

IMPORTANT POLICY NOTICE

To: Transplant Professionals
From: James B. Alcorn
Director, Policy
RE: Changes to OPTN Bylaws and Policies from actions at June 2015
Board of Directors Meeting
Date: July 1, 2015

This report summarizes changes to the OPTN Policies and Bylaws approved by the OPTN/UNOS Board of Directors at its June 2015 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 <http://optn.transplant.hrsa.gov/governance/policy-notices/>.

The [Evaluation Plan](#), which reviews specific details regarding how members will be assessed for compliance with OPTN policies and bylaws, will be updated to reflect changes resulting from the meeting.

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.

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Require Another Match Run Based on Infectious Disease Results

Sponsoring Committee:	Ad Hoc Disease Transmission Advisory Committee
Policies Affected:	Policies 1.2: Definitions; 2.9: Required Deceased Donor Infectious Disease Testing; 5.3.B: Infectious Disease Screening Criteria; 5.4.C: Liver Offers; 5.5.B: Host OPO and Transplant Hospital Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results, and 5.5.C OPO Requirements for Positive HIV Results
Distributed for Public Comment:	January 2015
Amended After Public Comment:	Yes
Effective Date:	Pending programming and notice to OPTN membership

Problem Statement

Review of OPTN data indicates that a large number of organ allocations take place using match runs that were executed before all test results were received. This presents a potential patient safety concern, as organs could unintentionally be allocated to a candidate who is not willing to accept offers from organs that test positive for a specific infectious disease. This could result in unintended donor-derived disease transmission. If we modify policy language to better define the processes that should be followed when new results are learned after the initial match run, we will reduce the opportunity for error and enhance patient safety.

Summary of Changes

Policy modifications include:

- Defining the term “primary potential transplant recipient.”
- Clarifying existing policy related to HIV nucleic acid test (NAT) requirements for deceased donor
- Removing the option for communicating completion of HIV, Hepatitis B, or Hepatitis C testing outside of policy requirements. Minimum testing must be completed as described in policy.
- Adding candidate donor infectious disease screening options in policy. This has been built into the WaitlistSM function of UNetSM for many years, but never outlined in policy.
- Clarifying policy requirements related to re-executing the match run for liver offers.
- Creating new policy that outlines when you must re-execute a match run based upon changes to a deceased donor’s infectious disease results.

New policy requirements will take effect once the following features have been programmed in UNetSM:

- A pop up message in DonorNetSM to remind OPOs of policy requirements related to re-executing the match run when the OPO learns new infectious disease results that will impact candidate appearance on match run.

- Functionality that will prevent the host OPO from sending electronic notifications on matches where serology was first noted as “negative”, “unknown”, “indeterminate” or “pending” and then changed to “positive.”
The host OPO will still be able to send electronic notifications on matches where the result is noted as “pending.” Additionally, if the OPO entered a “positive” result in error and then updated the result to negative, the system will allow the user to send electronic notifications from this original match.

What Members Need to Do

OPOs:

- Familiarize yourselves with new definition and policy requirements
- Educate your allocation staff about requirements to re-execute the match run when new infectious disease results are learned that are included in infectious disease screening criteria
- Use the newly re-executed match run to make any back up organ offers
- Update your internal policies and procedures to address changes made to OPTN Policy, including updating any internal documents or processes accordingly
- Educate all staff impacted by these changes (e.g. medical directors, laboratory directors, allocation coordinators, data entry coordinators, etc.)

Transplant hospitals:

- Familiarize yourselves with new policy requirements
- Educate transplant coordinator staff about new requirements to re-evaluate a provisionally accepted organ offer when they learn of new infectious disease results that could impact match run appearance due to infectious disease screening criteria
- Review informed consent policies in *Policy 15.3.A: Deceased Donors with Additional Risk Identified Pre-Transplant* with your transplant team staff who have these discussions with transplant candidates or their agents
- Update internal policies and procedures to address changes made to OPTN Policy, including updating any internal documents or processes accordingly
- Educate all staff impacted by these changes (e.g. transplant surgeons, transplant physicians, transplant coordinators, etc.)

Affected Policy/Bylaw Language:

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

1.2 Definitions

Primary potential transplant recipient

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

2.9 Required Deceased Donor Infectious Disease Testing

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

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

- a. HIV antibody (anti-HIV) donor screening test or HIV antigen/antibody (Ag/Ab) combination test
 - b. Hepatitis B surface antigen (HBsAg) donor screening test
 - c. Hepatitis B core antibody (anti-HBc) donor screening test
 - d. Hepatitis C antibody donor screening test (anti-HCV)
 - e. Hepatitis C ribonucleic acid (RNA) by donor screening or diagnostic NAT
 - f. Cytomegalovirus (CMV) antibody (anti-CMV) donor screening or diagnostic test
 - g. Epstein-Barr Virus (EBV) antibody (anti-EBV) donor screening or diagnostic test
 - h. Syphilis donor screening or diagnostic test
3. If the donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to the U.S. Public Health Services (PHS) Guideline, HIV RNA by donor screening or diagnostic NAT or HIV antigen/antibody (Ag/Ab) combination is also required unless either of the following is true:
- The donor has already been tested for HIV using the HIV Ag/Ab combination test according to section 2.a above.
 - The donor's only increased risk factor is having received hemodialysis within the past 12 months.

~~If a deceased donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to the U.S. Public Health Services (PHS) Guideline, testing must also include HIV ribonucleic acid (RNA) by donor screening or diagnostic NAT or HIV antigen/antibody (Ag/Ab) combination test. This does not apply to donors whose only increased risk factor is receiving hemodialysis within the preceding 12 months, as they are at risk only for HCV according to the U.S. Public Health Services (PHS) Guideline.~~

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.~~

5.3.B Infectious Disease Screening Criteria

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

Table 5-1: Donor Infectious Disease Screening Options

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

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

Prior to receiving an offer for a kidney with a Kidney Donor Profile Index (KDPI) score greater than 85%, transplant programs must obtain written, informed consent from each kidney candidate willing to receive offers for kidneys in this category.

Subsequent headings affected by the renumbering of this policy will also be changed as necessary.

5.4.C Liver Offers

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

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

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

5.5.A (Reserved)

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

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

1. When a deceased donor organ has *not* been accepted for a potential transplant recipient, then the OPO must do *all* of the following for each organ being allocated:
 - a. Stop allocation on the original match run for this donor
 - b. Re-execute the match run according to the infectious disease screening options as follows:
 - i. A new positive Cytomegalovirus (CMV) result will apply to re-execution of the intestine match run
 - ii. A new positive hepatitis B (HBcAb or HBV NAT) or hepatitis C (HCV Ab or HCV NAT) result will apply to re-execution of *all* organ types
 - c. Allocate the organ using this updated match run
2. When a deceased donor organ has already been accepted for a potential transplant recipient, the host OPO must do *all* of the following for each organ being allocated:
 - a. Report this new infectious disease test result to the first transplant hospital on the match run that accepted the organ as soon as possible, but within one hour, of receipt of the new test result

- b. Re-execute the match run for use as follows:
 - i. For re-allocation of the organ if the offer to the primary potential transplant recipient is declined after receipt of the positive infectious disease test
 - ii. For back-up organ offers based upon the new positive test result

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

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

5.5.C OPO Requirements for Positive HIV Results

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

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

5.56 Receiving and Accepting Organ Offers

Subsequent headings affected by the renumbering of this policy will also be changed as necessary.

Improving the OPTN Policy Development Process

Sponsoring Committee:	Executive
Policy/Bylaws Affected:	Bylaws Article 11.1.A (The Public Comment Period); Article 11.6 (Developing Organ Allocation Policies)
Distributed for Public Comment:	September 2014
Amended After Public Comment:	No
Effective Date:	September 1, 2015

Problem Statement

The current 'one size fits all' process for OPTN policy development does not provide flexibility for addressing different types of problems, especially those that are urgent or non-controversial. This model is inefficient and does not meet the needs of the transplant community.

Summary of Changes

This change to the OPTN Bylaws creates two new policy development tracks designed to allow the OPTN/UNOS Board to address emergency and non-controversial issues in a more efficient and expedient manner, while continuing to maintain the OPTN's cornerstone principles of transparency and community consensus. Specifically, the proposal includes the following:

- The Board may take action on a policy prior to public comment if the problem falls into one of the three categories below:
 1. A proposal necessitated by a pending statutory or regulatory change.
 2. A proposal required due to emergent public health issues or patient safety factors.
 3. A proposal necessitated by a new medical device or technology that affects organ allocation.

In these limited instances, the Board must specify a sunset date that is no more than 12 months beyond the policy's effective date and distribute the policy for public comment no more than 6 months after approval. The proposal will then come back to the Board for a decision after public comment.

- The Board may approve non-controversial and routine policy changes according to the following process:
 1. The sponsoring Committee distributes a public comment proposal (following the normal policy development process) for a new or existing policy and specifies in the policy language areas that will be eligible for future expedited updates.
 2. The Board approves the proposal, including policy language specifying that the particular policy section is eligible for expedited updates.
 3. At a later date, the sponsoring Committee develops a proposal for expedited action.
 4. The proposal is distributed for public comment. This public comment period can be shorter than the normal public comment period but must be at least 30 days.
 5. The sponsoring Committee considers public comments and recommends final adoption of the proposal.
 6. If an objection to the use of the expedited action is received during the public comment period by five members of the public, another OPTN committee, or four members of the

- Board of Directors, then the sponsoring Committee will notify the Executive Committee of the objections and the proposal will follow the normal OPTN policy development process.
7. If the specified number of objections in #6 above are not received during the public comment period, then the process will proceed as follows:
 - a) If no objections were raised during the public comment period, the proposal will become effective upon notice to the OPTN membership unless a different date is specified.
 - b) If one or more objections were raised, then the sponsoring Committee will submit the proposal for final action according to OPTN Bylaws section 11.2: *Submitting Policy Proposals to the Board of Directors*. This will require a review by the Board or Executive Committee before the proposal is adopted.

