UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

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IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: James B. Alcorn
Director, Policy

RE: Changes to OPTN Bylaws and Policies from actions at June Board of Directors Meeting

Date: July 23, 2014

The attached report summarizes changes to the OPTN Policies and Bylaws approved by the OPTN/UNOS Board of Directors at its June 2014 meeting. This policy notice provides the specific Policy and Bylaws language changes and the corresponding implementation dates.

When reviewing the language changes, please note that underlined language is new and what will be in effect upon implementation and language that is ~~struck~~ will be deleted upon implementation. The policy language used to denote the approved changes reflects the most recent version of policy that has been approved, but not necessarily what is currently implemented.

This policy notice, as well as changes from previous Board of Directors meetings, can be found at optn.transplant.hrsa.gov (click on “News,” and then select “View all Policy Notices”).

The Evaluation Plan, which reviews specific details regarding how members will be assessed for compliance with policies and bylaws, has also been updated to reflect the changes resulting from the meeting. It can also be found at optn.transplant.hrsa.gov (click on “Policy Management,” and then select “Evaluation Plan”).

Thank you for your careful review of this policy notice. If you have any questions about a particular Board of Directors’ action, please contact your regional administrator at (804) 782-4800.

Proposal to Modify Deceased Donor Testing Requirements

Sponsoring Committee: Ad Hoc Disease Transmission Advisory Committee

Policies Affected: Policies 2.3 (Evaluating and Screening Potential Deceased Donors), 2.4 (Deceased Donor Medical and Behavioral History), 2.5 (Hemodilution Assessment), 2.7 (HIV Screening of Potential Deceased Donors), 2.7.A (Exceptions to HIV Screening Requirement), 2.8 (Required Deceased Donor Information) and its subsections, 2.9 (Requested Deceased Donor Information) and its subsections, 2.10 (Post Recovery Follow Up and Reporting) and its subsections, 2.11 (Deceased Donor Management), 2.12 (Organ Procurement) and its subsections, 2.13 (Requirements for Controlled Donation after Circulatory Death (DCD) Protocols) and its subsections, Table 14-2: Requirements for Living Kidney Donor Medical Evaluations, 14.5.A (Living Kidney Donor Psychosocial Evaluation Requirements), and 16.4.D (Internal Labeling of Vessels)

Distributed for Public Comment: September 6, 2013

Amended After Public Comment: Yes

Effective Date: September 1, 2014

Problem Statement
Current deceased donor testing requirements are no longer in line with current testing practices in the field.

Changes
These new policies approved by the Board: • Remove the term “commercially available,” which was never clearly defined. • Replace general screening test requirements with pathogen-specific requirements. • Provide a new option for HIV testing using the combination antigen/antibody (Ag/Ab) diagnostic test, which is also recommended as a testing option in the 2013 PHS Guideline. • Simplify syphilis testing requirements, removing specific outdated testing language. • Require donor Toxoplasma screening, but provide the OPO flexibility in either completing the testing or sending an appropriate sample along with the heart for testing at the transplant hospital (already a common practice). • Require the OPO to report when a donor is not tested for HIV, Hepatitis B, or Hepatitis C according to policy. OPOs should report this information through the Improving Patient Safety Portal, according to policy.

Member Actions
OPOs should: • Familiarize themselves with the new policy requirements. Update internal policies and procedures to address any changes made based upon these policy modifications and update any internal documents or processes accordingly. • Coordinate with laboratories used for donor testing to determine whether they choose to utilize the new diagnostic testing option for HIV and confirm appropriateness of other required tests based upon the updated, more user friendly policy language. ➢ OPOs must test donors for HIV, HCV, and HBV using, at a minimum, the required FDA licensed, approved, or cleared screening tests specified in policy (with the exception of the new HIV Antigen/Antibody combination test, which is a diagnostic test). Any instance where testing is not completed per policy must be: (1) documented, (2) reported to the transplant hospitals prior to transplant, and (3) reported to the Improving Patient Safety portal within 24 hours. ➢ Until programming of a new field to capture this information is completed, OPOs that choose to use the new HIV antigen/antibody combination test must mark the anti-HIV screening field as "not done" and clearly note the use of the combination Ag/Ab test in the "Donor Highlights" field in DonorNet℠. ➢ Until programming to update RPR/VDRL label in DonorNet℠ is complete, OPOs that use testing other than RPR or VDRL must mark this field as "not done" and clearly document the use of a test other than RPR or VDRL to assess a donor for syphilis in the "Donor Highlights" field in DonorNet℠. • Develop internal policy on meeting requirements to either test heart donors for Toxoplasma or send a tube of blood for testing at the heart recipient transplant hospital. • Educate staff impacted by these testing requirement changes (e.g. medical directors, laboratory directors, procurement coordinators, data entry coordinators, etc.).

Affected Policy Language:
New language is underlined and language that will be deleted is ~~struck through.~~

2.3 Evaluating and Screening Potential Deceased Donors

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

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

2.4 Deceased Donor Medical and Behavioral History

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

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

following:

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

2.5 Hemodilution Assessment

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

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

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

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

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

2.7 HIV Screening of Potential Deceased Donors

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

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

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

~~1. The sample is qualified.~~
~~2. The HIV screening test completed by the host OPO is negative.~~
~~3. Blood for subsequent transfusions has been tested and found to be HIV negative.~~

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

2.7.A Exceptions to HIV Screening Requirement

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

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

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

In this case the receiving transplant hospital must:

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

2.7.B Informing Personnel

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

2.8 Required Deceased Donor ~~Information~~ General Risk Assessment

~~The host OPO is responsible for evaluating all deceased donors.~~

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

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

The host OPO is responsible for evaluating each potential donor in order to obtain ~~*All*~~ the following information: ~~is required for each potential deceased donor:~~

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

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

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

2.9 Required Deceased Donor Infectious Disease Testing

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

1. Blood and urine cultures

2. Infectious disease testing for all potential deceased organ donors using FDA licensed, approved or cleared tests, as listed below:

    a. HIV antibody (anti-HIV) donor screening test *or* HIV antigen/antibody (Ag/Ab) combination test
    b. Hepatitis B surface antigen (HBsAg) *and* Hepatitis B core antibody (anti-HBc) donor screening tests
    c. Hepatitis C antibody donor screening test (anti-HCV)
    d. Cytomegalovirus (CMV) antibody (anti-CMV) donor screening *or* diagnostic test
    e. Epstein-Barr Virus (EBV) antibody (anti-EBV) donor screening *or* diagnostic test
    f. Syphilis donor screening *or* diagnostic test

    Additionally, if, for any reason, HIV, HBV, or HCV testing is not performed as described above in #2, the host OPO must:

    1. Document in the donor record which test was used to assess the potential donor
    2. Provide this information to the receiving transplant hospital before transplant
    3. Report the reason for using another test to the OPTN Improving Patient Safety portal as soon as possible, but no later than 24 hours after organ recovery.

2.10 Additional Deceased Donor Testing

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

2.~~8~~11 Required Deceased Donor Information

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

1. Age

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

2.8~~1~~1.A Required Information for Deceased Kidney Donors

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

1. Donor name
2. Donor ID
3. Date of admission for the current hospitalization
4. Ethnicity
5. Relevant past medical or social history
6. Current history of abdominal injuries and operations
7. Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria
8. Current medication and transfusion history
9. Anatomical description, including number of blood vessels, ureters, and approximate length of each
10. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR51, DR52, DR53 and DQB antigens. The lab is encouraged to report splits for all loci as outlined in *Policy 4: Histocompatibility*.
11. Indications of sepsis
12. Injuries to or abnormalities of the blood
13. Assurance that final blood and urine cultures are pending
14. Final urinalysis
15. Final blood urea nitrogen (BUN) and creatinine
16. Recovery blood pressure and urine output information
17. Recovery medications
18. Type of recovery procedure, flush solution and method, and flush storage solution
19. Warm ischemia time and organ flush characteristics

2.8~~1~~1.B Required Information for Deceased Liver Donors

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

1. Donor name
2. Donor ID
3. Ethnicity
4. Height
5. Weight
6. Vital signs, including blood pressure, heart rate and temperature
7. Social history, including drug use
8. History of treatment in hospital including current medications, vasopressors, and hydration
9. Current history of hypotensive episodes, urine output, and oliguria
10. Indications of sepsis
11. Aspartate aminotransferase (AST)
12. Bilirubin (direct)
13. Other laboratory tests within the past 12 hours including:
    a. Alanine aminotransferase (ALT)
    b. Alkaline phosphatase
    c. Total bilirubin
    d. Creatinine
    e. Hemoglobin (hgb) and hemocrit (hct)

f. International normalized ration (INR) or Prothrombin (PT) if INR is not available, and partial thromboplastin time (PTT)
g. White blood cell count (WBC)

2.8~~1~~1.C Required Information for Deceased Heart Donors

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

1. Height
2. Weight
3. Vital signs, including blood pressure, heart rate, and temperature
4. History of treatment in hospital including vasopressors and hydration
5. Cardiopulmonary, social, and drug activity histories
6. Details of any documented cardiac arrest or hypotensive episodes
7. 12-lead interpreted electrocardiogram
8. Arterial blood gas results and ventilator settings
9. Cardiology consult or echocardiogram, if the hospital has the facilities
10. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, and DQB antigens
11. Toxoplasma antibody (Ab) test result or an appropriate donor sample sent with the heart for testing at the transplant hospital.

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

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

2.8~~1~~1.D Required Information for Deceased Lung Donors

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

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

If the host OPO cannot perform a bronchoscopy, it must document that it is unable to provide bronchoscopy results and the receiving transplant hospital may perform it. The lung recovery team may perform a confirmatory bronchoscopy provided unreasonable delays are avoided and deceased donor stability and the time limitations in *Policy 5.5.B: Time Limit for Acceptance* are maintained.

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

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

2.8~~1~~1.E Required Information for Deceased Pancreas Donors

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

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

2.9~~1~~2 Requested Deceased Donor Information

2.9~~1~~2.A Kidney

With each kidney offer, the host OPO should provide the recipient transplant hospital with the following biopsy information for all Expanded Criteria Donor (ECD) kidneys, and for all other kidneys at the request of the accepting surgeon:

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

2.~~9~~12.B Heart

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

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

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

- Male over 40 years old or female over 45 years old
- Segmental wall motion abnormality on echo
- Troponin elevation
- History of chest pain
- Abnormal electrocardiogram (ECG) consistent with ischemia or myocardial infarction
- History of *two or more* of the following:
  - Cocaine or amphetamine use
  - Diabetes
  - Hyperlipidemia
  - Hypertension
  - Intra-cerebral bleeding
  - Significant smoking
  - Strong family history of coronary artery disease

2.~~9~~12.C Lung

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

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

2.~~10~~13 Post Recovery Follow Up and Reporting

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

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

2.~~10~~13.A Reporting Requirements

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

1. Updates, such as the identification of any potential disease-causing organism and the sensitivity of the deceased donor to that organism, as the host OPO receives the information.

2. Medical-social history, testing, and laboratory assessments that identify malignant or infectious conditions that may adversely affect a potential transplant recipient.
3. Any known or suspected infectious or neoplastic conditions that may be transmitted to transplant recipients.

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

2.~~11~~14 Deceased Donor Management

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

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

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

2.~~12~~15 Organ Procurement

2.~~12~~15.A Conflicts of Interest

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

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

2.~~12~~15.B Organ Procurement Procedures

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

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

2.~~12~~15.B.i Required Tissue Typing and Blood Type Verification Materials

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

Table 2-1: Minimum Typing Materials

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

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

2.~~12~~15.C Authorization Requirement

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

2.~~12~~15.D Non-renal Organ Procurement

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

2.~~12~~15.E Multiple Organ Procurement

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

2.~~13~~16Requirements for Controlled Donation after Circulatory Death (DCD) Protocols

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

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

2.~~13~~16.A Agreement

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

2.~~13~~16.B Protocols

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

2.~~13~~16.C Potential DCD Donor Evaluation

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

2.~~13~~16.D Consent for DCD

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

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

2.~~13~~16.E Authorization for DCD

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

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

2.~~13~~16.F Withdrawal of Life Sustaining Medical Treatment or Support

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

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

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

2.~~13~~16.G Pronouncement of Death

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

2.~~13~~16.H Organ Recovery

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

2.~~13~~16.I DCD Potential Donor Who Converts to Brain Death after an Organ Offer Has Been Made

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

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

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

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

14.4.B Living Kidney Donor Medical Evaluation Requirements

A medical evaluation of the potential living kidney donor must be performed by the recovery hospital and by a physician or surgeon experienced in living donation. The goals of the medical evaluation are *all* of the following:

1. To assess the immunologic compatibility of the living donor to the recipient
2. To assess the general health and surgical risk of donation to the living donor including screening for conditions that may predict future complications from having only one kidney
3. To determine if there are diseases present that may be transmitted from the living donor to the recipient
4. To assess the anatomy and function of the living donor's kidneys

Documentation of the medical evaluation must be maintained in the donor medical record.

