7.1(F) Pediatric Heart Status 2

If the candidate registers on the waiting list before turning 18 years old but does not meet the criteria for Statuses 1A or 1B, then the candidate is Pediatric Status 2.

A candidate can be Pediatric Status 2 regardless of the candidate's age if the candidate was registered on the waiting list before turning 18 years old.

7.1(G) Inactive Candidates

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 heart offers.

7.2 Status Exceptions

7.2(A) Eligibility and Application

If *all* of the following occur, then a candidate may receive a Status 1A or 1B exception:

1. The candidate's transplant physician believes that a heart candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit comparable to that of other candidates at the requested status.
2. The candidate's transplant physician submits an application to the OPTN Contractor with the requested status and a rationale for incorporating the exceptional case as part of the status criteria.
3. The Regional Review Board (RRB) approves the application for a status exception. The RRB may review applications either prospectively or retrospectively. The RRB will report its decision and justification to the Thoracic Organ Transplantation Committee and the Membership and Professional Standards Committee (MPSC). The Committees will determine whether the exceptions are consistent with previous decisions across the country and appropriate with existing status criteria.

If the candidate is at least 18 years old at the time of registration and the candidate's Transplant Program requests an Adult Status 1A exception, then, in addition to the above three requirements, the candidate must be admitted at the Transplant Hospital that registered the candidate on the waiting list.

If the candidate is less than 18 years old at the time of registration and the candidate's Transplant Program requests a Pediatric Status 1A exception, then, in addition to the above three requirements, the candidate's life expectancy without a heart transplant must be less than 14 days.

7.2(B) Length of Exception and Extensions

A candidate's Adult or Pediatric Status 1A exception is valid for 14 days.

At the end of the Adult Status 1A exception, a candidate's Adult Status 1A will be downgraded to a Status 1B unless the candidate's transplant physician submits an application to the OPTN Contractor with the requested status and length of the exception and the Regional Review Board (RRB) prospectively approves the extension. The Thoracic Organ Transplantation Committee and the Membership and Professional Standards Committee (MPSC) will review these extensions and will determine whether the RRB's decision is consistent with previous decisions across the country and appropriate with existing status criteria.

A candidate's transplant physician may extend a pediatric Status 1A exception for an additional 14 days by submitting an updated application to the OPTN Contractor. At the end of the 14 day extension, a candidate's Pediatric Status 1A will be downgraded to a Status 1B unless the candidate's transplant physician submits an application to the OPTN Contractor with the requested status and length of the exception and the RRB prospectively approves the extension.

7.2(C) Overrides

If the RRB does not approve an exception or extension of an exception, then the candidate's transplant physician may continue to classify that candidate as a Status 1A exception; however, the Thoracic Organ Transplantation Committee will review these extensions and will determine whether the decision is consistent with previous decisions across the country and appropriate with existing status criteria. The Committee may also refer these matters to the Membership and Professional Standards Committee (MPSC) for appropriate action according to Appendix L of the OPTN/UNOS Bylaws.

7.2(D) Sensitized Patients

A Transplant Program may prioritize sensitized candidates within one or more local units as follows:

1. The candidate's transplant surgeon or physician must determine that the candidate's antibodies would react adversely to certain HLA antigens
2. All heart Transplant Programs, lung Transplant Programs, and the OPO within a local unit must agree to allocate a heart from a compatible donor to the sensitized candidate.

7.3 Waiting Time

Waiting time for heart candidates begins when the candidate is first registered as an active heart candidate on the waiting list. Waiting time is also calculated within each heart status; however, heart candidates do not accrue waiting time while inactive.

7.4 Classification Notes

7.4(A) Sorting Within Each Classification

Status 1A heart candidates are sorted by waiting time at Status 1A.

Status 1B heart candidates are sorted by waiting time at Statuses 1A and 1B.

Status 2 heart candidates are sorted by waiting time at Statuses 1A, 1B, and 2.

7.4(B) Status Update Schedule

If the attending physician does not recertify the qualifications for a status according to the time frames in Table 7-1: *Heart Status and Laboratory Value Update Schedule*, then the candidate's Status 1A will expire and the candidate will be downgraded to Status 1B. If the candidate's medical condition does not qualify for Status 1A or Status 1B, then the attending physician must classify the candidate as Status 2 or 7. Prior to downgrading any candidates upon expiration of any term for any status or exception, the OPTN Contractor will notify the candidate's Transplant Program.

Table 7-1: Heart Status and Laboratory Value Update Schedule

If the candidate is...	Then the status is valid for...	And the qualification must be recertified by an attending physician every...
Adult Status 1A(1)	30 days	n/a: this status may not be extended beyond 30 days. 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 Status 1A classification.
Adult Status 1A(2-4)	14 days	14 days from the date of the candidate's initial classification as Status 1A
Adult Status 1A(5)	7 days	7 days from the date of the candidate's initial classification as Status 1A
Adult Status 1B	Indefinitely	n/a: this status does not require any recertification
Adult Status 2	Indefinitely	n/a: this status does not require any recertification
Pediatric Status 1A(1-5)	14 days	14 days from the date of the candidate's initial classification as Status 1A
Pediatric Status 1B	Indefinitely	n/a: this status does not require any recertification
Pediatric Status 2	Indefinitely	n/a: this status does not require any recertification

Additionally, if a candidate's medical condition changes and makes the criterion used to justify that candidate's status is no longer accurate, then the candidate's Transplant Program must update the candidate's classification and report updated information to the OPTN Contractor within 24 hours of the change in medical condition.

7.4(C) Blood Typing for Heart Allocation

Heart candidate and donor blood types are matched according to *Table 7-2: Blood Typing for Heart Allocation*. Fields with a "●" indicate primary blood type matches. Fields with a "◐" indicate secondary blood type matches. Fields with a "○" indicate incompatible blood type matches.

Table 7-2: Blood Typing for Heart Allocation

Donor's Blood Type	Candidate is O	Candidate is A	Candidate is B	Candidate is AB
O	●	◐	●	◐
A	○	●	○	●
B	○	○	●	●
AB	○	○	○	●

7.4(D) Allocation of Domino Donor Hearts

If a Transplant Program recovers the native heart of a heart-lung recipient, then the Transplant Program that recovers this heart may transplant it into a second candidate registered at the same Transplant Program. The Transplant Program must select the second candidate according to Policy 7.5 *Heart Allocation Classifications and Rankings*.

If, however, the Transplant Program does not transplant the recovered, native heart into one of its candidates, then the heart must be allocated according to Policy 7.5 *Heart Allocation Classifications and Rankings*. For the purposes of allocating these hearts, the local unit of allocation is the local unit where the native heart of the heart-lung transplant recipient is recovered.

7.5 Heart Allocation Classifications and Rankings

7.5(A) Allocation of Hearts from Donors Aged 18 years and older

Hearts from donors aged 18-years or older are allocated to candidates in the following order:

Table 7-3: Allocation of Hearts from Donors Aged At Least 18 Years

Classification	Candidates that are within the...	And are...
1.	Donor hospital's local unit	Adult or Pediatric Status 1A and primary blood type match with the donor
2.	Donor hospital's local unit	Adult or Pediatric Status 1A and secondary blood type match with the donor
3.	Donor hospital's local unit	Adult or Pediatric Status 1B and primary blood type match with the donor
4.	Donor hospital's local unit	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.	Donor hospital's local unit	Adult or Pediatric Status 2 and primary blood type match with the donor
10.	Donor hospital's local unit	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

Classification	Candidates that are within the...	And are...
		type match with the donor
14.	Zone B	Adult or Pediatric Status 1B and secondary blood type match with the donor
15.	Zone A	Adult or Pediatric Status 2 and primary blood type match with the donor
16.	Zone A	Adult or Pediatric Status 2 and secondary blood type match with the donor
17.	Zone B	Adult or Pediatric Status 2 and primary blood type match with the donor
18.	Zone B	Adult or Pediatric Status 2 and secondary blood type match with the donor
19.	Zone C	Adult or Pediatric Status 1A and primary blood type match with the donor
20.	Zone C	Adult or Pediatric Status 1A and secondary blood type match with the donor
21.	Zone C	Adult or Pediatric Status 1B and primary blood type match with the donor
22.	Zone C	Adult or Pediatric Status 1B and secondary blood type match with the donor
23.	Zone C	Adult or Pediatric Status 2 and primary blood type match with the donor
24.	Zone C	Adult or Pediatric Status 2 and secondary blood type match with the donor
25.	Zone D	Adult or Pediatric Status 1A and primary blood type match with the donor
26.	Zone D	Adult or Pediatric Status 1A and secondary blood type match with the donor
27.	Zone D	Adult or Pediatric Status 1B and primary blood type match with the donor
28.	Zone D	Adult or Pediatric Status 1B and secondary blood type match with the donor
29.	Zone D	Adult or Pediatric Status 2 and primary blood type match with the donor
30.	Zone D	Adult or Pediatric Status 2 and secondary blood type match with the donor
31.	Zone E	Adult or Pediatric Status 1A and primary blood type match with the donor
32.	Zone E	Adult or Pediatric Status 1A and secondary blood type match with the donor
33.	Zone E	Adult or Pediatric Status 1B and primary blood type match with the donor
34.	Zone E	Adult or Pediatric Status 1B and secondary blood type match with the donor
35.	Zone E	Adult or Pediatric Status 2 and primary blood type match with the donor
36.	Zone E	Adult or Pediatric Status 2 and secondary blood

Classification	Candidates that are within the...	And are...
		type match with the donor
37.	Donor hospital's local unit	Pediatric Status 1A and blood type incompatible with the donor
38.	Donor hospital's local unit	Pediatric Status 1B and blood type incompatible with the donor
39.	Zone A	Pediatric Status 1A and blood type incompatible with the donor
40.	Zone A	Pediatric Status 1B and blood type incompatible with the donor
41.	Donor hospital's local unit	Pediatric Status 2 and blood type incompatible with the donor
42.	Zone B	Pediatric Status 1A and blood type incompatible with the donor
43.	Zone B	Pediatric Status 1B and blood type incompatible with the donor
44.	Zone A	Pediatric Status 2 and blood type incompatible with the donor
45.	Zone B	Pediatric Status 2 and blood type incompatible with the donor
46.	Zone C	Pediatric Status 1A and blood type incompatible with the donor
47.	Zone C	Pediatric Status 1B and blood type incompatible with the donor
48.	Zone C	Pediatric Status 2 and blood type incompatible with the donor
49.	Zone D	Pediatric Status 1A and blood type incompatible with the donor
50.	Zone D	Pediatric Status 1B and blood type incompatible with the donor
51.	Zone D	Pediatric Status 2 and blood type incompatible with the donor
52.	Zone E	Pediatric Status 1A and blood type incompatible with the donor
53.	Zone E	Pediatric Status 1B and blood type incompatible with the donor
54.	Zone E	Pediatric Status 2 and blood type incompatible with the donor
55.	Donor hospital's local unit	<i>In utero</i> and primary blood type match with the donor
56.	Donor hospital's local unit	<i>In utero</i> and secondary blood type match with the donor
57.	Zone A	<i>In utero</i> and primary blood type match with the donor
58.	Zone A	<i>In utero</i> and secondary blood type match with the donor
59.	Zone B	<i>In utero</i> and primary blood type match with the

Classification	Candidates that are within the...	And are...
		donor
60.	Zone B	<i>In utero</i> and secondary blood type match with the donor
61.	Zone C	<i>In utero</i> and primary blood type match with the donor
62.	Zone C	<i>In utero</i> and secondary blood type match with the donor
63.	Zone D	<i>In utero</i> and primary blood type match with the donor
64.	Zone D	<i>In utero</i> and secondary blood type match with the donor
65.	Zone E	<i>In utero</i> and primary blood type match with the donor
66.	Zone E	<i>In utero</i> and secondary blood type match with the donor
67.	Donor hospital's local unit	<i>In utero</i> and blood type incompatible with the donor
68.	Zone A	<i>In utero</i> and blood type incompatible with the donor
69.	Zone B	<i>In utero</i> and blood type incompatible with the donor
70.	Zone C	<i>In utero</i> and blood type incompatible with the donor
71.	Zone D	<i>In utero</i> and blood type incompatible with the donor
72.	Zone E	<i>In utero</i> and blood type incompatible with the donor

7.5(B) Allocation of Hearts from Donors Aged Less Than 18 Years

Hearts from donors aged less than 18 years are allocated to candidates in the following order:

Table 7-4: Allocation of Hearts from Donors Aged Less Than 18 Years

Classification	Candidates that are within the...	And are...
1.	Donor hospital's local unit or Zone A	Pediatric Status 1A and primary blood type match with the donor
2.	Donor hospital's local unit or Zone A	Pediatric Status 1A and secondary blood type match with the donor
3.	Donor hospital's local unit	Adult Status 1A and primary blood type match with the donor
4.	Donor hospital's local unit	Adult Status 1A and secondary blood type match with the donor
5.	Donor hospital's local unit or Zone A	Pediatric Status 1B and primary blood type match with the donor

Classification	Candidates that are within the...	And are...
6.	Donor hospital's local unit or Zone A	Pediatric Status 1B and secondary blood type match with the donor
7.	Donor hospital's local unit	Adult Status 1B and primary blood type match with the donor
8.	Donor hospital's local unit	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.	Donor hospital's local unit	Pediatric Status 2 and primary blood type match with the donor
14.	Donor hospital's local unit	Pediatric Status 2 and secondary blood type match with the donor
15.	Donor hospital's local unit	Adult Status 2 and primary blood type match with the donor
16.	Donor hospital's local unit	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, and registered under 18 years of age
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
51.	Zone D	Adult Status 1B and primary blood type match with the donor

Classification	Candidates that are within the...	And are...
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, and registered under 18 years of age
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
69.	Donor hospital's local unit or Zone A	Pediatric Status 1A and blood type incompatible with the donor
70.	Donor hospital's local unit or Zone A	Pediatric Status 1B and blood type incompatible with the donor
71.	Donor hospital's local unit	Pediatric Status 2 and blood type incompatible with the donor
72.	Zone B	Pediatric Status 1A and blood type incompatible with the donor
73.	Zone B	Pediatric Status 1B and blood type incompatible with the donor
74.	Zone C	Pediatric Status 1A and blood type incompatible

Classification	Candidates that are within the...	And are...
		with the donor
75.	Zone C	Pediatric Status 1B and blood type incompatible with the donor
76.	Zone D	Pediatric Status 1A and blood type incompatible with the donor
77.	Zone D	Pediatric Status 1B and blood type incompatible with the donor
78.	Zone E	Pediatric Status 1A and blood type incompatible with the donor
79.	Zone E	Pediatric Status 1B and blood type incompatible with the donor
80.	Donor hospital's local unit or Zone A	Primary blood type match with the donor and <i>in utero</i>
81.	Donor hospital's local unit or Zone A	Secondary blood type match with the donor and <i>in utero</i>
82.	Donor hospital's local unit or Zone A	Blood type incompatible with the donor and <i>in utero</i>
83.	Zone B	Primary blood type match with the donor and <i>in utero</i>
84.	Zone B	Secondary blood type match with the donor and <i>in utero</i>
85.	Zone B	Blood type incompatible with the donor and <i>in utero</i>
86.	Zone C	Primary blood type match with the donor and <i>in utero</i>
87.	Zone C	Secondary blood type match with the donor and <i>in utero</i>
88.	Zone C	Blood type incompatible with the donor and <i>in utero</i>
89.	Zone D	Primary blood type match with the donor and <i>in utero</i>
90.	Zone D	Secondary blood type match with the donor and <i>in utero</i>
91.	Zone D	Blood type incompatible with the donor and <i>in utero</i>
92.	Zone E	Primary blood type match with the donor and <i>in utero</i>
93.	Zone E	Secondary blood type match with the donor and <i>in utero</i>
94.	Zone E	Blood type incompatible with the donor and <i>in utero</i>

7.6 Administrative Rules

Reserved

7.7 Variances

Reserved

Notes

- For membership and personnel requirements for heart programs, see the OPTN Bylaws, Appendix H.
- For heart acceptance criteria, see Policy 5.1(D)*Heart Acceptance Criteria*.
- For potential heart donor testing requirements, see Policy 2.4: *Potential Donors Information* and 2.4(C)(II): *Heart*.
- For the Center for Disease Control and Prevention's (CDC) clinical growth chart, see http://www.cdc.gov/growthcharts/clinical_charts.htm.

History

Policy 3.7: Allocation of Thoracic Organs: 11/16/2000; 11/15/2001; 6/27/2002; 11/14/2002; 6/26/2003; 11/20/2003; 6/24/2004; 11/18/2004; 6/23/2005; 11/17/2005; 6/29/2006; 9/20/2006; 12/13/2006; 3/23/2007; 6/19/2008; 11/16/2009; 11/8/2010; *Policy 7: Allocation of Hearts*: 11/2012 (eff. 2/1/2013)

Notes

Reserved.

Policy 8: Allocation of Intestines

8.1	Statuses	97
8.2	Points	97
8.3	Waiting Time	98
8.4	Classification Notes	98
8.5	Intestine Allocation Classifications and Rankings	98
8.6	Administrative Rules	98
8.7	Variances	99

Introduction

This Policy contains requirements for the allocation of intestines and certain rules regarding intestine candidate registrations.

Policy Statement

8.1 Statuses

Transplant Programs must assign each candidate to one of the following status codes according to the medical condition of the candidate.

- Status 1: A candidate may be Status 1 if the candidate meets *any* of the following conditions: liver function test abnormalities; no longer have vascular access through the subclavian, jugular, or femoral veins for intravenous feeding; or has other medical indications that warrant intestinal organ transplantation on an urgent basis.
- Status 2: Any active candidate that does not meet the criteria for Status 1 must be registered as Status 2.
- Inactive: 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.

Transplant Programs must submit a *Status 1 Justification Form* to the OPTN Contractor to register a candidate's as Status 1. If the candidate's status changes from Status 1 to another status, then the Transplant Program must submit another *Status 1 Justification Form* to register the candidate as Status 1 again.

8.2 Points

Intestine candidates do not receive any points for priority of intestine allocation.

8.3 Waiting Time

Waiting time accrued by a candidate for an intestinal transplant also may be accrued for a liver-intestinal transplant, when it is determined that the candidate requires the multiple organs.

Inactive candidates will continue to accrue inactive waiting time up to a maximum of 30 days of inactive waiting time.

8.4 Classification Notes

8.4(A)(I) Sorting Within Each Classification

Within each allocation classification, candidates are sorted by waiting time.

8.5 Intestine Allocation Classifications and Rankings

Intestines are allocated to candidates in the following order:

Table 8-1: Allocation of Intestines

Classification	Candidates that are within the...	And are...
1.	Donor hospital's local unit	Status 1 and a blood type identical to the donor
2.	Donor hospital's local unit	Status 1 and a blood type compatible with the donor
3.	Donor hospital's local unit	Status 2 and a blood type identical to the donor
4.	Donor hospital's local unit	Status 2 and a blood type compatible with the donor
5.	Donor hospital's region	Status 1 and a blood type identical to the donor
6.	Donor hospital's region	Status 1 and a blood type compatible with the donor
7.	Donor hospital's region	Status 2 and a blood type identical to the donor
8.	Donor hospital'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

8.6 Administrative Rules

Reserved.

8.7 Variances

Reserved.

History

Policy 3.11: Intestinal Organ Allocation: 6/26/2003; 12/13/2006; 6/19/2008; Policy 8: Allocation of Intestines: 11/2012 (eff. 2/1/2013)

Notes

- *Reserved.*

Policy 9: Allocation of Kidneys

9.1	Calculated Panel Reactive Antibody	100
9.2	Exceptions	100
9.3	Points	101
9.4	Waiting Time	102
9.5	Classification Notes	102
9.6	Kidney Allocation Classifications and Rankings	104
9.7	Administrative Rules	114
9.8	Variances	115

Introduction

This Policy contains requirements for the allocation of kidneys and certain rules regarding kidney candidate registrations.

Policy Statement

9.1 Calculated Panel Reactive Antibody

A candidate's calculated panel reactive antibody (CPRA) is based upon the candidate's unacceptable antigens. In order to be classified as an unacceptable antigen, the Transplant Hospital must do *both* of the following:

- Define the criteria for unacceptable antigens that are considered as contraindications for transplantation
- Base unacceptable antigens on laboratory detection of HLA specific antibodies using at least one solid phase immunoassay using purified HLA molecules.

Transplant Hospitals may establish criteria for additional unacceptable antigens including, but not limited to, with multiple unexpected positive crossmatches. The CPRA will be calculated automatically when a Transplant Hospital reports unacceptable antigens to the OPTN Contractor. The 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.

9.2 Exceptions

After receiving an organ offer from a donor in the same local unit, a candidate's physician may use his medical judgment to transplant a candidate out of sequence due to medical urgency.

If there is more than one kidney transplant program in the local unit, then the candidate's physician must receive agreement from the other kidney transplant programs in the local unit and must maintain documentation of this decision in the candidate's medical record.

9.3 Points

Candidates receive points according to Table 9-1: *Kidney Points*.

Table 9-1: Kidney Points

If the candidate is...	And the following allocation sequence is used...	Then the candidate receives this many points...
Registered	A, B, C, D, E, F	1 point per year of waiting time
Registered	A, B, C, D, E, F	1 x ((rank of candidate's waiting time within the geographical distribution unit, from smallest to largest) / (number of candidates within the geographical distribution unit))
Aged 0-10 years old at the time of the match run and a zero antigen mismatch with the donor	A, B, C, D	4 points
Aged 0-10 years old at the time of the match run and the donor is aged <35	A, C	1 point
Aged 0-10 years old at the time of the match run and a zero antigen mismatch with a DCD donor that is aged <35 (regional and national levels of allocation only)	C	4 points
Aged 11-17 years old at the time of the match run and a zero antigen mismatch with the donor	A, B, C, D	3 points
Aged 11-17 years old at the time of the match run and a zero antigen	C	3 points

mismatch with a DCD donor aged <35 (regional and national levels of allocation only)		
A prior living donor, according to Policy 9.5(E): <i>Prior Living Organ Donors</i>	A, B, C, D	4 points
CPRA ≥ 80%	A, B, C, D	4 points
Share a match with the donor at one HLA-DR loci	A, B, C, D	1 point
Share a match with the donor at two HLA-DR loci	A, B, C, D	2 points

9.4 Waiting Time

If a candidate registers for a kidney after becoming 18 years of age, then the candidate’s waiting time will begin as soon as the candidate is both registered and meets any of the following criteria:

1. The candidate’s measured creatinine clearance, calculated creatinine clearance, or glomerular filtration rate (GFR) becomes less than or equal to 20 ml/min.
2. The candidate began dialysis that is regularly administered to an end stage renal disease patient in a hospital based, independent non-hospital based, or home setting.

If the candidate met either of the above two conditions prior to registration, waiting time will begin at the date and time of registration.

If a candidate registers for a kidney before becoming 18 years of age, the candidate’s waiting time will begin on the date of registration regardless of clinical characteristics.

9.5 Classification Notes

9.5(A) Expanded and Standard Donor Classifications

Kidneys from deceased donors are classified as either being from a standard criteria donor (SCD) or an expanded criteria donor (ECD). To be classified as an ECD, the donor must meet the criteria in Table 9-2: *ECD Criteria*. All other donors are classified as SCD.

Table 9-2: ECD Criteria

	Donor Characteristics	Donor <50 years of age	Donor 50-59 years of age	Donor ≥60 years of age
A	Cardiovascular accident as cause of death	SCD	SCD	ECD

B	History of hypertension (at any time)	SCD	SCD	ECD
C	Creatinine >1.5 mg/dl	SCD	SCD	ECD
	Any combination of the above characteristics (A-C)	SCD	ECD	ECD
	None of the above characteristics	SCD	SCD	ECD

For purposes of determining SCD/ECD designations, the most recent creatinine at the time of kidney placement is used.

9.5(B) Consent for ECD Kidneys

Prior to registration, transplant programs must obtain consent from candidates who are willing to accept an ECD kidney.

9.5(C) Sorting Within Each Classification

Within each classification, potential recipients of standard criteria kidneys are sorted by total points (highest to lowest).

Within each classification, potential recipients of expanded criteria kidneys are sorted by waiting time (longest to shortest).

9.5(D) Blood group Compatibility

Transplants are restricted by blood group in certain circumstances.

1. Blood group O kidneys must be transplanted only into blood group O candidates.
2. Exception: In cases of zero antigen mismatches, blood group O kidneys may be transplanted into candidates who have blood groups other than O.
3. Blood group B kidneys must be transplanted only into blood group B candidates
4. Exception: In cases of zero antigen mismatches, blood group O kidneys may be transplanted into candidates who have blood groups other than O.

9.5(E) Prior Living Organ Donors

A candidate will be classified as a prior living donor and receive priority for each kidney registration if *all* of the following conditions are met:

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

- The name of the recipient of the donated organ or organ segment
- The recipient’s Transplant Hospital
- The date of the transplant of the donated organ.

9.5(F) Highest Scoring High CPRA

To determine which candidates are in the “Highest Scoring High CPRA” classification:

1. Candidates are first sorted by total points (highest to lowest)
2. Candidates are then evaluated in order, to identify the first candidate with a CPRA less than 80%
3. Any candidate that has more points than the candidate identified in step two is included in the “Highest Scoring High CPRA” classification. These candidates will have a CPRA that is greater than or equal to 80%.

9.5(G) Expanded Criteria Donors

If an OPO 1) is allocating an expanded criteria donor (ECD) donor kidney and 2) does not identify, within six hours of post cross clamping of the donor aorta, any potential recipients that are within the donor’s local unit and are willing to receive an ECD kidney then the OPO must offer the kidney to potential recipients in the donor’s region according to Policy 9.6(E) *Allocation of Kidneys from Expanded Criteria Donors* or Policy 9.6(F) *Allocation of Kidneys from Expanded Criteria Donors Who Are Also Donation After Circulatory death Donors*.