What Members Need to Do

Members are not required to take any action as a result of this proposal. UNOS staff will educate the standing OPTN committees about the new policy development tracks and a framework for communicating proposed changes to allow for community input. The staff will also develop a structure for communicating and educating the transplant community on policy changes approved through the emergency or expedited process. The Executive Committee members feel strongly that every effort should be made to ensure that proposed expedited changes are communicated through webinars or other methods in order for the transplant community to be able to comment.

Affected Policy/Bylaw Language

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

Article XI: Adoption of Policies

11.1 Creating and Submitting Policy Proposals

Committees develop proposals for new policies or changes to existing policies and submit them to the Board of Directors for consideration. Committees developing proposals may also request review and comment from one or more additional Committees if necessary. For more information about OPTN Committees, see of these Bylaws.

Committees analyze policy proposals using select data to measure the effect of the proposal on the transplant community. The analysis includes baseline data that reflects how current policy is performing as well as projected outcomes to estimate the impact of the policy proposal. Data, analysis, and other information requested by the Committees are provided by the OPTN Contractor and Scientific Registry of Transplant Recipients (SRTR) contractor, as specified in their contracts with the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS).

Policy proposals include a summary that provides background information to explain the purpose of the proposal and the issues that were considered in developing the proposal.

A. The Public Comment Period

The public, including the transplant community, is usually included in the OPTN policy development process through the public comment process. Proposals to change organ allocation or membership requirements require public comment. However, some policy proposals do not require public comment, including:

- ~~■ Proposals that require immediate action due to patient health and safety factors.~~
- Proposals that clarify or correct existing policy rather than changing the intent or adding to the policy.
- Proposals that reflect administrative or non-substantive procedural changes that do not change the intent of the policy or do not impact the operations of the transplant community.

The public comment period is usually 45 days. ~~The sponsoring Committee may set a shorter period if a proposal needs to be expedited for patient health and safety reasons, but will make every effort to set a reasonable period to receive comments.~~

Proposals issued for public comment are distributed in the following ways:

1. Posted to the OPTN website at <http://optn.transplant.hrsa.gov> or mailed to all OPTN members and anyone who requests to be placed on the list.
2. Provided at regional meetings of the members.
3. Provided at meetings of interested Committees.

Comments received during the public comment period will be reviewed and addressed by the sponsoring Committee. Comments received after the end of the set public comment period may be reviewed and addressed at the discretion of the Chair of the sponsoring Committee.

Based on the comments received, the Committee may make modifications to the proposal, including withdrawal of the proposal. Should the Committee choose to recommend the policy proposal to the Board, the proposal will be updated to include the public comments and the Committee's responses and then presented to the Board of Directors as a final proposal.

11.6 Emergency Actions

Policy proposals that meet *at least one* of the following criteria may be adopted by the Board of Directors prior to public comment:

- A proposal that is necessitated by a pending statutory or regulatory change.
- A proposal that is required due to an emergent public health issue or patient safety factors.
- A proposal that is necessitated by a new medical device or technology that affects organ allocation.

Instead, the policy development process for these proposals will require *all* of the following steps:

1. The sponsoring Committee submits the proposal according to *11.2 Submitting Policy Proposals to the Board of Directors*.
2. The proposal designates a future date upon which the policy will expire, not more than 12 months beyond the policy's effective date.
3. The policy is distributed for public comment no more than 6 months after approval. This public comment period can be shorter than the normal public comment period but must be at least 30 days.

11.7 Expedited Actions

Policy proposals that are expected to be non-controversial may be adopted according to the following process:

1. The Board approves a new or revised policy that includes specific policy language defining components of the policy that will be eligible for future expedited updates as well as the anticipated frequency of updates.
2. At a later date (as directed by the policy timeline), the sponsoring Committee develops a proposal for expedited action as stipulated in the policy.
3. The proposal is distributed for public comment. This public comment period can be shorter than the normal public comment period but must be at least 30 days.
4. The sponsoring committee considers public comments and recommends final adoption of the proposal.
5. If an objection to the use of the expedited action is received during the public comment period by five members of the public, another OPTN committee, or 4 members of the Board of Directors, then the sponsoring Committee will notify the Executive Committee of the objections and proceed with the normal OPTN policy development process.
6. If the specified number of objections in #5 above are not received during the public comment period, then the process will proceed as follows:
 - a. If no objections were raised during the public comment period, the proposal will become effective upon notice to the OPTN membership, unless a different date is specified.
 - b. If one or more objections were raised, then the sponsoring Committee will submit the proposal for final action according to 11.2 Submitting Policy Proposals to the Board of Directors.

11.611.8 **Developing Organ Allocation Policies**

Policy proposals affecting organ allocation must specify the organ or combination of organs addressed in the policy and summarize how the proposal meets requirements of the OPTN Final Rule, *42 CFR Part 121*.

Histocompatibility Bylaws Rewrite Phase II

Sponsoring Committee:	Histocompatibility Committee
Policy/Bylaws Affected:	Bylaws Appendix C, Policies 4.2-4.3
Distributed for Public Comment:	September 29 – December 5, 2014
Amended After Public Comment:	Yes
Effective Date:	September 1, 2015

Problem Statement

Many of the OPTN Bylaws governing histocompatibility laboratories are out of date, vague, or more appropriately monitored by the histocompatibility accrediting agencies. The Board adopted the first phase of this project in 2013. This second phase cleans up sections pertaining to the education and experience required for approval as key laboratory personnel, along with performance indicators for the required testing performed and results reported to the OPTN.

Summary of Changes

The first phase of this project included changes that required all laboratories to comply with the requirements in the documents issued by ASHI and CAP (as of a certain date). The changes also expanded the definition of changes in key personnel, and required laboratories to submit a coverage plan to the OPTN. Those changes became effective February 1, 2014. The Board approved the following additional changes:

- Adding the general supervisor to the list of laboratory key personnel.
- Creating two pathways for approval of histocompatibility laboratory directors, the M.D./D.O. or earned doctoral degree pathways. Each pathway specifies particular education, experience, and certification requirements. The Committee also proposes the addition of a foreign equivalent qualifier for both pathways (current Bylaws are silent on foreign equivalent education and experience for laboratory directors).
- Simplifying requirements for the technical supervisor, general supervisor, and clinical consultant by only requiring that these individuals meet the requirements in the federal Clinical Laboratory Improvement Amendments (CLIA).
- Eliminating references to the histocompatibility technologist, since no requirements for this position are included in the Bylaws.
- Adding criteria for performance review of a histocompatibility laboratory, including HLA typing errors that result in an incompatible transplant or the reallocation of an organ.
- Removing sections that are out of date or more appropriately monitored by the histocompatibility accrediting agencies.

The second phase of the Bylaws rewrite contains changes dealing with education, certification, and experience requirements for laboratory key personnel, and performance indicators that will trigger a mandatory performance review of a laboratory.

This second phase includes a pathway for laboratory directors who were approved and served as directors before the 2003 requirement for their board certification, to have that requirement waived. This is a CLIA-based clause and requires waiving board certification for individuals already operating as a laboratory director prior to 2003. The Board approved an amendment to include this group of individuals as qualified laboratory directors.

Some commenters during public comment were concerned that the requirement that laboratory directors have publications in (greater than one) peer-reviewed journal was too stringent. The

Committee came to a compromise on this language. The revised language allows for either demonstrated participation in laboratory professional conferences or publications in peer-reviewed journals.

What Members Need to Do

- Histocompatibility laboratories should become familiar with the new bylaw and policy requirements for laboratories.
- Labs must report General Supervisor changes to UNOS.
- The OPTN will monitor HLA typing discrepancies.
- The addition of general supervisor(s) as key personnel will require IT programming; therefore, the implementation of that section will be delayed until programming is complete.

Affected Policy/Bylaw Language:

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

OPTN Bylaws Appendix C:

Membership Requirements for Histocompatibility Laboratories

C.1 Histocompatibility Laboratory Compliance

Each histocompatibility laboratory member must comply with *all* of the following:

1. All application provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.
2. All application provisions of the OPTN Final Rule, 42 CFR Part 121
3. The OPTN Charter
4. All OPTN Bylaws and Policies
5. The requirements in the Clinical Laboratory Improvement Amendments (CLIA) at 42 CFR § 493.1278, unless exempt
6. The requirements, as they apply to solid organ and islet transplantation, of the American Society for Histocompatibility and Immunogenetics (ASHI) ~~2012~~ 2013 Revised Standards for Accredited Laboratories, or the College of American Pathologists (CAP) Histocompatibility Checklist, Laboratory General Checklist, Flow Cytometry Checklist, and Team Leader Assessment of Director and Quality Checklist as of ~~September 25, 2012~~ April 21, 2014. This requirement does not mandate membership in either ASHI or CAP.

C.2 Facilities and Resources

Histocompatibility laboratories must have considerable facilities, equipment, and resources to ensure accurate, reliable and efficient testing.