The medical evaluation must include *all* of the components in *Table 14-2* below.

Table 14-2: Requirements for Living Kidney Donor Medical Evaluations

This evaluation must be completed:	Including evaluation for and assessment of this information:
A general living donor history	1. A personal history of significant medical conditions which include but are not limited to: a. Hypertension b. Diabetes c. Lung disease d. Heart disease e. Gastrointestinal disease f. Autoimmune disease g. Neurologic disease h. Genitourinary disease i. Hematologic disorders j. Bleeding or clotting disorders k. History of cancer 2. History of infections 3. A kidney-specific personal history including: a. Genetic renal diseases b. Kidney disease, proteinuria, hematuria c. Kidney injury d. Diabetes including gestational diabetes e. Nephrolithiasis f. Recurrent urinary tract infections 4. Active and past medications with special consideration for known nephrotoxic medications 5. Allergies 6. An evaluation for coronary artery disease
General family history	The living donor's family history of coronary heart disease and cancer
Kidney-specific family history	The living donor's family history of: • Kidney disease • Diabetes • Hypertension • Kidney Cancer
Social history	The living donor's history of: • Occupation, employment status, health insurance status, living arrangements, and social support • Smoking, alcohol and drug use and abuse • Criteria to assess increased risk for disease transmission as defined by the ~~PHS Guideline~~*U.S. Public Health Services (PHS) Guideline* • Psychiatric illness, depression, suicide attempts
Physical Exam	A physical exam of the living donor including: • Height • Weight • BMI • Examination of all major organ systems • Blood pressure taken on at least two different occasions or 24-hour or overnight blood pressure monitoring

This evaluation must be completed:	Including evaluation for and assessment of this information:
General laboratory and imaging tests	• Complete blood count (CBC) with platelet count • Blood type and screen • Prothrombin Time (PT) or International Normalized Ratio (INR) • Partial Thromboplastin Time (PTT) • Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin) • HCG quantitative pregnancy test for premenopausal women without surgical sterilization • Chest X-Ray • Electrocardiogram (ECG)
Other metabolic testing	• Fasting blood glucose • Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol) • Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high risk individuals

Kidney-specific tests	• Urinalysis or urine microscopy
	• Urine culture if clinically indicated
	• Measurement of urinary protein and albumin excretion
	• Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection
	• Hospitals must develop and comply with a protocol for polycystic kidney disease or other inherited renal disease as indicated by family history
	• Patients with a history of nephrolithiasis or nephrolithiasis (>3mm) identified on radiographic imaging must have a 24-hour urine stone panel measuring:
	  ○ Calcium
	  ○ Oxalate
	  ○ Uric acid
	  ○ Citric acid
	  ○ Creatinine
	  ○ Sodium

Anatomic assessment	An assessment to determine: • Whether the kidneys are of equal size • If the kidneys have masses, cysts, or stones • If the kidneys have other anatomical defects • Which kidney is more anatomically suited for transplant. The choice of test for radiologic imaging may be determined based on the local radiological expertise and surgical preference, and may include CT angiogram or MR angiogram.

This evaluation must be completed:	Including evaluation for and assessment of this information:
Transmissible disease screening	Infectious disease testing must include *all* the following: 1. CMV (Cytomegalovirus) antibody 2. EBV (Epstein Barr Virus) antibody 3. HIV 1,2 (Human Immunodeficiency Virus) antibody testing 4. HepBsAg (Hepatitis B surface antigen) 5. HepBcAB (Hepatitis B core antibody) 6. HepBsAB (Hepatitis B surface antibody) 7. HCV (Hepatitis C Virus) antibody testing 8. RPR (Rapid Plasma Reagin test for syphilis) Living donor recovery hospitals must determine if the potential donor is at increased risk for tuberculosis (TB) and if so testing must include screening for latent TB using either intradermal PPD or Interferon Gamma Release Assay (IGRA).
Endemic transmissible diseases	For the following infectious diseases, recovery hospitals must determine if the potential donor is from an endemic area, and if so must test for: • Strongyloides • Trypanosoma cruzi • West Nile
Cancer screening	Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) to screen for: • Cervical cancer • Breast cancer • Prostate cancer • Colon cancer • Skin cancer • Lung cancer

This evaluation must be completed:	Including evaluation for and assessment of this information:
Exclusion criteria	Kidney recovery hospitals may exclude a donor with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation. Kidney recovery hospitals must exclude all donors who meet *any* of the following exclusion criteria: • Is both less than 18 years old and mentally incapable of making an informed decision • Uncontrollable hypertension or history of hypertension with evidence of end stage organ damage • HIV • Diabetes • Active malignancy, or incompletely treated malignancy • High suspicion of donor coercion • High suspicion of illegal financial exchange between donor and recipient • Evidence of acute symptomatic infection (until resolved) • Diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality

14.5.A Living Kidney Donor Psychosocial Evaluation Requirements

This living kidney donor psychosocial evaluation must be performed by a psychiatrist, psychologist, or clinical social worker. Documentation of the psychosocial evaluation must be maintained in the living donor record and include *all* of the following components:

1. An evaluation for any psychosocial issues, including mental health issues, that might complicate the living donor's recovery and could be identified as potential risks for poor psychosocial outcome
2. An evaluation for the presence of behaviors that may increase risk for disease transmission as defined by the ~~U.S. PHS Guideline~~ *U.S. Public Health Services (PHS) Guideline*
3. A review of the living donor's history of smoking, alcohol, and drug use, abuse, and dependency
4. The identification of factors that warrant educational or therapeutic intervention prior to the final donation decision
5. The determination that the potential living donor understands the short and long-term medical and psychosocial risks for both the living donor and recipient associated with living donation
6. An assessment of whether the decision to donate is free of inducement, coercion, and other undue pressure by exploring the reasons for donating and the nature of the relationship, if any, to the transplant candidate
7. An assessment of the potential living donor's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes evaluating whether the potential donor has a realistic plan for donation and recovery, with social, emotional and financial support available as recommended
8. A review of the potential living donor's occupation, employment status, health insurance status, living arrangements, and social support
9. The determination that the potential living donor understands the potential financial implications of living

16.4.D Internal Labeling of Vessels

The rigid container holding the vessels and the outermost layer of the triple sterile barrier must have a completed OPTN vessel label. The OPTN Contractor distributes a standardized label that must be used for this purpose. The label must contain *all* of the following information:

1. Donor ID
2. Donor blood type
3. Donor blood subtype, if used for allocation
4. Recovery date
5. All infectious disease testing results
6. Description of the container contents
7. Whether the vessels are from a donor that meets the increased risk for disease transmission criteria in the ~~U.S. PHS Guideline~~*U.S. Public Health Services (PHS) Guideline*.
8. That the vessel is for use in organ transplantation only

To read the complete policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the "Policy Management" tab, then select "Policies." From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner.

To read the complete OPTN Bylaws language visit optn.transplant.hrsa.gov, select the "Policy Management" tab, then select "OPTN Bylaws." To read the complete UNOS Bylaws language visit www.unos.org, click on the "ABOUT US" box at the top of the screen, and then, in the left margin under "Governance," select "Bylaws."

Changes to Registration Fee

Sponsoring Committee: Finance

Policy/Bylaws Affected: Policy 3.4.A (Registration Fee)

Distributed for Public Comment: No

Effective Date: October 1, 2014

Problem Statement
On Oct. 1, 2014, the OPTN registration fee will decrease from $810 to $793.

Changes
UNOS will change Policy 3.4.A (Registration Fee) to reflect the registration fee decrease.

Member Actions
This change does not require any action on the part of OPTN members; the registration fee will automatically be decreased on the effective date.

Affected Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through.~~

3.4.A Registration Fee
The registration fee of $~~810~~793 for the registration of a transplant candidate is authorized by *42 C.F.R. § 121.5(c*) and *OPTN Bylaws Section 1.2(D): Registration Fees*.

To read the complete policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the "Policy Management" tab, then select "Policies." From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner.

To read the complete OPTN Bylaws language visit optn.transplant.hrsa.gov, select the "Policy Management" tab, then select "OPTN Bylaws." To read the complete UNOS Bylaws language visit www.unos.org, click on the "ABOUT US" box at the top of the screen, and then, in the left margin under "Governance," select "Bylaws."

Changes to Bylaws, Article VIII to Establish a Reserve Fund

Sponsoring Committee: Finance

Policy/Bylaws Affected: Article VIII (Fiscal Year)

Distributed for Public Comment: No

Effective Date: September 1, 2014

Problem Statement
The OPTN currently has no Bylaws requiring that a reserve fund be established and funded.

Changes
To mandate the establishment of a reserve fund, UNOS will change the current OPTN Bylaws Article VIII (Fiscal Year) to Article VIII (Financial Considerations) and add a new section (8.2 Reserve Fund) that explains why the fund is being created, how it will be funded, and how funds may be used.

Member Actions
This change does not require any action on the part of OPTN members.

Affected Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through.~~

Article VIII: ~~Fiscal Year~~ Financial Considerations

8.1 Fiscal Year

The fiscal year of the OPTN will begin on October 1 and end on the following September 30.

8.2 Reserve Fund

The OPTN Board of Directors will establish and maintain a reserve account to build cash reserves for unexpected revenue shortfalls, subject to OPTN contract requirements.

A. Reserve Fund Creation and Purpose

The reserve account is funded by a designated amount from OPTN registration fees. The Finance Committee will regularly assess the reserve account, and make recommendations to the Board of Directors on the amount of the reserve account and the designation of OPTN registration fees to be directed toward reserve funding. The Board of Directors may authorize additional transfers from the operating account to the reserve account at any time.

B. Reserve Fund Amount

The reserve account will be fully funded when it contains funds equal to three months of average budget operating expenses based on the then-current fiscal year. The reserve account may be held in several accounts with multiple financial institutions, and may contain cash or other short term investments.

C. Use of Reserve Funds and Notification

1. The Board will approve a revenue estimate for each fiscal year based on the projected number of registrations, the amount of the registration fee, and the amount of any federal appropriated funds.
2. Funds may be withdrawn from the reserve account if two conditions are met:
   a. A revenue shortfall equal to at least 3 percent of OPTN revenue for a fiscal year is projected to occur. The Executive Director will report to the Board the reason for the projected shortfall and the new revenue estimate for the fiscal year
   b. The amount of funds in the operating account is less than or equal to one month of average operating expenditures

If both conditions are met, the Executive Director may transfer the lesser of one-half of the amount of the projected shortfall or one-half of the amount of the balance of the reserve to the operating account.

At least 72 hours prior to any transfer from the reserve account, the Executive Director will provide written notification to the Board of Directors of the planned transfer.

To read the complete policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the “Policy Management” tab, then select “Policies.” From the UNOS website, select “Policies” from the “I am looking for:” box in the upper left hand corner.

To read the complete OPTN Bylaws language visit optn.transplant.hrsa.gov, select the “Policy Management” tab, then select “OPTN Bylaws.” To read the complete UNOS Bylaws language visit www.unos.org, click on the “ABOUT US” box at the top of the screen, and then, in the left margin under “Governance,” select “Bylaws.”

Histocompatibility Policy Rewrite

Sponsoring Committee: Histocompatibility Committee

Policy Affected: 4.0 (Histocompatibility), 2.8.C (Required Information for Deceased Heart Donors), and 2.8.D (Required Information for Deceased Lung Donors)

Distributed for Public Comment: September 2013

Amended After Public Comment: Yes

Effective Date: September 1, 2014, except for Policy 4.2 which will be effective pending programing and notice to the OPTN membership.