9.6 Kidney Allocation Classifications and Rankings

9.6(A) Allocation of Kidneys from Donors Aged Less than 35 Years

Kidneys from donors aged less than 35 years are allocated to candidates in the following order:

Table 9-3: Allocation of Kidneys from Donors Less Than 35

Classification	Candidates that are within the...	And are...
Classifications 1-10 apply to donors with any blood type		
1.	Donor hospital's local unit	Zero antigen mismatch and a blood type identical with the donor
2.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, 80%-100% CPRA, and a blood type identical with the donor
3.	Donor hospital's region	Zero antigen mismatch, 80%-100% CPRA, and a blood type identical with the donor
4.	Nation	Zero antigen mismatch, 80%-100% CPRA, and a blood type identical with the donor
5.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type identical with the donor

Classification	Candidates that are within the...	And are...
6.	Donor hospital's region	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type identical with the donor
7.	Nation	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type identical with the donor
8.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, CPRA ≥ 20% but < 80%, and a blood type identical with the donor
9.	Donor hospital's region	Zero antigen mismatch, CPRA ≥ 20% but < 80%, and a blood type identical with the donor
10.	Nation	Zero antigen mismatch, CPRA ≥ 20% but < 80%, and a blood type identical with the donor
Classifications 11-20 apply only for donors with blood type O		
11.	Donor hospital's local unit	Zero antigen mismatch and blood type B,
12.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, 80%-100% CPRA, and blood type B
13.	Donor hospital's region	Zero antigen mismatch, 80%-100% CPRA and blood type B
14.	Nation	Zero antigen mismatch, 80%-100% CPRA and blood type B
15.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and blood type B
16.	Donor hospital's region	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and blood type B
17.	Nation	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and blood type B
18.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, CPRA ≥ 20% but < 80%, and blood type B
19.	Donor hospital's region	Zero antigen mismatch, CPRA ≥ 20% but < 80%, and blood type B
20.	Nation	Zero antigen mismatch, CPRA ≥ 20% but < 80%, and blood type B
Classifications 21-41 apply to donors with any blood type		

Classification	Candidates that are within the...	And are...
21.	Donor hospital's local unit	Zero antigen mismatch and a blood type compatible with the donor
22.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, 80%-100% CPRA, and a blood type compatible with the donor
23.	Donor hospital's region	Zero antigen mismatch, 80%-100% CPRA, and a blood type compatible with the donor
24.	Nation	Zero antigen mismatch, 80%-100% CPRA, and a blood type compatible with the donor
25.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type compatible with the donor
26.	Donor hospital's region	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type compatible with the donor
27.	Nation	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type compatible with the donor
28.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, CPRA ≥ 20% but < 80%, and a blood type compatible with the donor
29.	Donor hospital's region	Zero antigen mismatch, CPRA ≥ 20% but < 80%, and a blood type compatible with the donor
30.	Nation	Zero antigen mismatch, CPRA ≥ 20% but < 80%, and a blood type compatible with the donor
31.	Donor hospital's local unit	Prior living organ donors
32.	Donor hospital's local unit	Highest scoring high CPRA
33.	Donor hospital's local unit	Candidates registered prior to turning 18 years old
34.	Any OPOs owed at least 2 payback kidneys	All remaining candidates
35.	Donor hospital's local unit	All remaining candidates
36.	Donor hospital's region	Highest scoring high CPRA
37.	Donor hospital's region	Candidates registered prior to turning 18 years old
38.	Donor hospital's region	All remaining candidates

Classification	Candidates that are within the...	And are...
39.	Nation	Highest scoring high CPRA
40.	Nation	Candidates registered prior to turning 18 years old
41.	Nation	All remaining candidates

9.6(B) Allocation of Kidneys from Standard Criteria Donors 35 Years and Older

Kidneys from standard criteria donors aged 35 years or older are allocated to candidates in the following order:

Table 9-4: Allocation of Kidneys from Donors Age 35 and Older

Classification	Candidates that are within the...	And are...
Classifications 1-10 apply to donors with any blood type		
1.	Donor hospital's local unit	Zero antigen mismatch and a blood type identical with the donor
2.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, 80%-100% CPRA, and a blood type identical with the donor
3.	Donor hospital's region	Zero antigen mismatch, 80%-100% CPRA, and a blood type identical with the donor
4.	Nation	Zero antigen mismatch, 80%-100% CPRA, and a blood type identical with the donor
5.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type identical with the donor
6.	Donor hospital's region	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type identical with the donor
7.	Nation	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type identical with the donor
8.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, CPRA ≥ 20% but < 80%, and a blood type identical with the donor

Classification	Candidates that are within the...	And are...
9.	Donor hospital's region	Zero antigen mismatch, CPRA \geq 20% but < 80%, and a blood type identical with the donor
10.	Nation	Zero antigen mismatch, CPRA \geq 20% but < 80%, and a blood type identical with the donor
Classifications 11-20 apply only for donors with blood type O		
11.	Donor hospital's local unit	Zero antigen mismatch and blood type blood type B
12.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, 80%-100% CPRA and blood type B
13.	Donor hospital's region	Zero antigen mismatch, 80%-100% CPRA and blood type B
14.	Nation	Zero antigen mismatch, 80%-100% CPRA and blood type B
15.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and blood type B
16.	Donor hospital's region	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and blood type B
17.	Nation	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and blood type B
18.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, CPRA \geq 20% but < 80%, and blood type B
19.	Donor hospital's region	Zero antigen mismatch, CPRA \geq 20% but < 80%, and blood type B
20.	Nation	Zero antigen mismatch, CPRA \geq 20% but < 80%, and blood type B
Classifications 21-35 apply to donors with any blood type		
21.	Donor hospital's local unit	Zero antigen mismatch and a blood type compatible with the donor
22.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, 80%-100% CPRA, and a blood type compatible with the donor
23.	Donor hospital's region	Zero antigen mismatch, 80%-100% CPRA, and a blood type compatible with the donor

Classification	Candidates that are within the...	And are...
24.	Nation	Zero antigen mismatch, 80%-100% CPRA, and a blood type compatible with the donor
25.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type compatible with the donor
26.	Donor hospital's region	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type compatible with the donor
27.	Nation	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type compatible with the donor
28.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, CPRA ≥ 20% but < 80%, and a blood type compatible with the donor
29.	Donor hospital's region	Zero antigen mismatch, CPRA ≥ 20% but < 80%, and a blood type compatible with the donor
30.	Nation	Zero antigen mismatch, CPRA ≥ 20% but < 80%, and a blood type compatible with the donor
31.	Donor hospital's local unit	Prior living organ donors
32.	Any OPOs owed at least 2 payback kidneys	All remaining candidates
33.	Donor hospital's local unit	All remaining candidates
34.	Donor hospital's region	All remaining candidates
35.	Nation	All remaining candidates

9.6(C) Allocation of Kidneys from Donation After Circulatory death Donors Aged less than 35 years

Kidneys from donors aged less than 35 years who donate after circulatory death are allocated to candidates in the following order:

Table 9-5: Allocation of Kidneys from DCD Donors <35

Classification	Candidates that are within the...	And are...
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Classification	Candidates that are within the...	And are...
Classification 1 applies to donors with any blood type		
1.	Donor hospital's local unit	Zero Antigen mismatch and a blood type identical with the donor
Classification 2 applies only for donors with blood type O		
2.	Donor hospital's local unit	Zero Antigen mismatch and blood type B
Classifications 3-14 apply to donors with any blood type		
3.	Donor hospital's local unit	Zero antigen mismatch and a blood type compatible with the donor
4.	Donor hospital's local unit	Prior living organ donors
5.	Donor hospital's local unit	Highest scoring high CPRA
6.	Donor hospital's local unit	Candidates registered prior to turning 18 years old
7.	Any OPOs owed at least 2 payback kidneys	All remaining candidates
8.	Donor hospital's local unit	All remaining candidates
9.	Donor hospital's region	Highest scoring high CPRA
10.	Donor hospital's region	Candidates registered prior to turning 18 years old
11.	Donor hospital's region	All remaining candidates
12.	Nation	Highest scoring high CPRA
13.	Nation	Candidates registered prior to turning 18 years old
14.	Nation	All remaining candidates

9.6(D) Allocation of Kidneys from Donation After Circulatory death Donors Aged 35 Years and Older

Kidneys from donors who donate after circulatory death and are 35 years old or older are allocated in the following sequence.

Table 9-6: Allocation of Kidneys from DCD Donors >=35 years old

Classification	Candidates that are within the...	And are...
Classification 1 applies to donors with any blood type		

1.	Donor hospital's local unit	Zero antigen mismatch and a blood type identical with the donor
Classification 2 applies only for donors with blood type O		
2.	Donor hospital's local unit	Zero antigen mismatch and blood type B
Classifications 3-8 apply to donors with any blood type		
3.	Donor hospital's local unit	Zero antigen mismatch and a blood type compatible with the donor
4.	Donor hospital's local unit	Prior living organ donors
5.	Any OPOs owed at least 2 payback kidneys	All remaining candidates
6.	Donor hospital's local unit	All remaining candidates
7.	Donor hospital's region	All remaining candidates
8.	Nation	All remaining candidates

9.6(E) Allocation of Kidneys from Expanded Criteria Donors

Kidneys from expanded criteria donors are allocated to candidates in the following order:

Table 9-7: Allocation of Kidneys from Expanded Criteria Donors

Classification	Candidates that are within the...	And are...
Classifications 1-10 apply to donors with any blood type		
1.	Donor hospital's local unit	Zero antigen mismatch and a blood type identical with the donor
2.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, 80%-100% CPRA, and a blood type identical with the donor
3.	Donor hospital's region	Zero antigen mismatch, 80%-100% CPRA, and a blood type identical with the donor
4.	Nation	Zero antigen mismatch, 80%-100% CPRA, and a blood type identical with the donor
5.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type identical with the donor
6.	Donor hospital's region	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type identical with the donor
7.	Nation	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type identical with the donor
8.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, CPRA ≥ 20% but < 80%, and a blood type identical with the donor

Classification	Candidates that are within the...	And are...
9.	Donor hospital's region	Zero antigen mismatch, CPRA \geq 20% but < 80%, and a blood type identical with the donor
10.	Nation	Zero antigen mismatch, CPRA \geq 20% but < 80%, and a blood type identical with the donor
Classifications 11-20 apply only for donors with blood type O		
11.	Donor hospital's local unit	Zero antigen mismatch and blood type B
12.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, 80%-100% CPRA, and blood type B
13.	Donor hospital's region	Zero antigen mismatch, 80%-100% CPRA, and blood type B
14.	Nation	Zero antigen mismatch, 80%-100% CPRA, and blood type B
15.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and blood type B
16.	Donor hospital's region	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and blood type B
17.	Nation	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and blood type B
18.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, CPRA \geq 20% but < 80%, and blood type B
19.	Donor hospital's region	Zero antigen mismatch, CPRA \geq 20% but < 80%, and blood type B
20.	Nation	Zero antigen mismatch, CPRA \geq 20% but < 80%, and blood type B
Classifications 21-34 apply to donors with any blood type		
21.	Donor hospital's local unit	Zero antigen mismatch and a blood type compatible with the donor
22.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, 80%-100% CPRA, and a blood type compatible with the donor
23.	Donor hospital's region	Zero antigen mismatch, 80%-100% CPRA, and a blood type compatible with the donor
24.	Nation	Zero antigen mismatch, 80%-100% CPRA, and a blood type compatible with the donor
25.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type compatible with the donor

Classification	Candidates that are within the...	And are...
26.	Donor hospital's region	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type compatible with the donor
27.	Nation	Zero antigen mismatch, younger than 18 years old at time of match, CPRA < 80%, and a blood type compatible with the donor
28.	Any OPOs owed at least 2 payback kidneys	Zero antigen mismatch, CPRA ≥ 20% but < 80%, and a blood type compatible with the donor
29.	Donor hospital's region	Zero antigen mismatch, CPRA ≥ 20% but < 80%, and a blood type compatible with the donor
30.	Nation	Zero antigen mismatch, CPRA ≥ 20% but < 80%, and a blood type compatible with the donor
31.	Any OPOs owed at least 2 payback kidneys	All remaining candidates
32.	Donor hospital's local unit	All remaining candidates
33.	Donor hospital's region	All remaining candidates
34.	Nation	All remaining candidates

9.6(F) Allocation of Kidneys from Expanded Criteria Donors Who Are Also Donation After Circulatory death Donors

Kidneys from expanded criteria donors who donate after circulatory death are allocated to candidates in the following order:

Table 9-8: Allocation of Kidneys from ECD/DCD Donors

Classification	Candidates that are within the...	And are...
Classification 1 applies to donors with any blood type.		
1.	Donor hospital's local unit	Zero antigen mismatch and a blood type identical with the donor
Classification 2 applies only to donors with blood type O		
2.	Donor hospital's local unit	Zero antigen mismatch and blood type B
Classifications 3-7 apply to donors with any blood type		
3.	Donor hospital's local unit	Zero antigen mismatch and a blood type compatible with the donor
4.	Any OPOs owed at least 2 payback kidneys	All remaining candidates
5.	Donor hospital's	All remaining candidates

	local unit	
6.	Donor hospital's region	All remaining candidates
7.	Nation	All remaining candidates

9.6(G) Double Kidney Allocation

An OPO must offer kidneys individually through one of the allocation sequences in Policies 9.6(A) – 9.6(E) before offering both kidneys to a single candidate unless the 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%.

9.7 Administrative Rules

9.7(A) Mandatory Sharing of Zero Antigen Mismatched Kidneys

Kidneys shared as zero antigen mismatches must be offered according to Table 9-9: *Organ Offer Limit*.

Table 9-9: Organ Offer Limit

If the donor is...	Then the OPO must offer the kidneys within this many hours of procurement...	And must make at least this many offers to identified zero antigen mismatch candidates...
SCD	8 hours	10
ECD	4 hours	5

9.7(B) Payback Requirements

OPOs are required to payback a kidney if a Transplant Program in the OPO's local unit accepts a kidney from another OPO due to *any* of the following reasons:

- Zero antigen mismatch,
- A voluntary arrangement in which the kidney is shared with another organ for the same recipient,
- A voluntary arrangement in which the candidate has a CPRA \geq 80% and a negative preliminary crossmatch.

If an OPO has a payback debt, the OPO must offer for payback any kidney from a donor between the ages of six and sixty, with the same blood type as the kidney which incurred the payback obligation, and are not from a DCD donor. An OPO may offer any other kidney for payback.

The OPTN Contractor manages the payback accounting system. When a payback kidney is identified, the OPTN Contractor will offer it to OPOs waiting for at least two kidneys of the same blood type as the payback kidney. The OPTN Contractor will offer the kidney to OPOs that meet these criteria in the order of the longest single outstanding debt.

OPOs are only allowed to accumulate nine kidney payback debts for all blood types combined. OPOs that accumulate six or more payback obligations in a single blood group may not accept a kidney from a donor of the same blood group as part of a voluntary arrangement. The OPO may retain the kidney for transplant only when it is transplanted with a heart, lung, liver, or pancreas into a single recipient.

OPOs that accumulate six or more kidney payback debts, within the blood type of a donor procured within the OPO's local unit, may not defer the obligation to offer the kidneys from this donor in satisfaction of payback debts unless the kidney is offered with a heart, lung, liver, or pancreas.

9.7(C) Choice of Right Versus Left Donor Kidney

The recipient Transplant Hospital offered a kidney for a candidate based upon priority on the waiting list may select which of the two kidneys it will receive, if both kidneys from the donor are transplantable.

However, when a kidney is offered to a zero antigen mismatched candidate, or for a kidney and non-renal organ transplant, the Host OPO determines whether to offer the left or the right kidney .

9.7(D) Multi-Organ, Kidney/Non-Kidney Exception

If a kidney is procured for a multi-organ, kidney/non-kidney transplant, and the kidney/non-kidney transplant is not performed, then the kidney retained for that transplant must be immediately offered for zero antigen mismatched candidates. This exception does not apply to kidney-islet or kidney-pancreas transplants.

9.8 Variances

Reserved

History

Policy 3.5: Allocation of Deceased Kidneys: 11/16/2000; 6/28/2001; 11/15/2001; 6/27/2002; 11/14/2002; 6/26/2003; 11/20/2003; 11/20/2003; 6/24/2004; 11/18/2004; 6/23/2005; 11/17/2005; 6/29/2006/ 9/20/2006; 12/13/2006/ 3/23/2007; 9/17/2007; 6/19/2008; 6/21/2010; Policy 9: Allocation of Kidneys: 11/2012 (eff. 2/1/2013)

Notes

- For membership and personnel requirements for kidney programs, see the OPTN Bylaws, Appendix E.

Policy 10: Allocation of Livers

10.1	Statuses and Scores	117
10.2	Status and Score Exceptions	120
10.3	Points	130
10.4	Waiting Time	131
10.5	Classification Notes	131
10.6	Liver Allocation Classifications and Rankings	134
10.7	Administrative Rules	140
10.8	Variances	140

Introduction

This Policy contains requirements for the allocation of livers and certain rules regarding liver candidate registrations.

Policy Statement

10.1 Statuses and Scores

10.1(A) Adult Status 1A

A candidate may be classified as Adult Status 1A if the candidate registered on the waiting list before turning 18 years of age, has a life expectancy without a liver transplant of less than 7 days, is in the intensive care unit (ICU), and has at least *one* of the following conditions:

1. Fulminant hepatic failure, defined as the onset of hepatic encephalopathy within 8-weeks of the first symptoms of liver disease, and has at least *one* of the following criteria:
 - i. Ventilator dependent
 - ii. Requiring dialysis, continuous veno-venous hemodilution (CVVH), or continuous veno-venous hemodialysis (CVVD)
 - iii. International normalized ratio (INR) greater than 2.0.
2. Primary non-function of a transplanted liver within 7-days of implantation, evidenced by at least *one* of the following:
 - i. Aspartate aminotransferase (AST) greater than or equal to 3,000 U/L and at least *one* of the following
 - INR greater than or equal to 2.5
 - Arterial pH less than or equal to 7.30
 - Venous pH equal to 7.25

- Lactate greater than or equal to 4 mMol/L
 - ii. Anhepatic candidate.
- 3. Hepatic artery thrombosis (HAT) in a transplanted liver within 7 days of implantation, evidenced by at least *one* of the following:
 - i. Aspartate aminotransferase (AST) greater than or equal to 3,000 U/L and at least *one* of the following
 - INR greater than or equal to 2.5
 - Arterial pH less than or equal to 7.30
 - Venous pH equal to 7.25
 - Lactate greater than or equal to 4 mMol/L
 - ii. Anhepatic candidate.
- 4. Acute decompensated Wilson's disease.

All laboratory results for tests in paragraphs (2) and (3) above must be from the same blood sample taken 24 hours to 7 days after the transplant.

Candidates with primary non-function of a transplanted liver that are recipients of segmental liver grafts may be classified as Adult Status 1A if they meet the requirements in paragraph (2) regardless of whether they meet the AST requirement.

The candidate's Transplant Hospital must submit a status justification form to the OPTN Contractor when registering and recertifying the candidate as Status 1A.

10.1(B) Pediatric Status 1A

A candidate may be classified as Pediatric Status 1A if the candidate registered on the waiting list before turning 18 years of age, has a life expectancy without a liver transplant is less than 7 days, and has at least *one* of the following conditions:

1. Fulminant hepatic failure, defined as the onset of hepatic encephalopathy within 8 weeks of the first symptoms of liver disease and has at least *one* of the following criteria:
 - i. Ventilator dependent
 - ii. Requiring dialysis, continuous veno-venous hemodilution (CVVH), or continuous veno-venous hemodialysis (CVVD)
 - iii. International Normalized Ratio (INR) greater than 2.0.
2. Primary non-function of a transplant liver within 7 days of implantation, 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. *One* of the following:
 - Arterial pH less than or equal to 7.30
 - Venous pH equal to 7.25
 - Lactate greater than or equal to 4 mMol/L.

The above laboratory results must be from the same blood sample taken within 24 hours to 7 days after the transplant.

3. Hepatic artery thrombosis (HAT) in a transplanted liver within 14 days of implantation.
4. Acute decompensated Wilson's disease.

The candidate's Transplant Hospital must submit a status justification form to the OPTN Contractor when registering and recertifying the candidate as Status 1A.

A candidate can be Pediatric Status 1A regardless of the candidate's age if the candidate was registered on the waiting list before turning 18 years old.

10.1(C) Pediatric Status 1B

A candidate may be classified as Pediatric Status 1B if the candidate meets *all* of the following requirements:

1. Registers on the waiting list before turning 18 years of age
2. Has a MELD/PELD greater than 25
3. Has at least *one* of the following conditions:
 - i. Is on a mechanical ventilator
 - ii. Has gastrointestinal bleeding requiring more than 30 cc/kg of red blood cell replacement within the previous 24 hours
 - iii. Is a liver-intestine candidate and has gastrointestinal bleeding requiring more than 10 cc/kg of red blood cell replacement within the previous 24 hours
 - iv. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemodilution (CVVH), or continuous veno-venous hemodialysis (CVVD)
 - v. Has a Glasgow Coma Score (GCS) less than 10 within 48 hours of the Status 1B registration or extension
 - vi. Has a biopsy proven hepatoblastoma without evidence of metastatic disease.

The candidate's Transplant Hospital must submit a status justification form to the OPTN Contractor when registering and recertifying the candidate as Status 1B.

A candidate can be Pediatric Status 1B regardless of the candidate's age, if the candidate was registered on the waiting list before turning 18 years old.

10.1(D) Inactive

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 liver offers.

10.1(E) MELD Score

Candidates who are at least 12 years of age receive a Model for End Stage Liver Disease (MELD) score equal to:

$$10 \times ((0.957 \times \log_e(\text{creatinine mg/dL}) + 0.378 \times \log_e(\text{bilirubin mg/dL}) + (1.120 \times \log_e(\text{INR}) + 0.643))$$

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

- Candidates with a creatinine value greater than 4.0 mg/dL
- Candidates who received two or more dialysis treatments within the prior week
- Candidates who received 24 hours of Continuous Veno-Venous Hemodialysis (CVVHD) within the prior week.

Laboratory values less than 1.0 are rounded up to 1.0.

MELD scores are rounded half up to whole numbers and are limited to a maximum of 40 points.

When submitting laboratory values to the OPTN Contractor, Transplant Hospitals must submit the most recent results including the dates of the laboratory tests.

10.1(F) PELD Score

Candidates who are less than 12 years of age receive a Pediatric End Stage Liver Disease (PELD) score equal to:

$$10 \times ((0.436 \text{ (if age is less than 1 year)} + (0.480 \times \log_e(\text{bilirubin mg/dL}) + (1.857 \times \log_e(\text{INR}) + (0.667 \text{ (if candidate has growth failure)} - (0.687 \times \log_e(\text{albumin g/dL})))$$

PELD scores for candidates registered for liver transplant before the candidate turns one year old continue to include the value assigned for age until the candidate turns two years old.

All laboratory values less than 1.0 are rounded up to 1.0.

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

PELD scores are rounded half up to whole numbers.

When submitting lab values to the OPTN Contractor, Transplant Hospitals must submit the most recent results including the dates of the laboratory tests.

10.2 Status and Score Exceptions

10.2(A) Status Exceptions

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 still

register a candidate at the desired status. However, the Liver and Intestinal Organ Transplantation Committee will retrospectively review candidates registered as Status 1A or 1B that do not meet the criteria in Policies 3.6-2(A) – (C). The Liver and Intestinal Organ Transplantation Committee may refer these matters to the Membership and Professional Standards Committee (MPSC) for appropriate action according to Appendix L of the OPTN/UNOS Bylaws.

10.2(B) MELD/PELD Exception Applications

If a candidate's Transplant Program believes that a candidate's MELD/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/PELD exception. The application must:

1. Include a request for a MELD/PELD score higher than the candidate's calculated MELD/PELD score.
2. Justify why accepted medical criteria considers the candidate to have an urgency and potential for benefit comparable to that of other candidates with that score.

Each RRB must review applications within 21 days of receiving the application. If the RRB does not approve the application, the candidate's transplant physician may appeal the decision and the RRB must meet with the physician by telephonic or other electronic communication means to review the case.

If the RRB does not approve the application within 21 days of receiving the application, the candidate's transplant physician may register the candidate at the requested higher MELD/PELD score. However, the Liver and Intestinal Organ Transplantation Committee will retrospectively review these registrations and may refer these matters to the Membership and Professional Standards Committee (MPSC) for appropriate action according to Appendix L of the OPTN/UNOS Bylaws.

The RRB will report its decisions and justifications to the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees. The Committees will determine whether the MELD/PELD exceptions are consistently evaluated and decided within regions and across the country. Additionally, the Committees will determine the continued appropriateness of existing MELD criteria.

10.2(C) MELD/PELD Exception Extensions

Transplant Programs may apply for a MELD/PELD score equivalent to a ten percentage point increase in the risk of candidate mortality every three months as long as the candidate meets the original criteria in the exception application. Within three months of registering a candidate at a higher MELD/PELD score, the candidate's transplant physician must apply to the RRB for prospective review of the MELD/PELD score extension.

If the transplant physician applies more than three days prior to the due date in *Table 10-5: Liver status update schedule* and the RRB does not review the extension before the due date,

the previously approved MELD/PELD score will be extended until the RRB reviews the extension.

If the candidate’s transplant physician does not apply for an extension or the RRB does not approve the extension, then the candidate will receive a MELD/PELD score calculated on the most recent laboratory values at the time of the extension.

10.2(D) Specific MELD/PELD Exceptions

Candidates meeting the criteria in Table 10-1: *Specific MELD/PELD Exceptions* are eligible for MELD/PELD score exceptions. Additionally, a candidate may receive a higher MELD/PELD score if the Regional Review Board (RRB) has an existing agreement for the diagnosis. These agreements must be renewed on an annual basis.

Table 10-1: Specific MELD/PELD Exceptions

If the candidate has...	And the candidate's Transplant Program submits a clinical narrative to the OPTN Contractor with the following information...	Then the candidate...
Cholangiocarcinoma	<i>See Policy 10.2(F): Candidates with Cholangiocarcinoma</i>	Will receive a MELD score of 22 or PELD score of 28; then will receive the MELD/PELD equivalent to a 10 percentage point increase in the candidate mortality equivalent every three months.
A Need for a Combined Liver-Intestine Transplant	A candidate awaiting a combined liver-intestine transplant that is both 1. Active on both waiting lists 2. Older than 17 years of age.	Will receive a MELD/PELD score equivalent to a ten percentage point increase in the candidate’s mortality risk within three months.
A Need for a Combined Liver-Intestine Transplant	A candidate awaiting a combined liver-intestine transplant that is both 1. Active on both waiting lists 2. 17 years of age or younger.	Will receive a 23 point increase in MELD/PELD score.
Cystic Fibrosis	A forced expiratory volume at one second (FEV ₁) that falls below 40%	Will receive a MELD score of 22 or PELD score of 28; then will receive the MELD/PELD equivalent to a 10 percentage point increase in the candidate’s mortality risk every three months.