A. Facilities

The laboratory must have:

1. Enough space and equipment so that procedures and tests can be performed accurately and efficiently.
2. Adequate facilities to store medical and test records for candidates, recipients, and donors.

B. Records Access

Records for active candidates must be immediately accessible onsite. Records for recipients and donors must be accessible as necessary to meet the clinical practice needs of any associated transplant hospital or OPO.

C. Transplant Program Affiliation

Histocompatibility laboratories must have written agreements with every transplant program the laboratory serves, unless clinical urgency prevents such an agreement. Written agreements between histocompatibility laboratories and transplant programs must include *all* of the following:

1. The sample requirements for typing and crossmatching.
2. The loci and level of resolution typed.
3. A process for requesting extended HLA typing.
4. A process for reporting and verifying HLA and unacceptable antigen data at the time of registration on the waiting list and any time there are changes.
5. A process for reporting HLA typing results to the OPTN Contractor.
6. A process for resolving HLA typing discrepancies and errors.
7. The maximum turnaround time from receipt of sample to reporting of results to the transplant program.
8. A process to obtain sensitization history for each patient.
9. The frequency of periodic sample collection.
10. The frequency of antibody screenings.
11. The criteria for crossmatching.
12. The assay format that will be used for antibody screening and for crossmatching.
13. The criteria for determining unacceptable antigens used during organ allocation.
14. The duration for which specimens need to be stored for repeat or future testing.
15. If desensitization is performed, then a protocol for monitoring antibody levels.
16. If the laboratory registers candidates for the transplant program, then a process for blood type verification according to *Policy 3.1.4: Waiting List* *Policy 3.3: Candidate Blood Type Determination and Reporting before Waiting List Registration*.
17. If post-transplant monitoring is performed, then a protocol for monitoring antibody levels.

D. OPO Affiliation

Histocompatibility laboratories must have written agreements with every OPO member the laboratory serves, unless clinical urgency prevents such an agreement. Written agreements between histocompatibility laboratories and OPOs must include *all* of the following:

1. The sample requirements for typing and crossmatching.
2. The loci and level of resolution typed.
3. A process for requesting extended HLA typing.
4. A process for reporting HLA typing results to the OPTN Contractor.
5. A process for resolving HLA typing discrepancies and errors.
6. The maximum turnaround time from receipt of donor sample to reporting of results to the OPO.
7. A process for prioritizing donors for histocompatibility testing.
8. The length of time for which donor specimens are required to be stored for repeat or future testing.

9. If the OPO performs crossmatching, then all methods used for crossmatching and the interpretation and reporting of the results.

C.3 Histocompatibility Laboratory Key Personnel

The laboratory must employ a histocompatibility laboratory director, a technical supervisor, a general supervisor, and a clinical consultant. One person may fill one or more positions.

The size and training of the histocompatibility laboratory staff must be enough to carry out the volume and variety of tests required to ensure accuracy and prompt completion of tests. All personnel must be licensed or meet the standards required by federal, state and local regulations.

If the laboratory provides histocompatibility testing for deceased kidney, kidney-pancreas, or pancreas transplants, then the laboratory must have personnel for the required histocompatibility testing available 24 hours a day, seven days a week.

A. Histocompatibility Laboratory Director Qualifications

The histocompatibility laboratory director ensures that the laboratory provides high quality and comprehensive histocompatibility and immunogenetics testing.

The histocompatibility laboratory director must meet the following requirements: for at least one of the following pathways:

Pathway 1:

1. Have an M.D. or D.O. from an accredited institution, or equivalent degree from another country
2. Have a license to practice medicine in the state where the laboratory is located
3. Be certified in anatomic and clinical or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology, or possess qualifications of those equivalent to those required for such certification
4. Have at least two years full-time experience directing or supervising clinical histocompatibility testing for solid organ transplantation

Pathway 2:

1. Have a doctoral degree in a medical, chemical, physical, biological, or clinical laboratory science from an accredited institution, or equivalent degree from another country
2. Have at least two years full-time, post-doctoral experience or four years pre-doctoral experience in immunology, histocompatibility, or immunogenetics, and two years post-doctoral training in directing or supervising clinical histocompatibility testing for solid organ transplantation
3. Certification as a Diplomate by the American Board of Histocompatibility and Immunogenetics, a high complexity laboratory director by the American Board of Bioanalysis, or a Diplomate by the American Board of Medical Laboratory Immunology. A professional who holds an earned doctoral degree but who does not hold one of these certifications may qualify if they were serving as director of an accredited laboratory performing human histocompatibility and immunogenetics testing before February 24, 2003

The MPSC will review, in consultation with the histocompatibility accrediting agencies, the credentials of professionals with foreign education or training and determine whether the foreign education or training is equivalent to that obtained in the United States.

- ~~1. The director must be an M.D., D.O., or Ph.D. in science, and must meet the qualifications of a director of high complexity testing according to federal CLIA requirements defined in 42CFR §493.1441. An M.D. or D.O. must also have a license to practice medicine in the state where the laboratory is located.~~
- ~~2. The director must have at least two years training or experience in histocompatibility testing in an OPTN approved training program or three years experience under an OPTN histocompatibility laboratory director.~~

Laboratory Director Candidate Requirements

Any professional being considered for the position of histocompatibility laboratory director who has not served in the role of laboratory director ~~1~~ prior to the date of application must also provide ~~one~~ all of the following:

- ~~■ Proof of certification by the American Board of Histocompatibility and Immunogenetics.~~
- ~~■ A portfolio of 50 cases, covered during the five years prior to the date of application that demonstrates the professional's analytical skills, ability to recognize and resolve testing and interpretation issues, and instances when the applicant made recommendations for additional testing or clinical care.~~
- ~~■ Proof of active laboratory interaction with transplant professionals.~~
- ~~■ A letter from the applicant that describes all experience in immunology and clinical histocompatibility testing, including A a summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks performed.~~
- ~~■ A current curriculum vitae or resume.~~
- ~~■ Demonstrated knowledge of the fundamentals of immunology, genetics, and histocompatibility testing and this knowledge should be reflected by participation in transplant or clinical laboratory professional conferences and or publications in peer-reviewed journals. An American Board of Histocompatibility and Immunogenetics Diplomate (ABHI D) certification is highly recommended.~~

~~If a portfolio is submitted, the portfolio may be also reviewed by an OPTN approved accrediting agency as part of their application process. The portfolio must include:~~

~~A log of 50 cases reviewed in each histocompatibility testing technique used in organ transplantation. Each case should include the date and a record identification number, along with a brief description and the testing technology used. A minimum of ten of these cases must include all the related worksheets and notes.~~

~~Cases that demonstrate the applicant's analytical skills, including the ability to recognize and resolve difficult testing and interpretation issues. These cases should also include instances when the applicant made recommendations for additional testing or clinical care.~~

~~In addition, laboratories must submit the following items as part of the application:~~

All documentation that verifies training and experience must be sent directly to the OPTN Contractor from all directors of histocompatibility laboratories where the training was obtained.

Laboratory Director Responsibilities

~~A histocompatibility laboratory director has the following responsibilities:~~

- ~~1. Ensure that the laboratory facilities are adequate and safe from physical, chemical, and biological hazards.~~
- ~~2. Provide consultation to clients on test results.~~
- ~~3. Be available to provide onsite, telephone or electronic consultation, as needed.~~
- ~~4. Ensure that an approved procedure manual is available to all technical personnel.~~
- ~~5. Supervise personnel to ensure that all duties are properly performed.~~
- ~~6. Ensure that a qualified General Supervisor is on site for all testing.~~
- ~~7. Ensure that there are current job descriptions and task assignments for all personnel.~~
- ~~8. Ensure that the performance of personnel is evaluated and documented at least semi-annually during the first year, and annually after that.~~
- ~~9. Be available to all staff members to address issues of concern.~~
- ~~10. Ensure that test systems provide quality results.~~
- ~~11. Ensure that the laboratory enrolls in appropriate proficiency testing programs.~~
- ~~12. Ensure that the laboratory has quality control and quality assurance programs.~~
- ~~13. Ensure that corrective action is taken if test systems deviate from performance specifications.~~
- ~~14. Ensure all required information is included on test reports.~~
- ~~15. Employ enough staff with appropriate training and experience.~~

B. Technical Supervisor Qualifications and Responsibilities

The technical supervisor must meet all the qualifications and fulfill the responsibilities for laboratory director as outlined in according to C.3.A Laboratory Director above and for technical supervisor as specified in according to 42 CFR 493. In addition, the supervisor must have at least two years of training in an OPTN approved training program or three years experience under a qualified OPTN histocompatibility laboratory director.

~~A technical supervisor has the following responsibilities:~~

- ~~1. Select appropriate test methodologies.~~
- ~~2. Establish performance criteria, validation, and quality control for all tests.~~
- ~~3. Ensure proficiency testing is performed properly and reviewed with staff.~~
- ~~4. Ensure that technical problems are resolved and corrective action is taken when appropriate.~~
- ~~5. Ensure that test reports are issued only when test systems are functioning properly.~~
- ~~6. Identify training needs and provide in service training as needed.~~
- ~~7. Evaluate staff competency and performance.~~

C. General Supervisor Qualifications

A general supervisor must meet the qualifications for a general supervisor according to Clinical Laboratory Improvement Amendments (CLIA) 42 CFR 493 and have at least three years of

experience in human histocompatibility or transplant immunology testing under the supervision of a qualified histocompatibility laboratory director or technical supervisor.