Problem Statement
Current OPTN policies governing histocompatibility testing are outdated, difficult to monitor due to ambiguous terms, and some are more appropriately monitored by American Society for Histocompatibility and Immunogenetics (ASHI) or College of American Pathologists (CAP). In addition, the policies are missing important requirements tied to quality testing and patient safety. Furthermore, OPTN policies are silent on crossmatching requirements for kidney transplantation.

Changes
• Twenty-eight sections moved out of policy and into a guidance document. • Reorganized the policy into seven sections that focus on the core of histocompatibility testing for solid organ transplantation. • Laboratories must ensure that HLA typing is accurately determined and reported according to the turnaround time specified in the written agreement between the laboratory and transplant program or OPO. • Laboratories must resolve HLA typing discrepancies within 30 days of notification of discrepant HLA typing results. • When performing an antibody screening, laboratories must use at least one solid phase immunoassay using purified HLA molecules. • When performing histocompatibility testing for kidney transplantation, laboratories must perform a final physical or virtual crossmatch and report the results to the transplant program prior to transplant. • When performing testing for blood type determination, laboratories must follow manufacturers' directions for materials and equipment used. • If the laboratory performs testing to determine histocompatibility between a donor and recipient, the laboratory must preserve enough specimen from the deceased donor to perform subsequent testing for at least five years after the transplant.

Member Actions
• Members must familiarize themselves with these updated policies and ensure that their laboratories are in compliance. • Upon programming and implementation, each histocompatibility laboratory involved in an HLA typing discrepancy must resolve the discrepancy by reporting a reason for the

discrepancy within 30 days of receiving notification in TIEDI® that a discrepancy has occurred.

Affected Policy Language:
New language is underlined and language that will be deleted is ~~struck through.~~

2.8.C Required Information for Deceased Heart Donors

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

1. Height
2. Weight
3. Vital signs, including blood pressure, heart rate, and temperature
4. History of treatment in hospital including vasopressors and hydration
5. Cardiopulmonary, social, and drug activity histories
6. Details of any documented cardiac arrest or hypotensive episodes
7. 12-lead interpreted electrocardiogram
8. Arterial blood gas results and ventilator settings
9. Cardiology consult or echocardiogram, if the hospital has the facilities
10. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, and DQB antigens

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

2.8.D Required Information for Deceased Lung Donors
The host OPO must provide all the following additional information for all deceased lung donor offers:

1. Height
2. Weight
3. Vital signs, including blood pressure, heart rate, and temperature
4. History of medical treatment in hospital including vasopressors and hydration
5. Smoking history
6. Cardiopulmonary, social, and drug activity histories
7. Arterial blood gases and ventilator settings on 5 cm/H20/PEEP including PO2/FiO2 ratio and preferably 100% FiO2, within 2 hours prior to the offer
8. Bronchoscopy results
9. Chest x-ray interpreted by a radiologist or qualified physician within 3 hours prior to the offer
10. Details of any documented cardiac arrest or hypotensive episodes
11. Sputum gram stain, with description of sputum
12. Electrocardiogram
13. Echocardiogram, if the OPO has the facilities
14. HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, and DQB antigens

If the host OPO cannot perform a bronchoscopy, it must document that it is unable to provide bronchoscopy results and the receiving transplant hospital may perform it. The lung recovery team may perform a confirmatory bronchoscopy provided unreasonable delays are avoided and deceased donor stability and the time limitations in Policy 5.5.B: Time Limit for Acceptance are maintained.

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

Policy 4: Histocompatibility

4.1 HLA Typing

4.1.A Requirements for Performing and Reporting HLA Typing

Laboratories must do *all* of the following:

1. Perform HLA typing on all potential transplant recipients and donors when requested by a physician or other authorized individuals.
2. Ensure that all HLA typing is accurately determined and report HLA typing results to the OPO or Transplant Program according to the turnaround time specified in the written agreement between the laboratory and any affiliated OPO or transplant program.
3. Report serological split level and molecular typing results to the OPO for all required HLA types according to Table 4.1 *HLA Typing Requirements for Deceased Donors*, whenever the lab performs HLA typing on deceased kidney, kidney-pancreas, and pancreas donors.
4. Report HLA typing results to the Transplant Program for all required HLA types, according to Table 4.2 *HLA Typing Requirements for Candidates,* whenever the laboratory performs HLA typing on candidates.

Table 4.1 shows HLA types required to be reported for deceased donors.

Table 4.1 HLA Typing Requirements for Deceased Donors

Organ	A	B	Bw4	Bw6	C	DR	DR51	DR52	DR53	DPB	DQB
Kidney	●	●	●	●	●	●	●	●	●		●
Pancreas	●	●	●	●	●	●	●	●	●		●
Kidney-Pancreas	●	●	●	●	●	●	●	●	●		●
Heart*	●	●	●	●	●	●	●	●	●	●	●
Lung*	●	●	●	●	●	●	●	●	●	●	●

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

Table 4.2 shows HLA types required to be reported for candidates.

Table 4.2: HLA Typing Requirements for Candidates

Organ	A	B	Bw4	Bw6	DR
Kidney alone	●	●	●	●	●
Pancreas alone	●	●	●	●	●
Kidney-Pancreas	●	●	●	●	●

4.2 Resolving Discrepant Donor and Recipient HLA Typing Results

Laboratories must submit donor and recipient histocompatibility forms to the OPTN Contractor after transplant according to Policy 18.0 *Data Submission Requirements*. After laboratories submit donor and recipient HLA typing results to the OPTN Contractor, the OPTN Contractor will provide a report to the laboratories including any discrepant HLA typing results.

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

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

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

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

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

The OPTN Contractor will remove all discrepant flags from HLA typing results that have been resolved. Discrepancies that have not been resolved will remain flagged. The Histocompatibility Committee will review, at least every three months, any outstanding discrepant typing recorded since the last review. The committee will use the results of these reviews to determine whether policy modifications are required.

4.3 Antibody Screening and Reporting

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

Whenever a laboratory is performing an antibody screening, the laboratory must do *all* of the following:

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

4.4 Crossmatching

D.4 (A) Crossmatching for Kidney Transplants

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

D.4 (B) General Crossmatching Requirements

Whenever a laboratory is performing a crossmatch, the laboratory must do *all* of the following:

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

4.5 Blood Type Determination

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

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

4.6 Preservation of Excess Specimens

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

4.7 HLA Antigen Values and Split Equivalences

HLA matching of A, B, and DR locus antigens is based on the antigens which are listed in Policy 4.8 *Reference Tables of HLA Antigen Values and Split Equivalences*. The Histocompatibility Committee must review and recommend any changes needed to the tables on or before June 1 of each year. For matching purposes, split antigens not on this list will be indicated on the waiting list as the parent antigens and will match only with the corresponding parent antigens.

4.8 Reference Tables of HLA Antigen Values and Split Equivalences

Tables 4-~~6~~3, 4-~~7~~4, and *4-~~8~~5* show patient-donor antigen combination and whether they are mismatches. For each candidate antigen, the donor antigens that are not mismatched are listed below. All other combinations

are considered mismatches. Antigens with an * indicate an allele that may not have a World Health Organization (WHO)-approved serologic specificity. Antigens given **99 means the patient locus was not tested.

Table 4-~~6~~3: HLA A Matching Antigen Equivalences

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

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

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

Table 4-~~7~~4: HLA B Matching Antigen Equivalences

Patient B Locus Antigen	Equivalent Donor Antigens
5	5
7	7, 703
8	8
12	12
13	13
14	14, 64, 65
15	15
16	16
17	17
18	18
21	21
22	22

Patient B Locus Antigen	Equivalent Donor Antigens
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

Patient B Locus Antigen	Equivalent Donor Antigens
58	58
59	59
60	60
61	61
62	62
63	63
64	64
65	65
67	67
70	70, 71, 72
71	71, 70

Patient B Locus Antigen	Equivalent Donor Antigens
72	72, 70
73	73
75	75, 15
76	76, 15
77	77, 15
78	78
81	81
82	82, *8201
703	703, 7
*0804	*0804, 8
*1304	*1304, 15, 21, 49, 50

Patient B Locus Antigen	Equivalent Donor Antigens
2708	2708, 27
3901	3901, 39
3902	3902, 39
*3905	*3905, 39
4005	4005, 50
5102	5102, 51, 53
5103	5103, 51
7801	7801
*8201	*8201, 82
** 99	(No equivalent)

Table 4-8: HLA DR Matching Antigen Equivalences

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

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

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

*** Indicates an allele; may not have a WHO-approved serologic specificity**
**** Code 99 means not tested**

Examples of how "Matching Antigen Equivalences" works:
If patient has B70: Donors with B70, B71, and B72 are considered not mismatched.
If patient has B71: Donors with B71 and B70 are considered not mismatched. Donors with B72 are considered mismatched.

Table 4-~~9~~5: HLA A Unacceptable Antigen Equivalences

Patient's Unacceptable A Locus Antigen	*Donor Equivalent Antigens*
1	1
2	2, 203, 210
3	3
9	9, 23, 24, 2403
10	10, 25, 26, 34, 66, *6601, *6602, 43
11	11
19	19, 29, 30, 31, 32, 33, 74
23	23

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

Patient's Unacceptable A Locus Antigen	*Donor Equivalent Antigens*
43	43
66	66, *6601, *6602
68	68
69	69
74	74
80	80
203	203
210	210
2403	2403
*6601	*6601
*6602	*6602

Table 4-~~10~~6: HLA B Unacceptable Antigen Equivalences

Patient's Unacceptable B Locus Antigen	*Donor Equivalent Antigens*
5	5, 51, 5103, 52,78
7	7, 703
8	8
12	12, 44, 45
13	13
14	14, 64, 65
15	15, 62, 63, 75, 76, 77
16	16, 38, 39
17	17, 57, 58
18	18
21	21, 49, 50, 4005
22	22, 54, 55, 56
27	27
35	35
37	37
38	38
39	39, 3901, 3902, *3905
40	40, 60, 61
41	41
42	42
44	44
45	45
46	46
47	47
48	48
49	49
50	50, 4005
51	51, 5103
52	52
53	53
54	54
55	55
56	56
57	57
58	58
59	59
60	60
61	61
62	62
63	63
64	64
65	65
67	67
70	70, 71, 72
71	71
72	72
73	73
75	75
76	76
77	77
78	78
81	81
82	82, *8201
703	703
*0804	*0804
*1304	*1304
2708	2708
3901	3901
3902	3902
*3905	*3905
4005	4005, 50
5102	5102
5103	5103
7801	7801, 78
*8201	*8201, 82

Patient's Unacceptable B Locus Antigen	*Donor Equivalent Antigens*
Bw4	Bw4, 5, 13, 17, 27, 37, 38, 44, 47, 49, 51, 52, 53, 57, 58, 59, 63, 77

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

Table 4-~~11~~7: HLA C Unacceptable Antigen Equivalences

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

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

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

Table 4-~~12~~8: HLA DR Unacceptable Antigen Equivalences

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

Patient's Unacceptable DR Locus Antigen	*Donor Equivalent Antigens*
9	9
10	10
11	11
12	12
13	13
14	14, 1403, 1404, 6
15	15
16	16

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

Table 4-~~13~~9: HLA DQ Unacceptable Antigen Equivalences

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

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

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

Examples of how "Unacceptable Antigen Equivalences" works:
If a patient has B70 listed as an "unacceptable antigen": Donors typed as B70, B71, and B72 are considered unacceptable. Donors typed as B73 and B75 are considered acceptable.

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

~~4.1 Guidelines for Written Contracts between Histocompatibility Laboratories and Transplant Programs~~

~~Histocompatibility laboratories must have written contracts with each transplant program they serve. These guidelines summarize the recommended elements to be included in these agreements.~~

~~4.1.A Recommended Elements for Histocompatibility Contracts~~

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

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

~~4.1.B Sensitization History~~

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

~~Table 4-1: Determining Sensitization~~

~~If this event occurred:~~	~~Then the laboratory should evaluate:~~	~~And note:~~
~~Any transplant~~	~~Date of transplant and organs transplanted~~	

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

4.1.C Detection of Antibodies

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

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

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

Assays should be used to:

1. Identify whether a patient has circulating antibodies to HLA class I and class II antigens:
   - Initial serial screening should include cytotoxicity and more sensitive tests to identify patients with antibodies.
   - Several sera should be evaluated to establish a baseline.

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

3. Monitor patients who do not currently have antibodies for the development of antibodies

using:

- Periodic screening of unsensitized patients to detect appearance of anti-HLA antibodies.
- Characterization of antibody specificity.