If the candidate has...	And the candidate's Transplant Program submits a clinical narrative to the OPTN Contractor with the following information...	Then the candidate...
Familial Amyloid Polyneuropathy (FAP)	All of the following: <ol style="list-style-type: none"> 1. Clear diagnosis of FAP 2. Echocardiogram showing the candidate has an ejection fraction greater than 40% 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 the MELD/PELD equivalent to a 10 percentage point increase in the candidate's mortality risk every three months.
Hepatic Artery Thrombosis (HAT)	Evidence within 14 days of transplantation but not meeting criteria for Status 1A in Policy 10-2(A)(3)	Will receive a MELD score of 40.
Hepatocellular Carcinoma (HCC)	<i>See Policy 10.2(G): Candidates with Hepatocellular Carcinoma</i>	<i>See Policy 10.2(G): Candidates with Hepatocellular Carcinoma</i>
Hepatopulmonary Syndrome (HPS)	All of the following: <ol style="list-style-type: none"> 1. Clinical evidence of portal hypertension 2. Evidence of a shunt 3. PaO₂ less than 60 mmHg on room air Additionally, the candidate should have no clinical evidence of underlying primary pulmonary disease.	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD/PELD equivalent to a 10 percentage point increase in the mortality risk every three months that the candidate's PaO ₂ remains under 60 mmHg.
Metabolic Disease	<i>See Policy 10.2(E): Pediatric Liver Candidates with Metabolic Diseases</i>	<i>See Policy 10.2(E): Pediatric Liver Candidates with Metabolic Diseases</i>

If the candidate has...	And the candidate's Transplant Program submits a clinical narrative to the OPTN Contractor with the following information...	Then the candidate...
Portopulmonary Syndrome	A mean pulmonary arterial pressure (MPAP) below 35 mmHg following intervention. Additionally, the diagnosis should include <i>all</i> of the following: <ol style="list-style-type: none"> 1. Initial mean pulmonary arterial pressure (MPAP) level 2. Initial pulmonary vascular resistance (PVR) level 3. Initial transpulmonary gradient 4. Documentation of treatment 5. Post-treatment MPAP less than 35 mmHg 6. Post treatment PVR less than 400 dynes/sec/cm⁵ 	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD/PELD equivalent to a 10 percentage point increase in the mortality risk every three months ever three months that a repeat heart catheterization confirms that the mean pulmonary arterial pressure (MPAP) remains below 35 mmHg.
Primary Hyperoxaluria	All of the following: <ol style="list-style-type: none"> 1. Alanine glyoxylate aminotransferase (AGT) deficiency proven by liver biopsy 2. Registered for a combined liver-kidney transplant 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, for six weeks or more 	Will receive a MELD score of 28 or PELD score of 41; then will receive a MELD/PELD equivalent to a 10 percentage point increase in the mortality risk every three months.

10.2(E) 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 another 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, the transplant physician may request an exception according to Policy 10.2(A): *Status Exceptions*. However, the Regional Review Board (RRB) will review these

application based on standards jointly developed by the Liver and Intestinal Organ Transplantation Committee and the Pediatric Transplantation Committee.

10.2(F) Candidates with Cholangiocarcinoma

A candidate will receive the MELD/PELD exception in Table 3.6-5 for cholangiocarcinoma, if the candidate's Transplant Hospital meets both of the following requirements:

1. Submit a written protocol for patient care for the Liver and Intestinal Organ Transplantation Committee that should include *all* of the following:
 - Candidate selection criteria
 - Administration of neoadjuvant therapy before transplantation
 - Operative staging to exclude any patient with regional hepatic lymph node metastases, intrahepatic metastases, or extrahepatic disease
 - Any data collection requested by the Liver and Intestinal Organ Transplantation Committee.
2. Document that the candidate meets *all* of the following:
 - a. Malignant appearing stricture on cholangiography and
 - b. *One* of the following:
 - i. Carbohydrate antigen 19-9 ≥ 100 U/mL
 - ii. Biopsy or cytology results demonstrating malignancy
 - iii. Aneuploidy.

Additionally, the following criteria should be met:

- The tumor should be considered unresectable because of technical considerations or underlying liver disease.
- If cross-sectional imaging studies demonstrate a mass, the mass should be three cm. or less.
- Intrahepatic and extrahepatic metastases should be excluded by cross-sectional imaging studies of the chest and abdomen at the time of the initial application for the MELD/PELD exception and every three months before the MELD/PELD score increases.
- Regional hepatic lymph node involvement and peritoneal metastases should be assessed by operative staging after completion of neoadjuvant therapy and before liver transplantation.
- Transperitoneal aspiration or biopsy of the primary tumor should be avoided.

10.2(G) Candidates with Hepatocellular Carcinoma

10.2(G)(I) Eligible Candidates

Upon submission of the required information to the OPTN Contractor, candidates with Hepatocellular Carcinoma (HCC) that have stage T2 lesions will receive a MELD/PELD score equivalent to a 15% risk of 3 month mortality. For the purposes of this section, stage T2 lesions include *any* of the following:

- One 5B lesion

- Two or three 5A, 5A-g, or 5B lesions, if all of the lesions are less than or equal to 3 cm
- Any 5T lesions

10.2(G)(II) Initial Assessment for Registration

Prior to applying for an exception, the candidate must undergo a thorough assessment that:

1. Evaluates the number and size of tumors using a dynamic contrast enhanced computed tomography (CT) or magnetic resonance imaging (MRI)
2. Rules out any extrahepatic spread or macrovascular involvement using a CT or MRI
3. Rules out metastatic disease using a CT of the chest
4. Indicates that the candidate is not eligible for resection
5. Reports the candidate’s alpha-fetoprotein level.

10.2(G)(III) Requirements for Imaging

Any imaging examination performed for a Hepatocellular Carcinoma (HCC) MELD/PELD score exception application should meet the criteria in Table 10-2: *Requirements for dynamic contrast-enhanced CT or MRI of the liver* and must be interpreted by a radiologist at a Transplant Hospital. If the scan is inadequate or incomplete, regardless of whether the equipment meets the criteria in *Table 10-2: Requirements for dynamic contrast-enhanced CT or MRI of the liver*, then the image will be classified as OPTN Class 0 and must be repeated or completed for the candidate to receive an HCC MELD/PELD exception.

Table 10-2: Requirements for dynamic contrast-enhanced CT or MRI of the liver

Feature	CT scans should meet the below specifications:	MRIs should meet the below specifications:
Breath-holding	n/a	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 before and during scan
Coil Type	n/a	Phased array multichannel torso coil, unless patient related factors precludes its use
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	2-3 mL/sec of extracellular gadolinium chelate that does not have dominant biliary excretion
Detector Type	Minimum of 8 detector rows and must be able to image the entire liver during brief late arterial phase time window	n/a
Dynamic Phases (Timing)	Use the bolus tracking or timing method	Use the bolus tracking method for timing contrast arrival for late arterial phase imaging.

Feature	CT scans should meet the below specifications:	MRIs should meet the below specifications:
		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.
Injector	Power injector, preferably dual chamber injector with saline flush	Dual chamber power injector
Mandatory dynamic phases on contrast enhanced CT or MRI	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	0) Pre-contrast T1W: do not change scan parameters for post contrast imaging: 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
Minimum sequences	n/a	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
Scanner Type	Multidetector row scanner	1.5T Tesla or greater main magnetic field strength. Low field magnets are not suitable.
Slice thickness	Minimum of 5 mm reconstructed slice thickness	5 mm or less for dynamic series, 8 mm or less for other imaging

10.2(G)(IV) Imaging Requirements for Class 5 Lesions

Nodules found on images of cirrhotic livers are classified according to *Table 10-3: Classification system for nodules seen on imaging of cirrhotic livers*. Use the largest dimension of each tumor to report the size of Hepatocellular Carcinoma (HCC) lesions.

Table 10-3: Classification system for nodules seen on imaging of cirrhotic livers

Class	Description
0	Incomplete or technically inadequate study

Class	Description
5A	Must meet <i>all</i> of the following: <ol style="list-style-type: none"> 1. Single nodule greater than 1 cm. and less than 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. <i>Both</i> of the following or a biopsy: <ul style="list-style-type: none"> • Washout during the later contrast phases • Peripheral rim enhancement (capsule/pseudocapsule) on delayed phase.
5A-g	Must meet <i>all</i> of the following: <ol style="list-style-type: none"> 1. Single nodule greater than 1 cm. and less than 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 less than or equal to 6 months apart. Growth criteria do not apply to ablated lesions.
5B	Must meet <i>all</i> of the following: <ol style="list-style-type: none"> 1. Single nodule diameter greater than or equal to 2cm. and less than or equal to 5cm. 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. <i>One</i> of the following: <ul style="list-style-type: none"> • Biopsy • Washout on portal venous/delayed phase • Late capsule or pseudocapsule enhancement • Growth (maximum diameter increase in the absence of ablative therapy) by 50% or more documented on serial MRI or CT obtained ≤ 6 month apart. Serial imaging and measurements should be performed on corresponding contrast phases with the same modality preferred. Growth criteria do not apply to previously ablated lesions.
5T	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 predicated on the pre-treatment classification of the nodules and require <i>both</i> : <ol style="list-style-type: none"> 1. Past loco-regional treatment for HCC (OPTN Class 5 lesion or biopsy proven prior to ablation) 2. 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).
5X	Two or more tumors with a maximum diameter greater than 3 cm <i>or</i> any tumor with a maximum diameter greater than 5 cm.

10.2(G)(V) Extensions of HCC Exceptions

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

To receive the extension, the Transplant Program must do *all* of the following every three months:

1. Submit an Hepatocellular Carcinoma (HCC) MELD/PELD score exception application with an updated narrative
2. Document the tumor using a CT scan or MRI
3. Specify the type of ablative therapy, if the number of tumors decrease 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.

Class 5T candidates will receive a MELD/PELD equivalent to a 10 percentage point increase in the candidate's mortality risk every three months, without Regional Review Board (RRB) review, even if the estimated size of residual viable tumor falls below stage T2 criteria.

If a candidate's tumors have been resected since the previous application, then the Transplant Program must submit the application to its RRB for prospective review.

10.2(G)(VI) HCC Holds

The following options are available while a candidate with an approved HCC Exception application is in inactive status:

1. The Transplant Hospital may choose to submit an extension application every 3 months, as described above, and the candidate will receive a MELD/PELD equivalent to a 10 percentage point increase in the mortality risk following each approved extension.
2. The Transplant Hospital may keep the candidate in inactive status for any length of time, without submission of an extension application every 3 months. However, prior to reactivation, the Transplant Hospital must submit an extension application. Once the extension application is approved and the candidate is reactivated, the candidate will be registered with the candidate's previously approved MELD/PELD exception score prior to inactivation.

If the number of tumors that can be documented at the time of extension is less than upon initial application or prior extension, the type of ablative therapy must be specified on the extension application.

If a candidate qualifies for an HCC Exception and is subsequently treated with ablative therapy, then the candidate will continue to receive a MELD/PELD equivalent to a 10 percentage point increase in the candidate's mortality risk every three months, without

Regional Review Board (RRB) review, regardless if the estimated size of residual viable tumor falls below stage T2 criteria.

For candidates whose tumors have been resected since the initial HCC application or prior extension, the extension application must receive prospective review by the applicable RRB.

10.2(G)(VII) Appeal for Candidates not Meeting Criteria

If the Regional Review Board (RRB) denies the initial HCC exception application, the Transplant Program may appeal through telephonic or other electronic communication means with the RRB. If the RRB finds the Transplant Program to be noncompliant with Policy 10.2(G): *Candidates with Hepatocellular Carcinoma*, then the RRB will refer the matter to the Liver and Intestinal Organ Transplantation Committee for review and possible action. 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 Membership and Professional Standards Committee (MPSC) for appropriate action according to Appendix L of the OPTN/UNOS Bylaws.

10.2(G)(VIII) 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 Hepatocellular Carcinoma (HCC), the radiology report must contain the prior and current dates of imaging, type of imaging and measurements of the nodule.

If a candidate receives a liver transplant while receiving an HCC MELD/PELD exception, the Transplant Hospital must send the recipient's *Post-Transplant Explant Pathology Form* to the OPTN Contractor within 60 days of the 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 the MELD/PELD exception.

The Liver and Intestinal Organ Transplantation Committee will review any Transplant Hospital where more than 10% of its HCC cases, within a one year period, are not supported by pathologic confirmation or subsequent submission of clinical information.

10.3Points

Points are assigned to liver candidates according to Table 10-4: *Liver Points* and are used for sorting candidates according to 10.5(A): *Sorting Within Each Classification*.

Table 10-4: Liver Points

If the candidate is...	Then the candidate receives this many points...
Status 1A or 1B and has a blood type identical to the donor	10 points
Status 1A or 1B and has a	5 points

If the candidate is...	Then the candidate receives this many points...
blood type compatible with the donor	
Status 1A or 1B and has a blood type that is incompatible with the donor's blood type	0 points
Status 1A or 1B, has a blood type O, and will accept a liver from a donor with a non-A ₁ blood type	5 points
Status 1A or 1B	10 x ((rank of candidate's waiting time within the classification, from smallest to largest) / (number of candidates within a classification))

10.4 Waiting Time

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

1. Waiting time at current MELD/PELD score
2. Previous waiting time accrued at current MELD/PELD score
3. Previous waiting time accrued at any MELD/PELD score higher than the current MELD/PELD score
4. Previous waiting time accrued at Status 1A and Status 1B.

10.5 Classification Notes

10.5(A) Sorting Within Each Classification

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

1. Total points (highest to lowest)
2. Total waiting time at Status 1A (highest to lowest)
3. Previous waiting time at Status 1 (highest to lowest)
4. Total waiting time (highest to lowest).

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

1. Total points (highest to lowest)
2. Total waiting time at Status 1B (highest to lowest)
3. Total waiting time (highest to lowest).

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

1. Identical blood types, compatible blood types, then incompatible blood types
2. Total waiting time (highest to lowest)

3. Then those waiting list positions assigned to candidates with a PELD score less than or equal to six are redistributed between those candidates according to their PELD 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/PELD score (highest to lowest)
4. Total waiting time (highest to lowest).

10.5(B) Status and Laboratory Values Update Schedule

Transplant Hospitals must update MELD/PELD scores according to Table 10-5: *Liver status update schedule*. The OPTN Contractor will notify the Transplant Hospital of the need to update a candidate's score within 48 hours of the deadline in Table 10-5: *Liver status update schedule*.

When submitting laboratory values to the OPTN Contractor, Transplant Hospitals must submit the most recent results including the dates of the laboratory tests. If a Transplant Hospital voluntarily reports laboratory values before the mandatory recertification period begins, as specified in Table 10-5, then the Transplant Hospital must submit laboratory values no older than 48 hours.

Table 10-5: Liver status update schedule

If candidate is:	The new laboratory values must be entered every:	The new laboratory values can be no older than:	The time period that mandatory recertification begins prior to the due date:
Status 1A or 1B	7 days	48 hours	48 hours
MELD 25 or greater (ages 18 or older)	7 days	48 hours	48 hours
MELD/PELD 25 or greater (ages less than 18)	14 days	72 hours	72 hours
MELD/PELD 19 to 24	1 Month	7 days	7 days
MELD/PELD 11 to 18	3 months	14 days	14 days
MELD/PELD 10 or less	12 months	30 days	30 days

Status 1B candidates indicating a gastrointestinal bleed as the initial Status 1B upgrade criteria must have had another bleed in the past 7 days prior to the upgrade in order to remain in Status 1B.

Status 1B candidates indicating a metabolic disease or a hepatoblastoma require recertification every three months with lab values no older than 14 days.

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 a Status 1A or 1B registration for the same candidate waiting on that specific transplant beyond 14 days accumulated time will result in a review of all Status 1A or 1B liver candidate registrations at the Transplant Hospital. A review will not occur if the request was for a candidate meeting the requirements for hepatoblastoma in Policy 10.1(C): *Pediatric Status 1B* or a metabolic disease in Policy 10.2(E): *Pediatric Liver Candidates with Metabolic Diseases*.

If a Transplant Hospital does not update the information, the candidate's score will revert to the candidate's previous MELD/PELD score. If the Transplant Hospital does not update the information by the deadline for the previous MELD/PELD score or does not have a previous MELD/PELD score, the candidate's MELD/PELD score will be six.

The Transplant Hospital must report final laboratory values to the OPTN Contractor before removing the candidate from the waiting list as transplanted or deceased.

10.5(C) Segmental Transplants

If a Transplant Program accepts a liver for segmental transplantation, it must make reasonable attempts to offer the remaining segment according to the allocation algorithms in Policy 10.6 *Liver Allocation Classifications and Rankings*.

If no Transplant Program accepts the segment before it is recovered, then the Transplant Program must offer the segment to candidates registered with the Transplant Program or any medically appropriate candidate on the waiting list.

Donors whose livers have the potential to be split must meet *all* of the following criteria:

1. Less than 40 years of age
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 match run will identify donors whose livers can be split and regional recipients willing to accept a segmental graft.

The Transplant Hospital that receives the primary whole graft organ offer will determine the method of splitting and use of the vessels.

10.5(D) Livers for Other Methods of Hepatic Support

OPOs must offer livers to all other candidates for at least six hours before offering the liver to candidates for other methods of hepatic support.

10.5(E) Blood Type and Liver Allocation

Blood type O donors may only be allocated to candidates that meet at least *one* of the following criteria:

- Adult or Pediatric Status 1A
- Pediatric Status 1B
- Blood type O with a MELD or PELD score greater than or equal to 30
- Blood type B with a MELD or PELD score greater than or equal to 30.

10.6 Liver Allocation Classifications and Rankings

10.6(A) Allocation of Liver from Donors Aged at Least 18 Years

Livers from donors aged 18 years or older are allocated to candidates in the following order:

Table 10-6: Allocation of Livers from Donors Aged At Least 18 Years

Classification	Candidates that are within the...	And are...
The following classifications appear for all blood types		
1.	Donor hospital's region	Adult or Pediatric Status 1A
2.	Donor hospital's region	Pediatric Status 1B
3.	Donor hospital's local unit	MELD/PELD of at least 40
4.	Donor hospital's region	MELD/PELD of at least 40
5.	Donor hospital's local unit	MELD/PELD of at least 39
6.	Donor hospital's region	MELD/PELD of at least 39
7.	Donor hospital's local unit	MELD/PELD of at least 38
8.	Donor hospital's region	MELD/PELD of at least 38
9.	Donor hospital's local unit	MELD/PELD of at least 37
10.	Donor hospital's region	MELD/PELD of at least 37
11.	Donor hospital's local unit	MELD/PELD of at least 36
12.	Donor hospital's region	MELD/PELD of at least 36
13.	Donor hospital's local unit	MELD/PELD of at least 35
14.	Donor hospital's	MELD/PELD of at least 35

	region	
15.	Donor hospital's local unit	MELD/PELD of at least 15
16.	Donor hospital'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.	Donor hospital's local unit	MELD/PELD less than 15
21.	Donor hospital's region	MELD/PELD less than 15
22.	Nation	MELD/PELD less than 15
The following classifications only appear on O blood type donor matches		
23.	Donor hospital's local unit	MELD/PELD of at least 15 and compatible blood type
24.	Donor hospital's region	MELD/PELD of at least 15 and compatible blood type
25.	Donor hospital's local unit	MELD/PELD less than 15 and compatible blood type
26.	Donor hospital's region	MELD/PELD less than 15 and compatible blood type
27.	National	Any MELD/PELD and compatible blood type
The following classifications appear for all blood types		
28.	Donor hospital's local unit	Adult or Pediatric Status 1A and in need of other method of hepatic support
29.	Donor hospital's local unit	Pediatric Status 1B and in need of other method of hepatic support
30.	Donor hospital's local unit	Any MELD/PELD and in need of other method of hepatic support
31.	Donor hospital's region	Adult or Pediatric Status 1A and in need of other method of hepatic support
32.	Donor hospital's region	Pediatric Status 1B and in need of other method of hepatic support
33.	Donor hospital's region	Any MELD/PELD and in need of other method of hepatic support
34.	Nation	Adult or Pediatric Status 1A and in need of other method of hepatic support
35.	Nation	Pediatric Status 1B and in need of other method of hepatic support
36.	Nation	Any MELD/PELD and in need of other method of hepatic support
The following classifications only appear on O blood type donor matches		
37.	Donor hospital's local unit	Any MELD/PELD in need of other method of hepatic support, and a blood type compatible with the donor
38.	Donor hospital's region	Any MELD/PELD in need of other method of hepatic support, and blood type compatible with the donor

39.	Nation	Any MELD/PELD in need of other method of hepatic support, and blood type compatible with the donor
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10.6(B) Allocation of Liver from Donors Aged 11 to 17 Years

Livers from donors aged 11 to 17 years are allocated to candidates in the following order:

Table 10-7: Allocation of Livers from Donors Aged 11 to 17 Years

Classification	Candidates that are within the...	And are...
The following classifications appear for all blood types		
1.	Donor hospital's local unit	Pediatric Status 1A
2.	Donor hospital's region	Pediatric Status 1A
3.	Donor hospital's local unit	Adult Status 1A
4.	Donor hospital's region	Adult Status 1A
5.	Donor hospital's local unit	Pediatric Status 1B
6.	Donor hospital's region	Pediatric Status 1B
7.	Donor hospital's region	Any PELD
8.	Donor hospital's local unit	MELD of at least 15 and 12 to 17 years of age
9.	Donor hospital's local unit	MELD of at least 15 and at least 18 years of age
10.	Donor hospital's region	MELD of at least 15 and 12 to 17 years of age
11.	Donor hospital's region	MELD of at least 15 and at least 18 years of age
12.	Donor hospital's local unit	MELD less than 15 and 12 to 17 years of age
13.	Donor hospital's local unit	MELD less than 15 and least 18 years of age
14.	Donor hospital's region	MELD less than 15 and 12 to 17 years of age
15.	Donor hospital's region	MELD less than 15 and at least 18 years of age
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 of age
21.	Nation	Any MELD and at least 18 years of age

The following classifications only appear on O blood type donor matches		
22.	Donor hospital's region	Any PELD, , and compatible blood type
23.	Donor hospital's local unit	MELD at least 15, 12 to 17 years of age, and Compatible blood type
24.	Donor hospital's local unit	MELD at least 15, at least 18 years of age, and compatible blood type
25.	Donor hospital's region	MELD at least 15, 12 to 17 years of age, and compatible blood type
26.	Donor hospital's region	MELD at least 15, at least 18 years of age, and compatible blood type
27.	Donor hospital's local unit	MELD less than 15, 12 to 17 years of age, and compatible blood type
28.	Donor hospital's local unit	MELD less than 15, at least 18 years of age, and compatible blood type
29.	Donor hospital's region	MELD less than 15, 12 to 17 years of age, and compatible blood type
30.	Donor hospital's region	MELD less than 15, at least 18 years of age, and compatible blood type
31.	Nation	0 to 11 years of age and compatible blood type
32.	Nation	12 to 17 years of age and compatible blood type
33.	Nation	Any MELD, at least 18 years of age, and compatible blood type
The following classifications appear for all blood types		
34.	Donor hospital's local unit	Adult or Pediatric Status 1A and in need of other method of hepatic support
35.	Donor hospital's local unit	Pediatric Status 1B and in need of other method of hepatic support
36.	Donor hospital's local unit	Any MELD/PELD and in need of other method of hepatic support
37.	Donor hospital's region	Adult or Pediatric Status 1A and in need of other method of hepatic support
38.	Donor hospital's region	Pediatric Status 1B and in need of other method of hepatic support
39.	Donor hospital'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
The following classifications only appear on O blood type donor matches		
43.	Donor hospital's local unit	Any MELD/PELD in need of other method of hepatic support, and compatible blood type
44.	Donor hospital'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

10.6(C) Allocation of Liver from Donors Aged 0 to 10 Years

Livers from donors aged 10 years or younger are allocated are allocated to candidates in the following order:

Table 10-8: Allocation of Livers from Donors Aged 0 to 10 Years

Classification	Candidates that are within the...	And are...
The following classifications appear for all blood types		
1.	Donor hospital's region	Pediatric Status 1A
2.	Nation	Pediatric Status 1A
3.	Donor hospital's local unit	Adult Status 1A
4.	Region	Adult Status 1A
5.	Region	Pediatric Status 1B
6.	Region	Any PELD
7.	Donor hospital's local unit	MELD of at least 15 and 12 to 17 years of age
8.	Donor hospital's local unit	MELD of at least 15 and at least 18 years of age
9.	Region	MELD of at least 15 and at least 12 to 17 years of age
10.	Region	MELD of at least 15 and at least 18 years of age
11.	Donor hospital's local unit	MELD less than 15 and 12 to 17 years of age
12.	Donor hospital's local unit	MELD less than 15 and at least 18 years of age
13.	Region	MELD less than 15 and 12 to 17 years of age
14.	Region	MELD less than 15 and at least 18 years of age
15.	Nation	Status 1A and 12 to 17 years of age
16.	Nation	Status 1A and at least 18 years of age
17.	Nation	Status 1B and 0 to 17 years of age
18.	Nation	Any PELD
19.	Nation	Any MELD and 12 to 17 years of age
20.	Nation	Any MELD and at least 18 years of age
The following classifications only appear on O blood type donor matches		
21.	Region	Any PELD and compatible blood type
22.	Donor hospital's local unit	MELD of at least 15, 12 to 17 years of age, and compatible blood type
23.	Donor hospital's local unit	MELD of at least 15, at least 18 years of age, and compatible blood type
24.	Region	MELD of at least 15, 12 to 17 years of age, and compatible blood type
25.	Region	MELD of at least 15, at least 18 years of age, and compatible blood type
26.	Donor hospital's local unit	MELD less than 15, 12 to 17 years of age, and compatible blood type

Classification	Candidates that are within the...	And are...
27.	Donor hospital's local unit	MELD less than 15, at least 18 years of age, and compatible blood type
28.	Region	MELD less than 15, 12 to 17 years of age, and compatible blood type
29.	Region	MELD less than 15, at least 18 years of age, and compatible blood type
30.	Nation	Any PELD and compatible blood type
31.	Nation	Any MELD, 12 to 17 years of age, and compatible blood type
32.	Nation	Any MELD, at least 18 years of age, and compatible blood type
The following classifications appear for all blood types		
33.	Donor hospital's local unit	Adult or Pediatric Status 1A and in need of other method of hepatic support
34.	Donor hospital's local unit	Pediatric Status 1B and in need of other method of hepatic support
35.	Donor hospital's local unit	Any MELD/PELD and in need of other method of hepatic support
36.	Donor hospital's region	Adult or Pediatric Status 1A and in need of other method of hepatic support
37.	Donor hospital's region	Pediatric Status 1B and in need of other method of hepatic support
38.	Donor hospital'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
The following classifications only appear on O blood type donor matches		
42.	Donor hospital's local unit	Any MELD/PELD, any age, in need of other method of hepatic support, and compatible blood type
43.	Donor hospital'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

10.7 Administrative Rules

10.7(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 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 audit of the Member.

10.7(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 the candidates receive a transplant while registered at Status 1A or 1B, 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.

10.8 Variances

10.8(A) Open Variance – Segmental Liver Transplantation

This variance only applies when a Transplant Program transplants a right lobe or right trisegment of the liver. This variance does not apply when a Transplant Program transplants a left lobe or left lateral 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 allocation algorithm used to allocate the right lobe or trisegment. 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 Donation Service Area (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 hold until the Transplant Program can review results and surgical practices.