A general supervisor must have *one* of the following:

- ~~A bachelor's degree and at least three years experience in human histocompatibility or transplant immunology testing under the supervision of a qualified director or technical supervisor.~~
- ~~A related associate's degree or certificate, as required by CLIA, and five years of supervised experience if a bachelor's degree has not been earned. A Certified Histocompatibility Specialist (CHS ABHI) certification is strongly recommended.~~

D. Histocompatibility Technologist Qualifications

A histocompatibility technologist must meet the qualifications for a histocompatibility technologist according to ~~CLIA 42 CFR 493~~, and must have had one year of supervised experience in human histocompatibility or transplantation immunology testing, regardless of academic degree or other training and experience. ~~Either CHS ABHI or Certified Histocompatibility Technologist (CHT ABHI) certification is strongly recommended.~~

~~E. Histocompatibility Technician Qualifications~~

~~The term histocompatibility technician is applied to trainees and other laboratory personnel with less than one year's supervised experience in human histocompatibility or transplantation immunology testing, regardless of academic degree or other training and experience.~~

~~FE. Clinical Consultant Qualifications and Responsibilities~~

~~The clinical consultant must meet all the qualifications for laboratory director as outlined in C.3.A. *Laboratory Director* above and for clinical consultant according to ~~42 CFR 493~~. A qualified clinical consultant must be available to consult with and provide opinions about the appropriateness of histocompatibility or transplantation immunology tests ordered. The clinical consultant will interpret test results in consideration of patient diagnosis and management. Required qualifications are described in detail in the final version of the CLIA Regulations.~~

~~The clinical consultant must be an M.D., D.O. or Ph.D. in science. An M.D. or D.O. must also have a license to practice medicine in the state where the laboratory is located. A Ph.D. must be board certified by an accrediting agency accepted by the U.S. Department of Health and Human Services (HHS). The clinical consultant must also have experience in clinical transplantation.~~

~~A histocompatibility laboratory clinical consultant has the following responsibilities:~~

- ~~1. Ensure that test reports include all information required for test interpretation.~~
- ~~2. Ensure that consultation is available at all times to evaluate patient and donor compatibility for organ transplantation and that availability is communicated with laboratory clients.~~
- ~~3. Assist clients in test selection.~~
- ~~4. Assist clients in the interpretation of reported test results.~~
- ~~5. Report assessed risks associated with the degree and specificity of allosensitization and crossmatch results.~~

GF. Competency Testing and Continuing Education of Staff

The laboratory must test its staff for competency in performing test procedures. The testing must be done annually, and must be completed for each type of test the staff performs.

The director, technical supervisor, and all technical staff must participate in continuing education in histocompatibility, immunogenetics or clinical transplantation as required for accreditation by national, state, and local regulatory agencies.

C.4 Laboratory Coverage Plan

The histocompatibility laboratory director, in conjunction with the technical supervisor, general supervisor, and clinical consultant, must submit a detailed Laboratory Coverage Plan to the OPTN Contractor. The Laboratory Coverage Plan must describe how continuous coverage is provided by laboratory personnel.

The Laboratory Coverage Plan must address *all* of the following:

1. The laboratory must document that qualified key personnel are providing coverage at all times, including during the entire application process for changes in key personnel, regardless of the status of the application.
2. The laboratory must document that the laboratory director, technical supervisor, general supervisor, and clinical consultant are available to provide onsite, telephone, or electronic consultation to facilitate organ acceptance and transplantation.
3. The laboratory must document if any of the responsibilities designated to the laboratory director, technical supervisor, or clinical consultant will be performed by other laboratory staff. This documentation must include a list of the duties delegated, the times when the duties will be delegated, the qualifications of the staff that will perform the delegated duties, and the quality systems in place to ensure the duties are correctly performed.
4. If the laboratory is engaged in histocompatibility testing for deceased kidney, kidney-pancreas, or pancreas donor transplants, then the laboratory must document that key personnel and qualified testing personnel are available 24 hours a day, 7 days a week to provide laboratory coverage, unless a written explanation is provided that justifies the current level of coverage to the satisfaction of the MPSC.
5. If any key personnel serves more than one histocompatibility laboratory, then the Laboratory Coverage Plan must specify how continuous coverage will be provided at each histocompatibility laboratory served.

C.5 Changes in Key Laboratory Personnel

A. Change in Laboratory Director, Technical Supervisor, General Supervisor, or Clinical Consultant

When the histocompatibility laboratory is informed that the laboratory director, technical supervisor, general supervisor, or clinical consultant plans to leave or otherwise ends active participation in the laboratory, the laboratory must:

1. Notify the OPTN Contractor in writing within seven business days of when the laboratory becomes aware of the change in key personnel.
2. Submit a completed Personnel Change Application to the OPTN Contractor no less than 30 days before the end of the individual's active employment or change in status. The

Personnel Change Application must document that the new or acting laboratory director, technical supervisor, clinical consultant, and general supervisor meet the requirements of these Bylaws.

3. Submit an updated Laboratory Coverage Plan no less than 30 days before the date of departure that specifies how continuous coverage will be provided at the laboratory by all key personnel during and after the transition period to a new or acting laboratory director, technical supervisor, or clinical consultant.
4. If the histocompatibility laboratory receives less than 60 days notice of the key personnel change, then the laboratory must submit a completed Personnel Change Application and updated Laboratory Coverage Plan to the OPTN Contractor within 30 days of the date of departure.

A change in key personnel can be any of the following:

1. Departure of the director, technical supervisor, general supervisor, or clinical consultant.
2. Any key personnel unavailable to perform responsibilities for more than 30 days.
3. Reinstatement of the previously designated laboratory director, technical supervisor, general supervisor, or clinical consultant.
4. Any key personnel that accepts additional responsibilities for more than 30 days at another histocompatibility laboratory.

B. Failure to Notify the OPTN Contractor of Key Personnel Changes

Any histocompatibility laboratory that fails to inform the OPTN Contractor of a change in the laboratory director, technical supervisor, general supervisor, or clinical consultant or to submit the required Personnel Change Application within the periods specified above will be reviewed by the MPSC. The MPSC may impose a sanction, including, but not limited to, any of the following:

1. Notice of Uncontested Violation
2. Letter of Warning
3. Letter of Reprimand

Failure to inform the OPTN Contractor of changes in key personnel or to submit the required Personnel Change Application will result in a recommendation that the Board of Directors take appropriate adverse actions. Additionally, the Board of Directors may notify the Secretary of Health and Human Services (HHS) of the violation.

C.6 Histocompatibility Laboratory Policies and Procedures

~~The overall performance of a laboratory is the best indication of the quality of leadership, technical supervision, and clinical consultation being provided. The sections below describe the areas that are monitored and assessed by the OPTN Histocompatibility Committee or the accrediting agencies approved by the OPTN Contractor, and are used to measure the laboratory's performance.~~

A. ~~Criteria for Mandatory Performance Review of Director, Technical Supervisor or Clinical Consultant~~ a Histocompatibility Laboratory

The OPTN Contractor may review a histocompatibility laboratory if at any time it has *any* of the following performance indicators:

- Failure to comply with the requirements and regulations according to *Histocompatibility Laboratory Compliance*.
- Any of the following performance indicators on external proficiency testing:
 1. Less than 100% ~~successful~~ satisfactory performance in an ABO external proficiency testing program.
 2. For programs other than ABO, a less than 80% ~~successful~~ satisfactory performance on more than one in an external histocompatibility proficiency testing program within a year the previous twelve months.
- Accreditation revoked by any OPTN approved histocompatibility regulatory agency.
- A focused re-inspection by any OPTN approved histocompatibility regulatory agency.
- Restrictions imposed on the laboratory by any OPTN approved histocompatibility regulatory agency.
- One or more HLA typing or reporting errors on a deceased or living donor that results or could result in an incompatible transplant or the re-allocation of an organ to someone other than the intended recipient.

A histocompatibility laboratory will also be reviewed if it has *two or more* of the following performance indicators annually:

- ~~Error rates not within acceptable limits as defined by the laboratory quality assurance program.~~
- ~~Test completion times that are not within acceptable limits as defined by the laboratory quality assurance program.~~
- ~~Incomplete or missing proof of training, continuing education, and competency evaluations for all personnel as required by the OPTN Contractor.~~
- ~~Incomplete or missing records of all continuing education for testing staff, director, technical supervisor or clinical consultant.~~
- ~~Incomplete or missing documentation of annual director review of training and competency evaluation for all testing staff.~~
- Unresolved or repeat ~~D~~deficiencies identified during inspections conducted by OPTN approved regulatory agencies that are in violation of OPTN Contractor standards. When deficiencies are cited, laboratories must document that the deficiencies have been corrected.
- Complaints from transplant programs, OPOs, or other clients that have not been documented, investigated and resolved.
- Incomplete submission of all OPTN Contractor forms or forms not submitted within the 180 day time limit.
- ~~Significant discrepancies in deceased donor HLA typing results.~~

B. Information Required from Laboratories with Unsatisfactory Performance

The OPTN Contractor may request at any time from a histocompatibility laboratory with unsatisfactory performance *any* of the following:

- Letters from the affiliated transplant program physicians or coordinators or OPO staff describing the level of interaction and involvement of the director, technical supervisor and clinical consultant.
- Interviews with transplant program or OPO staff.
- Laboratory complaint log and documentation of resolutions from other healthcare professionals.
- Samples of laboratory reports that demonstrate the review of patient history, notation of unusual results, and recommendations for additional testing.
- Documentation of any professional extracurricular commitments, including estimates of time required, for laboratory director, technical supervisor, general supervisor, consultant and clinical consultant outside of the histocompatibility laboratory. ~~This may include other employment, current committee assignments, teaching commitments, students mentored, research commitments, grants, and all other patient care responsibilities.~~
- Quality Assessment and Performance Improvement records.
- Other material as requested.