4.1.D Periodic Sample Collection

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

4.1.E Crossmatching Strategies

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

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

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

Table 4-3: Recommended Elements for Crossmatching Strategies

Element:	Options:
Selection of technique(s)	Refer to *Table 4-2: Assays to Identify Antibody to HLA*: Screening, Specificity, or Crossmatching.
Selection of serum	5. Stability of a candidate's antibody response incorporated into choice of time between serum collection and transplant. 1. Use of historic serum.
Timing	6. 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 below provides the requirements of HLA typing of HLA A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, and DQB Antigens. Laboratories should report splits for all loci shown in *Policy 4.16: Reference Tables of HLA Antigen Values and Split Equivalences*.

Table 4-4: Requirements for HLA Typing

If a Laboratory:	Then the Laboratory Must:
Performs deceased donor typing for kidney, kidney-pancreas, pancreas, or pancreas islet allocation	Report serological split level and molecular typing results for all required antigens prior to organ offers.
Uses cytotoxicity techniques to perform HLA typing	Conform to all relevant standards in *Policy 4.8: Cytotoxicity Methods*.

Uses nucleic acid analysis, to perform HLA typing	Conform to all relevant standards in *Policy 4.10: Nucleic Acid Analysis*.
Uses alternative methods for HLA typing	Define the procedures, validate the procedures, and include sufficient controls to ensure accurate assignment of HLA types. The laboratory must conform to all relevant standards from the above sections.

4.2.A Typing Assignment

Laboratories must do *all* of the following:

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

4.2.B Reagent Validation

Laboratories must do *all* of the following:

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

4.2.C HLA Typing by Nucleic Acid Analysis

Laboratories must do *all* of the following:

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

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

HLA matching of A, B, and DR locus antigens is based on the antigens which are listed in *Policy 4.16: Reference Tables of HLA Antigen Values and Split Equivalences*. These tables will be updated annually by the Histocompatibility Committee. For matching purposes, split antigens not on this list will be indicated on the waiting list as the parent antigens and will match only with the corresponding parent antigens. Laboratories are encouraged to assign all splits.

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

4.4 Resolving Discrepant Donor and Recipient HLA Typing Results

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

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

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

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

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

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 corrected typing results should report the corrected HLA typing to the OPTN Contractor as resolved. The laboratory must also identify the specific reason for the discrepant typing.

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

4.5 Antibody Screening

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

Table 4-5: Requirements for Antibody Screening

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

4.5.A Techniques

Laboratories must do *all* of the following:

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

4.5.B Sera Testing

Laboratories must do *all* of the following:

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

4.5.C Panel and Target Selection

Laboratories must do *all* of the following:

1. Use a sufficient number of antigen panels that are in phenotypic distribution with respect to individual antigens or cross-reactive groups (CREGs) for the population served and for the intended use of the test results.
2. Maintain documentation of the HLA class I or class II phenotypes of the panel.
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 protocol in place to evaluate the extent of sensitization of each candidate at the time of initial evaluation and following potentially sensitizing events, based on the antibody characteristics that are clinically relevant to each Transplant Hospital's protocols.
2. A program to periodically screen serum samples from each candidate for antibody to HLA antigens.
3. A written protocol establishing the frequency of screening serum samples and data to support this policy.

Laboratories should do *all* of the following:

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

4.6.D Crossmatching

Laboratories must do *both:*

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

4.6.E Techniques

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

Laboratories must also:

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

4.6.F Samples

Laboratories must do *both*:

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

4.7 Other Organ and Islet Cell Transplantation

Laboratories must do *all* of the following:

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

4.8 Cytotoxicity Methods

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

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

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

4.10 Nucleic Acid Analysis

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. Store samples under conditions that preserve their integrity if a laboratory does not use nucleic acids immediately after purification.
5. Use nucleic acids of sufficient quality to ensure reliable test results.

4.10.B Electrophoresis

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

The laboratory must establish criteria for accepting validity of each gel and of each lane of the gel and determine and validate acceptable electrophoretic conditions for each assay.

4.10.C Analysis

Laboratories must do *all* of the following:

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

4.10.D Template Amplification

4.10.D.i Facilities and Equipment

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

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

4.10.D.ii Reagents

All reagents used in the amplification assay must:

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

4.10.E Primers

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

Laboratories must also do *all* of the following:

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

4.10.F Amplification Templates

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

4.10.G Contamination

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

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

4.10.H Controls and Quality Assurance

Laboratories must also do *all* of the following:

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

4.10.I Technique-Specific Standards

4.10.I.i Oligonucleotide Probe Assays

Laboratories must also do *all* of the following:

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 on the use of a monoclonal antibody that detects an appropriate cluster designated antigen.
4. Establish and document the optimum serum-to-cell ratio.

4.11.C Controls

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

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

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

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

4.11.D Interpretation

Laboratories must also do *both*:

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

4.11.E Immunophenotyping By Flow Cytometry

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

4.11.F Cell Preparation

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

4.11.G Quality Control

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

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

Laboratories must also do *all* of the following:

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

4.11.H Reagents

Laboratories must also do *all* of the following:

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

4.12 ELISA

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 CPRA Determination

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

4.13.E Histocompatibility Typing

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

4.14 Chimerism Analysis

Laboratories performing engraftment and chimerism testing using nucleic acid analysis must conform to all pertinent standards in *Policy 4.10: Nucleic Acid Analysis*.

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

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

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

4.14.A Analysis and Reports

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

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

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

~~If results are reported in a quantitative or semi-quantitative manner, criteria for evaluating the relative amounts of recipient and donor in a mixed chimeric sample must be established.~~

~~When mixed chimerism is not detected, reports must state the sensitivity level of the assay.~~

~~4.15 Preservation of Zero Mismatch Tissue Typing Materials~~

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

To read the complete policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the "Policy Management" tab, then select "Policies." From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner.

Proposal To Establish Minimum Requirements for

Living Liver Donor Follow-up

Sponsoring Committee: Living Donor

Policies Affected: 14.1.B (Required Protocols for Liver Recovery Hospitals), 18.1 (Data Submission Requirements), 18.2 (Timely Collection of Data), 18.5 (Living Donor), 18.5.A (Reporting Requirements after Donation), 18.5.B (Reporting Requirements after Living Liver Donation), 18.5.B (Submission of Living Donor Death and Organ Failure), 18.5.C (Reporting of Non-transplanted Living Donor Organs), and 18.5.D (Reporting of Living Donor Organs Not Transplanted in the Intended Recipient)

Distributed for Public Comment: September 2013

Amended After Public Comment : Yes

Effective Date: September 1, 2014 and pending programming and notice to OPTN membership.

Problem Statement

The OPTN relies on living donor follow-up (LDF) forms to collect data on the short-term health status of living donors. Data on living donors since 2006 show that many hospitals do not report meaningful living donor follow-up information at the the required reporting intervals. To enable the OPTN to better analyze the short-term effects of living donation, the transplant community must improve how they report patient information on the LDF form.

Changes

Living liver donor recovery hospitials will be required to report specific fields for donor status and clinical information for at least 80% of their living liver donors, and report laboratory data for at least:

- 75% of living liver donors on the 6-month follow form
- 70% of living liver donors on the one-year follow-up form

We will not require the following three fields for donor status or clinical information until we have updated the LDF form and have completed the related programming:

- Loss of medical (health, life) insurance due to donation
- Incisional hernia due to donation
- Platelet count

You will be notified before you are required to report these additional fields.

Member Actions

Living liver donor recovery hospitals will continue to report living donor follow-up at 6 months, 1 year, and 2 years from the date of donation. Once the programming is implemented, you will need to complete the required fields for donor status, clinical information and laboratory

data for the form to be considered complete. Completing the additional fields will help contribute to the new minimum required thresholds for follow-up.

Affected Policy Language:
New language is underlined and language that will be deleted is ~~struck through.~~

14.1.B Required Protocols for Liver Recovery Hospitals

Liver recovery hospitals must develop and comply with written protocols to address all phases of the living donation process. Specific protocols must include the evaluation, pre-operative, operative, and post-operative care of the living liver donor~~, and submission of required follow up forms at 6 months, one-year, and two-years post-donation~~.

Liver recovery hospitals must document that all phases of the living donation process were performed in adherence to the hospital's protocols.

18.1 Data Submission Requirements

OPOs must provide donor information required for organ placement to the OPTN Contractor in an electronic data format as defined and required by the computer system. Deceased donor information required for organ placement must be submitted prior to organ allocation.

Members must report data to the OPTN using standardized forms. *Table 18-1* shows the member responsible for submitting each data form and when the Member must submit the following materials to the OPTN Contractor.

Table 18-1: Data Submission Requirements

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For the following groups:
Histocompatibility Laboratory	*Donor histocompatibility* (DHS)	30-days after the OPO submits the deceased donor registration	For each donor typed by the laboratory

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For the following groups:
Histocompatibility Laboratory	*Recipient histocompatibility* (RHS)	*Either* of the following: • 30-days after the transplant hospital removes the candidate from the waiting list because of transplant • 30-days after the transplant hospital submits the *recipient feedback*	For each transplant recipient typed by the laboratory
OPOs, all	*Death notification records* (DNR)	30-days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	For all imminent neurological deaths and eligible deaths in its DSA
OPOs, all	*Monthly Donation Data Report: Reported Deaths*	30-days after the end of the month in which a donor hospital reports a death to the OPO	For all deaths reported by a hospital to the OPO
Allocating OPO	*Potential transplant recipient* (PTR)	30-days after the match run date by the OPO or the OPTN Contractor	For each deceased donor organ that is offered to a potential recipient
Host OPO	*Deceased donor feedback*	5 business days after the procurement date	

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For the following groups:
Host OPO	*Deceased donor registration* (DDR)	30 days after the *deceased donor feedback* form is submitted and disposition is reported for all organs	For all deceased donors and authorized but not recovered potential deceased donors
Recovery Hospitals	*Living donor feedback*	The time prior to donation surgery	For each potential living donor organ recovered at the hospital
Recovery Hospitals	*Living donor registration* (LDR)	60 days after the Recovery Hospital submits the *living donor feedback* form	For each living donor organ recovered at the hospital
Recovery Hospitals	*Living donor follow-up* (LDF)	~~*See Policy 18.5.A: Reporting Requirements after Donation*~~ 60 days after the six-month, 1-year, and 2-year anniversary of the donation date	For each living donor organ recovered at the hospital
Transplant hospitals	*Organ specific transplant recipient follow-up* (TRF)	1. 30-days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure 2. 14-days from notification of the recipient's death or graft failure	For each recipient followed by the hospital
Transplant hospitals	*Organ specific transplant recipient registration* (TRR)	60-days after transplant hospital submits the *recipient feedback* form	For each recipient transplanted by the hospital

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For the following groups:
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60-days after transplant hospital submits the *recipient feedback* form	For each liver recipient transplanted by the hospital
Transplant hospitals	*Recipient feedback*	24-hours after the transplant	For each recipient transplanted by the hospital
Transplant hospitals	*Recipient malignancy* (PTM)	30-days after the transplant hospital reports the malignancy on the *transplant recipient follow- up* form	For each recipient, with a reported malignancy, that is followed by the hospital
Transplant hospitals	*Transplant candidate registration* (TCR)	30-days after the transplant hospital registers the candidate on the waiting list	For each candidate on the waiting list or recipient transplanted by the hospital

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients and living donors is based on recipient or living donor status at a time as close as possible to the specified transplant event anniversary. *Table 18-2: Timely Data Collection* sets standards for when the member must collect the data from the patient.

Table 18-2: Timely Data Collection

Information is timely if	Collects this information	Within this time period:
Transplant hospital	*Organ specific transplant recipient registration* (TRR)	When the transplant recipient is discharged from the hospital or six-weeks following the transplant date, whichever is first

Recovery hospital	*Living donor registration* (LDR)	When the living donor is discharged from the hospital or six-weeks following the transplant date, whichever is first
Recovery hospital	*Living donor follow-up* (LDF)	~~within the 60-days prior to or after the form due date~~ 60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date

18.5 Living Donor Data Submission Requirements

The follow up period for living donors will be a minimum of two years.

The OPTN Contractor will calculate follow-up rates separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.

Living donor follow-up reporting requirements do not apply to any transplant recipient whose replaced or explanted organ is donated to another candidate.