History

Policy 3.6: Allocation of Livers: 11/16/2000; 6/28/2001; 11/15/2001; 6/27/2002; 11/14/2002; 6/26/2003; 11/20/2003; 6/24/2004; 11/18/2004; 6/23/2005; 11/17/2005; 12/13/2006; 9/17/2007; 6/19/2008; 3/2/2009; 11/16/2009; 6/21/2010; 6/29/2011; 11/14/2011; *Policy 10: Allocation of Livers:* 11/2012 (eff. 2/1/2013)

Notes

- For liver acceptance and screening criteria, see Policy 5.1(B): *Liver Acceptance Criteria*.
- 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/UNOS Bylaws, Appendix F.
- For the American College of Radiology Imaging network (ACRIN) protocol regarding the Diagnosis of Hepatocellular Carcinoma, see http://www.acrin.org/Portals/0/Protocols/6690/ACRIN6690_Amend1_v090110_master_ForOnline.pdf.

Policy 11: Allocation of Lungs

11.1	Priorities and Scores	142
11.2	Priority and Score Exceptions	158
11.3	Waiting Time	161
11.4	Classification Notes	161
11.5	Lung Allocation Classifications and Rankings	164
11.6	Administrative Rules	170
11.7	Variances	170

Introduction

This Policy contains requirements for the allocation of lungs and lung candidate registrations.

Policy Statement

11.1 Priorities and Scores

11.1(A) Lung Candidates Less Than 12 Years of Age – Priority Level

If a lung candidate is less than 12 years of age, lung allocation is determined for a candidate by priority level that is based on medical urgency.

Regardless of priority, a lung candidate may be inactive if the candidate is temporarily unsuitable to be a recipient. A candidate will not receive any organ offers while registered as inactive.

11.1(B) Priority Level 1

Table 11-1: *Requirements for Priority 1* outlines the requirements for a priority 1 candidate.

Table 11-1: Requirements for Priority 1

If the candidate has...	And meets at least one of the following criteria...
Respiratory failure	<ul style="list-style-type: none"> 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 mmHg, or a venous PCO_2 greater than 56 mmHg

<p>Pulmonary hypertension</p>	<ul style="list-style-type: none"> • Has pulmonary vein stenosis involving 3 or more vessels • Exhibits <i>any</i> of the following, in spite of medical therapy: • cardiac index less than 2 L/min/M², syncope • hemoptysis • suprasystemic PA pressure on cardiac catheterization or by echocardiogram estimate.
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The OPTN Contractor will provide 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 programs must submit an exception request to the Lung Review Board.

11.1(C) Priority Level 2

If a lung candidate does not meet any of the above criteria, then the candidate is priority 2.

11.1(D) Frequency of Reporting Clinical Data for Priority

A transplant program may update clinical data used to justify a candidate’s priority at any time. See Policy 5.B.III: *Reporting Clinical Data for Candidates Less Than 12 Years of Age* for more information.

The OPTN Contractor will assess the currency of lung variables for each candidate on every six-month anniversary date. If a lung candidate is inactive, the candidate will not receive any deceased donor lung offers.

11.1(E) Candidates at Least 12 Years of Age - Lung Allocation Score (LAS) System

Candidates who are at least 12 years of age receive priority for deceased donor lung offers based on the Lung Allocation Score (LAS), as well as geography and blood type.

The LAS calculation uses all of the following measures:

1. 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.
2. Post-transplant Survival Measure, which is the expected number of days a candidate will live during the first year post-transplant.
3. Transplant Benefit Measure, which is the difference between the post-transplant survival measure and the waiting list urgency measure.

The LAS calculation uses the difference between transplant benefit and waiting list urgency:

$$\text{Raw Allocation Score} = (\text{Transplant Benefit Measure} - \text{Waiting List Urgency Measure})$$

A Raw Allocation Score ranges from negative 730 to positive 365 days. 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:

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

where

$$PTAUC = \sum_{k=0}^{364} S_{TX}(k)$$

$$S_{TX}(t) = S_{TX,0}(t) e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \dots + \alpha_q Y_q}$$

$$WLAUC = \sum_{k=0}^{364} S_{WL}(k)$$

$$S_{WL}(t) = S_{WL,0}(t) e^{\beta_1 X_1 + \beta_2 X_2 + \dots + \beta_p X_p}$$

The LAS calculation includes the following components:

- PTAUC = The area under the post-transplant survival probability curve during the first post-transplant year.
- $S_{TX,0}(t)$ = The baseline post-transplant survival probability at time t according to Table 11-5: *Baseline post-transplant survival probabilities*.
- $S_{TX}(t)$ = The expected post-transplant survival probability at time t for an individual candidate.
- Y_j = The value of the j^{th} covariate for an individual candidate.
- α_j = The coefficient for covariate j from the post-transplant model according to Table 11-3.
- WLAUC = The area under the waiting list survival probability curve during the next year.
- $S_{WL,0}(t)$ = The baseline waiting list survival probability at time t according to Table 11-4: *Baseline Waiting List Survival (SWL(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} covariate for an individual candidate
- β_i = The coefficient for covariate i from the waiting list model according to Table 11-2.

Table 11-2 lists the covariates and coefficients in the waiting list survival model.

Table 11-2: Waiting List Mortality Calculation, Covariates, and Their Coefficients

For this covariate:	The following coefficient is used in the LAS calculation:
1. Age (per 10 years)	0.01
2. Bilirubin (per 1 mg/dL)	0.04 if bilirubin is at least 1.0 mg/dL 0.00 if bilirubin is less than 1.0 mg/dL
3. Bilirubin increase of at least 50% (See Policy 11.1(E)(III) <i>Bilirubin in the Lung Allocation Score</i>)	1.41 if diagnosis Group B 0.00 if diagnosis Groups A, C, and D
4. Body mass index (BMI) per 1 kg/m ²	-0.13*(20 - BMI) if BMI less than 20
5. Cardiac index	0.54 if the cardiac index is less than 2 L/min/m ² 0.00 if the cardiac index is greater than 2 L/min/m ²
6. Central venous pressure (CVP) per 1 mm Hg	0.02*(CVP - 7) if CVP greater than 7 (diagnosis Group B only) 0.00 if less than 7 mm Hg for diagnosis Group B 0.00 for candidates in diagnosis Groups A, C, and D
7. Ventilation status	0.68 if continuous mechanical ventilation needed 0.00 if no continuous mechanical ventilation needed
8. Serum creatinine per 1 mg/dL (Policy 11.1(E)(IV) <i>Creatinine in the Lung Allocation Score</i>)	0.50 if at least 18 years of age 0.00 if less than 18 years of age
9. Diabetes	0.47 if diabetic 0.00 if not diabetic
10. Diagnosis	0.00 if diagnosis Group A 1.58 if diagnosis Group B 1.23 if diagnosis Group C 0.63 if diagnosis Group D
11. Detailed diagnosis	0.67 if bronchiectasis -0.63 if Eisenmenger's syndrome -0.32 if lymphangiomyomatosis 0.45 if obliterative bronchiolitis (not-retransplant) -0.21 if pulmonary fibrosis, not idiopathic -0.46 if sarcoidosis with PA mean pressure greater than 30 mm Hg 0.93 if sarcoidosis with PA mean pressure of 30 mm Hg or less
12. Forced vital capacity (FVC) (per 10%)	-0.18* (80-FVC/10) if FVC is less than 80% for

For this covariate:	The following coefficient is used in the LAS calculation:
(See Policy 11.1(E)(I) <i>Lung Disease Diagnosis Group Classifications</i>)	diagnosis Group D 0.00 if greater than 80% for diagnosis Group D 0.00 for candidates in diagnosis Groups A, B, or C
13. Functional Status	-0.45 if no assistance needed with activities of daily living 0.00 if some or total assistance needed with activities of daily living
14. Oxygen needed at rest (per L/min)	0.02 if diagnosis Group B 0.12 if diagnosis Groups A, C, and D
15. PCO ₂ (per 10 mm Hg): current (See Policy 11.1(E)(II) <i>PCO₂ in the Lung Allocation Score</i>)	0.11*(PCO ₂ -40)/10 if PCO ₂ is at least 40 mm Hg 0.00 if PCO ₂ is less than 40 mm Hg
16. PCO ₂ increase of at least 15% (See Policy 11.1(E)(II) <i>PCO₂ in the Lung Allocation Score</i>)	0.23 if PCO ₂ increase is at least 15% 0.00 if PCO ₂ increase is less than 15%
17. Pulmonary artery (PA) systolic pressure (per 10 mm Hg)	0.42* (PA systolic-40) for diagnosis Group A if the PA systolic pressure is greater than 40 mm Hg 0.00 for diagnosis Group A if the PA systolic pressure is 40 mm Hg or less 0.05 for diagnosis Groups B, C, and D
18. Six minute walk distance (per 100 feet)	-0.08

Table 11-3: *Post-Transplant Survival Calculation, Covariates, and Their Coefficients* lists the covariates and corresponding coefficients in the waiting list and post-transplant survival models.

Table 11-3: Post-Transplant Survival Calculation, Covariates, and Their Coefficients

For this covariate:	The following coefficient is used in the LAS calculation:
1. Age per year	0.02 if greater than 45 years of age 0.00 if less than 45 years of age
2. Serum creatinine at transplant (per 1 mg/dL)	0.09 if at least 18 years of age 0.00 if less than 18 years
3. Creatinine, increase of at least 150% (See Policy 11.1(E)(IV) <i>Creatinine in the Lung Allocation Score</i>)	0.77 if increase in creatinine is at least 150%, and when the higher value determining this increase is at least 1 mg/dL 0.00 otherwise
4. Cardiac index	0.35 if less than 2 L/min/m ² 0.00 if greater than 2 L/min/m ²
5. Ventilation status	0.61 if continuous mechanical ventilation needed 0.00 if ventilation needed
6. Diagnosis group A	0.00
Diagnosis group B	0.61
Diagnosis group C	0.36

For this covariate:	The following coefficient is used in the LAS calculation:
Diagnosis group D	0.46
7. Detailed diagnosis	0.19 if bronchiectasis
	0.91 if eisenmenger's syndrome
	-1.52 if lymphangioliomyomatosis
	-1.21 if obliterative bronchiolitis (not-retransplant)
	-0.07 if pulmonary fibrosis, not idiopathic
	-0.04 if sarcoidosis with PA mean pressure greater than 30 mm Hg
	-0.14 if sarcoidosis with PA mean pressure of 30 mm Hg or less
8. Oxygen needed at rest (L/min)	0.07 if diagnosis Group A 0.02 if diagnosis Groups B, C, and D
9. Functional Status	-0.19 if no assistance needed with activities for daily living 0.00 if some or total assistance needed with activities for daily living
10. Six-minute-walk-distance	-0.00045*(1200 - 6mw) 0.00 if six-minute-distance-walked is more than 1200 feet

Table 11-4: Baseline Waiting List Survival (SWL(t)) Probability provides the baseline waiting list probabilities, which are used in the LAS calculation.

Table 11-4: Baseline Waiting List Survival (SWL(t)) Probability

t=Time (in days)	SWL(t)						
0	1.000000	18	0.998362	36	0.997242	54	0.996363
1	0.999991	19	0.998259	37	0.997181	55	0.996305
2	0.999925	20	0.998220	38	0.997137	56	0.996191
3	0.999867	21	0.998068	39	0.997121	57	0.996119
4	0.999746	22	0.998036	40	0.997121	58	0.995942
5	0.999598	23	0.997972	41	0.997019	59	0.995942
6	0.999499	24	0.997868	42	0.996946	60	0.995909
7	0.999371	25	0.997770	43	0.996916	61	0.995909
8	0.999305	26	0.997742	44	0.996849	62	0.995873
9	0.999218	27	0.997667	45	0.996780	63	0.995846
10	0.999085	28	0.997626	46	0.996731	64	0.995846
11	0.998990	29	0.997540	47	0.996780	65	0.995614
12	0.998887	30	0.997473	48	0.996731	66	0.995553
13	0.998816	31	0.997391	49	0.996644	67	0.995553
14	0.998730	32	0.997327	50	0.996543	68	0.995553
15	0.998660	33	0.997297	51	0.996518	69	0.995500
16	0.998588	34	0.997274	52	0.996397	70	0.995479
17	0.998455	35	0.997242	53	0.996397	71	0.995349

Organ Procurement and Transplantation Network (OPTN) Policies
 Policy 11: Allocation of Lungs

t=Time (in days)	SWL(t)
72	0.995293
73	0.995136
74	0.994965
75	0.99481
76	0.994774
77	0.994702
78	0.994702
79	0.994634
80	0.994565
81	0.994547
82	0.994465
83	0.994465
84	0.994297
85	0.994297
86	0.994297
87	0.994297
88	0.994181
89	0.994077
90	0.993807
91	0.993715
92	0.993308
93	0.993220
94	0.993807
95	0.993715
96	0.993308
97	0.993220
98	0.993160
99	0.993098
100	0.993061
101	0.993005
102	0.993005
103	0.992938
104	0.992938
105	0.992883
106	0.992883
107	0.992851
108	0.992762
109	0.992724
110	0.992643
111	0.992643
112	0.992562
113	0.992089
114	0.992064

t=Time (in days)	SWL(t)
115	0.992040
116	0.991997
117	0.991966
118	0.991940
119	0.991940
120	0.991940
121	0.991514
122	0.991514
123	0.991514
124	0.991514
125	0.991488
126	0.991462
127	0.991393
128	0.991307
129	0.991307
130	0.991270
131	0.991236
132	0.991236
133	0.991053
134	0.991012
135	0.991012
136	0.990978
137	0.990978
138	0.990978
139	0.990936
140	0.990901
141	0.990901
142	0.990811
143	0.990739
144	0.990595
145	0.990595
146	0.990540
147	0.990540
148	0.990540
149	0.990540
150	0.990540
151	0.990540
152	0.990384
153	0.990333
154	0.990333
155	0.990333
156	0.990245
157	0.990245

t=Time (in days)	SWL(t)
158	0.990245
159	0.990145
160	0.989689
161	0.989689
162	0.989652
163	0.989575
164	0.989575
165	0.988903
166	0.988873
167	0.988873
168	0.988784
169	0.988722
170	0.988695
171	0.988695
172	0.988695
173	0.988655
174	0.988655
175	0.988655
176	0.988625
177	0.988548
178	0.988548
179	0.988548
180	0.988062
181	0.988062
182	0.988062
183	0.988021
184	0.987934
185	0.987885
186	0.987885
187	0.987885
188	0.987885
189	0.987856
190	0.987856
191	0.987856
192	0.987856
193	0.987856
194	0.987608
195	0.987359
196	0.987299
197	0.987263
198	0.987155
199	0.987122
200	0.986530

t=Time (in days)	SWL(t)
201	0.986530
202	0.986480
203	0.985963
204	0.985926
205	0.985926
206	0.985820
207	0.985820
208	0.985742
209	0.985742
210	0.985742
211	0.985708
212	0.985708
213	0.985541
214	0.985541
215	0.985541
216	0.985450
217	0.985450
218	0.985450
219	0.985330
220	0.985265
221	0.985265
222	0.985265
223	0.985265
224	0.985265
225	0.984621
226	0.984549
227	0.984549
228	0.984549
229	0.984549
230	0.984489
231	0.984489
232	0.984396
233	0.984324
234	0.984280
235	0.984079
236	0.984079
237	0.984015
238	0.984015
239	0.984015
240	0.984015
241	0.983835
242	0.983835
243	0.983792

Organ Procurement and Transplantation Network (OPTN) Policies
 Policy 11: Allocation of Lungs

t=Time (in days)	SWL(t)
244	0.983753
225	0.984621
226	0.984549
227	0.984549
228	0.984549
229	0.984549
230	0.984489
231	0.984489
232	0.984396
233	0.984324
234	0.984280
235	0.984079
236	0.984079
237	0.984015
238	0.984015
239	0.984015
240	0.984015
241	0.983835
242	0.983835
243	0.983792
244	0.983753
245	0.983753
246	0.983753
247	0.983697
248	0.983636
249	0.983636
250	0.983636
251	0.983636
252	0.983243
253	0.983243
254	0.983243
255	0.983097
256	0.983097
257	0.983097
258	0.983097
259	0.983097
260	0.983097
261	0.983097
262	0.983052
263	0.983052
264	0.983052
265	0.983052
266	0.983052

t=Time (in days)	SWL(t)
267	0.983052
268	0.982960
250	0.983636
251	0.983636
252	0.983243
253	0.983243
254	0.983243
255	0.983097
256	0.983097
257	0.983097
258	0.983097
259	0.983097
260	0.983097
261	0.983097
262	0.983052
263	0.983052
264	0.983052
265	0.983052
266	0.983052
267	0.983052
268	0.982960
269	0.982960
270	0.982960
271	0.982797
272	0.982797
273	0.982797
274	0.982797
275	0.982700
276	0.982603
277	0.982603
278	0.982511
279	0.982457
280	0.982457
281	0.982457
282	0.982413
283	0.982323
284	0.982323
285	0.982323
286	0.982323
287	0.982323
288	0.982323
289	0.982323
290	0.982323
291	0.981916
292	0.981878
293	0.981827
294	0.981827
295	0.981573
296	0.981319
297	0.980775
298	0.980775
299	0.980519
300	0.980397
301	0.980397
302	0.980397
303	0.980397
304	0.980397
305	0.980397
306	0.980397
307	0.980339
308	0.980339
309	0.980339
310	0.980339
311	0.980339
312	0.980339
313	0.980339
314	0.980339
315	0.980218
290	0.982323

t=Time (in days)	SWL(t)
291	0.981916
292	0.981878
276	0.982603
277	0.982603
278	0.982511
279	0.982457
280	0.982457
281	0.982457
282	0.982413
283	0.982323
284	0.982323
285	0.982323
286	0.982323
287	0.982323
288	0.982323
289	0.982323
290	0.982323
291	0.981916
292	0.981878
293	0.981827
294	0.981827
295	0.981573
296	0.981319
297	0.980775
298	0.980775
299	0.980519
300	0.980397
301	0.980397
302	0.980397
303	0.980397
304	0.980397
305	0.980397
306	0.980397
307	0.980339
308	0.980339
309	0.980339
310	0.980339
311	0.980339
312	0.980339
313	0.980339
314	0.980339
315	0.980218
316	0.980218

t=Time (in days)	SWL(t)
317	0.980218
318	0.980129
319	0.980129
320	0.980016
321	0.980016
322	0.980016
323	0.979773
324	0.979773
325	0.979671
326	0.979671
327	0.979164
328	0.979164
329	0.979164
330	0.979164
331	0.979100
332	0.979100
333	0.978935
333	0.978935
334	0.978935
335	0.978817
336	0.978817
337	0.978817
338	0.978817
339	0.978817
340	0.978817
341	0.978597
342	0.978597
343	0.978301
344	0.978250
345	0.978250
346	0.978250
347	0.978117
348	0.978037
348	0.978037
349	0.978037
350	0.978037
351	0.978037
352	0.977937
353	0.977937
354	0.977937
355	0.977855
356	0.977855
357	0.977855

Organ Procurement and Transplantation Network (OPTN) Policies

Policy 11: Allocation of Lungs

358	0.977710
359	0.977710

360	0.976881
361	0.976881

362	0.976881
363	0.976709

364	0.976709
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Table 11-5: *Baseline post-transplant survival probabilities* provides the baseline post-transplant survival probabilities, which are used in the LAS calculation.

Table 11-5: Baseline post-transplant survival probabilities

t=Time (in days)	S _{TX} (t)						
0	1.000000	44	0.982578	89	0.973845	134	0.966994
0	0.998946	45	0.982300	90	0.973630	135	0.966702
1	0.997558	46	0.982160	91	0.973416	136	0.966483
2	0.996895	47	0.981952	92	0.973416	137	0.966483
3	0.996364	48	0.981882	93	0.973202	138	0.966410
4	0.995498	49	0.981394	94	0.973059	139	0.966263
5	0.995165	50	0.981115	95	0.972916	140	0.966190
6	0.994565	51	0.980836	96	0.972629	141	0.966190
7	0.994164	52	0.980416	97	0.972415	142	0.965971
8	0.993963	53	0.980207	98	0.972415	143	0.965751
9	0.993360	54	0.980137	99	0.972128	144	0.965678
10	0.993159	55	0.979926	100	0.971984	145	0.965311
11	0.992487	56	0.979646	101	0.971769	146	0.965165
12	0.992353	57	0.979436	102	0.971697	147	0.965018
13	0.991949	58	0.979085	103	0.971553	148	0.965018
14	0.991679	59	0.978874	104	0.971337	149	0.964724
15	0.991207	60	0.978733	105	0.971265	150	0.964651
16	0.990531	61	0.978452	106	0.971193	151	0.964504
17	0.990260	62	0.978382	107	0.971121	152	0.964357
18	0.989921	63	0.978170	108	0.971049	153	0.964063
19	0.989582	64	0.978100	109	0.970977	154	0.963843
20	0.989514	65	0.977959	110	0.970761	155	0.963696
21	0.988902	66	0.977818	111	0.970689	156	0.963475
22	0.988220	67	0.977818	112	0.970617	157	0.963328
23	0.987810	68	0.977536	113	0.970545	158	0.963107
24	0.987469	69	0.977254	114	0.970473	159	0.962738
25	0.987263	70	0.977042	115	0.970329	160	0.962517
26	0.987058	71	0.976971	116	0.969968	161	0.962443
27	0.986578	72	0.976901	117	0.969824	162	0.962296
28	0.986304	73	0.976759	118	0.969679	163	0.962074
29	0.986030	74	0.976547	119	0.969607	164	0.961927
30	0.985961	75	0.976476	120	0.969390	165	0.961705
31	0.985755	76	0.976193	121	0.969101	166	0.961631
32	0.985480	77	0.975909	122	0.968956	167	0.961557
33	0.985136	78	0.975767	123	0.968667	168	0.961483
34	0.984929	79	0.975625	124	0.968594	169	0.961483
35	0.984515	80	0.975483	125	0.968377	170	0.961409
36	0.984446	81	0.975483	126	0.968159	171	0.961113
37	0.984170	82	0.975483	127	0.968086	172	0.961113
38	0.983825	83	0.974985	128	0.967868	173	0.961039
39	0.983479	84	0.974985	129	0.967796	174	0.960965
40	0.983202	85	0.974700	130	0.967504	175	0.960891
41	0.983063	86	0.974700	131	0.967359	176	0.960743
42	0.982855	87	0.974415	132	0.967140	177	0.960595
43	0.982716	88	0.973987	133	0.967140	178	0.960446

Organ Procurement and Transplantation Network (OPTN) Policies
 Policy 11: Allocation of Lungs

t=Time (in days)	S _{TX} (t)
179	0.960446
180	0.960372
181	0.960298
182	0.960149
183	0.960075
184	0.959852
185	0.959778
186	0.959703
187	0.959629
188	0.959554
189	0.959480
190	0.959256
191	0.959107
192	0.959033
193	0.959033
194	0.958735
195	0.958585
196	0.958585
197	0.958511
198	0.958361
199	0.958062
200	0.958062
201	0.957987
202	0.957987
203	0.957913
204	0.957763
205	0.957613
206	0.957538
207	0.957388
208	0.957313
209	0.957238
210	0.957163
211	0.957163
212	0.956938
213	0.956863
214	0.956788
215	0.956713
216	0.956638
217	0.956488
218	0.956263
219	0.956263
220	0.956187
221	0.956112
222	0.956037
223	0.955887
224	0.955736
225	0.955736
226	0.955736
227	0.955661
228	0.955661

t=Time (in days)	S _{TX} (t)
229	0.955510
230	0.955510
231	0.955209
232	0.955209
233	0.955134
234	0.954983
235	0.954832
236	0.954681
237	0.954530
238	0.954455
239	0.954228
240	0.954228
241	0.954077
242	0.954077
243	0.953925
244	0.953850
245	0.953850
246	0.953774
247	0.953774
248	0.953698
249	0.953623
250	0.953395
251	0.953319
252	0.953016
253	0.953016
254	0.952712
255	0.952712
256	0.952712
257	0.952484
258	0.952408
259	0.952332
260	0.952256
261	0.952180
262	0.952104
263	0.951876
264	0.951800
265	0.951648
266	0.951648
267	0.951572
268	0.951495
269	0.955736
270	0.955661
271	0.950656
272	0.950579
273	0.950427
274	0.950274
275	0.950121
276	0.950121
277	0.949815
278	0.949662

t=Time (in days)	S _{TX} (t)
279	0.949662
280	0.949585
281	0.949585
282	0.949432
283	0.949355
284	0.949279
285	0.949279
286	0.949202
287	0.949202
288	0.949126
289	0.949049
290	0.948896
291	0.948819
292	0.948819
293	0.948589
294	0.948359
295	0.948282
296	0.948128
297	0.948052
298	0.947975
299	0.947821
300	0.947667
301	0.947667
302	0.947360
303	0.947360
304	0.947360
305	0.947360
306	0.947283
307	0.947283
308	0.947206
309	0.947129
310	0.946975
311	0.946821
312	0.946821
313	0.946821
310	0.946975
311	0.946821
312	0.946821
313	0.946821
312	0.946821
313	0.946821
314	0.946744
315	0.946590
316	0.946436
317	0.946359
318	0.946359
319	0.946204
320	0.946204
321	0.946127
322	0.946050

t=Time (in days)	S _{TX} (t)
323	0.946050
324	0.945896
325	0.945818
326	0.945587
327	0.945432
328	0.945432
329	0.945355
330	0.945278
331	0.945123
332	0.945123
333	0.944968
334	0.944891
335	0.944736
336	0.944581
337	0.944504
338	0.944194
339	0.944039
340	0.943961
341	0.943729
342	0.943651
343	0.943573
344	0.943418
345	0.943341
346	0.943108
347	0.943030
348	0.943030
349	0.942952
350	0.942719
351	0.942719
352	0.942719
353	0.942641
354	0.942485
355	0.942485
356	0.942173
357	0.942017
358	0.941783
356	0.942173
357	0.942017
358	0.941783
359	0.941705
360	0.941627
361	0.941549
362	0.941549
363	0.941315
364	0.941315

11.1(E)(I) Lung Disease Diagnosis Group Classifications

The LAS calculation makes use of diagnosis Groups A, B, C, and D. The diagnoses that are included in each group are listed below.