C. Periodic Reviews

In order to determine compliance with the ~~OPTN Final Rule, 42 CFR Part 121, these Bylaws, and OPTN Policy requirements and regulations according to~~ C.1. Histocompatibility Laboratory Compliance, histocompatibility laboratory members will be reviewed, including on-site reviews, and must fulfill any requests for information from the OPTN Contractor. Failure to comply with these rules and requirements will be cause for corrective action as described in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

D. Regulatory Agency Adverse Actions

If any regulatory agency takes a final adverse action against a histocompatibility laboratory, the laboratory must notify the OPTN Contractor within 10 business days. The histocompatibility laboratory must also provide any documents relating to the final adverse action to the OPTN Contractor, along with the final determination of the regulatory agency.

E. Inactive Status

A histocompatibility laboratory that is voluntarily inactive, declared inactive or withdraws from membership will be ineligible and may not provide histocompatibility testing to any OPTN members.

C.7 Histocompatibility Laboratory Testing Requirements

~~The laboratory must perform tests only at the written or electronic request of an authorized person. The laboratory must ensure that the request includes:~~

- ~~1. The test subject's name or other unique identifier.~~
- ~~2. The name and address or other identification of the person who ordered the test.~~
- ~~3. Date of specimen collection.~~
- ~~4. Time of specimen collection, if significant to the test.~~
- ~~5. Tests ordered.~~

Oral requests for laboratory tests are permitted only if the laboratory obtains written authorization for testing within 30 days of the request.

A. Handling of Specimens

Histocompatibility laboratories must have available and follow written policies and procedures for specimen collection. Laboratories must follow these guidelines when handling and processing specimens for testing:

1. Each blood or tissue sample submitted for testing must be individually labeled with the name or other unique identification number for the individual and the date of collection.
2. The laboratory must maintain a system to ensure reliable specimen identification throughout collection, processing, testing and reporting. The laboratory must have criteria for specimen rejection and a process to ensure that rejected specimens are not tested.
3. If the laboratory draws blood samples, it must use a procedure that ensures minimal possibility of infection of the donor and contamination of the sample. All needles and syringes must be disposable.
4. Laboratory personnel must handle and transport all blood and tissue samples as though they could transmit infectious diseases.
5. The laboratory must confirm and document that anticoagulant and preservation solutions do not interfere with test performance. The anticoagulant or preservation solutions used must preserve the specimen integrity for the length of time and under the storage conditions the laboratory procedures require between sample collection and testing.

B. Handling of Reagents

The laboratory must properly label and store all reagents according to manufacturer's instructions or regulatory agency requirements to maintain optimal reactivity and specificity. Any deviation from a manufacturer's instructions for storage or any local storage guidelines must be explained by the laboratory.

Reagents, solutions, culture media, controls, calibrators, and other supplies must be labeled to indicate:

1. Identity including titer, strength or concentration.
2. Recommended storage requirements.
3. Preparation and expiration date, if any.

Laboratories must have a policy for quality control of each shipment and lot of reagents, and must adhere to the policy. Laboratories must ensure that:

1. Reagents from different lots of commercial kits are not mixed.
2. A process is in place to document the lot of reagents used in tests.
3. Each new shipment and lot of reagent is tested for quality and performance before test results using these reagents are reported.

C. Testing Standards

Laboratories must meet requirements for testing accuracy and completeness as established by the OPTN Board of Directors through the OPTN Contractor policy development process. These standards are established to ensure accurate and dependable histocompatibility testing consistent with current technology and the availability of reagents. These testing standards establish minimal criteria that all histocompatibility laboratories must meet.

The following testing standards have been prepared by the Histocompatibility Committee, and approved by the OPTN Board of Directors:

1. All procedures used in histocompatibility testing must conform to established protocols and be independently validated by the laboratory prior to use for clinical testing.
2. Each procedure must include quality assurance measures to monitor test performance.
3. Laboratories using its approval by the OPTN Contractor as proof of compliance to these standards must be current OPTN members.

The laboratory must perform at least twice a year a side by side comparison of any test results if it:

1. Performs the same test using different methods or instruments.
2. Performs the same test at multiple sites.

The laboratory must verify or establish for each testing method the performance requirements for accuracy, precision, analytical sensitivity and specificity, and the acceptable range of test results. The laboratory must have appropriate controls for each test to evaluate test performance and accuracy.

Proficiency Testing and Competency Evaluation

The laboratory must participate in at least one external proficiency testing program, if available, for each analyte to assess the laboratory's ability to accurately perform testing. If an external proficiency program is not available, the laboratory must use other procedures that meet CLIA requirements to validate performance at least semi-annually for each analyte. The laboratory must test proficiency samples in the same manner as that for testing clinical samples.

The laboratory must determine and document the cause for each unsatisfactory proficiency test result. Unsatisfactory performance can be *either* of the following:

- Less than 80 percent correct for an entire year for a specific analyte or within a single survey.
- Two out of three consecutive surveys graded as unsatisfactory.

If a laboratory's performance in an external proficiency testing program is unsatisfactory, the laboratory must participate in an enhanced proficiency testing program until given a satisfactory result.

D. Quality Assurance

Laboratories must have ongoing procedures for monitoring and evaluating its quality assurance program including procedures to evaluate corrective action taken. Laboratories must document

~~and assess problems identified during quality assurance reviews, discuss them with the staff, and take corrective action to prevent recurrences. Ineffective policies and procedures must be revised based on the outcome of the evaluation.~~

~~Laboratories must document all quality assurance activities including problems identified and corrective action taken, for a minimum of two years or the period required by local, state, federal and OPTN regulations.~~

~~If any error or discrepancies in test results are detected, the laboratory must promptly:~~

- ~~1. Notify the person ordering or using the test results.~~
- ~~2. Issue corrected results and reports.~~
- ~~3. Maintain copies of both the original and the corrected report for a minimum of two years or the period required by local, state and federal regulations.~~

~~Laboratories must also have a process for addressing any discrepancies in HLA typing results for the same individual as reported by different laboratories or at different times as described in *Policy 4.4: Resolving Discrepant Donor and Recipient HLA Typing Results.*~~

E. Procedure Manual

~~All laboratory procedures must be detailed in a procedure manual that is readily available and located where the procedures are performed. Manufacturer product inserts are not acceptable in place of a written procedure.~~

~~The Laboratory Director must review the procedure manual at least annually and document this review in the manual. The Director must approve any new procedures or changes in existing procedures and record this approval in the manual by signing and dating the manual when the changes are made.~~

F. Records and Test Reports

~~The laboratory must record the following information for each test performed:~~

- ~~1. Test requisition.~~
- ~~2. Subject identification number.~~
- ~~3. Accession number or unique identification of the specimen.~~
- ~~4. The tissue source of the specimen.~~
- ~~5. The dates of specimen collection and receipt.~~
- ~~6. The time of specimen receipt, if relevant.~~
- ~~7. The condition and disposal of the specimens that do not meet the criteria for acceptability.~~
- ~~8. The records and dates for specimen testing including the staff that performed the tests.~~
- ~~9. The tests, the type of specimen used for testing, test data and results.~~
- ~~10. Copies of preliminary and final reports, including dates.~~
- ~~11. Documented review of these by the Director or Technical Supervisor or other staff member who meets at least the minimum requirements of General Supervisor.~~

~~The laboratory must have record storage systems that enable it to report results in a timely, accurate, reliable and confidential manner. Records may be saved in computer files provided that back up files (either electronic or hard copies) are maintained to prevent loss of data.~~

~~The laboratory must ensure test subject confidentiality throughout the parts of the testing process that are under the laboratory's control.~~

~~All test reports must contain:~~

- ~~1. The name and address or other unique identifier of the laboratory or institution.~~
- ~~2. The date of sample collection.~~
- ~~3. The date of sample testing when pertinent to the interpretation of the test.~~
- ~~4. The name or unique identifier of each individual tested.~~
- ~~5. The date of the report.~~
- ~~6. The test results.~~
- ~~7. The units of measurement, if applicable.~~

~~Reports must be reviewed by the Director, or Technical Supervisor, or a staff member who meets at least the minimum requirements of a General Supervisor prior to release. All deceased donor HLA typing or crossmatch reports must be reviewed during the next day of regular laboratory operation.~~

Waiting List Data Verification

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

G. Service Requirements

~~All complaints and problems reported to any laboratory must be documented. The Laboratory must investigate complaints and take corrective action as necessary.~~

~~The laboratory must have a system in place to document problems that result from communications failures between the laboratory and the individual who orders tests or receives results.~~

~~The laboratory must, upon request, make available to clients a list of the test methods employed by the laboratory, a list of performance specifications for each method and a list of interfering factors that could affect interpretation of test results. Updates on testing information must be provided whenever changes occur that affect test results or the interpretation of test results.~~

HA. Subcontracting

~~A histocompatibility laboratory may use another laboratory as a subcontractor to perform testing. If a histocompatibility laboratory refers testing to another laboratory, the subcontracting laboratory must be *both*:~~