18.5.A Reporting Requirements after Living Kidney Donation

~~The follow up period for living donors will be a minimum of two years.~~

The recovery hospital must report accurate, complete, and timely follow up data for donor status and clinical information using the LDF form for at least:

- 60% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 70% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 80% of their living kidney donors who donate after December 31, 2014

The recovery hospital must report accurate, complete, and timely follow up kidney laboratory data using the LDF form for at least:

- 50% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 60% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 70% of their living kidney donors who donate after December 31, 2014

Required kidney ~~D~~donor ~~S~~status and ~~C~~linical ~~I~~information includes *all* of the following**:**

1. Patient status
2. Working for income, and if not working, reason for not working
3. Has the donor been readmitted since last LDR or LDF form was submitted?
4. Kidney complications
5. Maintenance dialysis

6. Donor developed hypertension requiring medication
7. Diabetes
8. Cause of death, if applicable and known

Required ~~K~~kidney ~~L~~laboratory ~~D~~data includes *all* of the following:

1. Serum creatinine
2. Urine protein

~~The OPTN Contractor will calculate follow up rates separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.~~

18.5.B Reporting Requirements after Living Liver Donation

The recovery hospital must report accurate, complete, and timely follow-up data using the LDF form for living liver donors who donate after September 1, 2014, as follows:

1. Donor status and clinical information for 80% of their living liver donors.
2. Liver laboratory data for at least:
    - 75% of their living liver donors on the 6 month LDF
    - 70% of their living liver donors on the one year LDF

Required liver donor status and clinical information includes all of the following:

- Patient status
- Cause of death, if applicable and known
- Working for income, and if not working, reason for not working
- Hospital readmission since last LDR or LDF was submitted
- Liver complications, including the specific complications
    - Abscess
    - Bile leak
    - Hepatic resection
    - Liver Failure
    - Registered on the liver candidate waiting list

Required liver laboratory data includes *all* of the following:

- Alanine aminotransferase
- Alkaline phosphatase
- Total bilirubin

18.5.~~B~~C Submission of Living Donor Death and Organ Failure

Recovery hospitals must report all instances of a living donor's death or failure of the living donor's remaining organ function within 72 hours after the hospital becomes aware of the living donor death or failure of the living donor's remaining organ function. Living donors' remaining organ failure is defined as registering for liver transplant for liver donors, and as transplant, listing for transplant, or the need for dialysis for kidney

donors. Recovery hospitals must report these incidents through the OPTN Contractor's Improving Patient Safety System for a period of two years from the date of the donation. The MPSC will review and report all adverse events to the OPTN Board of Directors.

18.5.~~C~~D Reporting of Non-transplanted Living Donor Organs

The recovery hospital must report any time a living donor organ is recovered but not transplanted into any recipients. Recovery hospitals must report these incidents through the OPTN Patient Safety System within 72 hours of organ recovery. The MPSC will review and report all cases of non-transplanted living donor organs to the OPTN Board of Directors.

18.5.~~D~~E Reporting of Living Donor Organs Not Transplanted in the Intended Recipient

If a living donor organ is recovered for an intended recipient but ultimately redirected and transplanted to a different recipient, then all required donor and recipient information must still be reported to the OPTN Contractor.

Transplant hospitals must report these incidents through the OPTN Improving Patient Safety System within 72 hours of organ recovery. The Membership and Professional Standards Committee will review and report all cases of redirected living donor organs to the OPTN Board of Directors.

To read the complete policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the "Policy Management" tab, then select "Policies." From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner.

Add Deadlines to Kidney Paired Donation Pilot Program Operational Guidelines for Preliminary Response, Performing Crossmatch, and Reporting Final Acceptance

Sponsoring Committee: Kidney Transplantation Committee

Operational Guideline Affected: KPD Contact Responsibilities

Distributed for Public Comment: No

Effective Date: September 1, 2014

Problem Statement
The OPTN/UNOS Kidney Paired Donation Pilot Program (KPDPP) is currently governed by the KPDPP Operational Guidelines, as well as OPTN/UNOS Policies and Bylaws. The guidelines and policies do not specify a timeframe for transplant programs involved in a potential KPDPP exchange to respond to offers and report crossmatch results. Candidates and donors in a pending exchange are not eligible to appear on subsequent match runs, and may miss other potential KPDPP matching opportunities if the transplant programs involved in the exchange do not respond in a timely manner.

Changes
The Operational Guidelines will be modified to incorporate deadlines for transplant programs involved in an OPTN/UNOS KPDPP exchange for: 1. Preliminary responses to exchange offers 2. Performing a crossmatch and reporting the results in the KPD system 3. Making the matched donor's required medical records available to the matched recipient's transplant hospital 4. Reviewing the matched donor's medical records 5. Indicating final acceptances or refusals The Operational Guidelines will also include a mechanism for requesting an extension to these deadlines. Failure to adhere to the deadlines, absent an approved extension, will result in termination of the exchange.

Member Actions
Members participating in the OPTN/UNOS KPDPP must familiarize themselves with the new deadlines. When involved in an exchange, the members must perform all responsibilities within the established deadlines. Members must also learn how to request an extension.

Affected Operational Guidelines Language:
New language is <u>underlined</u> and language that will be deleted is ~~struck through.~~

KPD Contact Responsibilities

1. Purpose: To define the duties of the KPD contact

2. Procedures:

    a. Each transplant center must designate a primary KPD Contact and an alternate to fulfill the duties described below. (Note: For the purposes of the KPD Contact Responsibilities Operational Guideline, KPD Contact refers to both the primary KPD Contact and the alternate.)

    b. The KPD contact's site administrator must make sure that his/her contact information (phone number, e-mail address, and mailing address) are up-to-date in the UNOS membership database. ~~Additionally, the KPD Contact must keep the address for the lab or the transplant center where the potential living donor blood sample should be sent for crossmatch updated in the system.~~

    c. The primary and/or alternate KPD contact or their proxy must participate in regular conference calls to discuss operations of the KPD Pilot Program. ~~(Attendance at every call is not required, but the contact must attend some calls and will be responsible for obtaining any information communicated during a missed meeting.)~~

    d. If the KPD contact is not available for any period of time, the contact may designate a proxy from the same center. The proxy will be responsible for all of the normal duties of the KPD contact during this time frame.

    e. The KPD contact is responsible for making sure all data is entered for candidates and potential living donors. ~~The KPD contact will receive an e-mail before each match run is generated with information on which potential living donors and candidates are not eligible to be entered in the match run because of lack of required data.~~ The KPD contact and the alternate will receive ~~an e-mail~~ notification ~~when each match run results are available~~of match offers via email. The KPD contact is responsible for forwarding this information to anyone else at the transplant center who needs to know this information.

    f. The KPD contact's information (both primary and alternate) will be ~~given~~ provided on the Exchange Report to the KPD contacts (both primary and alternate) ~~for any candidate/donor pair that has matched to a candidate/donor pair at that center~~for all matches in an exchange. The primary KPD contact must make sure that someone at the center is in charge of communicating with the matched candidate's or donor's center for each case.

    g. The KPD contact is responsible for coordinating the crossmatch process by making sure the potential living donor blood sample is sent to the matched candidate's center and by providing an address for where the matched potential living donor's blood sample should be sent.

h. The KPD contact is responsible for making sure acceptances and refusals for matches are entered into the system within the specified time frame listed below: ~~(match run time line will be provided before each match run).~~
    i. For any KPD exchange, each of the transplant hospitals receiving the match offer must report a preliminary response to the OPTN Contractor within 2 business days of receiving the offer or the exchange will be automatically terminated.
    ii. The KPD matched donor transplant hospital must provide the matched candidate's transplant hospital the name and location of where the crossmatch kit is to be sent within 1 business day of receiving the notification of exchange acceptance. If this information is not provided to the matched candidate's transplant hospital within 1 business day of receiving notification of exchange acceptance, the exchange will be terminated.
    iii. The KPD candidate's transplant hospital must perform a crossmatch and report the results of the crossmatch to the OPTN Contractor and the matched donor's transplant hospital within 13 days of receiving notification of the exchange acceptance. If the results of the crossmatch are not reported to the OPTN Contractor within 13 days of notification of exchange acceptance, the exchange will be terminated.
    iv. The transplant hospital registering the potential donor in KPD must make all of the donor records accessible to the matched candidate's transplant hospital within 2 business days of receiving the notification of exchange acceptance. If the donor records are not shipped within 2 business days of receiving the notification of exchange acceptance, the exchange will be terminated. The donor records must include any updated serology and NAT testing results, and must indicate whether the donor is increased risk according to the PHS Guidelines.
    v. The matched candidate's transplant hospital must review the donor records and report a final acceptance or refusal to the OPTN Contractor within 13 days of notification of exchange acceptance. If the matched candidate's transplant hospital does not report an acceptance or refusal to the OPTN contractor within the timeframe, the exchange will be terminated.

The deadlines can be postponed for Guidelines h.iii, h.iv and h.v if all transplant hospitals in the exchange consent. The transplant hospital requesting the extension must submit the request in writing to the OPTN Contractor explaining the reason for the request and providing an updated date by which the transplant hospital will perform. The OPTN Contractor will notify all of the transplant hospitals in the exchange of the request.

Upon receipt of the request for extension, the transplant hospitals in the exchange will have 1 business day to respond to the request for extension. If all other transplant hospitals in the exchange agree to the extension, it will be granted and the exchange will not be terminated. If any of the transplant hospitals in the exchange fail to respond to the request for extension within 1 business day of receiving the request, the request will not be granted. If the extension request is

submitted before the deadline defined by the guidelines, the exchange will not terminate until the resolution of the extension request.

To read the complete Operational Guidelines language visit optn.transplant.hrsa.gov. From the OPTN website, select the “Resources” tab, then select “Kidney Paired Donation Pilot Program.”

Convert Prioritization Points from the OPTN/UNOS Kidney Paired Donation Pilot Program Operational Guidelines into OPTN/UNOS Policy

Sponsoring Committee: Kidney Transplantation Committee

Policy Affected: Policy 13.7.E (Prioritization Points). The Prioritization Points section of the Kidney Paired Donation Pilot Program (KPDPP) Operational Guidelines is also affected.

Distributed for Public Comment: March 2012

Amended After Public Comment: Yes

Effective Date: September 1, 2014

Problem Statement
The OPTN/UNOS KPDPP is transitioning from a pilot program to a permanent function of the OPTN. The transition requires the KPDPP to ultimately be governed by OPTN Policies and Bylaws, rather than the Operational Guidelines which currently apply to certain aspects of the KPDPP, including the prioritization points.

Changes
• Except for some non-substantive language clarifications, the language regarding prioritization points in the Operational Guidelines will not change when it is transitioned to OPTN Policy. • OPTN Policy will include the process for reinstating waiting time for KPDPP candidates that experience immediate and permanent non-function of a transplanted kidney. • The prioritization points section will be removed from the Operational Guidelines.

Member Actions
Transitioning the prioritization points to policy does not impose additional requirements on members. Transplant programs requesting waiting time reinstatement for KPDPP candidates must follow the waiting time reinstatement process for deceased donor kidney transplant recipients.

Affected Policy Language:
New language is underlined and language that will be deleted is ~~struck through.~~

13.7.E OPTN KPD Prioritization Points
~~*Reserved*~~

All OPTN KPD matches receive 100 base points. KPD matches will receive additional points according to *Table 13-2: OPTN KPD Prioritization Points* when the OPTN Contractor identifies all possible matches and exchanges from the list of eligible KPD

donors and candidates. The OPTN Contractor will then prioritize the set of exchanges with the highest total point value.

Table 13-2: OPTN KPD Prioritization Points

If the:	Then the match will receive:
Candidate is a 0-ABDR mismatch with the potential donor	200 points
Candidate has a CPRA greater than or equal to 80%	125 points
Candidate is a prior living organ donor	150 points
Candidate was less than 18 years old at the time the candidate was registered in the OPTN KPD program	100 points
Candidate and potential donor are registered for the OPTN KPD program in the same region	25 points
Candidate and potential donor are registered for the OPTN KPD program in the same DSA	25 points
Transplant hospital that registered both the candidate and potential donor in the OPTN KPD program is the same	25 points
Potential donor has at least one of the other antibody specificities reported for the candidate	- 5 points

13.7.F OPTN KPD Waiting Time Reinstatement

KPD waiting time begins on the day the candidate's transplant hospital registers the candidate in the OPTN KPD program. Candidates accrue 0.07 points per day from the date the candidate is registered ~~on~~ in the OPTN KPD program. A candidate will accrue KPD waiting time at both active and inactive status in the OPTN KPD program.