Group A

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

- 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
- Lymphangioliomyomatosis
- Obstructive lung disease
- Primary ciliary dyskinesia;
- Sarcoidosis with mean pulmonary artery pressure of 30 mm Hg or less
- Tuberos sclerosis
- Wegener's granuloma – bronchiectasis

Group B

A candidate is in Group B if the candidate has any of the following diagnosis:

- 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 diagnosis:

- 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 diagnosis:

- ABCA3 transporter mutation
- Alveolar proteinosis
- Amyloidosis
- Acute respiratory distress syndrome or pneumonia
- Bronchoalveolar carcinoma (BAC)
- Carcinoid tumorlets
- Chronic pneumonitis of infancy
- Constrictive bronchiolitis
- CREST – Restrictive
- Eosinophilic granuloma
- Fibrosing Mediastinitis
- Graft versus host disease (GVHD)
- Hermansky Pudlak syndrome
- Hypersensitivity pneumonitis
- Idiopathic interstitial pneumonia, with 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
- Nonspecific interstitial pneumonia
- Lymphocytic interstitial pneumonia
- Respiratory bronchiolitis-associated interstitial lung disease
- Idiopathic pulmonary hemosiderosis
- Lung retransplant or graft failure: acute rejection
- Lung retransplant or graft failure: non-specific
- Lung retransplant or graft failure: obliterative bronchiolitis-obstructive
- Lung retransplant or graft failure: obliterative bronchiolitis-restrictive
- Lung retransplant or graft failure: obstructive
- Lung retransplant or graft failure: other specify
- Lung retransplant or graft failure: primary graft failure
- Lung retransplant or graft failure: restrictive
- Lupus
- Mixed connective tissue disease
- Obliterative bronchiolitis: non-retransplant
- Occupational lung disease: other specify

- Paraneoplastic pemphigus associated Castleman's disease
- Polymyositis
- Pulmonary fibrosis other specify cause
- Pulmonary hyalinizing granuloma
- Pulmonary telangiectasia – restrictive
- Rheumatoid disease
- Sarcoidosis with mean pulmonary artery pressure higher than 30 mm Hg
- Scleroderma – restrictive
- Secondary pulmonary fibrosis (specify cause)
- Silicosis
- Sjogren's syndrome
- Surfactant protein B mutation
- Surfactant protein C mutation
- Teratoma
- Wegener's granuloma – restrictive

11.1(E)(II) PCO_2 in the Lung Allocation Score

Use of PCO_2 in the Lung Allocation Score

The LAS calculation uses two measures of PCO_2 , current PCO_2 and increase in PCO_2 .

Current PCO_2

Current PCO_2 is the PCO_2 value with the most recent test date and time reported to the OPTN Contractor. A program may report a PCO_2 value from an arterial, venous, or capillary blood gas test. All blood gas values will be converted to an arterial value as follows:

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

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

Increase in PCO_2

An increase in PCO_2 that is at least 15% will influence a candidate's LAS. The increase-in- PCO_2 calculation uses the highest and lowest values of PCO_2 . The test date of the lowest value must be earlier than the test date of the highest value. Test dates of these highest and lowest values cannot be more than 6 months apart. The increase in PCO_2 calculation could use an expired lowest value, but not an expired highest value. The equation for this increase-in- PCO_2 calculation is:

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

Once a candidate receives an influence due to the 15% or greater increase in PCO_2 , the LAS calculation assesses whether to maintain that influence. To maintain the influence of the

PCO₂ increase, the candidate's current PCO₂ value must be at least 15% higher than the lowest value used in the increase-in-PCO₂ calculation. The equation for this maintenance calculation is:

$$\frac{\text{Current PCO}_2 - \text{Lowest PCO}_2}{\text{Lowest PCO}_2}$$

The increase maintenance calculation occurs either when the current PCO₂ value expires or a new current PCO₂ value is entered.

11.1(E)(III) Bilirubin in the Lung Allocation Score

Use of Bilirubin in the Lung Allocation Score

The LAS calculation uses two measures of total bilirubin:

1. Current bilirubin (for all candidates)
2. Increase in bilirubin (for diagnosis Group B only)

Current Bilirubin

Current bilirubin is the total bilirubin value with the most recent test date and time reported to the OPTN Contractor. A current bilirubin value of at least .7 mg/dL has an influence in the candidate's LAS.

Increase in Bilirubin (Diagnosis Group B Only)

An increase in bilirubin that is at least 50% will influence a candidate's LAS for diagnosis Group B. The increase-in-bilirubin calculation uses the highest and lowest values of bilirubin. The test date of the lowest value must be earlier than the test date of the highest value. The highest value must be at least .7 mg/dL. Test dates of these highest and lowest values cannot be more than 6 months apart. The increase in bilirubin calculation could use an expired lowest value, but not an expired highest value. The equation for this increase-in-bilirubin calculation is:

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

Once a candidate receives an influence due to a 50% or greater increase in bilirubin, the LAS calculation assesses whether to maintain that influence. To maintain the influence of the bilirubin increase, the candidate's current bilirubin value must be at least 50% higher than the lowest value used in the increase-in-bilirubin calculation. The equation for this maintenance calculation is:

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

The increase maintenance calculation occurs either when the current bilirubin value expires or a new bilirubin value is entered.

11.1(E)(IV) Creatinine in the Lung Allocation Score

Use of creatinine in the Lung Allocation Score

The LAS calculation uses two measures of creatinine:

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

Current Creatinine

Current creatinine is the serum creatinine value with the most recent test date and time reported to the OPTN Contractor. The LAS calculation uses current creatinine only for candidates who are at least 18 years of age.

Increase in Creatinine

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

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

If a candidate's LAS is influenced by an increase in creatinine, then the LAS calculation will assess whether to maintain that influence. To maintain the influence of the increase in creatinine, the candidate's current creatinine value must be at least 150% higher than the lowest value used in the increase-in-creatinine calculation. The equation for this maintenance calculation is:

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

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

11.2 Priority and Score Exceptions

11.2(A) Sensitized Candidates

A transplant program may prioritize a sensitized candidate and not use the allocation rules in *Policy 3.7* if *both* of the following conditions are met:

1. The candidate's transplant surgeon or physician determines that the candidate's antibodies would react adversely to certain donor cell antigens.
2. The OPO serving the transplant program, as well as each lung transplant program served by that OPO, must agree to prioritize allocation of a lung from a compatible donor to the sensitized candidate.

11.2(B) Exceptions for Lung Candidates at Least 12 Years of Age

An exception case requires prospective review by the Lung Review Board (LRB). A transplant program may request an exception for a candidate three months before the candidate is 12 years of age. Transplant programs may request approval of estimated values, diagnosis, or a specific Lung Allocation Score. The transplant program will accompany each request for special case review with a supporting narrative.

Once complete, the request must be sent to the OPTN Contractor. The LRB will have seven calendar days to reach a decision, starting from the date that the contractor sends the request to the LRB. If a request is denied by the LRB upon initial review, then the center may choose to appeal the decision for reconsideration by the LRB.

The program will have seven calendar days from the date of the initial request denial to appeal. The Lung Review Board will have seven calendar days to reach a decision on the appeal, starting from the date that the contractor sends the appealed request to the Lung Review Board. If the Lung Review Board has not completed its review of an initial request or an appeal within seven calendar days of receiving it, then the candidate will receive the requested LAS, diagnosis, or estimated value, and the request or appeal will be forwarded to the Thoracic Organ Transplantation Committee for further review. Should the LRB deny a transplant program's initial request or appealed request for an estimated value or a specific LAS, the transplant program has the option to override the decision of the LRB.

If the transplant program elects to override the decision of the LRB, then the request or appeal will be automatically referred 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 for appropriate action according to *Appendix L: Reviews, Actions, and Due Process* of the OPTN Bylaws.

Estimated values will remain valid until an actual value or a new estimated value is provided to the OPTN Contractor as required by the procedures described in this Policy. A diagnosis that has been approved by the LRB or the Thoracic Organ Transplantation Committee will remain valid indefinitely or until an adjustment is requested and, if

necessary, approved by the LRB. A specific LAS granted by the LRB will remain valid for six months from the entry date (or the candidate's twelfth birthday, whichever occurs later). If the candidate continues to be on the waiting list six months after the entry date, then the candidate's LAS will be computed as described in Policy 11.1(E) *Candidates at Least 12 Years of Age - Lung Allocation Score (LAS) System* above unless a new LAS request is entered as described in this policy or the transplant program chooses to use the computed LAS instead.

The Thoracic Committee will establish guidelines for special case review by the LRB.

11.2(C) Exceptions for Lung Candidates Less than 12 Years of Age

In its review of exception requests, the Lung Review Board will follow the prospective review process in Policy 11.2: *Priority and Score Exceptions*.

11.2(D) Lung Review Board Composition

The Lung Review Board (LRB) has seven lung transplant surgeons or physicians, at least one of whom primarily cares for pediatric lung transplant candidates. The OPTN Contractor will randomly select these seven LRB members from transplant programs with active adult and pediatric lung transplant components.

LRB members serve two-year terms. The OPTN Contractor will stagger service terms among the LRB members so that no more than four terms will expire at the same time.

To prevent a conflict of interest during case reviews, each LRB member must appoint an alternate member from the member's transplant program.

If an LRB member leaves his transplant program, then the transplant program's alternate LRB member will become the primary member, and the transplant program must appoint another alternate.

The chair of the Thoracic Organ Transplantation Committee will be one of the LRB members as the LRB Chair. The LRB's chair serves in this capacity for a maximum of two years, beginning on July 1 of the calendar year of the appointment. The LRB Chair serves as a voting member on the Thoracic Organ Transplantation Committee.

The LRB Chair will appoint a vice-chair to the LRB. The vice-chair may be a non LRB-member. The LRB vice-chair is a non-voting member who assumes the LRB chairmanship at the conclusion of the LRB Chair's term. The LRB vice-chair assists the LRB chair as requested by the LRB chair. The LRB vice-chair is not a member of the Thoracic Organ Transplantation Committee.

11.2(E) Responsibilities of the LRB Members

The LRB member must vote within 72 hours on each exception case and participate on case review conference calls as needed. Each LRB member casts one vote on each case reviewed. If the alternate LRB member votes, the primary member's vote on the given case becomes invalid.

An LRB member cannot vote on any case submitted by the member's transplant program.

11.2(F) Voting Procedures

When the LRB receives an exception request, it will have seven days to decide whether to grant or deny the request. If the LRB does not complete its review within seven days, then *both* of the following will occur:

1. The candidate will receive the requested LAS or priority
2. The Thoracic Organ Transplantation Committee will decide whether the candidate clinically deserves the higher priority or LAS.

To approve the request, a majority of the LRB must approve the request.

The OPTN Contractor will notify the transplant program about the LRB's decision.

Alternatively, the LRB may refer a request to the Thoracic Organ Transplantation Committee for review and judgment. In such referrals, the OPTN Contractor will provide in writing the number of previous case referrals from that transplant program and the outcome of those referrals.

11.2(G) Appealing an LRB Decision

If a transplant program is not satisfied with the LRB's decision on a request, the transplant program may initiate an appeal. To appeal an LRB's decision, the transplant program must do so within seven days of receiving the LRB's decision from the OPTN Contractor. After seven days, the transplant program forfeits their right to appeal.

In the appeal, the transplant program must submit a new exception request, provide new information supporting the request, and address any comments of dissenting LRB members.

The LRB will vote on the appeal. If the transplant program is not satisfied with the result, it may request a conference call with the LRB to further appeal the decision, or request that the Thoracic Organ Transplantation Committee review the case.

The transplant program may make a final appeal to the Thoracic Organ Transplantation Committee if a satisfactory conclusion cannot be met at the LRB level. The transplant program must submit to the OPTN Contractor any additional information that it wants this committee to consider.

Individual patients are not eligible to appeal LRB rulings. Only transplant programs may submit applications and appeals.

11.2(H) Overriding an LRB Decision

If the transplant program disagrees with the decision of the LRB, it may implement the requested exception. However, the Thoracic Organ Transplantation Committee will retrospectively review the case. The Thoracic Organ Transplantation Committee's review may result in the transplant program's referral to the Membership and Professional Standards Committee for action as outlined in *Appendix L: Reviews, Actions, and Due Process* of the OPTN Bylaws.

11.3 Waiting Time

11.3(A) Lung Candidates at Least 12 Years of Age

Waiting time for candidates at least 12 years of age begins when the candidate is registered on the waiting list. These candidates do not accrue any waiting time while inactive.

Candidates awaiting a lung transplant on the waiting list at inactive status will be subject to the same requirements for updating candidates' clinical data as indicated in Policy 11.4(B): *Status and Clinical Data Update Schedule* and will not accrue any waiting time while at inactive status.

11.3(B) Lung Candidates Less than 12 Years of Age

Waiting time for candidates less than 12 years of age begins when the candidate is registered on the waiting list.

11.4 Classification Notes

11.4(A) Sorting Within Each Classification

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

1. Lung Allocation Score (LAS)
2. Total active waiting time (longest to shortest)

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

1. Pediatric priority waiting time (longest to shortest)
2. Total waiting time (longest to shortest)
3. LAS variable update date and time (most recent to oldest)
4. LAS exception date (earliest to oldest approval)

Among Priority 2 candidates, allocation ranking considers total waiting time for receiving deceased donor lung offers. Total waiting time includes 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.

A priority 1 lung candidate's waiting time 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 for receiving a deceased donor lung offer, allocation ranking will also consider this total waiting time.

Within each priority, candidates receive their rankings according to blood type and then by waiting time, in descending order.

11.4(B) Status and Clinical Data Update Schedule

11.4(B)(I) Reporting Clinical Data for Candidates at Least 12 Years of Age

When registering a candidate who is at least 12 years of age for lung transplantation, transplant programs must report to the OPTN Contractor clinical data corresponding to the covariates shown in Table 11-2: *Waiting List Mortality Calculation, Covariates, and Their Coefficients* and Table 11-3: *Post-Transplant Survival Calculation, Covariates, and Their Coefficients*. The transplant program must maintain source documentation in the candidate's chart.

Except as noted in Policy 11.4(B)(II) *Reporting Data for Candidates with LASs of 50 or Higher* transplant programs must report to the OPTN Contractor LAS covariate data for a candidate by every six-month anniversary date. The LAS system defines a six-month anniversary date as first occurring six months from the date of initial registration, then every six months thereafter.

The LAS system will consider a covariate's value to be expired if the covariate's test date is six-months older than the most recent six-month anniversary date. The LAS system will consider actual values or approved estimated values for pulmonary pressures to be valid until the transplant program updates them with new actual values or new approved estimated values.

Transplant programs do not need to report every six months LAS covariate data that requires a heart catheterization to obtain. For LAS covariate data that requires a heart catheterization, the transplant program may determine the frequency of performing the heart catheterization. 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. The transplant program must maintain source documentation of all heart catheterization test results in the candidate's chart.

If values for certain covariates are missing, expired, or below a threshold, then the LAS calculation will use a substituted value to calculate the candidate's LAS. *Table 11-6: Data Substituted for Missing or Expired Actual Values in Calculating the LAS* lists the covariates for which the LAS calculation will use substituted data if the actual values are missing, expired, or below a threshold.

Table 11-6: Data Substituted for Missing or Expired Actual Values in Calculating the LAS

If this covariate's value is missing, expired, or below the threshold value:	Then the LAS calculation will use this substituted value:
Bilirubin: current	0.7 mg/dL if the actual value is missing, expired, or less than 0.7 mg/dL
Body mass index	100 kg/m ² if the actual value is missing or expired
Cardiac index	3.0 L/min/m ² if the actual value is missing
Central venous pressure	5 mm Hg if the actual value is missing or less than 5 mm Hg
Continuous mechanical ventilation	<ul style="list-style-type: none"> • No mechanical ventilation in the waiting list model if the actual value is missing or expired • Continuous mechanical ventilation in the post-transplant model if the actual value is missing or expired
Serum creatinine	0.1 mg/dL in the waiting list model if the actual value is missing or expired 40 mg/dL in the post transplant model for candidates at least 18 years of age if the actual value is missing or expired
Diabetes	No diabetes if the actual value is missing or expired
Forced vital capacity (FVC)	150% for diagnosis Group D if the actual value is missing or expired
Functional Status	<ul style="list-style-type: none"> • No assistance needed in the waiting list model if the actual value is missing or expired • Some or total assistance needed in the post-transplant model if the actual value is missing or expired
Oxygen needed at rest	<ul style="list-style-type: none"> • No supplemental oxygen needed in the waiting list model if the actual value is missing or expired • 26.33 L/min in the post transplant model if the actual value is missing or expired

11.4(B)(II) Reporting Data for Candidates with LASs of 50 or Higher

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

1. Assisted ventilation
2. Supplemental oxygen
3. Current PCO₂

If a program does not perform a PCO₂ test in that time, then it does not need to provide this update to the OPTN Contractor. While the candidate's score remains 50 or higher, a program must continue to assess and report any observed change in the three clinical variables no less frequently than 14 days from the date of the previous assessment.

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

11.4(B)(III) Reporting Clinical Data for Candidates Less than 12 Years of Age

A transplant program may update clinical data used to justify a candidate's priority at any time. For a candidate classified as Priority 1, a program must update each qualifying criterion, except criteria that requires a heart catheterization, at least once in each six month period following the candidate's registration on the lung transplant waiting list. For clinical data that requires a heart catheterization, the transplant program may determine the frequency of performing the heart catheterization.

If more than six months elapse without data updates after the candidate's last six-month anniversary of waiting list registration, then the candidate's Priority 1 will become Priority 2.

Candidates awaiting a lung transplant on the waiting list at inactive status are subject to the same requirements for updating clinical data.

11.4(C) Blood Type

A candidate whose blood type is identical to the donor's will receive the single or double lung offer before a candidate whose blood type is compatible with the donor's.

11.5 Lung Allocation Classifications and Rankings

11.5(A) Donors Aged 18 Years and Older

The OPTN allocates single and double lungs from donors at least 18 years of age in the following order:

Table 11-7: Allocation of Lungs from Donors at Least 18 Years of Age

Classification	Candidates that are within the...	And are...
1.	Donor hospital's local unit	At least 12 years of age and have a blood type identical to the donor
2.	Donor hospital's local unit	At least 12 years of age and have a blood type compatible with the donor
3.	Donor hospital's local unit	Priority 1, less than 12 years of age, and have a blood type identical to the donor
4.	Donor hospital's local unit	Priority 1, less than 12 years of age, and have a blood type compatible with the donor
5.	Donor hospital's local unit	Priority 2, less than 12 years of age, and have a blood type identical to the donor
6.	Donor hospital's local unit	Priority 2, less than 12 years of age, and have a blood type compatible with the donor

Classification	Candidates that are within the...	And are...
7.	Zone A	At least 12 years of age and have a blood type identical to the donor
8.	Zone A	At least 12 years of age and have a blood type compatible with the donor
9.	Zone A	Priority 1, less than 12 years of age, and have a blood type identical to the donor
10.	Zone A	Priority 1, less than 12 years of age, and have a blood type compatible with the donor
11.	Zone A	Priority 2, less than 12 years of age, and have a blood type identical to the donor
12.	Zone A	Priority 2, less than 12 years of age, and have a blood type compatible with the donor
13.	Zone B	At least 12 years of age and have a blood type identical to the donor
14.	Zone B	At least 12 years of age and have a blood type compatible with the donor
15.	Zone B	Priority 1, less than 12 years of age, and have a blood type identical to the donor
16.	Zone B	Priority 1, less than 12 years of age, and have a blood type compatible with the donor
17.	Zone B	Priority 2, less than 12 years of age, and have a blood type identical to the donor
18.	Zone B	Priority 2, less than 12 years of age, and have a blood type compatible with the donor
19.	Zone C	At least 12 years of age and have a blood type identical to the donor
20.	Zone C	At least 12 years of age and have a blood type compatible with the donor
21.	Zone C	Priority 1, less than 12 years of age, and have a blood type identical to the donor
22.	Zone C	Priority 1, less than 12 years of age, and have a blood type compatible with the donor
23.	Zone C	Priority 2, less than 12 years of age, and have a blood type identical to the donor
24.	Zone C	Priority 2, less than 12 years of age, and have a blood type compatible with the donor
25.	Zone D	At least 12 years of age and have a blood type identical to the donor
26.	Zone D	At least 12 years of age and have a blood type compatible with the donor
27.	Zone D	Priority 1, less than 12 years of age, and have a blood type identical to the donor
28.	Zone D	Priority 1, less than 12 years of age, and have a blood type compatible with the donor
29.	Zone D	Priority 2, less than 12 years of age, and have a blood type identical to the donor

Classification	Candidates that are within the...	And are...
30.	Zone D	Priority 2, less than 12 years of age, and have a blood type compatible with the donor
31.	Zone E	At least 12 years of age and have a blood type identical to the donor
32.	Zone E	At least 12 years of age and have a blood type compatible with the donor
33.	Zone E	Priority 1, less than 12 years of age and have a blood type identical to the donor
34.	Zone E	Priority 1, less than 12 years of age, and have a blood type compatible with the donor
35.	Zone E	Priority 2, less than 12 years of age, and have a blood type identical to the donor
36.	Zone E	Priority 2, less than 12 years of age, and have a blood type compatible with the donor

11.5(B) Donors Aged 12 to 17 Years of Age

The OPTN allocates single and double lungs from donors 12 to 17 years of age in the following order:

Table 11-8: Allocation of Lungs from Donors 12 to 17 Years of Age

Classification	Candidates that are within the...	And are...
1.	Donor hospital's local unit	12 to 17 years of age and have a blood type identical to the donor
2.	Donor hospital's local unit	12 to 17 years of age and have a blood type compatible with the donor
3.	Donor hospital's local unit	Status 1, less than 12 years of age, and have a blood type identical to the donor
4.	Donor hospital's local unit	Status 1, less than 12 years of age, and have a blood type compatible with the donor
5.	Donor hospital's local unit	Status 2, less than 12 years of age, and have a blood type identical to the donor
6.	Donor hospital's local unit	Status 2, less than 12 years of age, and have a blood type compatible with the donor
7.	Donor hospital's local unit	At least 18 years and have a blood type identical to the donor
8.	Donor hospital's local unit	At least 18 years of age and have a blood type compatible with the donor
9.	Zone A	12 to 17 years of age and have a blood type identical to the donor
10.	Zone A	12 to 17 years of age and have a blood type compatible with the donor
11.	Zone A	Priority 1, less than 12 years of age, and have a blood type identical to the donor

Classification	Candidates that are within the...	And are...
12.	Zone A	Priority 1, less than 12 years of age, and have a blood type compatible with the donor
13.	Zone A	Priority 2, less than 12 years of age, and have a blood type identical to the donor
14.	Zone A	Priority 2, less than 12 years of age, and have a blood type compatible with the donor
15.	Zone A	At least 18 years of age and have a blood type identical to the donor
16.	Zone A	At least 18 years of age and have a blood type compatible with the donor
17.	Zone B	12 to 17 years of age and have a blood type identical to the donor
18.	Zone B	12 to 17 years of age and have a blood type compatible with the donor
19.	Zone B	Priority 1, less than 12 years of age, and have a blood type identical to the donor
20.	Zone B	Priority 1, less than 12 years of age, and have a blood type compatible with the donor
21.	Zone B	Priority 2, less than 12 years of age, and have a blood type identical to the donor
22.	Zone B	Priority 2, less than 12 years of age, and have a blood type compatible with the donor
23.	Zone B	At least 18 years of age and have a blood type identical to the donor
24.	Zone B	At least 18 years of age and have a blood type compatible with the donor
25.	Zone C	12 to 17 years of age and have a blood type identical to the donor
26.	Zone C	12 to 17 years of age and have a blood type compatible with the donor
27.	Zone C	Priority 1, less than 12 years of age, and have a blood type identical to the donor
28.	Zone C	Priority 1, less than 12 years of age, and have a blood type compatible with the donor
29.	Zone C	Priority 2, less than 12 years of age, and have a blood type identical to the donor
30.	Zone C	Priority 2, less than 12 years of age, and have a blood type compatible with the donor
31.	Zone C	At least 18 years of age and have a blood type identical to the donor
32.	Zone C	At least 18 years of age and have a blood type compatible with the donor
33.	Zone D	12 to 17 years of age and have a blood type identical to the donor
34.	Zone D	12 to 17 years of age and have a blood type compatible with the donor

Classification	Candidates that are within the...	And are...
35.	Zone D	Priority 1, less than 12 years of age, and have a blood type identical to the donor
36.	Zone D	Priority 1, less than 12 years of age, and have a blood type compatible with the donor
37.	Zone D	Priority 2, less than 12 years of age, and have a blood type identical to the donor
38.	Zone D	Priority 2, less than 12 years of age, and have a blood type compatible with the donor
39.	Zone D	At least 18 years of age and have a blood type identical to the donor
40.	Zone D	At least 18 years of age and have a blood type compatible with the donor
41.	Zone E	12 to 17 years of age and have a blood type identical to the donor
42.	Zone E	12 to 17 years of age and have a blood type compatible with the donor
43.	Zone E	Priority 1, less than 12 years of age, and have a blood type identical to the donor
44.	Zone E	Priority 1, less than 12 years of age, and have a blood type compatible with the donor
45.	Zone E	Priority 2, less than 12 years of age, and have a blood type identical to the donor
46.	Zone E	Priority 2, less than 12 years of age, and have a blood type compatible with the donor
47.	Zone E	At least 18 years of age and have a blood type identical to the donor
48.	Zone E	At least 18 years of age and have a blood type compatible with the donor

11.5(C) Donors Less Than 12 Years of Age

The OPTN allocates single and double lungs from donors less than 12 years in the following order:

Table 11-9: Allocation of Lungs from Donors Less than 12 Years of Age

Classification	Candidates that are within the...	And are...
1.	Donor hospital's local unit, Zone A, or Zone B	Priority 1, less than 12 years of age, and have a blood type identical to the donor
2.	Donor hospital's local unit, Zone A, or Zone B	Priority 1, less than 12 years of age, and have a blood type compatible with the donor
3.	Donor hospital's local unit, Zone A, or Zone B	Priority 2, less than 12 years of age, and have a blood type identical to the donor
4.	Donor hospital's local unit, Zone A, or Zone B	Priority 2, less than 12 years of age, and have a blood type compatible with the

Classification	Candidates that are within the...	And are...
		donor
5.	Donor hospital's local unit or Zone A	12 to 17 years of age and have a blood type identical to the donor
6.	Donor hospital's local unit or Zone A	12 to 17 years of age and have a blood type compatible with the donor
7.	Donor hospital's local unit	At least 18 years of age and have a blood type identical to the donor
8.	Donor hospital's local unit	At least 18 years of age and have a blood type compatible with the donor
9.	Zone A	At least 18 years of age and have a blood type identical to the donor
10.	Zone A	At least 18 years of age and have a blood type compatible with the donor
11.	Zone B	12 to 17 years of age and have a blood type identical to the donor
12.	Zone B	12 to 17 years of age and have a blood type compatible with the donor
13.	Zone B	At least 18 years of age and have a blood type identical to the donor
14.	Zone B	At least 18 years of age and have a blood type compatible with the donor
15.	Zone C	Priority 1, less than 12 years of age, and have a blood type identical to the donor
16.	Zone C	Priority 1, less than 12 years of age, and have a blood type compatible with the donor
17.	Zone C	Priority 2, less than 12 years of age, and have a blood type identical to the donor
18.	Zone C	Priority 2, less than 12 years of age, and have a blood type compatible with the donor
19.	Zone C	12 to 17 years of age and have a blood type identical to the donor
20.	Zone C	12 to 17 years of age and have a blood type compatible with the donor
21.	Zone C	At least 18 years of age and have a blood type identical to the donor
22.	Zone C	At least 18 years of age and have a blood type compatible with the donor
23.	Zone D	Priority 1, less than 12 years of age, and have a blood type identical to the donor
24.	Zone D	Priority 1, less than 12 years of age, and have a blood type compatible with the donor
25.	Zone D	Priority 2, less than 12 years of age, and have a blood type identical to the donor

Classification	Candidates that are within the...	And are...
26.	Zone D	Priority 2, less than 12 years of age, and have a blood type compatible with the donor
27.	Zone D	12 to 17 years of age and have a blood type identical to the donor
28.	Zone D	12 to 17 years of age and have a blood type compatible with the donor
29.	Zone D	At least 18 years of age and have a blood type identical to the donor
30.	Zone D	At least 18 years of age and have a blood type compatible with the donor
31.	Zone E	Priority 1, less than 12 years of age, and have a blood type identical to the donor
32.	Zone E	Priority 1, less than 12 years of age, and have a blood type compatible with the donor
33.	Zone E	Priority 2, less than 12 years of age, and have a blood type identical to the donor
34.	Zone E	Priority 2, less than 12 years of age, and have a blood type compatible with the donor
35.	Zone E	12 to 17 years of age and have a blood type identical to the donor
36.	Zone E	12 to 17 years of age and have a blood type compatible with the donor
37.	Zone E	At least 18 years of age and have a blood type identical to the donor
38.	Zone E	At least 18 years of age and have a blood type compatible with the donor

11.6 Administrative Rules

Reserved.