- ~~1. CLIA certified or unless exempt under federal law.~~

- ~~2. OPTN-approved, ASHI accredited, or CAP accredited for that testing.~~

~~The laboratory director must review and approve all test results returned from the subcontracting laboratory before release. For all testing performed by a subcontractor laboratory, the results must be returned to the referring laboratory and released only after the review and approval of the Director of the laboratory. The identity of the subcontracting laboratory and that portion of the testing for which it bears responsibility must be noted in the report of the histocompatibility laboratory. A copy of the testing laboratory's report must be kept on file by the laboratory receiving the results.~~

~~Proficiency testing must not be referred to another laboratory.~~

IB. Submission Requirements for New Laboratories

~~A new histocompatibility laboratory is defined as one that has not yet been approved as an OPTN histocompatibility laboratory member.~~

~~If a laboratory seeking OPTN membership has not previously been approved as an OPTN histocompatibility laboratory member, then the laboratory must submit procedures and test validation data for all categories and methods of testing performed to the OPTN Contractor upon request unless the testing is performed, without exception, by another approved laboratory. These materials must be submitted an OPTN-approved histocompatibility laboratory accrediting agency.~~

JC. Submission Requirements for Laboratories Using New Techniques

~~A new technique is defined as a major change or addition in testing methodology, including but not limited to:~~

- ~~■ The addition of molecular typing for class I or class II.~~
- ~~■ A major addition or change in the method used for molecular typing.~~
- ~~■ The addition of flow cytometry phenotyping or crossmatching.~~
- ~~■ A major addition or change in the method used for antibody identification or crossmatching.~~

~~Laboratories adding or changing test methods must submit all of the following to the OPTN Contractor:~~

- ~~1. Procedures and test validation data for the new tests and methods to an OPTN-approved histocompatibility laboratory accrediting agency, with a copy to the OPTN Histocompatibility Committee. The laboratory must also submit the~~
- ~~2. The curriculum vitae for the histocompatibility laboratory director documenting experience in the new testing, any related publications, and number of years of experience as the histocompatibility laboratory director of another laboratory approved for the new testing techniques~~

~~The curriculum vitae should include qualifications such as publications and years of experience as the Director of another laboratory approved for the new techniques. A summary of the histocompatibility laboratory director review of five twenty cases for each type of test, including~~

~~the testing and interpretation, may be submitted instead if the director does not have documented experience in the new testing techniques.~~

~~The following data are required when a histocompatibility laboratory begins using a new testing technique:~~

- ~~1. A summary of the internal validation data and the Director's summary of that data.~~
- ~~2. The step by step procedure including worksheets and list of reagents.~~
- ~~3. The clinical protocol that validates the use of the procedure.~~
- ~~4. The program for training staff in the new testing technique.~~
- ~~5. Documentation of the training of staff that will be performing the test and reviewing the test results.~~
- ~~6. Performance requirements, including accuracy, precision, sensitivity, specificity, reportable range of test results, normal values, and any other relevant characteristics.~~
- ~~7. Quality control procedures.~~
- ~~8. Calibration data for necessary equipment.~~
- ~~9. Quality assurance data.~~
- ~~10. Evidence that the laboratory is currently enrolled in a Proficiency Testing (PT) program for the test, if available.~~
- ~~11. Tests results including worksheets and sample reports with interpretation of 10 samples including at least one of each of the test materials that will be used by the laboratory. Laboratories without access to a particular type of sample may request that it be supplied by another OPTN accredited laboratory. Multiple samples from the same individual may not be used.~~
- ~~12. Externally blinded side by side validation tests using specimens from an OPTN accredited laboratory, or well characterized reference materials (ASHI repository or commercial panels) equivalent to those provided by the selected PT program, or a complete year of PT. A combination of these may also be used to meet this requirement.~~

~~Results from the reference laboratory and the validating laboratory must be reported independently.~~

OPTN Policies

4.2 Requirements for Laboratory Review of Reports

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

4.3 Requirements for Waiting List Data Verification

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

4.24 Resolving Discrepant Donor and Recipient HLA Typing Results

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

Informed Consent for Kidney Paired Donation (KPD)

Sponsoring Committee: **Kidney Transplantation
Committee**

Policy/Bylaws Affected: **13.3 (Informed Consent for Candidates);
13.4 (Informed Consent for KPD Donors);
13.6.A (Requirements for Match Run
Eligibility for Candidates); and 13.6.B
(Requirements for Match Run Eligibility for
Potential KPD Donors)**

Distributed for Public Comment: **September 2014**

Amended After Public Comment: **Yes**

Effective Date: **December 1, 2015**

Problem Statement

In November 2012, the OPTN/UNOS Board of Directors approved that we include several KPD guidelines in OPTN policy, but the Board withheld some sections, including KPD informed consent guidelines for candidates and donors, for further development.

Summary of Changes

The policy changes require transplant programs that register the paired candidates and donors to inform candidates and donors of the risks and benefits of participating in the KPD program and the logistics of the KPD program's matching process. These risks and benefits include prioritization information and consequences of shipping kidneys. Other changes include requiring additional informed consent elements for non-directed donors (NDDs) and bridge donors participating in any KPD program. These informed consent requirements are intended to be supplemental and additional to the requirements required in *Policy 14.3: Informed Consent Requirements*.

What Members Need to Do

All transplant hospitals participating in paired donation, either as a recovery hospital or a transplant hospital, must become familiar with the requirements in this proposal. Once policy is implemented on December 1, 2015, transplant hospitals must comply with the informed consent requirements in this proposal. Members will be expected to inform patients based on the proposed language. However, the proposed language will not change the current routine monitoring of OPTN members. Members are required to provide documentation as requested.

Affected Policy/Bylaw Language:

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

13.3 Informed Consent for KPD Candidates

Reserved

13.3.A Release of Protected Health Information

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

13.3.B Agreement to Accept a Shipped Kidney

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

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

13.3.C Additional Requirements for KPD Candidates

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

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

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

13.4 Informed Consent for ~~Potential~~KPD Donors

Reserved

13.4.A Release of Protected Health Information (PHI)

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

13.4.B General KPD Donor Informed Consent

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

13.4.C Additional Requirements for KPD Donors

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

1. The KPD program's matching requirements
2. KPD donors and candidates do not choose their match
3. A KPD donor or a candidate may decline a match
4. The possibility of helping more than one candidate receive a transplant
5. The possibility that the paired donor may have to wait to find a match
6. The possibility that the paired donor might have to wait longer to donate after a match has been identified because of logistical issues
7. The possibility that the paired candidate might not receive a transplant because of an unexpected issue with the matched donor's kidney found during or after surgery
8. The possibility that the paired donor's kidney might not be transplanted or the paired donor's matched candidate might not receive a transplant because of unexpected events
9. The KPD program's remedy for failed KPD exchanges and that the remedy does not include any additional priority for the paired candidate on the deceased donor waiting list
10. The possibility that the matched candidate's insurance might not cover travel costs if the paired donor travels to the matched recipient transplant hospital
11. The possibility that the paired donor's paired recipient and the paired donor's matched recipient might not have equal outcomes
12. The possibility of the paired donor's name appearing on the matched candidate's insurance estimation of benefits
13. That the donor's kidney could be lost in transport, and other potentially negative consequences related to shipping a kidney
14. That the paired donor may require additional testing, including multiple blood draws for crossmatching
15. The KPD program's rules for when members are allowed to facilitate meetings between matched donors and recipients

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

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

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

1. Participating in KPD
2. Donating to a candidate waiting for a deceased donor kidney according to *Policy 14.7.B: Placement of Non-directed Living Donor Kidneys*

3. Any other options available in the NDD's donation service area

13.4.E Additional Requirements for Bridge Donors

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

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

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

13.6 Matching within the OPTN KPD Program

13.6.A Requirements for Match Run Eligibility for Candidates

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

1. The candidate's transplant hospital must comply with Policies *5.5.A: Receiving and Reviewing Organ Offers* and *5.5.D: Blood Type Verification upon Receipt*
2. The candidate's transplant hospital must complete the informed consent process according to ~~KPD Operational Guidelines~~ *Policy 13.3: Informed Consent for KPD Candidates*
3. The candidate's transplant hospital must submit *all* the information for these required fields to the OPTN Contractor:
 - a. Candidate details, including *all* of the following:
 - Last name
 - First name
 - SSN
 - Date of birth
 - Gender
 - Ethnicity
 - ABO
 - Whether the candidate has signed an agreement to participate in the OPTN KPD program
 - Whether the candidate has signed a release of protected health information
 - Whether the candidate is a prior living donor

- KPD status: active, inactive or removed. A candidate must have current active status in the OPTN KPD program to be eligible for a match run.
- b. Candidate choices, including *all* of the following
- Whether the candidate would be willing to travel, and, if so, the transplant hospitals to which a candidate would be willing to travel or the distance the candidate is willing to travel
 - Whether the candidate is willing to accept a shipped kidney, and, if so, from which transplant hospitals the candidate would be willing to accept a shipped kidney
 - Minimum and maximum acceptable donor age
 - Minimum acceptable donor creatinine clearance or glomerular filtration rate (GFR)
 - Maximum acceptable donor BMI
 - Maximum acceptable systolic and diastolic blood pressure
 - Whether the candidate is willing to accept a hepatitis B core antibody positive KPD donor, a CMV positive KPD donor, and an EBV positive KPD donor
 - Whether the candidate would be willing to accept a left kidney, right kidney, or either kidney
- ~~4. The candidate must have current active status in the OPTN KPD program~~
- ~~4.~~ 5. The candidate must have at least one active and eligible potential KPD donor registered in the OPTN KPD program
- ~~5.~~ 6. The candidate's transplant hospital must submit a response for all previous match offers for the candidate in the OPTN KPD program, including reasons for refusing offers
- ~~6.~~ 7. The candidate must not be in a pending exchange in the OPTN KPD program