The OPTN Contractor will reinstate OPTN KPD waiting time to recipients, without interruption, if the OPTN KPD candidate experiences immediate and permanent non-function of any transplanted kidney and the KPD candidate is re-registered in the OPTN KPD program. Immediate and permanent non-function of a transplanted kidney is defined as *either*:

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

KPD waiting time will be reinstated when the OPTN Contractor receives a request for reinstatement of KPD waiting time and the required supporting documentation from the KPD candidate's transplant hospital.

Affected Operational Guidelines Language:

~~Prioritization Points~~

~~1. Purpose: To describe the candidate characteristics and the match characteristics that receive priority or additional points in the Kidney Paired Donation Pilot Program~~

~~2. Procedures:~~

~~a. Each match between a candidate and potential living donor receives a base of 200 points.~~

~~b. Zero antigen mismatches between a potential living donor and a candidate receive an additional 200 points.~~

~~c. Highly sensitized (e.g., probability of positive crossmatch≥ 80%) candidates receive an additional 125 points.~~

~~d. Candidates who are prior living organ donors receive an additional 150 points.~~

~~e. Pediatric (i.e., age < 18 years) candidates receive an additional 100 points.~~

~~f. Candidates entered in the OPTN KPD Pilot Program receive 0.07 points per day beginning on the day the candidate is added to the OPTN KPD Pilot Program.~~

~~g. Matches between candidates and potential living donors who are in the same region receive 25 points in addition to the base number of points.~~

~~h. Matches between candidates and potential living donors who are in the same donation service area (DSA) receive 50 points in addition to the base number of points.~~

~~i. Matches between candidates and potential living donors who are located at the same center receive 75 points in addition to the base number of points.~~

~~j. Matches between candidates and donors who have one or more of the candidate's other antibody specificities receive -5 points.~~

~~k. The waiting list candidate and the non-directed donor in a donor chain will be assigned no points.~~

To read the complete policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the "Policy Management" tab, then select "Policies." From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner.

To read the complete Operational Guidelines language visit optn.transplant.hrsa.gov. From the OPTN website, select the "Resources" tab, then select "Kidney Paired Donation Pilot Program."

Add Serum Sodium to the MELD Score

Sponsoring Committee(s): Liver and Intestinal Organ Transplantation Committee

Policy/Bylaws Affected: Policy 9.1 (MELD Score)

Distributed for Public Comment: March 2013

Amended After Public Comment: Yes

Effective Date: Pending programming and notice to OPTN membership

Problem Statement
The Model for End-stage Liver Disease (MELD) score was implemented in 2002 to reduce death on the liver waiting list and is assigned to candidates age 12 and older. The MELD score does not include serum sodium (Na) concentration which is an important predictor of survival among candidates for liver transplantation.

Changes
Currently, candidates who are at least 12 years old receive an initial $MELD_{(i)}$ score equal to: $0.957 \times Log_e(\text{creatinine mg/dL}) + 0.378 \times Log_e(\text{bilirubin mg/dL}) + 1.120 \times Log_e(\text{INR}) + 0.643$. Upon implementation, the MELD score will be recalculated to incorporate serum sodium for candidates with a MELD score greater than 11. These candidates' MELD scores will be calculated according to the initial MELD formula, and the MELD-Na score will be derived using the initial MELD score and the serum sodium value as follows: $MELD\text{-}Na = MELD_{(i)} + 1.32 \times (137\text{-}Na) - [0.033 \times MELD_{(i)} * (137\text{-}Na)]$ Sodium values less than 125 mmol/L will be set to 125, and values greater than 137 mmol/L will be set to 137. These changes will not apply to candidates with a MELD score less than 12.

Member Actions
The OPTN computer match system currently requires that transplant programs enter the information necessary to calculate the MELD-Na score. Transplant programs are expected to enter and update accurate information as required by Policies.

Affected Policy/Bylaw Language:
New language is underlined and language that will be deleted is ~~struck through.~~

9.1.D MELD Score

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

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

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

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

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

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

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

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

To read the complete policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the "Policy Management" tab, then select "Policies." From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner.

Revised Method for Identifying programs for Transplant Program Post-transplant Performance Reviews

Sponsoring Committee: Membership and Professional Standards (MPSC)

Bylaws Affected: Bylaws Appendix D. Membership Requirements for Transplant Hospitals and Transplant Programs, Section D.10 A., and Appendix M. Definitions

Distributed for Public Comment: September 2013

Amended After Public Comment: No

Effective Date: January 1, 2015

Problem Statement
The MPSC reviews post-transplant outcomes of transplant programs to identify underperforming programs and works with them to implement performance improvement measures. The current method to identify which programs need review works well for high-volume programs, but does not work well for low- and medium-volume programs.

Changes
The Scientific Registry of Transplant Recipients (SRTR) will use a new statistical methodology, the Bayesian methodology, to identify programs for review. Additionally, the MPSC established new thresholds for identifying potential under-performing programs. This revision also adds language clarifying the current MPSC practice of requesting that a member voluntarily inactivate its program or a component of the program, or withdraw a program based on patient safety concerns resulting from a review of the program's graft and patient survival. There is no change in the way the MPSC will inquire about or review a program.

Member Actions
• Members must familiarize themselves with these updated Bylaws. • Members will not report data differently. The SRTR will not use data differently to produce the program specific reports.

Affected Bylaw Language:
New language is underlined and language that will be deleted is ~~struck through.~~

Bylaws Appendix D. Membership Requirements for Transplant Hospitals and Transplant Programs

D.10 Additional Transplant Program Requirements

A. Transplant Program ~~Survival Rates~~Performance
The MPSC will conduct reviews of transplant program performance to identify underperforming transplant programs and require the implementation of quality assessment and performance improvement measures. One measure of transplant

program performance is triggered through a review of the one-year graft and patient survival rates. The MPSC utilizes performance metrics produced by the Scientific Registry of Transplant Recipients (SRTR) as the principal tool to identify transplant programs that have lower than expected outcomes.

For programs performing 10 or more transplants in a 2.5 year period, t~~T~~he MPSC will review a transplant program if it has a higher hazard ratio of mortality or graft failure than would be expected ~~low survival rate compared to the expected survival rate~~ for that transplant program. The criteria used to identify programs with a hazard ratio that is higher than expected will include *either* of the following:

1. The probability is greater than 75% that the hazard ratio is greater than 1.2.
2. The probability is greater than 10% that the hazard ratio is greater than 2.5.

For programs performing 9 or fewer transplants in a 2.5 year period, the MPSC will review a transplant program if the program has one or more events in a 2.5 year cohort.

The MPSC review will be to determine if the higher hazard ratio ~~low survival rate~~ or events can be explained by patient mix or some other unique clinical aspect of the transplant program. If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program ~~in question~~, the ~~member~~program, in cooperation with the MPSC, will adopt and promptly implement a plan for quality improvement. The member's failure to adopt and promptly implement a plan for quality improvement will constitute a violation of OPTN obligations.

~~The MPSC may conduct a peer visit to the program at member expense and may require the member to adopt a plan for quality improvement. The MPSC may also require, at its discretion, that the member participate in an informal discussion.~~

As part of this process, the MPSC may conduct a peer visit to the program at member expense. The MPSC may also require, at its discretion, that the member participate in an informal discussion. The informal discussion may be with the MPSC, a subcommittee, or a work group, as determined by the MPSC. The informal discussion will be conducted according to the principles of confidential medical peer review, as described in *Appendix L* of these Bylaws. The informal discussion is not an adverse action or an element of due process. A member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.

The MPSC may recommend that a member inactivate a program or a component of a program or withdraw its designated transplant program status based on patient safety concerns arising from review of the program's graft and patient survival. If the program fails to inactivate or withdraw its designated transplant program status when the MPSC recommends it do so, the MPSC may recommend that the Board of Directors take appropriate action as defined in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

~~While the precise statistical criteria may be selected by the MPSC, the initial criteria used to identify programs with low patient or graft survival rates will include *all* of the following:~~

~~1. The finding that *observed events* minus *expected events* is greater than 3.~~

2. The finding that the *observed events* divided by *expected events* is greater than 1.5.
3. There exists a one-sided *p value* less than 0.05.

Observed events are deaths or graft losses as reported in UNET℠ database. *Expected events* are deaths or graft losses as calculated using organ-specific transplant models.

Those programs whose actual observed patient or graft survival rates fall below their expected rates by more than a threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC, subject to Board approval.

If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, the member, in cooperation with the MPSC, will adopt and promptly implement a plan for quality improvement. The member's failure to do so will constitute a violation of OPTN obligations.

Appendix M: Definitions

E

Event
Any death or graft loss that occurred within one year of transplant.

To read the complete OPTN Bylaws language visit optn.transplant.hrsa.gov, select the "Policy Management" tab, then select "OPTN Bylaws." To read the complete UNOS Bylaws language visit www.unos.org, click on the "ABOUT US" box at the top of the screen, and then, in the left margin under "Governance," select "Bylaws."

Patient Notification of Functional Inactivity Due to Lack of Transplant Activity

Sponsoring Committee: Membership and Professional Standards Committee

Bylaws Affected: Bylaws, Appendix D Membership Requirements for Transplant Hospitals and Transplant Programs, Sections 9 and 10; Appendix K Transplant Program Inactivity, Withdrawal, and Termination, Sections 1 and 3; and Appendix M Definitions

Distributed for Public Comment: September 2013

Amended After Public Comment: Yes

Effective Date: September 1, 2014

Problem Statement
The Performance Analysis and Improvement Subcommittee (PAIS) of the MPSC conducts reviews of programs that have not performed a transplant during a defined period. Programs that have not performed a transplant during this defined period are considered functionally inactive under the Bylaws. PAIS became concerned that that candidates on the waiting list at functionally inactive programs wait longer for transplant and may not be aware of the lack of transplant activity at the program where they are listed.

Changes
• The revision requires programs to notify candidates and potential candidates of their lack of transplant activity within 30 days of being notified that the MPSC is reviewing the program for functional inactivity. The provision notes specific items to be included in the notification letter. • Revisions were also made to remove confusing language and eliminate duplication in the Bylaws regarding functional inactivity, voluntary inactivation, and waiting list inactivity.

Member Actions
• Members must familiarize themselves with these updated Bylaws. • Programs identified as functionally inactive must send a notification letter to all of its candidates and potential candidates. Programs must send the letters within 30 days after they are notified by the MPSC that their program is being reviewed for functional inactivity. The letter must include the following: 1. The dates identified in the MPSC notification during which no transplants were performed. 2. The reason no transplants were performed. 3. The options available to the candidates, including multiple listing or transfer of accrued waiting time to another transplant hospital 4. A copy of the OPTN Contractor's Patient Information Letter

The program will then be required to provide the MPSC with proof that patients were notified along with its response to the inquiry about the program's functional inactivity.

Affected Bylaw Language:
New language is underlined and language that will be deleted is ~~struck through.~~

Appendix D.9 Review of Transplant Program Functional Activity

A. Functional Inactivity

Each transplant program must remain functionally active by performing a minimum number of transplants. Transplant program functional activity will be reviewed periodically by the MPSC. Any program identified as functionally inactive will have the opportunity to explain its inactivity in a report to the MPSC. For purposes of these Bylaws, functional inactivity is defined as ~~*any* of the following:~~ the failure to perform a transplant during the periods defined in the table below:

~~1. The inability to serve potential candidates, candidates, recipients, potential living donors, or living donors for a period of 15 or more consecutive days.~~
2. ~~The failure to perform a transplant during the periods defined in the table below:~~

Program Type	Inactive Period
Kidney, Liver or Heart	3 consecutive months
Pancreas ~~and~~ or Lung	6 consecutive months
Stand-alone pediatric transplant programs	12 consecutive months

~~Given their experimental and evolving nature, f~~Functional inactivity thresholds ~~and waiting list notification requirements for functional inactivity~~ have not been established for pancreatic islet and intestinal transplant programs.