11.7 Variances

Reserved.

Notes

For membership and personnel requirements for lung programs, see *Appendices I and J* of the OPTN Bylaws.

History

Organ Procurement and Transplantation Network (OPTN) Policies

Policy 1:

Policy 3.7: Allocation of Thoracic Organs: 11/16/2000; 11/15/2001; 6/27/2002; 11/14/2002; 6/26/2003; 11/20/2003; 6/24/2004; 11/18/2004; 6/23/2005; 11/17/2005; 6/29/2006; 9/20/2006; 12/13/2006; 3/23/2007; 6/19/2008; 11/16/2009; 11/8/2010; *Policy 11: Allocation of Lungs:* 11/2012 (eff. 2/1/2013)

Notes

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

Policy 12: Allocation of Pancreas and Pancreas Islets

12.1	Calculated Panel Reactive Antibody	172
12.2	Points	172
12.3	Waiting Time	172
12.4	Classification Notes	174
12.5	Pancreas and Pancreas Islet Allocation Classifications and Rankings	177
12.6	Administrative Rules	178
12.7	Variances	179

Introduction

This Policy contains requirements for the allocation of kidney-pancreas, pancreas, and pancreas islets, and certain rules regarding such candidate registrations.

Policy Statement

12.1 Calculated Panel Reactive Antibody

Pancreatic candidates will receive a calculated panel reactive antibody (CPRA) value according to Policy 9.1: *Calculated Panel Reactive Antibody*.

12.2 Points

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

12.3 Waiting Time

12.3(A) Pancreas and Pancreas Islet Waiting Time Criteria

Waiting time for pancreas and pancreas islet candidates begins when the candidate is first registered as an active pancreas or pancreas islet candidate on the waiting list.

Pancreas and pancreas islet candidates continue to accrue waiting time while classified as inactive.

12.3(B) Kidney-Pancreas Waiting Time Criteria for Candidates Aged Less than 18 Years

In order to accrue waiting time for a kidney-pancreas transplant, a kidney-pancreas candidate, who is less than 18 years of age at the time of kidney-pancreas registration, does not have to meet the qualifying criteria according to Policy 12.3(C) *Kidney-Pancreas Waiting Time Criteria for Candidates Aged 18 Years or Older*. Waiting time will begin when the candidate qualifies for waiting time according to Policy 9.4 *Waiting Time*.

12.3(C) Kidney-Pancreas Waiting Time Criteria for Candidates Aged 18 Years or Older

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

1. Qualify for a kidney transplant according to Policy 9.4: *Waiting Time*
2. Meet *one* of the following criteria:
 - a. Is on insulin and C-peptide less than or equal to 2 ng/mL
 - b. Is on insulin and C-peptide greater than 2 ng/mL and has a body mass index (BMI) less than or equal to the maximum allowable BMI.

The maximum allowable BMI is 28 kg/m². Every six months, the OPTN Contractor will determine the percent of kidney-pancreas candidates that meet criteria 2(b) above. The OPTN Contractor will then modify the maximum allowable BMI according to Table 12-1: *Maximum Allowable BMI*.

Table 12-1: Maximum Allowable BMI

If...	Then...
The percent of active kidney-pancreas candidates that meet criteria 2(b) is greater than 15%	The OPTN Contractor will reduce the maximum allowable BMI by 2 kg/m ²
The percent of active kidney-pancreas candidates that meet criteria 2(b) is less than 10%	The OPTN Contractor will increase the maximum allowable BMI by 2 kg/m ²

The maximum allowable BMI may never exceed 30 kg/m². 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.

Transplant Programs must document when and how a kidney-pancreas candidate qualified for waiting time.

For candidates who qualify for kidney-pancreas waiting time, waiting time will begin when the candidate qualifies for waiting time according to Policy 9.4 *Waiting Time*.

Kidney-pancreas candidates continue to accrue waiting time while registered on the waiting list as inactive.

12.4 Classification Notes

12.4(A) Order of Allocation to Kidney, Kidney-Pancreas, and Pancreas Candidates

If a Host OPO only has a pancreas to offer for allocation, then the Host OPO must offer the pancreas to pancreas and pancreas islet candidates but not kidney-pancreas candidates according to Policy 12.5 *Pancreas and Pancreas Islet Allocation Classifications and Rankings*.

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 according to Policy 6.5: *Allocation of Kidney-Pancreas*.

12.4(B) Sorting Within Each Classification

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

12.4(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 *either*:

- Allocate the organ according to the match run under Policy 9.6 *Kidney Allocation Classifications and Rankings* and allocate the pancreas according to Policy 12.5 *Pancreas and Pancreas Islet Allocation Classifications and Rankings*
- Allocate the organ for the remaining zero antigen mismatched potential recipients

If the Host OPO continues to offer kidney-pancreas for zero antigen mismatched potential recipients beyond the 10th zero antigen mismatched potential recipient, a kidney payback will be generated according to Policy 9.7(B): *Payback Requirements*.

If the Host OPO shares a zero antigen mismatched kidney-pancreas through the OPTN Contractor, then the Host OPO must submit to the OPTN Contractor a completed *Kidney Payback Accounting Sheet* within 5 business days of recovering the organs. The OPTN Contractor will not assign a payback credit until the OPTN Contractor does *both*:

1. Receives the *Kidney Payback Accounting Sheet* documenting the zero antigen mismatch share
2. Verifies that the Transplant Hospital reported the cross clamp and final acceptance.

If the Host OPO does not complete both steps above within 5 business days of the organ recovery, then the Host OPO forfeits the payback credit.

12.4(D) Blood Type For Kidney-Pancreas Allocation

Blood types for kidney-pancreas candidates and donors are matched according to Table 12-2: *Blood Typing for Kidney-Pancreas Allocation*. Fields with a “●” indicate identical blood type matches. Fields with a “◐” indicate permissible blood type matches. Fields with a “○” indicate impermissible blood type matches. Fields with a “◑” indicate permissible blood type matches only if the candidate is has a zero antigen mismatch with the donor and has a CPRA greater than or equal to 80%; otherwise the match is impermissible.

Table 12-2: Blood Typing for Kidney-Pancreas Allocation

Donor's Blood Type	Candidate is O	Candidate is A	Candidate is B	Candidate is AB
O	●	◐	◐	◐
A	○	●	○	◐
B	○	○	●	◐
AB	○	○	○	●

12.4(E) Pancreas Islet Status

If a pancreas islet candidate meets any of the following criteria, then the candidate may be active on the waiting list; if, however, a pancreas islet candidate does not meet *any* of the following criteria, then the candidate will be inactive on the waiting list:

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

If the Transplant Hospital changes a candidate's status from inactive to active, the Transplant Hospital must document that the candidate met the above criteria.

If a candidate's clinical condition changes and the candidate becomes inactive, the Transplant Hospital must report this change 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 record when the Transplant Hospital learned of this change.

If the candidate is active and is insulin dependent, then the Transplant Hospital must document in the candidate's record every six months the candidate's insulin status.

If the candidate is active and is insulin independent, then the Transplant Hospital must document in the candidate's record every six months the candidate's insulin status and HbA1c value. The Transplant Hospital must use the most recent HbA1c test performed within the last six months when determining whether the candidate meets the criteria for active status. The test date must be documented in the candidate's candidate record.

12.4(F) Medical Suitability of Pancreatic Islets

Pancreatic 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 will determine and document *both*:

1. Whether the pancreatic islet preparation meets the Transplant Hospital's islet product release criteria contained in the IND
2. Whether the pancreatic islets are medically suitable or medically unsuitable for the candidate that accepted the islets.

If the pancreatic islets are medically unsuitable for the candidate, the Transplant Hospital must also document the reason the islets were medically unsuitable for the candidate.

If the Transplant Hospital determines that the pancreatic 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 is responsible for documenting compliance with this Policy.

12.5 Pancreas and Pancreas Islet Allocation Classifications and Rankings

12.5(A) Donors 50 years of age and less with a BMI less than or equal to 30 kg/m²

Pancreata, kidney-pancreata, and pancreas islets from donors 50 years of age or less and who have a Body Mass Index (BMI) less than or equal to 30 kg/m² will be allocated to candidates in the following order:

Table 12-3: Allocation of Kidneys and Pancreata from Donors 50 years of age and less with a BMI less than or equal to 30 kg/m²

Classification	Candidates that are within the...	And...
1.	Donor hospital's local unit	Have a zero antigen mismatch with the donor, have a CPRA greater than or equal to 80%, and are either pancreas or kidney-pancreas candidates
2.	Donor hospital's local unit	Have a CPRA greater than or equal to 80% and are either pancreas or kidney-pancreas candidates
3.	Donor hospital's region	Have a zero antigen mismatch with the donor, have a CPRA greater than or equal to 80%, and are either pancreas or kidney-pancreas candidates
4.	Nation	Have a zero antigen mismatch with the donor, have a CPRA greater than or equal to 80%, and are either pancreas or kidney-pancreas candidates
5.	Donor hospital's local unit	Are pancreas or kidney-pancreas candidates
6.	Donor hospital's region	Have a CPRA greater than or equal to 80% and are either pancreas or kidney-pancreas candidates
7.	Donor hospital's region	Are pancreas or kidney-pancreas candidates
8.	Nation	Have a CPRA greater than or equal to 80% and are either pancreas or kidney-pancreas candidates
9.	Nation	Are pancreas or kidney-pancreas candidates
10.	Donor hospital's local unit	Are pancreas islet candidates
11.	Donor hospital's region	Are pancreas islet candidates
12.	Nation	Are pancreas islet candidates

12.5(B) Donors greater than 50 years of age or from donors who have a BMI greater than 30 kg/m²

Pancreata, kidney-pancreata, and pancreas islets from donors greater than 50 years of age or from donors who have a Body Mass Index (BMI) greater than 30 kg/m² are allocated to candidates in the following order:

Table 12-4: Allocation of Kidneys and Pancreata from donors greater than 50 years of age or from donors who have a BMI greater than 30 kg/m²

Classification	Candidates that are within the...	And...
1.	Donor hospital's local unit	Have a zero antigen mismatch with the donor, have a CPRA greater than or equal to 80%, and are either pancreas or kidney-pancreas candidates
2.	Donor hospital's local unit	Have a CPRA greater than or equal to 80% and are either pancreas or kidney-pancreas candidates
3.	Donor hospital's region	Have a zero antigen mismatch with the donor, have a CPRA greater than or equal to 80%, and are either pancreas or kidney-pancreas candidates
4.	Nation	Have a zero antigen mismatch with the donor, have a CPRA greater than or equal to 80%, and are either pancreas or kidney-pancreas candidates
5.	Donor hospital's local unit	Are pancreas or kidney-pancreas candidates
6.	Donor hospital's local unit	Are pancreas islet candidates
7.	Donor hospital's region	Are pancreas islet candidates
8.	Nation	Are pancreas islet candidates
9.	Donor hospital's region	Have a CPRA greater than or equal to 80% and are either pancreas or kidney-pancreas candidates
10.	Donor hospital's region	Are pancreas or kidney-pancreas candidates
11.	Nation	Have a CPRA greater than or equal to 80% and are either pancreas or kidney-pancreas candidates
12.	Nation	Are pancreas or kidney-pancreas candidates

12.6 Administrative Rules

12.6(A) Facilitated Pancreas Allocation

If no candidate accepts a pancreas offer from the OPTN Contractor within five hours of the offer or the procurement of the pancreas is anticipated to occur within one hour, then the

OPTN Contractor may offer the pancreas to pancreas candidates who meet *all* of the following criteria:

1. Candidates who have not previously received an offer for that pancreas
2. Candidates in order of the match run
3. Pancreas candidates registered at Transplant Hospitals that previously agreed to accept any pancreas offered according to this section and that may have been procured outside of the Transplant Hospital's local unit. The Transplant Hospital must document this agreement in writing.

12.7 Variances

Reserved.

History

Policy 3.8: Pancreas Allocation: 6/27/2002; 6/26/2003; 11/20/2003; 6/24/2004; 11/18/2004; 12/13/2006; 6/19/2008; 3/2/2009; 11/8/2010; Policy 12: Allocation of Pancreas and Pancreas Islets: 11/2012 (eff. 2/1/2013)

Notes

- For membership requirements for pancreas and pancreatic islet Transplant Programs, see OPTN Bylaws Appendix G.
- For potential pancreas donor testing requirements, see Policy 2.4: *Potential Donors Information*.
- For pancreas acceptance criteria, see Policy 5.1(E): *Pancreas Acceptance Criteria*.

Policy 13: Living Donation

Reserved

The Living Donation policy is not included in the plain language rewrite of the policies because the Living Donor committee and the Board are considering several substantive proposals to current Policy 12 (Living Donation).

Policy 14: Kidney Paired Donation

Reserved.

Policy 15: Identification of Transmissible Diseases in Organ Recipients

15.1	Patient Safety Contact	182
15.2	Candidate Screening Requirements	182
15.3	Informed Consent	183
15.4	Requirements When There is an Increased Risk of Transmissible Disease	183
15.5	Reporting of Unexpected Potential and Proven Transmissions of Disease	184

Introduction

This Policy covers the detection of and reporting of disease transmission through deceased donor and living donor organ transplantation. It also sets requirements for potential transplant recipients to give informed consent to transplant organs with diseases.

Policy Statement

15.1 Patient Safety Contact

Each OPO and Transplant Program must identify a Patient Safety Contact. Each OPO and Transplant Program must also develop a process for how the Patient Safety Contact will communicate with and disseminate information from the OPTN Contractor about potential disease transmissions. The Patient Safety Contact must do *all* of the following:

1. Be available 24 hours a day
2. Receive potential disease transmission notifications from the OPTN Contractor
3. Receive pertinent medical information that may affect or change recipient care
4. Communicate any information regarding potential disease transmissions to the medical professional responsible for clinical care of the recipient at the Transplant Program as soon as possible, but at the latest within 24 hours of becoming aware of the potential disease transmission related to that recipient's donor
5. Communicate the current clinical status of any recipient to the OPTN Contractor when the Transplant Program is notified of a potential or proven disease transmission related to that recipient's donor

15.2 Candidate Screening Requirements

To be eligible for an organ transplant, patients must undergo testing for HIV, Hepatitis B, and Hepatitis C, unless such testing would violate state or federal laws. Transplant Programs should offer counseling to patients who test positive for any of the above.

A patient who tests positive for HIV may still receive an organ transplant unless there is a documented contraindication to transplantation based on state law or the Transplant Hospital's

policies. A Transplant Program should inform health care personnel, who care for a patient or candidate that tests positive for HIV, only when necessary for medical decisions.

15.3 Informed Consent

Transplant Programs must inform candidates of the general risks of transmissible disease including *all* of the following information:

1. Donors are only required to undergo testing for the diseases listed in Policy 2.4(B)
Donor Tests
2. It is not possible to screen potential donors for all transmissible diseases
3. Transmissible diseases may be identified after transplantation.

The Transplant Program must do *all* of the following:

1. Explain these risks and obtain informed consent from the candidate or agent before transplant
2. Document this consent in the candidate's medical record

15.4 Requirements When There is an Increased Risk of Transmissible Disease

15.4(A) Risk Requiring Action

Transplant Programs must fulfill the requirements of Policies 15.4(B)-(C) when any of the following occur:

1. The donor has a known transmissible disease
2. The donor has a recognized increased risk for disease transmission according to the Transplant Program's medical judgment
3. The donor meets the guidelines for increased-risk for disease transmission as specified in the U.S. Public Health Service Guidelines
4. The donor screening was performed on a hemodiluted specimen
5. New clinically relevant findings about the donor are recognized post-transplant.

15.4(B) Required Action

The Transplant Program must do *all* of the following:

1. Explain the risks to the potential recipient, recipient, or agent
2. Document the risk and notification in the potential recipient or recipient's medical record
3. Follow the recipient of such an organ for the development of the transmissible disease.

If the Transplant Program discovers the risk prior to transplantation, it must receive informed consent from the potential recipient or agent prior to transplantation. The Transplant Program must document the informed consent in the potential recipient or recipient's medical record.

15.4(C) Offers to Potential Recipients and Recipients

Transplant Programs must offer *all* of the following to potential recipients and recipients of organs from donors at increased risk for transmitting disease:

1. Additional post-transplant testing for the transmissible disease
2. Treatment of or prophylaxis for the transmissible disease
3. Routine post-transplant follow-up care.

15.5 Reporting of Unexpected Potential and Proven Transmissions of Disease

15.5(A) Transplant Program's Notifications

The Transplant Program must notify the Host OPO (for deceased donor transplants) or the Recovery Hospital (for living donor transplants) and provide available documentation as soon as possible, but at the latest within 24 hours of discovering any unexpected potential or proven transmission of a disease from a transplanted donor organ. Additionally, Transplant Programs must notify the OPTN Contractor of any unexpected potential or proven transmission of a disease from a transplanted donor organ.

15.5(B) Recovery Hospital and Host OPO's Notifications

If a Recovery Hospital or Host OPO learns of a potential or proven transmission of disease from a transplanted living donor or deceased donor organ to a recipient, it must do *all* of the following:

1. Report the event to the Patient Safety Contact at every Transplant Program and tissue bank that received an organ or tissue from the donor, as soon as possible, but at the latest within 24 hours of the initial notification to the Recovery Hospital or Host OPO. This notification must include any test results and diagnosis from the suspected donor or affected recipient that may be pertinent to acute patient care including results of all tests that were not available at the time of procurement or recovery. The Recovery Hospital or Host OPO must document that it shared this information with all recipient Transplant Hospitals and tissue banks.
2. Report the event to the OPTN Contractor as soon as possible, but at the latest within 24 hours of the initial notification to the Recovery Hospital or Host OPO.
3. For deceased donors only, complete and submit the *Potential Disease Transmission Report* to the OPTN Contractor within 24 hours of the initial notification to the OPTN Contractor. The report must include *all* of the following:
 - The name of the recipient Transplant Program's Patient Safety Contact and tissue bank's personnel that received notification of the potential transmission
 - The disposition of all organs, tissues, and vessels
 - Any information regarding remaining donor samples for additional testing
 - Any notifications to state or local health department for nationally notifiable infectious diseases

- Whether an autopsy was performed on the donor
- 4. Submit a *Potential Disease Transmission Donor Follow-Up Report* 45 days after the initial notification to the OPTN Contractor, if requested by the Ad Hoc Disease Transmission Advisory Committee
- 5. Provide any additional information related to the donor requested by OPTN Contractor
- 6. Manage the review, in partnership with OPTN Contractor, to determine whether the organ donor was diagnosed with a potentially transmissible disease.
- 7. If a Recovery Center learns new information regarding a living donor, during the first two years post donation, (including but not limited to new or follow-up testing results, donor death or autopsy reports) that indicates risk of potential transmission of disease or malignancy, then the Recovery Center must do *all* of the following actions:
 - Report the new information to local, state or federal public health authorities, as required by law
 - Disclose to the living donor that a potential disease transmission or malignancy must be reported to the recipient Transplant Hospital and the OPTN Contractor
 - Notify the recipient Transplant Hospital
 - Report the potential transmission to the OPTN Contractor.

15.5(C) Transplant Program’s Responsibilities

Any Transplant Program treating a recipient that received an organ from a donor who is the subject of a *Potential Disease Transmission Report* is responsible for *all* of the following:

1. Responding to Host OPO, Recovery Hospital and OPTN Contractor requests for information regarding recipients in a timely fashion and communicating updated information regarding recipient condition, test results, diagnosis, and plans for treatment and follow-up
2. Submitting copies of any pertinent test results to OPTN Contractor
3. Notifying recipients involved in cases of proven transmissions and documenting this notification in the recipient medical record as required in Policy 15.4 *Requirements When There is an Increased Risk of Transmissible Disease*
4. Submitting a *Potential Disease Transmission Recipient Follow-Up Report* within 45 days of the initial notification to the OPTN contractor, if requested by the Ad Hoc Disease Transmission Advisory Committee
5. Providing any additional information related to the recipient requested by OPTN Contractor.

History

Policy 4: Identification of Transmissible Diseases in Organ Recipients: 11/18/2004; 11/8/2010;
Policy 15: Identification of Transmissible Diseases in Organ Recipients: 11/2012 (eff. 2/1/2013)

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 identification of transmissible diseases in organ donors, see Policy 2.4 *Potential Donors Information*.

- For restrictions on the use of organs from donors infected with HIV, see Policy 2.5 *HIV Screening of Potential 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: Packaging, Labeling, Shipping, and Storage

16.1	Organs That Remain in the Same Operating Room Suite as the Intended Recipient	187
16.2	Packaging and Labeling Responsibilities	187
16.3	Order of Labeling and Packaging	188
16.4	Internal Packaging and Labeling	188
16.5	External Packaging and Labeling	190
16.6	Documentation Accompanying the Organ or Vessel	191
16.7	Verification of Information	191
16.8	Vessel Recovery, Transplant, and Storage	191
16.9	Transportation Responsibilities	193

Introduction

This Policy contains requirements for packaging and labeling organs, blood and tissue typing material, and vessels. The requirements help to prevent organ waste; promote the safe and efficient use of donated organs; define terms and responsibilities related to packaging, labeling, and transporting organs, blood and tissue typing specimens, and vessels; and for the recovering, storing, and using vessels in solid organ recipients.

Policy Statement

16.1 Organs That Remain in the Same Operating Room Suite as the Intended Recipient

When organs are recovered and remain in the same operating room suite as the intended recipient, the Host OPO and Transplant Hospital must develop and follow a procedure to ensure the correct donor organ is transplanted into the correct recipient. Time-outs must occur before the organ leaves the donor operating room and again when the organ arrives at the potential recipient's operating room. During these time-outs and before the transplant occurs, the Transplant Hospital must confirm and document that a member of the transplant team identified the correct organ for the correct potential recipient.

16.2 Packaging and Labeling Responsibilities

Transplant Hospitals and Host OPOs must follow the requirements in Policy 16.2: *Packaging and Labeling Responsibilities et seq* to package deceased donor organs, tissue typing specimens, and vessels that travel outside their recovery facilities. The Host OPO is responsible for packaging and

labeling organs, tissue typing material, and vessels. The Host OPO must make reasonable efforts to package and label organs, tissue typing specimens, and vessels in a timely fashion. Transplant Hospital staff may not leave the operating room without allowing the Host OPO to package and label the organs, tissue typing specimens, and vessels according to this Policy. If a Transplant Hospital fails to comply with this Policy, the Host OPO must notify the OPTN Contractor.

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.

16.3 Order of Labeling and Packaging

The Host OPO must package all organs, tissue typing material, and vessels in a sterile environment using universal precautions. The Host OPO should package vessels in the donor operating room. The Host OPO may either package vessels with or separate from organs.

Package and label organs, tissues, and vessels in the following order (from inside to outside):

1. Organ, tissue typing material, or vessels
2. Triple sterile barrier, as applicable
3. Internal label
4. Cooling material
5. External transport container and external label.

Acceptable external transport containers only include disposable shipping boxes, coolers, and mechanical preservation machines.

16.4 Internal Packaging and Labeling

16.4(A) Packaging

A triple sterile barrier must protect organs and vessels. The rigid container may always be used as one layer of the triple sterile barrier and is required to be one layer in some situations. Table 16-1: *Internal Packaging Requirements* describes which organs require a rigid container and whether the rigid container must be used as one layer of the triple sterile barrier.

Table 16-1: Internal Packaging Requirements

If this organ or vessel is shipped...	Then, is a rigid container required?	If used, must the rigid container be one layer of the triple sterile barrier?
Heart	Optional	Optional
Intestine	Optional	Optional
Kidney	Yes	Optional
Liver	Optional	Optional
Lung	Optional	Optional
Pancreas	Yes	Optional
Vessels packaged	Yes	Yes

separately from the organ		
Vessels packaged with the organ	Optional	Optional

If organs, tissue typing material or vessels are transported outside the recovery facility, they must be placed immediately into the external package after internal packaging is complete.

16.4(B) Labeling

16.4(B)(I) Organs

The outer layer of the triple sterile barrier or the rigid container holding each organ must have a completed, OPTN internal label. However, if the organ is transported in a mechanical preservation device, the container holding the organ may instead display the organ type, blood type and subtype, if used for allocation, and the donor I.D.

16.4(B)(II) 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 I.D. and at least *one* of the following identifiers:

1. Locally assigned unique I.D.
2. Donor date of birth
3. Donor initials.

If the donor I.D. or blood type is not available during the donor’s preliminary evaluation, then 1) the specimen container must include a locally assigned unique identifier and one of the above identifiers; and 2) the Host OPO must document in the donor record any identifiers used to label the specimen container. Additionally, each specimen’s label should contain description of the container contents and the recovery date and time. The donor blood type and subtype, if used for allocation, should be included on tissue typing material but may not be included on blood samples

16.4(B)(III) Vessels

The outer layer of the triple sterile barrier and the rigid container holding the vessels must have a completed, OPTN vessel label. The label must contain *all* of the following:

1. Donor I.D.
2. Donor blood type and subtype, if used for allocation
3. Recovery date
4. All infectious disease testing results
5. Description of the container contents
6. Whether the vessels are from a donor that meets the high-risk criteria in the U.S. Public Health Service Guidelines.
7. That the vessel is “for use in organ transplantation only.”