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

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

1. The transplant hospital registering the potential KPD donor must perform blood typing and subtyping as required by *Policy 14.4.A: Living Donor Blood type Determination* with the following modifications:
 - a. The transplant hospital registering the potential KPD donor must report the potential KPD donor's actual blood type to the OPTN Contractor
 - b. Someone, other than the person who reported the potential KPD donor's blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential KPD donor's actual blood type to the OPTN Contractor
 - c. The potential KPD donor is not eligible for a KPD match run until the transplant hospital verifies and reports two identical blood types
2. The transplant hospital registering the potential KPD donor must complete the informed consent process according to ~~KPD Operational Guidelines~~ *Policy 13.4: Informed Consent for KPD Donors.*
3. The transplant hospital registering the potential KPD donor must complete the medical evaluation process according to *Policy 14: Living Donation.*

4. The transplant hospital registering the potential KPD donor must submit the information for the required fields below to the OPTN Contractor:
 - a. Donor details, including *all* of the following:
 - Last name
 - First name
 - SSN
 - Date of birth
 - Gender
 - Ethnicity
 - ABO
 - Height and weight
 - Whether the potential KPD donor is a non-directed donor or a paired donor
 - If the potential KPD donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential KPD donor's relationship to the candidate
 - Whether the potential KPD donor has signed an agreement to participate in the OPTN KPD program
 - Whether the potential KPD donor has signed a release of protected health information
 - Whether the potential KPD donor has signed an informed consent as required in policy
 - Whether the potential KPD donor has undergone a medical evaluation as required in *Policy 14.4: Medical Evaluation Requirements for Living Donors*.
 - Whether the potential KPD donor has had all age appropriate cancer screenings as defined by the American Cancer Society
 - KPD status: active, inactive or removed. A donor must have current active status in the OPTN KPD program to be eligible for a match run.
 - b. Clinical information, including *all* of the following:
 - The number of anti-hypertensive medications the potential KPD donor is currently taking
 - Systolic and diastolic blood pressure with date (either 24-hour monitoring or two measurements)
 - Creatinine clearance or glomerular filtration rate (GFR), date, and method
 - Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results
 - c. Donor choices, including *all* of the following:
 - Whether the potential KPD donor would be willing to travel, and, if so, the transplant hospitals to which the potential KPD donor would be willing to travel or the distance the donor is willing to travel
 - Whether the potential KPD donor is willing to ship a kidney
 - Whether the potential KPD donor is willing to donate a left kidney, right kidney, or either kidney
 - Whether the KPD candidate-donor pair and the transplant hospital are willing to participate in a three-way exchange or a donor chain
 - Whether the potential KPD donor and the transplant hospital are willing for the potential KPD donor to be a bridge donor

- d. Donor HLA as defined in *Policy 13.5.C: Histocompatibility Requirements for KPD Donors*
- ~~5.~~ The potential KPD donor must have current active status in the OPTN KPD program
 5. ~~6.~~ The potential KPD donor must be paired to an active and eligible candidate registered in the OPTN KPD program or be a non-directed donor
 6. ~~7.~~ The transplant hospital registering the potential KPD donor must submit a response for all previous match offers for the potential KPD donor in the OPTN KPD program, including reasons for refusing offers
 7. ~~8.~~ The potential KPD donor must not be in a pending exchange in the OPTN KPD program

Convert KPD Contact Responsibilities and Donor Pre-Select Requirements from the OPTN/UNOS Kidney Paired Donation Pilot Program Operational Guidelines into OPTN Policy

Sponsoring Committee:	Kidney Transplantation Committee
Policy/Bylaws Affected:	Bylaws Appendix E.5 Kidney Transplant Programs that Perform Living Donor Recovery; and Policies 13.5.C (HLA Typing Requirements for OPTN KPD Donors), 13.7.E (Prioritization Points), 13.7.F (OPTN KPD Waiting Time Reinstatement), 13.9.B (Logistical Requirements), 13.10 (Crossmatching Protocol), 13.11 (Transportation of Kidneys), and 13.12 (Communication between KPD Donors and Recipients)
Distributed for Public Comment:	September 2015
Amended After Public Comment:	Yes
Effective Date:	September 1, 2015, except for Policy 13.11 (Receiving and Accepting Match Offers) which is effective pending programming

Problem Statement

The OPTN/UNOS Kidney Paired Donation Pilot Program (KPDPP) is transitioning from a pilot program to a permanent program. As such, the Kidney Committee and Board of Directors believe it is appropriate to continue transitioning sections of the operational guidelines into OPTN Policy. Including these sections in OPTN Policy is consistent with the principles of transparency and public participation that are hallmarks of the KPDPP and the OPTN/UNOS. We previously transitioned other sections of the operational guidelines to OPTN Policy in November 2012 and June 2014.

Summary of Changes

These policy changes aim to make the KPDPP's matching process more efficient, by ensuring that transplant hospitals respond to offers and perform exchange responsibilities in a timely fashion, and by requiring the pre-selection of donors for sensitized candidates in order to avoid futile match offers.

What Members Need to Do

Once the transition is implemented on September 1, 2015, any transplant programs participating in the KPDPP must pre-accept any potential donors shown for candidates with a CPRA greater than or equal to 90 percent to potentially receive an offer from that donor. Any donors that are not pre-accepted will be

treated as pre-refused. Candidates do not receive offers from pre-refused donors. Pre-refusals and pre-acceptances may be entered for candidates with a lower CPRA; while doing so is not mandatory, it will make the match process more efficient.

Every transplant program participating in the KPDPP must appoint a KPD contact and alternate, and report their contact information to UNOS. The deadlines established in *Policy 13.11: Receiving and Accepting KPD Match Offers* will be effective pending programming. The KPD contact must become familiar with all of the deadlines triggered by the receipt of a match offer. This ensures that exchanges in which their candidates or donors are participating do not terminate because of missed deadlines.

You will be expected to accurately report data based upon the proposed language. However, the proposed language will not change the way UNOS currently monitors members. Any data entered in UNetSM may be subject to OPTN review, and you must provide documentation, if we request it.

Affected Policy/Bylaw Language:

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

OPTN Bylaws

F. Kidney Paired Donation (KPD)

~~Members~~ Transplant hospitals that choose to participate in the OPTN KPD program must do *all* of the following:

1. Meet all the requirements of *Section E.5: Kidney Transplant Programs that Perform Living Donor Recovery* above.
2. Notify the OPTN Contractor in writing if the transplant hospital decides to participate in the OPTN KPD program. A transplant hospital must notify the OPTN Contractor in writing if it decides to quit its participation in the OPTN KPD program.
3. Provide to the OPTN Contractor a primary KPD contact that is available to facilitate the KPD match offer and transplant, and provide at least one alternate kidney paired donation KPD contact that is a member of the hospital's staff and can fulfill the responsibilities required by policy.
4. ~~Members that choose to participate in any OPTN kidney paired donation program must agree to follow the kidney paired donation program rules (Operational Guidelines). Potential violations may be forwarded by the Kidney Transplantation Committee to the MPSC for review.~~

The requirements for the OPTN KPD Program are described in detail in *OPTN Policy 13*.

OPTN Policies

13.5.C HLA Typing Requirements for OPTN KPD Donors

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

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

- HLA-C
- HLA-DR
- HLA-DR51
- HLA-DR52
- HLA-DR53
- HLA-DQA
- HLA-DQB
- HLA-DPB

13.7.E Donor Pre-Acceptance and Pre-Refusal

If an OPTN KPD candidate has a CPRA greater than or equal to 90%, then the candidate’s transplant hospital must pre-accept or pre-refuse potential donors. The OPTN KPD candidate will only be matched with donors that are pre-accepted. If a donor is not pre-accepted, the donor will automatically be treated as pre-refused and will not be matched with the candidate.

If an OPTN KPD candidate has a CPRA less than 90%, then the candidate’s transplant hospital has the option to pre-accept or pre-refuse potential donors. These candidates will automatically be matched with all potential donors, unless the candidate’s transplant hospital exercises the option to pre-refuse a potential donor.

13.7.EF Prioritization Points

All OPTN KPD matches receive 100 base points. KPD matches will receive additional points according to *Table 13-2: OPTN KPD Prioritization Points* when the OPTN Contractor identifies all possible matches and exchanges from the list of eligible KPD donors and candidates. The OPTN Contractor will then prioritize the set of exchanges with the highest total point value.

Table 13-2: OPTN KPD Prioritization Points

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

If the:	Then the match will receive:
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.FG OPTN KPD Waiting Time Reinstatement

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

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

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

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

13.9.B Logistical Requirements

In KPD donor chains in the OPTN KPD program, surgeries may or may not occur simultaneously. A KPD candidate must receive a kidney within 24 hours of the same day his paired KPD donor donates. A KPD candidate-donor pair will always have the option to have surgery on the same day. KPD donor surgeries must be scheduled to occur within 3 weeks of the day the paired candidate receives a transplant.

A chain must end with a donation to a KPD candidate on the deceased donor waiting list at the transplant hospital that entered the non-directed donor that started that chain or with a KPD bridge donor who will be included in a later match run. The transplant hospital that enters the NDD can choose whether the chain can end with a bridge donor or a donation to the deceased donor waitlist. The transplant hospital registering the potential KPD donor may refuse to allow the potential KPD donor to serve as a bridge donor at any point in the process.