B. Notification Requirements for Transplant Program Functional Inactivity

If a transplant program is notified by the MPSC that the program has been identified as functionally inactive, the transplant program must provide written notice to

1. Potential candidates
2. All candidates registered on the waiting list.

Written notice must be provided within 30 days of the date of the MPSC notification to the program and must include *all* of the following:

1. The dates identified in the MPSC notification during which no transplants were performed.
2. The reason no transplants were performed.

3. The options available to the candidates, including multiple listing or transfer of accrued waiting time to another transplant hospital
4. A copy of the OPTN Contractor's Patient Information Letter

~~B.~~C. Review of Member Functional Inactivity

As part of its review of a program's functional inactivity, t~~T~~he MPSC may ~~also~~ require~~, at its discretion,~~ that the member participate in an informal discussion ~~regarding a performance review~~. The informal discussion may be with the MPSC, a subcommittee, or a work group, as determined by the MPSC. The informal discussion will be conducted according to the principles of confidential medical peer review, as described in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws. The discussion is not an adverse action or an element of due process. A member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.

~~A functionally inactive transplant program should voluntarily inactivate for a period of up to 12 months by providing written notice to the Executive Director. If the transplant program expects to be inactive for more than 12 months, the member should relinquish designated transplant program status as required in these Bylaws.~~

The MPSC may recommend that a program inactivate or withdraw its designated transplant program status due to the program's functional inactivity. If the program fails to inactivate or withdraw its designated transplant program status when the MPSC recommends it do so, the MPSC may recommend that the Board of Directors take appropriate action as defined in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the program's inactivity.

D.10 Additional Transplant Program Requirements
B. Patient Notification Requirements for Waiting List Inactivation

A transplant program must provide written notice to candidates if it does *either or both* of the following:

1. Inactivates its waiting list ~~or is unable to perform transplants~~ for 15 or more consecutive days.
2. Inactivates its waiting list ~~or is unable to perform transplants~~ for 28 or more cumulative days during any calendar year.

A t~~T~~ransplant p~~P~~rogram must provide written notice *each* time it reaches either of the inactive waiting list thresholds listed above. Written notice must include *all* of the following:

1. The reason for the inactivity
2. The expected length of time that the waiting list will be inactive
3. The explanation that during the period of inactivity, organs cannot be accepted on the candidate's behalf at this transplant program

4. The options available to the candidate during this period, including multiple listing or transferring of accrued waiting time to another Transplant Hospital
5. How the candidates will be notified when the waiting list is reactivated or if the expected length of inactivation is extended
6. A copy of the ~~UNOS~~ OPTN Contractor's Patient Information Letter

Note: If written notice is required because a t~~T~~ransplant p~~P~~rogram exceeded the inactive waiting list threshold due to *cumulative* periods of inactivation, then the written notice must also include the dates of each instance of waiting list inactivation.

Written notice must be provided within the periods defined in the table below:

For…	Written Notice Must be Provided…
Periods of waiting list inactivation scheduled at least 30 days in advance	30 days before inactivity begins.
Periods of waiting list inactivation scheduled less than 30 days in advance	No more than 7 days following the initial date of waiting list inactivation.
Any periods of waiting list inactivation related to a cumulative period of inactivation	No more than 7 days following the last date of the inactive period that caused the transplant program to exceed the inactive waiting list threshold.

Appendix K: Transplant Program Inactivity, Withdrawal, and Termination

This appendix defines transplant program inactivity, withdrawal, and termination, and outlines what members must do to be in compliance with OPTN obligations during these periods.

K.1 Transplant Program Inactivity

Transplant programs must remain active in transplantation to maintain membership in the OPTN. There are two types of member inactivity:

1. Short-term Inactivity
2. Long-term Inactivity

A member may voluntarily inactivate a transplant program, on a short-term or long-term basis, for reasons including but not limited to:

- The inability to meet functional activity requirements.
- The inability to serve potential candidates, candidates, recipients, potential living donors, or living donors for a period of 15 or more consecutive days.
- Temporarily lacking required physician or surgeon coverage.
- A substantial change in operations that requires an interruption in transplantation.

For more information about the functional activity requirements for transplant programs, see *Section D.9 Review of Transplant Program Functional Inactivity* of these Bylaws.

A. Program Component Cessation

Programs that cease performing a specific type of transplant (e.g. the living donor component of a transplant program, or cessation of only pediatric or only adult transplants in a transplant program that performs both), must notify every patient affected by the cessation, including:

- Potential candidates, including those currently in the referral or evaluation process
- All candidates registered on the waiting list
- Potential living donors, including those currently in the referral process, in the evaluation process, or awaiting donation

For more information about the notification content and timing requirements, see *Appendix K, Sections K.3-4:* of these Bylaws.

K.3 Long-term Inactive Transplant Program Status

Long-term inactivity occurs when a transplant program is inactive for 15 or more consecutive days~~, resulting in an inactive UNet℠ waiting list status and an inactive membership status~~.

Members should voluntarily inactivate a transplant program that is not able to serve potential candidates, candidates, living donors, or recipients for 15 or more consecutive days. Voluntary inactivation may extend for a period of up to 12 months.

Long term inactivation results in an inactive waiting list status and an inactive membership status.

A. Notice to the OPTN Contractor of Long-term Inactive Status

When a member will voluntarily inactivate a transplant program for 15 or more consecutive days, it must provide written notice, including the reasons for inactivation, to the OPTN Executive Director.

B. Notice to the Patients of Long-term Inactive Status

When a member intends to inactivate a transplant program for 15 or more consecutive days, it must provide written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being treated by the transplant program. Written notice should be provided at least 30 days prior to the planned inactivation date by a method that can be tracked and that provides proof of receipt, such as:

- Commercial overnight delivery service
- Secure electronic communication
- Registered or certified mail, return receipt requested

Written notice must be provided no later than 7 days after inactivation and include *all* of the following:

1. The reasons for inactivating the transplant program.
2. Explanation that although the patient is still on the waiting list, the candidate cannot receive an organ offer through this program while it is inactive.
3. Options for potential candidates, candidates, recipients, and living donors to transfer to another transplant program.
4. The phone number of the inactive program's administrative office that can help with transferring to another transplant program.

The member must provide to the OPTN Contractor a sample of each type of patient notice it sends to potential candidates, candidates, recipients, and living donors along with a list of patients who received the notice.

If a natural disaster adversely affects the function of a transplant program, the patient notification requirements will be applied reasonably and flexibly.

Appendix M: Definitions

F

~~**Functional Inactivity**~~

~~Functional inactivity is when a transplant program meets *any or all* of the following:~~
~~1. The inability to serve potential candidates, candidates, recipients, or living donors for a period of 15 or more consecutive days.~~
~~2. An inactive waiting list for 15 or more consecutive days, or 28 or more cumulative days over any 365 consecutive day period.~~
~~3. The failure to perform a transplant during the periods defined in the table below:~~

~~**Program Type**~~	~~**Inactive Period**~~
~~Kidney, Liver or Heart~~	~~3 consecutive months~~
~~Pancreas and Lung~~	~~6 consecutive months~~
~~Stand-alone pediatric transplant programs~~	~~12 consecutive months~~

L

~~**Long-term Inactivity**~~

~~A transplant program that is inactive for 15 or more consecutive days. Long-term inactivity results in an inactive UNet℠ waiting list status and an inactive membership status.~~

To read the complete OPTN Bylaws language visit optn.transplant.hrsa.gov, select the "Policy Management" tab, then select "OPTN Bylaws." To read the complete UNOS Bylaws language visit www.unos.org, click on the "ABOUT US" box at the top of the screen, and then, in the left margin under "Governance," select "Bylaws."

Proposal to Change Pediatric Heart Allocation Policy

Sponsoring Committees: Thoracic Organ Transplantation Committee and Pediatric Transplantation Committee

Policy Affected: Policies 3.4.H (In Utero Candidate Registrations); 5.3.C (Pediatric Heart Acceptance Criteria); 6.1 (Status Assignments); 6.1.D (Pediatric Heart Status 1A Requirements); 6.1.E (Pediatric Heart Status 1B Requirements); 6.1.F (Pediatric Heart Status 2 Requirements); 6.3 (Status Exceptions); 6.3.A (RRB and Committee Review of Status Exceptions); 6.4 (Waiting Time); 6.5.A (Allocation of Hearts by Blood Type); 6.5.B (Sorting Within Each Classification); 6.5.C (Allocation of Hearts from Donors at Least 18 Years Old); and 6.5.D (Allocation of Hearts from Donors Less Than 18 Years Old)

Distributed for Public Comment: March 2013

Amended After Public Comment: Yes

Effective Date: To be determined, implementation pending programming

Problem Statement
Pediatric heart candidates continue to face high mortality rates while on the waiting list. Previous modifications to policy decreased the death rates for status 1A and 1B pediatric heart candidates, but their waiting list mortality rates remain unacceptably high.

Changes
The Board approved four modifications to pediatric heart allocation policy: • Pediatric heart status 1A and 1B criteria are redefined • To qualify for ABO-incompatible heart offers, the isohemagglutinin titers are increased to 1:16 or less for candidates who are one year of age or older but registered before their second birthday • Allocation priority of urgent potential heart recipients registered before their first birthday and potential transplant recipients eligible to receive ABO-incompatible heart offers was changed • The option to register heart candidates as *in utero* was eliminated.

Member Actions
Upon implementation, members will need to use the new pediatric heart status 1A and 1B definitions to register pediatric heart candidates. If a pediatric heart candidate is already registered at the time of implementation, then the new Status 1A and 1B definitions will apply to these candidates at the time of their next status recertification or change. If a member is caring for status 1A or 1B candidates registered on or after their first birthday but before their second birthday and have isohemagglutinin titer levels no greater than 1:16, the program should consider the appropriateness of registering these patients as eligible for an ABO-incompatible heart transplant. Finally, upon implementation, members can no longer register *in utero* candidates on the waiting list. The OPTN contractor will contact members with

candidates registered *in utero* at the time of implementation to remove the candidate from the waiting list until the candidate is born.

Affected Policy Language:
New language is underlined and language that will be deleted is ~~struck through.~~

~~3.4.H In Utero Candidate Registrations~~

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

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

5.3.C Pediatric Heart Acceptance Criteria to Receive Hearts from Donors of Any Blood Type

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

~~The candidate will be eligible for heart offers from deceased donors of any blood type if the candidate meets at least *one* of the following conditions:~~

~~1. Candidate is *in utero*~~

~~2. Candidate is less than one year old at the time of the match run, and meets *both* of the following:~~

~~a. Is registered as status 1A or 1B.~~
~~b. Has reported current isohemagglutinin titer information for A or B blood type antigens to the OPTN Contractor within the last 30 days.~~

~~3. Candidate is at least one year old at the time of the match run, and meets *all* of the following:~~

~~a. Is registered prior to turning two years old.~~
~~b. Is assigned status 1A or 1B.~~
~~c. Has reported to the OPTN Contractor current isohemagglutinin titers levels less than or equal to 1:41:16 for A or B blood type antigens from a blood sample collected to the OPTN Contractor within the last 30 days. The candidate must not have received treatments that may have reduced isohemagglutinin titers to 1:16 or less within 30 days of when this blood sample was collected.~~
~~d. Has *not* received treatments within the last 30 days that may have reduced titer values to 1:4 or less.~~

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

- ~~At the time of registration (except *in utero* candidates).~~

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

6.1 Status Assignments

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

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

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

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

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

A candidate ~~of any age is assigned a pediatric status if the candidate was~~ registered on the waiting list before turning 18 years old remains eligible for pediatric status until the candidate has been removed from the waiting list ~~and has not yet received a heart transplant~~.