16.5 External Packaging and Labeling

16.5(A) Disposable Shipping Box

If the organ, tissue typing material, or vessel is shipped commercially, it 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 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 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.

16.5(B) Cooler

If the organ recovery team is transporting the organ themselves to the potential recipient's Transplant Hospital, they can transport the organs, tissue typing material, and vessels in a cooler. Coolers must have proper insulation and enough cooling material to protect the organs during normal conditions of transport. A cooler may be reused only if all labels from previous donor organs are removed, the cooler is cleaned, and the cooler is sanitized.

16.5(C) Mechanical Preservation Machine

Organs may be transported using a mechanical preservation machine. Mechanical preservation machines may be reused only if all labels from previous donor organs are removed.

16.5(D) Labeling

A label, that under normal conditions of transport will remain secured, must be affixed to the outside of the external transport container. Disposable shipping boxes and coolers must have the OPTN external label. Mechanical preservation machines must have a label that contains the same information as the OPTN external label.

The OPTN external label must contain *all* of the following:

1. The donor I.D.
2. The sender's name and telephone number
3. The donor's blood type and subtype, if used for allocation
4. A description of the specific content of the box
5. The OPTN Contractor's telephone number

16.6 Documentation Accompanying the Organ or Vessel

16.6(A) Organ Documentation

Each external transport container holding a transported organ must include the source documentation for *all* of the following:

1. Blood type and subtype, if used for allocation
2. Infectious disease testing results
3. Medical and behavioral history information
4. Donor evaluation information
5. Complete record of the donor
6. Donor authorization form
7. Organ quality information as noted in Policy 2.7(B) *Procedures*

Donor documentation must be placed in a watertight container in *any* of the following:

- A location specifically designed for documentation
- Between the inner and external transport containers

16.6(B) Vessel Documentation

If vessels are not shipped in the same package as the organ, then the vessel package must include copies of all organ documentation.

16.7 Verification of Information

16.7(A) Verification of Information Before Shipping

After completing the labels and documentation for organs and vessels above, the Host OPO must have a separate person verify the accuracy of the information on the labels and accompanying documentation against the source documentation. The Host OPO must document that these verifications occurred.

16.7(B) Verification of Information Upon Receipt

Upon arrival of the organ at the Transplant Hospital and prior to implantation, the Transplant Hospital must verify the accuracy of the donor I.D. and the donor's blood type and subtype, if used for allocation, against the potential recipient's blood type and subtype, if used for allocation. The Transplant Hospital must document that these verifications occurred.

16.8 Vessel Recovery, Transplant, and Storage

16.8(A) Vessel Recovery And Transplant

To recover and use vessels in an organ transplant, the donor authorization forms must include language indicating that the vessels will be used for transplant. The vessels can only

be used for the implantation or modification of an organ transplant. Transplant Hospitals may not store for subsequent use any hepatitis C antibody positive (HCV) or hepatitis B surface antigen positive (HBsAg) extra vessels.

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.

If the Transplant Hospital stores vessels and later uses the vessels for the intended recipient or another recipient, it must notify the OPTN Contractor.

Prior to implantation, the Transplant Hospital must verify the donor vessel's: blood type and subtype, if used for allocation; all serology results; container contents; date of expiration; and the UNOS Donor ID of the vessel with the blood type and subtype, if used for allocation. The Transplant Hospital must also verify the blood type and subtype of the intended recipient, if used for allocation, and all serology results of the recipient prior to implantation. The documentation of these verifications must be maintained within the recipient medical record.

16.8(B) Vessel Storage

The Transplant Hospital must designate a person to do *all* of the following:

1. Monitor and maintain all records relating to the use and management of vessels
2. Monitor the refrigerator storing the vessels
3. Destroy expired vessels
4. Report the vessel's use or disposal to the OPTN Contractor within five days of when the Transplant Hospital uses or disposes of the vessels.

Additionally, the Transplant Hospitals must do *all* of the following:

1. Store vessels in a Food and Drug Administration (FDA) approved preservation solution
2. Package and label vessels as required by Policy 16.4 *Internal Packaging and Labeling*
3. Store vessels in a secured refrigerator with a temperature monitor and maintain the temperature no colder than 2 degrees Celsius and no warmer than 8 degrees Celsius
4. Monitor vessels daily with documented security and temperature checks
5. Store vessels up to a maximum of 14 days from the recovery date
6. Maintain a log of stored vessels.

The transplant surgeon must always have access to the donor information prior to using the vessels in any recipient.

16.9 Transportation Responsibilities

16.9(A) Transportation Arrangements

The Host OPO must arrange transportation to and from the local airport for non-local organ recovery teams.

16.9(B) Transportation Costs

If deceased donor kidneys, associated tissue typing, and associated vessels are shipped without any other organs, the Host OPO is responsible for all transportation costs. Otherwise, the Member receiving the organ, tissue typing material, or vessels is responsible for the costs to travel from the last Member to the receiving Member's location.

History

Policy 5: Standardized Packaging, Labeling, and Transporting of Organs, Vessels, and Tissue Typing Materials : 6/26/2003; 11/20/2003; 11/18/2004; 6/23/2005; 6/26/2007; 2/20/2008; 6/19/2008; 11/16/2009; 11/8/2010; *Policy 16: Packaging, Labeling, Shipping, and Storage*: 11/2012 (eff. 2/1/2013)

Notes

- For tissue typing requirements, see Policy 4: *Histocompatibility*.
- 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	194
17.2	Importation of Deceased Donor Organs from Foreign Sources	195

Introduction

This Policy contains requirements regarding the transplantation and registration of non-US citizen/non-US resident patients.

Policy Statement

17.1 Registration and Transplants of Non-US Citizens/Non-US Residents

17.1(A) Referrals

Members may not enter into contracts with foreign organizations for the transplantation of non-US citizen/non-US resident patients; however, Members may register individual non-US citizen/non-US resident patients on the waiting list.

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 transplantations 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

17.2(A) Methods for Importing Deceased Donor Organs from Foreign Sources

Members that import deceased donor organs, which are procured outside of the United States, may only do so according to the requirements for either an organ import agreement or an ad hoc organ import. Additionally, any Member that imports a deceased donor organ from a foreign organization must perform all of the following actions:

1. Allocate the organs according to the applicable organ allocation policies
2. Report the required information about the donor and the organ, as specified in Policy 2.4 *Potential Donors Information* and Policy 2.5 *HIV Screening of Potential Donors*
3. Obtain official documentation that the foreign organization is authorized by an appropriate agency of its national government as a transplant hospital or organ procurement program
4. Obtain official documentation that the foreign organization is authorized by an appropriate agency of its national government as authorized to export organs for transplantation

17.2(B) Organ Import Agreement

Before a Member may enter into organ import agreement with a foreign organization, the agreement must be reviewed by the Ad Hoc International Relations Committee and approved by the OPTN Board of Directors. Member must submit the agreement for review by the Ad Hoc International Relations Committee and approval by the Board of Directors. An organ import agreement may not exceed two years in duration from the date that it is approved by the Board of Directors. If a Member wants to extend their agreement, then the Member must submit an updated agreement, within two years of when the agreement was approved by the Board, for review by the Ad Hoc International Relations Committee and approval by the Board of Directors prior to the expiration of the formal, deceased donor import agreement.

If a Member with an organ import agreement with a foreign organization receives a deceased donor organ offer from that foreign organization, then the Member must report the event to the OPTN Contractor within 72 hours of receiving the offer.

Each proposed organ import agreement must include *all* of the following components:

- 1) A description of the basis for the agreement
- 2) A description of the expected benefits to the Member and the foreign organization
- 3) The credentials of the foreign entity
- 4) The number and type of deceased donor organs anticipated to be imported into the United States
- 5) A plan for reporting the results of the agreement

- 6) A requirement for the donor organization to submit documentation certifying the authorization from the donor, or the donor's agent, to procure his organs
- 7) A requirement for the donor organization to submit to the importing Member, documentation of the donor's blood type, and subtype when used for allocation
- 8) A requirement for the donor organization to submit documentation certifying that the donor met brain death or donation after circulatory death (DCD) protocols in compliance with OPTN obligations.

17.2(C) Ad Hoc Organ Import

If a Member is not an OPO, does not have a organ import agreement, and receives a deceased donor organ offer from a foreign organization, then the Member must report the event to the OPTN Contractor immediately so that the OPTN Contractor can allocate the organ.

If an OPO does not have an organ import agreement and receives a deceased donor organ offer from a foreign organization, then the OPO must provide *all* of the following to the OPTN Contractor:

- Documentation from the donor organization certifying the authorization from the donor, or his agent, to procure his organs
- Documentation from the donor organization verifying the donor's blood type, and subtype when used for allocation
- Documentation certifying that the donor met brain death or donation after circulatory death (DCD) protocols in compliance with OPTN obligations.

The Ad Hoc International Relations Committee will review each ad hoc deceased donor import.

History

Policy 6: Transplantation of Non-Resident Aliens: 6/23/2003; 6/24/2004; 6/23/2005; 11/17/2008;
Policy 17: International Organ Transplantation: 11/2012 (eff. 2/1/2013)

Notes

- For more on the issue of international organ transplantation, see the Declaration of Istanbul.

Policy 18: Data Submission Requirements

18.1	Data Submission Requirements	197
18.2	Timely Collection of Data	199
18.3	Recording and Reporting the Outcomes of Organ Offers	199
18.4	Data Submission Standard	200

Introduction

This Policy sets requirements for data submission by Members.

Policy Statement

18.1 Data Submission Requirements

Members must report data to the OPTN using standardized forms. Table 18-1: *Data Submission Forms* shows the Member responsible for submitting each data form and when the Member must submit the form to the OPTN Contractor.

Table 18-1: Data Submission Forms

The following Member	Must submit the following form to the OPTN Contractor	Within	Notes
All OPOs	<i>Death notification records (DNR)</i>	30-days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	For all imminent neurological deaths and eligible deaths in its local unit
All OPOs	<i>Monthly Donation Data Report: Reported Deaths</i>	30-days after the end of the month in which a donor hospital reports a death to the OPO	For all deaths reported by a hospital to the OPO
Allocating OPO	<i>Potential transplant recipient (PTR)</i>	30-days after the match run date by the OPO or the OPTN Contractor	For each deceased donor organ that is offered to a potential recipient
Histocompatibility Laboratory	<i>Donor histocompatibility (DHS)</i>	30-days after the OPO submits the deceased donor registration	

Organ Procurement and Transplantation Network (OPTN) Policies
 Policy 18: Data Submission Requirements

The following Member	Must submit the following form to the OPTN Contractor	Within	Notes
Histocompatibility Laboratory	<i>Recipient histocompatibility (RHS)</i>	30-days after the transplant	For each transplant recipient typed by the laboratory
Host OPO	<i>Deceased donor feedback</i>	5 business days after the procurement date	
Host OPO	<i>Deceased donor registration (DDR)</i>	30 days after the <i>deceased donor feedback</i> form is submitted and disposition is reported for all organs	For all deceased donors and authorized but not recovered potential deceased donors
Recovery Hospitals	<i>Living donor feedback</i>	Prior to surgery	For each living donor recovered at the hospital
Recovery Hospitals	<i>Living donor follow-up (LDF)</i>	30-days after the six-months, one-year, and two-year anniversaries of the donation date	For each living donor recovered at the hospital
Recovery Hospitals	<i>Living donor registration (LDR)</i>	60-days after the Recovery Hospital submits the <i>living donor feedback</i> form	For each living donor recovered at the hospital
Transplant Hospitals	<i>Organ specific transplant recipient follow-up (TRF)</i>	5. 30-days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure; and 6. 14-days from notification of the recipient's death or graft failure	For each recipient followed at the hospital
Transplant Hospitals	<i>Organ specific transplant recipient registration (TRR)</i>	60-days after Transplant Hospital submits the <i>recipient feedback</i> form	For each recipient transplanted at the hospital

The following Member	Must submit the following form to the OPTN Contractor	Within	Notes
Transplant Hospitals	<i>Recipient feedback</i>	24-hours after the transplant	For each recipient transplanted at the hospital
Transplant Hospitals	<i>Recipient malignancy (PTM)</i>	30-days after the Transplant Hospital reports the malignancy on the <i>transplant recipient follow-up</i> form	For each recipient, with a reported malignancy, that is followed at the hospital
Transplant Hospitals	<i>Transplant candidate registration (TCR)</i>	30-days after the Transplant Hospital registers the candidate on the waiting list	For each candidate on the waiting list or recipient transplanted at the hospital

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN Contractor. Table 18-2: *Timely Data Collection* sets standards for the timely collection of data.

Table 18-2: Timely Data Collection

Information is timely if this Member...	Collects this information for this form...	Within this time period...
Transplant Hospital	<i>organ specific transplant recipient registration (TRR)</i>	when the transplant recipient is discharged from the hospital or six-weeks following the transplant date, whichever is first
Transplant Hospitals	<i>living donor registration (LDR)</i>	when the living donor is discharged from the hospital or six-weeks following the transplant date, whichever is first
Recovery Hospitals	<i>living donor follow-up (LDF)</i>	within the 60-days prior to the form due date

18.3 Recording and Reporting the Outcomes of Organ Offers

The Allocating OPO and the Transplant Hospitals that offered the organs share responsibility for reporting the outcomes of all organ offers. OPOs, Transplant Hospitals, and the OPTN Contractor

may report this information. OPOs are responsible for reporting, to the OPTN Contractor within 30-days of the match run date, the outcomes of organ offers.

The OPO or the OPTN Contractor must obtain potential transplant recipient (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 confirm or amend 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.

18.4 Data Submission Standard

18.4(A) Timely Data Submission

Table 18-3: *Data Submission Standard* 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%	potential transplant recipient (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.

18.4(B) Living Donor Follow-up Form

Recovery hospitals must submit at least 90% of their required living donor follow-up (LDF) forms with accurate and timely information. LDF forms must contain *all* of the following data to be considered accurate:

1. Donor status
2. Cause of death, if applicable and known
3. Patient status
4. Whether the donor is working for income and, if not working, the reason for not working
5. Kidney clinical information
6. Diabetes
7. Donor developed hypertension requiring medication
8. Maintenance dialysis
9. Serum creatinine
10. Urine protein
11. Complications
12. Whether the donor was readmitted since the last LDF form was submitted
13. Any kidney complications.

History

Policy 7: Data Submission Requirements: 6/28/2001; 11/15/2001; 6/27/2002; 11/14/2002; 6/26/2003; 11/20/2003; 6/24/2004/ 11/18/2004; 11/17/2005; 3/22/2006; 6/29/2006; 9/20/2006; 12/13/2006; 3/23/2007; 6/26/2007; 2/20/2008; 6/19/2008; Policy 18: Data Submission Requirements: 11/2012 (eff. 2/1/2013)

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: Release of Data

19.1	Requests for Data	202
19.2	Requests for Confidential Information	202
19.3	Requests for Person Identified Data	203
19.4	Requests for Personnel Data	203
19.5	Requests for Person Level Data	204
19.6	Extraordinary Data Requests	204

Introduction

This Policy sets rules for the release of data by the OPTN Contractor.

Policy Statement

19.1 Requests for Data

The OPTN Contractor may provide data upon request except as limited by this Policy, federal or state laws, or the OPTN contract. Regardless of any restrictions in this Policy, the OPTN Contractor will release any data required by federal or state laws or the OPTN contract.

The OPTN Contractor may prescribe specific administrative requirements necessary to protect confidential information, patient welfare, or patient privacy.

If a requestor does not comply with any requirements of Policy 19: *Release of Data*, then the OPTN Contractor may withhold additional data from future data requests.

19.2 Requests for Confidential Information

The OPTN Contractor may not release confidential information unless *all* of the following occur:

1. The request is necessary to perform a function on behalf of the OPTN
2. The requestor is one of the following:
 - An individual bound by a fiduciary responsibility to the OPTN or a contractual obligation to the OPTN Contractor to maintain the confidentiality of such information
 - An individual acting on behalf of the Board of Directors
 - An individual acting on behalf of a permanent standing or ad hoc committee
3. The request is approved by the Executive Director.

Recipients of confidential information have no ownership rights in any of the confidential information.

19.3 Requests for Person Identified Data

An individual may receive, or authorize another requestor to receive, any data pertaining to that individual.

Regardless of any restrictions in Policy 19.2 *Requests for Confidential Information*, the OPTN Contractor may release person identified data according to Table 19-1: *Requests for Person Identified Data*.

Table 19-1: Requests for Person Identified Data

If the Requestor is...	Then the OPTN Contractor may release the following person identified data:
Authorized to receive confidential information according to Policy 19.2 Requests for Confidential Information	Confidential information according to Policy 19.2 <i>Requests for Confidential Information</i>
Laboratory	HLA information of deceased donors and recipients typed by that Laboratory when discrepant HLA information is reported to the OPTN Contractor
Member	Data previously submitted by the Member to the OPTN Contractor
Member	Data that are necessary for the Member to prepare a report required by the OPTN
OPO	Recipient characteristics and outcomes data for each transplanted organ that was recovered by the OPO
Transplant Program	Recipient characteristics and outcomes for each organ offer received by the Transplant Program
Transplant Program	Data about whether the Transplant Program's candidate is multiply registered, but not where the candidate is multiply registered.
Transplant Program and its affiliated Laboratory	Prior donor's HLA information for any recipients under the Transplant Program's care

If the OPTN Contractor does not approve a request for person-identified data, then the requestor may appeal the request to the Policy Oversight Committee (POC).

19.4 Requests for Personnel Data

The OPTN Contractor may not release contact information for personnel at Member institutions unless the Executive Director approves the request. Individuals requesting this information must submit a signed Data Use Agreement (DUA) before receiving the data. The requestor must maintain a copy of this DUA and provide it to the OPTN Contractor upon request.

19.5 Requests for Person Level Data

Individuals requesting person level data from the OPTN Contractor must fulfill *all* of the following requirements:

1. Submit a signed Data Use Agreement (DUA) before receiving the data. The requestor must maintain a copy of this DUA and provide it to the OPTN Contractor upon request.
2. Will not use the data for any purpose that could have a negative impact on patient welfare
3. Will neither attempt nor permit others to attempt to learn the identity of any person whose information is contained in the data
4. Will include the following disclaimer in any publication using the released data: The data reported here have been supplied by [name of the OPTN Contractor] as the Organ Procurement and Transplantation Network. The interpretation and reporting of these data are the responsibility of the author and in no way should be seen as an official policy of or interpretation by the OPTN or the U.S. Government.
5. Will include the source and date of the data in any publication or graphic presentation using the released data.

If the OPTN Contractor does not approve a request for person-level data, then the requestor may appeal the request to the Policy Oversight Committee (POC).

19.6 Extraordinary Data Requests

If an individual requests an extraordinary volume of data or makes a request that requires an extraordinarily lengthy programming time or any statistical analysis by the OPTN Contractor, then the individual must submit a written concept paper to the OPTN Contractor. The OPTN Contractor will review each request; approve or deny the request; and prioritize approved requests based on importance to the OPTN, scientific or clinical merit, and the potential ability to address the question.

History

Policy 9: Release of Information to the Public: 6/28/2001; 11/15/2001; 6/26/2003; *Policy 10: Access to Data:* 6/28/2001; *Policy 19: Release of Data:* 11/2012 (eff. 2/1/2013)

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	205
20.2	Airfare and Rail Reimbursement	205
20.3	Hotel Reimbursement	206
20.4	Other Transportation	206
20.5	Meals	207
20.6	Miscellaneous Expenses	208
20.7	Non-Reimbursable Expenses	208
20.8	Filing Expense Reports	208

Introduction

This Policy addresses reimbursements for travel expenses.

Policy Statement

20.1 Eligibility for Reimbursement

20.1(A) General Eligibility Requirements

The OPTN Contractor will reimburse approved travel costs for members, contractors, and OPTN Contractor staff who are traveling for OPTN Contractor business. OPTN Contractor employees and contractors must receive authorization from their Director or Travel Approver before confirming travel arrangements. OPTN Contractor staff will approve 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 UNOS Conference Planning and Travel to arrange all OPTN Contractor related travel and obtain a low-cost coach fare that will accommodate the traveler's needs. If the traveler chooses not to accept those flight

arrangements, the OPTN Contractor will reimburse only up to the amount *UNOS Conference Planning and Travel* would have paid.

Travelers should book airline reservations at least one month in advance of travel.

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.

UNOS Conference Planning and Travel 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 will 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 date travelled.

20.4(B) Transportation To and From the Airport

The OPTN Contractor will reimburse *all* of the following costs:

- Transportation between the airport and the traveler's home.
- Transportation between the airport and the meeting location.
- Parking fees at the airport from which the traveler departs.

Travelers should use the least expensive, convenient option to travel to and from airports. The OPTN Contractor will not reimburse limousines unless the cost is shared with another traveler and the total cost to the OPTN Contractor is no more expensive than cab fare.

20.4(C) Rental Cars

The OPTN Contractor will not reimburse rental cars if less expensive modes of travel are available. The traveler must elect rental car insurance coverage and should minimize additional rental car fees. If the traveler elects to rent a car when less expensive modes of travel are available, the OPTN Contractor will reimburse up to the amount of the estimated cab fare needed for the duration of the stay.

20.4(D) Provided Ground Transportation

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.

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. 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. 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; 11/14/2011; *Policy 20: Travel Expense and Reimbursement*: 11/2012 (eff. 2/1/2013)

Notes

Reserved.

OPTN Policies: Index

B

Blood Typing	
Candidate.....	38
Donor.....	24
Kidney-Pancreas Allocation	175
Liver Allocation.....	134
Lung Allocation.....	164
Packaging and Labeling.....	189
Verification after transportation.....	191

C

Consent	
For ECD Kidneys.....	103

D

DCD.....	<i>See Donation after Circulatory Death</i>
Donation after Circulatory Death.....	33
Donor	
Blood Typing.....	24
Donor Tests	25
Evaluation	23
HIV Screening.....	31
Organ Recovery	32
Potential Donor Information	24

E

Emergencies	20
-------------------	----

H

Heart	
Acceptance Criteria.....	71
Adult Heart Status 1A.....	82
Adult Heart Status 1B.....	83
Adult Heart Status 2.....	83
Allocation of	82
Pediatric Heart Status 1A	83
Pediatric Heart Status 1B	84
Pediatric Heart Status 2	84
Requested Donor Information	29
Required Donor Information.....	25
Status Exceptions.....	85
Histocompatibility	46
HIV	
Prohibition on Use of HIV Positive Organs.....	32
Screening of Potential Donors.....	31

I

In Utero	
Registration of <i>In Utero</i> Candidates	38
Intestine	
Acceptance Criteria	72
Allocation of.....	97
Statuses.....	97

K

Kidney	
Acceptance Criteria	70
Allocation of.....	100
Requested Donor Information.....	29
Required Donor Information	25

L

Liver	
Acceptance Criteria	70
Adult Status 1A.....	117
Allocation of.....	117
MELD Score.....	119
Pediatric Status 1A.....	118
Pediatric Status 1B.....	119
PELD Score	120
Requested Donor Information	25
Special organ offer rules.....	73
Status and Score Exceptions.....	120

Living Donor

Priority for Kidney Allocation.....	103
-------------------------------------	-----

Lung

Acceptance Criteria	71
Allocation of.....	142
Lung Allocation Score.....	143
Priority and Score Exceptions	158
Priority Level 1	142
Priority Level 2	143
Requested Donor Information.....	30
Required Donor Information	25

M

Multi-Organ	
Allocation	10, 77
Allocation of heart-lung.....	77
Allocation of Kidney-Pancreas	81

Organ Procurement and Transplantation Network (OPTN) Policies
OPTN Policies: Index

Allocation of Liver-Intestine from Donors Aged 0 to 10 Years	78	R	Registration Fee	38
Allocation of Liver-Intestine from Donors Aged at Least 11 Years	80		Renal.....	<i>See Kidney</i>
Multi-Organ Candidate Registration	38		Review Board	
Waiting Time Assignments.....	42		Heart Exceptions	85
P			Liver Exceptions	120
Pancreas			Lung Exceptions.....	158
Acceptance Criteria	72		Rules of Construction.....	1
Allocation of	172	T		
Required Donor Information	25		Thoracic	<i>See Lung, See Heart</i>
Patient Notification	39	V		
Pediatric		Variations		
Allocation of Hearts from Donors Aged Less Than 18 Years	91	Application	18	
Allocation of Liver from Donors Aged 0 to 10 Years.....	138	Generally	18	
Allocation of Lungs from Donors Less Than 12 Years of Age.....	168	Heart	96	
Incompatible Blood Type, Heart Candidates...	72	Intestine.....	99	
Kidney Points.....	101	Kidney.....	115	
Lung Pediatric Priority Levels.....	142	Liver	140	
Pediatric Heart Status 1A	83	Lung.....	170	
Pediatric Heart Status 1B	84	Open Variance – Segmental Liver		
Pediatric Heart Status 2	84	Transplantation	140	
Pediatric Kidney-Pancreas Waiting Time		Pancreas	179	
Criteria	173	Vessel Recovery, Transplant, and Storage.....	191	
Pediatric Liver Candidates with Metabolic		W		
Diseases	124	Waiting Time		
Pediatric Liver Status 1A	118	Assignments for Multi-Organ Candidates	42	
Pediatric Liver Status 1B	119	For Inactive Candidates.....	39	
PELD Score.....	120	Modifications.....	40	
		Reinstatement for Non-Function of		
		Transplanted Organ	43	
		Transfers and Multiple Registrations.....	44	