6.1.D Pediatric Heart Status 1A Requirements

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

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

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

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

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

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

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

6.1.E Pediatric Heart Status 1B Requirements

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

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

1. Requires infusion of one or more inotropic agents ~~low dose single inotropes~~ but does not qualify for pediatric Status 1A. The OPTN Contractor ~~will~~ maintains a list of the OPTN-approved ~~specific~~ status 1B qualifying ~~inotropes~~ inotropic agents and doses.
2. Is less than ~~six months~~one year old at the time of the candidate's initial registration and has a diagnosis of hypertrophic or restrictive cardiomyopathy. ~~and does not meet the criteria for pediatric status 1A.~~

- ~~Is in the less than 5th percentile for the candidate's expected height or weight according to the most recent Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics pediatric clinical growth chart.~~
- ~~Is 1.5 or more standard deviations below the candidate's expected height growth or weight growth according to the most recent CDC National Center for Health Statistics pediatric clinical growth chart~~

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

6.1.F Pediatric Heart Status 2 Requirements

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

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

6.1.G Inactive Adult and Pediatric Candidates

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

6.3 Status Exceptions

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

Table 6-3: Exception Qualification and Periods

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

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Pediatric status 1A	• Candidate is admitted to the transplant hospital that registered the candidate on the waiting list • ~~Candidate life expectancy of less than 14 days without a heart transplant~~ • Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for Status 1A-exceptions	14 days	• ~~One 14 day extension by submitting an updated application to the OPTN Contractor~~ • ~~Successive extensions then require a conference with the RRB~~ • Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively • If no extension request is submitted, the candidate will be assigned ~~downgraded to~~ pediatric status 1B
Pediatric status 1B	• Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for Status 1B exceptions	Indefinite	• Not required as long as candidate's medical condition remains the same

The candidate's transplant physician must submit a~~n application~~ justification form to the OPTN Contractor with the requested status and the rationale for granting the status exception.

6.3.A RRB and Committee Review of Status Exceptions

The heart RRB reviews all applications for status exceptions. If an adult status 1A exception request is not approved by the RRB, the candidate's transplant program may override the decision and list the candidate at the requested status. If a pediatric status 1A or status 1B exception request is not approved by the RRB, the candidate's transplant program may override the decision and list the candidate at the requested status, subject to automatic review by the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee may review the RRB's decisions and rationale, and may refer any case to the Membership and Professional Standards Committee (MPSC) for further review.

6.4 Waiting Time

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

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

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

Waiting time does not accrue while the candidate is inactive.

6.5 Heart Allocation Classifications and Rankings

6.5.A Allocation of Hearts by Blood Type

Within each heart status and geographical zone classification, hearts ~~will be~~ are first allocated to primary blood type candidates then to secondary blood type candidates according to the ~~primary~~ blood type matching requirements in *Table 6-5* below~~:~~.

Table 6-5: ~~Primary~~ Blood Type Matching ~~Requirements~~ Prioritization for Heart Allocation

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

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

Pediatric candidates that are at least one year of age at the time of the match run but registered before their second birthday and are eligible to receive a heart from a deceased donor of any blood type will be classified as a secondary blood type match candidate, unless they are a primary blood type match candidate per Table 6-5.

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

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

6.5.B Eligibility for Heart Offers from Deceased Donors of Any Blood Type

The candidate will be eligible for heart offers from deceased donors of any blood type if the candidate meets at least *one* of the following conditions:

Candidate is less than one year old at the time of the match run, and meets both of the following:

a. Is registered as status 1A or 1B.
b. Has reported isohemagglutinin titer information for A or B blood type antigens to the OPTN Contractor within the last 30 days.

Candidate is at least one year old at the time of the match run, and meets all of the following:

a. Is registered prior to turning two years old.
b. Is registered as status 1A or 1B.
c. Has reported to the OPTN Contractor isohemagglutinin titers less than or equal to 1:16 for A or B blood type antigens from a blood sample collected within the last 30 days. The candidate must not have received treatments that may have reduced isohemagglutinin titers to 1:16 or less within 30 days of when this blood sample was collected.

Accurate isohemagglutinin titers must be reported for candidates eligible to accept a heart from a deceased donor of any blood type according to Table 6-6 below, at all of the following times:

1. Upon initially indicating a candidate is willing to accept a heart from a deceased donor of any blood type.
2. Every 30 days after initially indicating a candidate is willing to accept a heart from a deceased donor of any blood type.

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

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

Accurate isohemagglutinin titers ~~must~~ will be reported for recipients of a heart with an incompatible blood type, according to Table 6-7, as follows:

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

Table 6-7: Isohemagglutinin Titer Reporting Requirements for a Recipient of a Heart from a Donor with an Incompatible Blood Type

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

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

6.5.~~B~~C Sorting Within Each Classification

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

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

Hearts from deceased donors at least 18 years old are allocated to candidates according to *Table 6-~~6~~8* below.

Table 6-~~6~~8: Allocation of Hearts from Deceased Donors At Least 18 Years Old

Classification	Candidates that are within the:	And are:
1	OPO's DSA	Adult or pediatric status 1A and primary blood type match with the donor
2	OPO's DSA	Adult or pediatric status 1A and secondary blood type match with the donor
3	OPO's DSA	Adult or pediatric status 1B and primary blood type match with the donor
4	OPO's DSA	Adult or pediatric status 1B and secondary blood type match with the donor
5	Zone A	Adult or pediatric status 1A and primary blood type match with the donor
6	Zone A	Adult or pediatric status 1A and secondary blood type match with the donor
7	Zone A	Adult or pediatric status 1B and primary blood type match with the donor
8	Zone A	Adult or pediatric status 1B and secondary blood type match with the donor
9	OPO's DSA	Adult or pediatric status 2 and primary blood type match with the donor
10	OPO's DSA	Adult or pediatric Status 2 and secondary blood type match with the donor

11	Zone B	Adult or pediatric status 1A and primary blood type match with the donor
12	Zone B	Adult or pediatric status 1A and secondary blood type match with the donor
13	Zone B	Adult or pediatric status 1B and primary blood type match with the donor
14	Zone B	Adult or pediatric status 1B and secondary blood type match with the donor
15	Zone A	Adult or pediatric status 2 and primary blood type match with the donor
16	Zone A	Adult or pediatric status 2 and secondary blood type match with the donor
17	Zone B	Adult or pediatric status 2 and primary blood type match with the donor
18	Zone B	Adult or pediatric status 2 and secondary blood type match with the donor
19	Zone C	Adult or pediatric status 1A and primary blood type match with the donor
20	Zone C	Adult or pediatric status 1A and secondary blood type match with the donor
21	Zone C	Adult or pediatric status 1B and primary blood type match with the donor
22	Zone C	Adult or pediatric status 1B and secondary blood type match with the donor
23	Zone C	Adult or pediatric status 2 and primary blood type match with the donor
24	Zone C	Adult or pediatric status 2 and secondary blood type match with the donor
25	Zone D	Adult or pediatric status 1A and primary blood type match with the donor
26	Zone D	Adult or pediatric status 1A and secondary blood type match with the

		donor
27	Zone D	Adult or pediatric status 1B and primary blood type match with the donor
28	Zone D	Adult or pediatric status 1B and secondary blood type match with the donor
29	Zone D	Adult or pediatric status 2 and primary blood type match with the donor
30	Zone D	Adult or Pediatric Status 2 and secondary blood type match with the donor
31	Zone E	Adult or pediatric status 1A and primary blood type match with the donor
32	Zone E	Adult or pediatric status 1A and secondary blood type match with the donor
33	Zone E	Adult or pediatric status 1B and primary blood type match with the donor
34	Zone E	Adult or pediatric status 1B and secondary blood type match with the donor
35	Zone E	Adult or pediatric status 2 and primary blood type match with the donor
36	Zone E	Adult or pediatric status 2 and secondary blood type match with the donor
~~**37**~~	~~OPO's DSA and Zone A~~	~~*In utero* and primary blood type match with the donor~~
~~**38**~~	~~OPO's DSA and Zone A~~	~~*In utero* and secondary blood type match with the donor~~
~~**39**~~	~~OPO's DSA and Zone A~~	~~*In utero* and blood type incompatible with the donor~~
~~**40**~~	~~Zone B~~	~~*In utero* and primary blood type match with the donor~~
~~**41**~~	~~Zone B~~	~~*In utero* and secondary blood type match with the donor~~
~~**42**~~	~~Zone B~~	~~*In utero* and blood type incompatible with the donor~~
~~**43**~~	~~Zone C~~	~~*In utero* and primary blood type match~~

		~~with the donor~~
~~**44**~~	~~Zone C~~	~~*In utero* and secondary blood type match with the donor~~
~~**45**~~	~~Zone C~~	~~*In utero* and blood type incompatible with the donor~~
~~**46**~~	~~Zone D~~	~~*In utero* and primary blood type match with the donor~~
~~**47**~~	~~Zone D~~	~~*In utero* and secondary blood type match with the donor~~
~~**48**~~	~~Zone D~~	~~*In utero* and blood type incompatible with the donor~~
~~**49**~~	~~Zone E~~	~~*In utero* and primary blood type match with the donor~~
~~**50**~~	~~Zone E~~	~~*In utero* and secondary blood type match with the donor~~
~~**51**~~	~~Zone E~~	~~*In utero* and blood type incompatible with the donor~~

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

A heart from a pediatric donor will be allocated to a pediatric heart candidate by status and geographical location before being allocated to a candidate at least 18 years old according to *Table 6-~~7~~*9 below.

Table 6-~~7~~9: Allocation of Hearts from Donors Less Than 18 Years Old

Classification	Candidates that are within the:	And are:
1	OPO's DSA or Zone A	Pediatric status 1A and primary blood type match with the donor
2	OPO's DSA or Zone A	Pediatric status 1A and secondary blood type match with the donor
3	OPO's DSA	Adult status 1A and primary blood type match with the donor
4	OPO's DSA	Adult status 1A and secondary blood type match with the donor
5	OPO's DSA or Zone A	Pediatric status 1B and primary blood type match with the donor

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

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

Classification	Candidates that are within the:	And are:
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
52	Zone D	Adult status 1B and secondary blood type match with the donor
53	Zone D	Pediatric status 2 and primary blood type match with the donor
54	Zone D	Pediatric status 2 and secondary blood type match with the donor
55	Zone D	Adult status 2 and primary blood type match with the donor
56	Zone D	Adult status 2 and secondary blood type match with the donor
57	Zone E	Pediatric status 1A and primary blood type match with the donor
58	Zone E	Pediatric status 1A and secondary blood type match with the donor
59	Zone E	Adult status 1A and primary blood type match with the donor

Classification	Candidates that are within the:	And are:
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	OPO's DSA or Zone A	Pediatric status 1A and blood type incompatible with the donor
70	OPO's DSA or Zone A	Pediatric status 1B and blood type incompatible with the donor
71	OPO's DSA	Pediatric status 2 and blood type incompatible with the donor
72	Zone B	Pediatric status 1A and blood type incompatible with the donor
73	Zone B	Pediatric status 1B and blood type incompatible with the donor
74	Zone C	Pediatric status 1A and blood type incompatible with the donor
75	Zone C	Pediatric status 1B and blood type incompatible with the donor
76	Zone D	Pediatric status 1A and blood type incompatible with the donor
77	Zone D	Pediatric status 1B and blood type incompatible with the donor

Classification	Candidates that are within the:	And are:
78	Zone E	Pediatric status 1A and blood type incompatible with the donor
79	Zone E	Pediatric status 1B and blood type incompatible with the donor
~~**80**~~	~~OPO's DSA or Zone A~~	~~*In utero* and primary blood type match with the donor~~
~~**81**~~	~~OPO's DSA or Zone A~~	~~*In utero* and secondary blood type match with the donor~~
~~**82**~~	~~OPO's DSA or Zone A~~	~~*In utero* and blood type incompatible with the donor~~
~~**83**~~	~~Zone B~~	~~*In utero* and primary blood type match with the donor~~
~~**84**~~	~~Zone B~~	~~*In utero* and secondary blood type match with the donor~~
~~**85**~~	~~Zone B~~	~~*In utero* and blood type incompatible with the donor~~
~~**86**~~	~~Zone C~~	~~*In utero* and primary blood type match with the donor~~
~~**87**~~	~~Zone C~~	~~*In utero* and secondary blood type match with the donor~~
~~**88**~~	~~Zone C~~	~~*In utero and* blood type incompatible with the donor~~
~~**89**~~	~~Zone D~~	~~*In utero* and primary blood type match with the donor and~~
~~**90**~~	~~Zone D~~	~~*In utero* and secondary blood type match with the donor~~
~~**91**~~	~~Zone D~~	~~*In utero* and blood type incompatible with the donor~~
~~**92**~~	~~Zone E~~	~~*In utero* and primary blood type match with the donor~~
~~**93**~~	~~Zone E~~	~~*In utero* and secondary blood type match with the donor~~
~~**94**~~	~~Zone E~~	~~*In utero* and blood type incompatible with the donor~~

To read the complete policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the “Policy Management” tab, then select “Policies.” From the UNOS website, select “Policies” from the “I am looking for:” box in the upper left hand corner.