OPTN Policies: List of Tables

Table 1-1: Open Variance Applications	19
Table 2-1: Donor Information	25
Table 2-2: Minimum Typing Materials	33
Table 3-1: HLA Requirements	38
Table 3-2: Patient Notification.....	39
Table 3-3: Waiting Time for Inactive Candidates.....	39
Table 3-4: Review of Waiting Time Modification Applications.....	41
Table 3-5: Standard Waiting Time Modifications	42
Table 3-6: Waiting Time Assignments for Multi-Organ Candidates.....	42
Table 3-7: Waiting Time Reinstatements.....	43
Table 4-1: Determining Sensitization	47
Table 4-2: Assays to Identify Antibody Screening or Crossmatching.....	48
Table 4-3: Recommended Elements for Crossmatching Strategies.....	49
Table 4-4: Requirements for HLA Typing	50
Table 4-5: Requirements for Antibody Screening	53
Table 4-6: HLA A Matching Antigen Equivalences.....	64
Table 4-7: HLA B Matching Antigen Equivalences.....	65
Table 4-8: HLA DR Matching Antigen Equivalences	65
Table 4-9: HLA A Unacceptable Antigen Equivalences.....	66
Table 4-10: HLA B Unacceptable Antigen Equivalences	67
Table 4-11: HLA C Unacceptable Antigen Equivalences.....	67
Table 4-12: HLA DR Unacceptable Antigen Equivalences.....	68
Table 4-13: HLA DQ Unacceptable Antigen Equivalences.....	68
Table 5-1: Medical Urgency Points for Other Organs	75
Table 5-2: Distance Points for Other Organs.....	76
Table 6-1: Allocation of Combined Liver-Intestines from Donors Aged 0 to 10 Years.....	78
Table 7-1: Heart Status and Laboratory Value Update Schedule.....	87
Table 7-2: Blood Typing for Heart Allocation.....	87
Table 7-3: Allocation of Hearts from Donors Aged At Least 18 Years.....	88
Table 7-4: Allocation of Hearts from Donors Aged Less Than 18 Years.....	91
Table 8-1: Allocation of Intestines.....	98
Table 9-1: Kidney Points	101
Table 9-2: ECD Criteria.....	102
Table 9-3: Allocation of Kidneys from Donors Less Than 35	104
Table 9-4: Allocation of Kidneys from Donors Age 35 and Older.....	107
Table 9-5: Allocation of Kidneys from DCD Donors <35.....	109
Table 9-6: Allocation of Kidneys from DCD Donors >=35 years old	110
Table 9-7: Allocation of Kidneys from Expanded Criteria Donors.....	111
Table 9-8: Allocation of Kidneys from ECD/DCD Donors	113
Table 9-9: Organ Offer Limit.....	114
Table 10-1: Specific MELD/PELD Exceptions.....	122

Table 10-2: Requirements for dynamic contrast-enhanced CT or MRI of the liver	126
Table 10-3: Classification system for nodules seen on imaging of cirrhotic livers	127
Table 10-4: Liver Points.....	130
Table 10-5: Liver status update schedule	132
Table 10-6: Allocation of Livers from Donors Aged At Least 18 Years	134
Table 10-7: Allocation of Livers from Donors Aged 11 to 17 Years	136
Table 10-8: Allocation of Livers from Donors Aged 0 to 10 Years.....	138
Table 11-1: Requirements for Priority 1	142
Table 11-2: Waiting List Mortality Calculation, Covariates, and Their Coefficients	145
Table 11-3: Post-Transplant Survival Calculation, Covariates, and Their Coefficients.....	146
Table 11-4: Baseline Waiting List Survival (SWL(t)) Probability.....	147
Table 11-5: Baseline post-transplant survival probabilities.....	151
Table 11-6: Data Substituted for Missing or Expired Actual Values in Calculating the LAS.....	163
Table 11-7: Allocation of Lungs from Donors at Least 18 Years of Age.....	164
Table 11-8: Allocation of Lungs from Donors 12 to 17 Years of Age	166
Table 11-9: Allocation of Lungs from Donors Less than 12 Years of Age	168
Table 12-1: Maximum Allowable BMI.....	173
Table 12-2: Blood Typing for Kidney-Pancreas Allocation.....	175
Table 12-3: Allocation of Kidneys and Pancreata from Donors 50 years of age and less with a BMI less than or equal to 30 kg/m ²	177
Table 12-4: Allocation of Kidneys and Pancreata from donors greater than 50 years of age or from donors who have a BMI greater than 30 kg/m ²	178
Table 16-1: Internal Packaging Requirements.....	188
Table 18-1: Data Submission Forms.....	197
Table 18-2: Timely Data Collection.....	199
Table 18-3: Data Submission Standard	200
Table 19-1: Requests for Person Identified Data	203

Organ Procurement and Transplantation Network (OPTN) Policies
 Crosswalk: Current to Rewrite

	5-1(C)	3.5.11.5	9-3		
	5-1(D)	3.5.11.5.1	9-3	3.6	5-4
	5-1(E)	3.5.11.6	9-3		10
	5-1(F)		9-5(E)		10-1
3.3.3	5-1(A)	3.5.12	9-3		10-1(A)
	5-1(B)	3.5.12.1	3-4		10-2(A)
	5-1(C)		9-4		10-5(A)
	5-1(D)	3.5.12.1.1	9-3		10-5(C)
	5-1(E)	3.5.13	9-7(C)		10-6(B)
	5-1(F)	3.5.14	4-3		10-6(C)
	5-1(G)	3.5.15	5-2(B)(V)		Cut
3.3.4	5-1(A)	3.5.16	4-4	3.6.1	5-1(B)
3.3.5	5-2(B)(III)	3.5.17	4-1(E)	3.6.10	5-1(B)
3.3.6	5-3(C)	3.5.2	9-5(D)		10-5(D)
3.3.6.1	2-9(F)	3.5.3	9-7(B)		10-6
3.3.6.1.1	2-9(F)	3.5.3.1	1-2	3.6.11	5-1(B)
		3.5.3.3	1-2		10-5(C)
			9-7(A)	3.6.12	10-8(A)
			9-7(C)	3.6.13	4-1(A)
3.4	1	3.5.3.3.1	9-6(A)		4-1(E)
3.4.1	2-7(A)		9-6(B)	3.6.2	5-1(B)
3.4.10	Cut		9-6(C)		10-3
3.4.11	1-4(A)		9-6(D)		10-5(A)
3.4.11.1	1-4(B)	3.5.3.3.2	9-5(D)	3.6.2.1	10-6(B)
3.4.11.2	1-4(C)		9-6(A)		10-6(C)
	1-4(D)		9-6(B)		10-5(E)
3.4.11.3	1-4(E)		9-6(C)	3.6.2.2	5-1(B)
3.4.2	5-3(B)		9-6(D)		5-1(D)
3.4.3	2-8		9-6(E)	3.6.3	3-4
	5-2(B)(II)	3.5.3.4	9-7(D)		3-5
3.4.4	1-5	3.5.3.5	9-7(A)		10-4
3.4.5	5-2(B)(II)	3.5.4	12-5		10-5
3.4.6	5-2(B)	3.5.4.1	Cut		10-5(A)
3.4.7	5-3(A)	3.5.5	9-7(B)	3.6.4	10-2
3.4.8	1-3	3.5.5.1	9-5	3.6.4.1	10-1
3.4.8.1	1-3(A)	3.5.5.1.1	9-7(B)		10-1(A)
3.4.8.2	1-3(B)	3.5.5.1.2	9-7(B)		10-2(A)
3.4.8.3	1-3(C)	3.5.5.2	9-6(A)		10-1(D)
3.4.8.4	1-3(D)		9-6(D)		10-1(E)
3.4.8.5	1-3(E)		9-6(B)		10-2(B)
3.4.8.6	1-3(F)		9-6(C)		10-5(B)
3.4.9	Cut		9-5(D)	3.6.4.1.1	10-5(B)
		3.5.5.3	9-7(B)	3.6.4.2	10-1(B)
3.5	9	3.5.6	9-1		10-1(C)
	9-1	3.5.6.2	9-1		10-1(D)
3.5.1	9-5(A)		9-5(G)		10-1(F)
3.5.10	Cut	3.5.6.3	9-1		10-2(B)
3.5.11	9-3	3.5.6.4	1-2		10-5(B)
3.5.11.1	3-4	3.5.7	9-6(G)	3.6.4.2.1	10-5(B)
	9-3	3.5.8	9-6(E)	3.6.4.3	10-2(B)
	9-4	3.5.9	2-4(B)	3.6.4.4	10-2(G)(I)
3.5.11.2	1-2	3.5.9.1	2-4(B)		10-2(G)(II)
	9-3		2-7(B)		10-2(G)(III)
3.5.11.3	9-1	3.5.9.2	2-4(C)(I)		10-2(G)(IV)
3.5.11.4	9-2				10-2(G)(V)

Organ Procurement and Transplantation Network (OPTN) Policies
 Crosswalk: Current to Rewrite

8.2.8	20-2(B)	4-2(A)	4-19(D)(I)
8.3	20-3	4-2(B)	13
8.4	20-4	4-2(C)	
8.4.1	20-4(A)	4-2(D)	
8.4.2	20-4(B)	4-5	
8.4.3	20-4(C)	4-5(A)	
8.4.4	20-4(D)	4-5(B)	
8.5	20-5	4-5(C)	
8.5.1	20-5(A)	4-6	
8.5.2	20-5(B)	4-6(A)	
8.5.3	20-5(C)	4-6(B)	
8.6	20-6	4-6(C)	
8.6.1	20-6(A)	4-6(D)	
8.6.2	20-6(B)	4-6(E)	
8.6.3	20-6(C)	4-6(F)	
8.7	20-7	4-7	
8.8	20-8	4-8	
8.8.1	20-8(A)	4-8(A)	
8.8.2	20-8(C)	4-8(B)	
		4-8(C)	
		4-8(D)	
9	19	4-9	
9.1	19-1	4-10	
9.2	19-2	4-10(A)	
9.3	19-3	4-10(B)	
9.4	19-4	4-10(C)	
9.5	19-5	4-10(D)	
9.6	19-6	4-10(D)(II)	
9.7	1-2	4-10(E)	
		4-10(F)	
		4-10(G)	
11	3-2(A)	4-10(H)	
		4-10(I)	
		4-10(I)(I)	
		4-10(I)(II)	
		4-10(J)	
		4-11	
		4-11(A)	
		4-11(B)	
		4-11(C)	
		4-11(D)	
		4-11(E)	
		4-11(F)	
		4-11(G)	
		4-11(H)	
		4-12	
		4-12(A)	
		4-12(B)	
Bylaws	1-2	4-13	
	2-9(B)	4-13(A)	
	2-9(C)	4-13(B)	
	2-9(D)	4-13(C)	
	2-9(E)	4-13(D)	
	3-3	4-13(E)	
	4-2	4-14	

Crosswalk: Rewrite to Current

The following crosswalk shows the location of the policy in the policy rewrite and the corresponding source from the current policies. Please note that the rewritten policies include any policies adopted by the Board but not yet implemented and any policies that may be approved by the Board at their November 2012 meeting. Sections were cut if they were expired or redundant material.

Rewritten Location	Former Location	Rewritten Location	Former Location	Rewritten Location	Former Location
	1				
1	3.1	1-3(A)	3.4.8.1		2.2.4.3
1	3.4	1-3(B)	3.4.8.2		2.2.4.4
1-1(E)	7.5	1-3(C)	3.4.8.3		2.2.4.5
1-2	2.2.3.1	1-3(D)	3.4.8.4		2.2.4.6
	3.1.1	1-3(E)	3.4.8.5		3.5.9
	3.1.2	1-3(F)	3.4.8.6		3.5.9.1
	3.1.3	1-4(A)	3.1.4.1		3.6.9
	3.1.4		3.4.11		3.6.9.1
	3.1.5	1-4(B)	3.4.11.1		3.7.12
	3.1.6	1-4(C)	3.4.11.2		3.7.12.1
	3.1.7	1-4(D)	3.4.11.2		3.7.12.3
	3.1.8	1-4(E)	3.4.11.3		3.8.2.2
	3.1.9	1-5	3.4.4	2-4(C)(I)	3.5.9.2
	3.1.10			2-4(C)(II)	3.7.12.1
	3.1.11				3.7.12.2
	3.1.12	2		2-4(C)(III)	3.7.12.1
	3.1.13	2	2		3.7.12.3
	3.2.1.2	2-1	2.1	2-4(D)	3.7.12.4
	3.5.3.1		2.4		2.2.5
	3.5.3.3		2.5.6	2-5(A)	2.2.6
	3.5.6.4		2.9		2.2.3.2
	3.5.11.2		3.3.1		2.2.3.3
	3.7.2		7.5	2-5(B)	2.2.3.4
	3.8	2-2	2.2	2-5(C)	2.2.3.3
	6.1		2.2.1	2-6	2.2.3.5
	6.1.1		2.2.2		2.3
	6.1.2		2.2.2.1		2.3.1
	7.1		2.2.2.2		2.3.2
	7.1.1		2.2.2.3		2.3.3
	7.1.2		2.5.1		2.3.4
	7.1.4	2-3	2.2.3	2-7(A)	2.3.5
	7.1.6		2.2.3.1	2-7(B)	3.4.1
	7.1.7	2-4	3.7.12		2.5
	9.7	2-4(A)	3.2.4		2.5.2
	12.1	2-4(B)	2.2.3.2		2.5.3
	Bylaws		2.2.4		2.5.4
1-3	3.4.8		2.2.4.1		2.6
	3.7.1		2.2.4.2		3.5.9.1
					5.8

Organ Procurement and Transplantation Network (OPTN) Policies
 Crosswalk: Rewrite to Current

	5.8.1	3.6.3	4-10(I)(II)	Bylaws
	5.8.2	3.8.7.2	4-10(J)	Bylaws
	5.8.3	3.2.1.8.1	4-11	Bylaws
	5.8.4	3.2.1.8.2	4-11(A)	Bylaws
2-7(C)	2.5.7	3.2.1.8.3	4-11(B)	Bylaws
2-8	2.7	3.2.1.8.4	4-11(C)	Bylaws
	2.7.1	3.2.7	4-11(D)	Bylaws
	3.4.3	3.8.5	4-11(E)	Bylaws
2-9	2.8	3.8.5.1	4-11(F)	Bylaws
2-9(A)	2.8	3.8.5.2	4-11(G)	Bylaws
2-9(B)	Bylaws	3.2.4.2	4-11(H)	Bylaws
2-9(C)	Bylaws	3.8.5	4-12	Bylaws
2-9(D)	Bylaws	3.8.5.1	4-12(A)	Bylaws
2-9(E)	Bylaws	3.8.5.2	4-12(B)	Bylaws
2-9(F)	3.3.6.1	3.8.5.3	4-13	Bylaws
.....	3.3.6.1.1	3.8.6	4-13(A)	Bylaws
		3.11.5.1	4-13(B)	Bylaws
	3	3.6.6	4-13(C)	Bylaws
3	3.2	3.8.5.3	4-13(D)	Bylaws
3-1	3.2.1.1	3.8.7.5	4-13(E)	Bylaws
	3.2.1.2	3.2.2	4-14	Bylaws
	3.2.1.3	3.2.1.9	4-15	Appendix 3A
3-2(A)	11	3.2.4.1	4-19(D)(I)	Bylaws
3-2(B)	3.1.13	3.6.6	4-2	Bylaws
	3.1.4	3.7.13	4-2(A)	Bylaws
	3.1.4.1	3.7.14	4-2(B)	Bylaws
	3.1.4.2	3.8.6	4-2(C)	Bylaws
	3.1.4.3	3.8.7.2	4-2(D)	Bylaws
	3.2.1	3.8.7.5	4-3	3.5.14
3-2(C)	3.2.1.5	3.11.5		Appendix 3A
	3.8.2.1		4-4	3.5.16
3-2(D)	3.1.13			Appendix 3C
	3.2.1.6	4	4-5	Bylaws
	3.2.1.7	4-1	4-5(A)	Bylaws
	3.7.8	4-1(A)	4-5(B)	Bylaws
	3.8.2.1	3.7.16	4-5(C)	Bylaws
3-3	3.8.1	Appendix 3D	4-6	Bylaws
	3.8.1.1	4-1(B)	4-6(A)	Bylaws
	3.8.1.2	Appendix 3D	4-6(B)	Bylaws
	3.8.1.3	4-1(C)	4-6(C)	Bylaws
	3.8.7	4-1(D)	4-6(D)	3.8.2.3
	3.11.6	4-1(E)		Bylaws
	Bylaws	3.6.13	4-6(E)	Bylaws
3-4	3.2.6	3.7.16	4-6(F)	Bylaws
	3.5.11.1	Appendix 3D	4-7	Bylaws
	3.5.12.1	4-10	4-8	Bylaws
	3.6.3	Bylaws	4-8(A)	Bylaws
	3.7.9	4-10(A)	4-8(B)	Bylaws
	3.7.9.3	Bylaws	4-8(C)	Bylaws
	3.8.3.4	4-10(B)	4-8(D)	Bylaws
	3.8.4.3	Bylaws	4-9	Bylaws
	3.8.7.2	4-10(C)		
	3.11.1	Bylaws		
	3.11.6	4-10(D)		
3-5	3.2.1.8	4-10(D)(II)		
		Bylaws		
		4-10(E)		
		Bylaws		
		4-10(F)		
		Bylaws		
		4-10(G)		
		Bylaws		
		4-10(H)		
		Bylaws		
		4-10(I)		
		Bylaws		
		4-10(I)(I)		
		Bylaws		

Organ Procurement and Transplantation Network (OPTN) Policies
 Crosswalk: Rewrite to Current

5-1(A).....	3.3.3	6-1.....	3.9.3	3.5.11.5.1
	3.3.4	6-2.....	3.7.7	3.5.11.6
5-1(B).....	3.2.5	6-3.....	3.11.4.2	3.5.12
	3.3.2	6-4.....	3.6.4.8	3.5.12.1.1
	3.3.3		3.11.4	12.9.3
	3.6.1			9-4.....
	3.6.2			3.5.11.1
	3.6.2.2	7		3.5.12.1
	3.6.10	7.....	3.7	9-5.....
	3.6.11	7-1(A).....	3.7.3	3.5.5.1
5-1(C).....	3.3.2	7-1(B).....	3.7.3	9-6(A).....
	3.3.3	7-2(D).....	3.7.1.1	3.5.3.3.1
5-1(D).....	3.3.2	7-3.....	3.7.9	3.5.3.3.2
	3.3.3		3.7.9.1	3.5.5.2
	3.6.2.2	7-4(A).....	3.7.9	12.9.4
	3.7.8	7-4(B).....	3.7.9.1	9-6(D).....
	3.7.8.1		3.7.4	3.5.3.3.1
5-1(E).....	3.3.2	7-4(C).....	3.7.8	3.5.3.3.2
	3.3.3	7-4(D).....	3.7.15	3.5.5.2
	3.8.4.1	7-6.....	3.7.1	9-6(E).....
5-1(F).....	3.3.2	7-5.....	3.7.1	3.5.3.3.2
	3.3.3		3.7.2	3.5.8
5-1(G).....	3.3.3	7-1(C).....	3.7.3	3.5.5.1.1
5-2.....	3.6.5.1	7-1(D).....	3.7.4	3.5.5.1.2
	3.6.7	7-1(E).....	3.7.4	3.5.5.3
5-2(A).....	3.2.1.4	7-2.....	3.7.3	9-7(A).....
	3.2.4		3.7.4	3.5.3.5
	6.2.1	7-5(A).....	3.7.8	9-7(B).....
5-2(B).....	3.1.5		3.7.10	3.5.3
	3.3.1	7-5(B).....	3.7.5	3.5.5
	3.4.6		3.7.8	3.5.5.1.1
5-2(B)(I).....	3.6.5.1		3.7.10.1	3.5.5.1.2
	3.6.7			3.5.5.3
5-2(B)(II).....	3.4.3	8		9-7(C).....
	3.4.5	8.....	3.11	3.5.13
5-2(B)(III).....	3.3.5	8-1.....	3.11.1	3.5.3.3
	3.8.3.6	8-5.....	3.11.3	9-7(D).....
5-2(B)(IV).....	3.1.13	8-3.....	3.11.1	3.5.3.4
	3.2.4		3.11.4.1	12.9.4
5-2(B)(V).....	3.5.15		3.11.6	3.5.3.3.1
	3.6.8	8-4(A)(I).....	3.11.2	3.5.3.3.2
	3.7.14			3.5.5.2
	3.9.4	9		9-6(C).....
5-3(A).....	3.1.2	9.....	3.5	3.5.3.3.1
	3.4.7	9-1.....	3.5	3.5.3.3.2
5-3(B).....	3.4.2		3.5.11.3	3.5.5.2
5-3(C).....	3.3.6		3.5.6	9-5(A).....
	3.6.5		3.5.6.2	3.5.1
5-4.....	3.2.4		3.11.2	9-5(D).....
	3.6		3.11.6	3.5.3.3.2
5-5.....	3.9		3.11.2	3.5.5.2
5-5(A).....	3.9.1	9-2.....	3.5.11.4	9-5(E).....
5-5(B).....	3.9.2	9-3.....	3.5.11	12.9.3
			3.5.11.1	3.5.11.6
			3.5.11.2	9-5(G).....
			3.5.11.5	3.5.6.2
6				
				10
				10.....
				3.6
				10-1.....
				3.6
				3.6.4.1
				10-1(A).....
				3.6
				3.6.4.1
				10-1(B).....
				3.6.4.2
				10-1(C).....
				3.6.4.2
				10-2.....
				3.6.4
				10-2(A).....
				3.6
				3.6.4.1
				10-2(B).....
				3.6.4.1

Organ Procurement and Transplantation Network (OPTN) Policies
 Crosswalk: Rewrite to Current

	3.6.4.2		3.7.6.3.2		4.1.1
	3.6.4.3		3.7.9.2		4.1.2
	3.6.4.5	11-1(B)(I)	3.7.2	15-3	4.2.3
	3.6.4.7	11-1(B)(II)	3.7.2	15-4(A)	4.2
10-2(D)	3.6.4.5.1	11-1(B)(III)	3.7.2		4.3
	3.6.4.5.2	11-2(A)	3.7.1.1	15-4(B)	4.2.1
	3.6.4.5.3	11-3	3.7.9		4.3
	3.6.4.5.4		3.7.9.2	15-4(C)	4.2.2
	3.6.4.5.5		3.7.9.3		4.3.1
	3.6.4.5.6	11-4	3.7.9.3	15-5(A)	4.5
10-2(F)	3.6.4.5.6	11-5	3.7.2	15-5(B)	4.5
10-3	3.6.2		3.7.6		4.5.1
10-4	3.6.3		3.7.8.2	15-5(C)	4.5.2
10-5	3.6.3	11-5(B)	3.7.11.1		
10-6	3.6.10	11-5(A)	3.7.11		
10-6(B)	3.6	11-5(C)	3.7.11.1		
	3.6.2.1	11-2	3.7.1		
10-6(C)	3.6		3.7.6.4		
	3.6.2.1				
10-7(B)	3.6.4.6				
	3.6.9.2	12	3.8	16	5
10-8(A)	3.6.12	12-4(A)	3.8.7.2	16-1	5.9
10-1(D)	3.6.4.1	12-4(B)	3.8.3.1		5.9.1
	3.6.4.2		3.8.3.3	16-2	5
10-1(E)	3.6.4.1		3.8.4.1		5.1
10-1(F)	3.6.4.2		3.8.4.2	16-3	5.1
10-2(G)(I)	3.6.4.4	12-4(C)	3.8.3.5	16-4	5.2
10-2(G)(II)	3.6.4.4	12-5(A)	3.8.3.1	16-4(A)	5.2
10-2(G)(III)	3.6.4.4		3.8.3.3		5.2
10-2(G)(IV)	3.6.4.4	12-6(A)	3.8.3.4	16-4(A)	5.2
10-2(G)(V)	3.6.4.4	12-5	3.5.4	16-4(B)	5.1.3
10-2(G)(VI)	3.6.4.4		3.8.3		5.4
10-2(G)(VII)	3.6.4.4	12-3	3.8.1	16-4(B)(I)	5.4.1
10-2(G)(VIII)	3.6.4.4		3.8.6	16-4(B)(II)	5.4.2
10-5(A)	3.6	12-3(A)	3.8.4.3		5.4.2
	3.6.2		3.8.7.2	16-4(B)(III)	5.8.2
	3.6.3	12-3(B)	3.8.1.4.1		5.10.2
10-5(B)	3.6.4.1		3.8.4.3	16-5	5.2
	3.6.4.1.1	12-3(C)	3.8.1.4	16-5(A)	5.1.1
	3.6.4.2		3.8.4.3	16-5(B)	5.1.2
	3.6.4.2.1	12-4(E)	3.8.3.2		5.1.2
	3.6.6		3.8.7.1	16-5(C)	5.1.3
10-5(C)	3.6	12-4(F)	3.8.7.3	16-5(D)	5.1.3
	3.6.11		3.8.7.4		5.3
10-5(D)	3.6.10			16-6	5.5
10-5(E)	3.6.2.1			16-6(A)	5.5.1
		13		16-6(B)	5.5.2
		n/a		16-7	5.6
				16-7(A)	5.6.1
				16-7(B)	3.1.2
					5.7
11	3.7	14		16-8	5.10
11-1(A)	3.7.6.2	n/a		16-8(A)	5.10.1
11-1(A)(I)	3.7.6.2				5.10.2
11-1(A)(II)	3.7.6.2	15		16-8(B)	5.10.1
11-1(B)	3.7.6.1	15	4		5.10.2
	3.7.6.3	15-1	4.4	16-9	5.11
	3.7.6.3.1	15-2	4.1	16-9(A)	2.5.8

Organ Procurement and Transplantation Network (OPTN) Policies
 Crosswalk: Rewrite to Current

16-9(B)	5.11.1	19-4	9.4
	5.11.2	19-5	9.5
	5.11.3	19-6	9.6
17		20	
17	6	20	8
17-1	6.2	20-1	8.1
17-1(A)	6.2.2	20-1(A)	8.1.1
17-1(B)	6.3	20-1(B)	8.1.2
17-1(C)	6.3.1	20-2	8.2
17-2(A)	6.4	20-2(A)	8.2.1
17-2(B)	6.4.1		8.2.2
17-2(C)	6.4.2	20-2(B)	8.2.3
17-4(A)	6.4.1.1		8.2.4
17-4(B)	6.4.1.1		8.2.5
			8.2.7
			8.2.8
18		20-2(C)	8.2.6
18	7	20-3	8.3
18-1	3.2.4.1	20-4	8.4
	3.6.6	20-4(A)	8.4.1
	3.7.14	20-4(B)	8.4.2
	3.8.6	20-4(C)	8.4.3
	3.11.5	20-4(D)	8.4.4
	7	20-5	8.5
	7.1.3	20-5(A)	8.5.1
	7.2	20-5(B)	8.5.2
	7.3	20-5(C)	8.5.3
	7.3.1	20-6	8.6
	7.4	20-6(A)	8.6.1
	7.4.1	20-6(B)	8.6.2
	7.5.1	20-6(C)	8.6.3
	7.6	20-7	8.7
	7.7	20-8	8.8
	12.8.1	20-8(A)	8.8.1
	12.8.2	20-8(C)	8.8.2
	12.8.3		
18-2	7.3.1		
	7.4.2		
18-3	7.6		
	7.6.1		
	7.6.1.1		
	7.6.1.2		
	7.6.2		
	7.6.2.1		
	7.6.2.2		
	7.8		
18-4(A)	7.8.1		
	7.8.2		
	7.9		
19			
19	9		
19-1	9.1		
19-2	9.2		
19-3	9.3		