13.10 OPTN KPD Crossmatching Protocol Requirements

The matched candidate's transplant hospital must do *all* of the following:

1. Perform a physical crossmatch between the matched candidate and the matched donor before the matched donor's recovery is scheduled.
2. Perform a final crossmatch prior to transplant.
3. Report all crossmatching results to the OPTN Contractor and the matched donor's transplant hospital.

If, at any time, the matched candidate's transplant hospital refuses a match offer due to an unacceptable positive crossmatch between the candidate and the matched donor, then the matched candidate is ineligible for subsequent match runs. The candidate will remain ineligible until *all* of the following are completed:

1. The matched candidate's physician or surgeon or their designee and the histocompatibility laboratory director or the director's designee review the unacceptable antigens reported for the candidate.
2. The matched candidate's transplant hospital reports to the OPTN Contractor that the review has occurred.

~~The paired donor's transplant hospital is responsible for arranging shipment of the paired KPD donor's blood sample to the matched candidate's transplant hospital or the laboratory specified by the matched candidate's transplant hospital.~~

The KPD candidate's transplant hospital is responsible for performing the crossmatch and reporting the results to the OPTN Contractor and the matched KPD donor's transplant hospital.

13.11 Receiving and Accepting KPD Match Offers

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

Table 13-3: Deadlines for Performing Responsibilities upon Receiving a KPD Match Offer

<u>The following members:</u>	<u>Must:</u>	<u>Within:</u>
<u>Each transplant hospital receiving a match offer</u>	<u>Report to the OPTN Contractor a preliminary response</u>	<u>2 business days of receiving the match offer.</u>
<u>The matched candidate's transplant hospital and the matched donor's transplant hospital</u>	<u>Agree in writing upon all of the following:</u> <ul style="list-style-type: none"> • <u>contents required in the crossmatch kit</u> • <u>instructions for the donor</u> • <u>address at which to send the completed blood samples</u> 	<u>4 business days of receiving the match offer.</u>
<u>The matched donor's transplant hospital</u>	<u>Report to the OPTN Contractor the agreed upon date of the crossmatch</u>	<u>4 business days of receiving the match offer.</u>

<u>The following members:</u>	<u>Must:</u>	<u>Within:</u>
<u>The matched donor's transplant hospital</u>	<p><u>Make all of the following matched donor's records accessible to the matched candidate's transplant hospital:</u></p> <ul style="list-style-type: none"> • <u>any serologic and nucleic acid testing (NAT) results that have not already been shared with the matched candidate's transplant hospital</u> • <u>whether the matched donor is increased risk according to the U.S Public Health Services (PHS) Guideline</u> • <u>additional records requested by the matched candidate's transplant hospital</u> 	<u>4 business days of receiving the match offer.</u>
<u>The matched candidate's transplant hospital</u>	<u>Report to the OPTN Contractor the results of the crossmatch</u>	<u>15 business days of receiving the match offer.</u>
<u>The matched candidate's transplant hospital</u>	<u>Review the matched donor's records and confirm acceptance or report a refusal of the match offer to the OPTN Contractor</u>	<u>15 business days of the match offer.</u>

If the matched candidate's and matched donor's transplant hospitals do not meet any of the deadlines above, then the exchange will be terminated unless a transplant hospital requests an extension. If a transplant hospital submits an extension request before the deadline, the exchange will not terminate until the resolution of the extension request or the deadline is reached, whichever comes last.

13.11.A Requesting a Deadline Extension for a KPD Exchange

The transplant hospital may request an extension for any of the deadlines in Table 13-3 by submitting a request in writing to the OPTN Contractor. This written request must include the reason for the request and the new requested deadline date. Upon receipt of the request for extension, the OPTN Contractor will notify all of the transplant hospitals in the exchange. Upon notification, the transplant hospitals in the exchange must respond to the request for extension within 2 business days. If all other transplant hospitals in the exchange agree to the extension, it will be granted. If any of the transplant hospitals in the exchange refuse the extension request, the extension will not be granted.

The transplant hospitals will have two business days to respond to the extension request. At the end of the first business day, the OPTN Contractor will send a second notification to any transplant hospital that has not yet responded. If any of the transplant hospitals fail to respond to the extension request at the end of the second business day, the extension will not be granted and the exchange will be terminated.

13.142 Transportation of Kidneys

For any KPD exchange, the recovery hospital is responsible for packaging, labeling, and transporting kidneys from donors according to *Policy 16.2: Organs Recovered by Living Donor Recovery Hospitals*.

In the OPTN KPD program, the recovery hospital must specify *both* of the following:

1. The location where the recovered kidney must be picked up for transport to the recipient's transplant hospital.
2. The name and telephone number of the person or company who will package and label the kidney.

The recipient's transplant hospital must document *both* of the following:

1. The location where the recovered kidney must be delivered.
2. The name and telephone number of the person or company who will be transporting the kidney from the time that the kidney is recovered until the kidney is delivered to the location specified by the KPD recipient's transplant hospital.

The recovery and recipient hospitals must complete this documentation, along with the date and time it was documented, before the potential KPD donor enters the operating room for the kidney recovery surgery and must maintain this documentation in the donor's medical record.

13.123 Communication between KPD Donors and Recipients

The following rules apply to communication between KPD donors and matched KPD recipients that participated in an OPTN KPD program exchange. These rules do not apply to meetings between potential KPD donors and paired KPD candidates.

Members can facilitate communication such as meetings or other correspondence between KPD donors and their matched recipients that participated in an OPTN KPD program exchange only if *all* of the following conditions are met:

1. All the KPD donors and recipients participating in the communication agree on the conditions of the meeting or correspondence.
2. The meeting or correspondence occurs after the donor kidney recovery and transplant surgeries have been completed.
3. The transplant hospital establishes and complies with a written protocol for when KPD donors and their matched recipients can communicate. This protocol must include, at a minimum, the timing of the meeting or correspondence and what staff must be involved.
4. ~~The~~ The transplant hospital complies with the written protocol for when KPD donors and recipients can communicate. The transplant hospital must maintain documentation of compliance in the KPD donor's or matched recipient's medical record.

Improve UNetSM Reporting of Aborted Procedures and Non-transplanted Organs

Sponsoring Committee:	Living Donor
Policy Affected:	18.1 (Data Submission Requirements) and 18.6 (Reporting of Living Donor Adverse Events)
Distributed for Public Comment:	January 2015
<u>Amended After Public Comment:</u>	Yes
<u>Effective Date:</u>	Pending implementation and notice to members

Problem Statement

Current policy does not specifically require members to report these two types of incidents in the UNetSM system:

1. Aborted procedures that occur after the potential donor receives anesthesia and before the living donor organ is recovered (i.e., the potential donor does not actually donate)
2. Procedures where the living donor organ is recovered but the organ is not transplanted into any recipient.

In both cases, we need to amend the Living Donor Feedback/Add Donor Form so members can report these events to the OPTN, and we need to generate appropriate living donor data submission forms for donors whose organs were recovered, but not transplanted into a recipient.

If an aborted living donor recovery procedure should occur, not amending the answer to the aborted procedure item post-operatively is problematic for the following reasons:

- The UNetSM System does not automatically update the feedback form
- Under current policy, aborted living donor recovery procedures may have been under-reported to the OPTN

Summary of Changes

We've changed policy requirements to specifically require reporting two types of incidents in the UNetSM system:

1. Aborted procedures that occur after the potential donor receives anesthesia and before the living donor organ is recovered (i.e., the potential donor does not actually donate)
2. Procedures where the living donor organ is recovered but the organ is not transplanted into any recipient.

What Members Need to Do

Recovery hospitals must amend the Living Donor Feedback form or contact UNOS to amend this form if one of your potential living donors received anesthesia but did not donate an organ or if the organ was recovered but not transplanted into any recipient. You must amend the form or contact UNOS within 72 hours after the donor organ recovery procedure.

Affected Policy/Bylaw Language:

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

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 accurate 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.

This policy does not apply to VCA-only donors or VCA information for donors and recipients; however, for VCA-only procurements, host OPOs must submit to the OPTN Contractor the deceased donor registration (DDR) within 30 days after the procurement date.

Table 18-1: Data Submission Requirements

<i>The following member:</i>	<i>Must submit the following materials to the OPTN Contractor:</i>	<i>Within:</i>	<i>For the following groups:</i>
Histocompatibility Laboratory	<i>Donor histocompatibility (DHS)</i>	30-days after the OPO submits the deceased donor registration	For each donor typed by the laboratory
Histocompatibility Laboratory	<i>Recipient histocompatibility (RHS)</i>	<i>Either of the following:</i> <ul style="list-style-type: none"> • 30-days after the transplant hospital removes the candidate from the waiting list because of transplant • 30-days after the transplant hospital submits the <i>recipient feedback</i> 	For each transplant recipient typed by the laboratory
OPOs, all	<i>Death notification records (DNR)</i>	30-days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	For all imminent neurological deaths and eligible deaths in its DSA
OPOs, all	<i>Monthly Donation Data Report: Reported Deaths</i>	30-days after the end of the month in which a donor hospital reports a death to the OPO	For all deaths reported by a hospital to the OPO

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For the following groups:
Allocating OPO	<i>Potential transplant recipient (PTR)</i>	30-days after the match run date by the OPO or the OPTN Contractor	For each deceased donor organ that is offered to a potential recipient
Host OPO	<i>Deceased donor feedback</i>	5 business days after the procurement date	
Host OPO	<i>Deceased donor registration (DDR)</i>	30 days after the <i>deceased donor feedback</i> form is submitted and disposition is reported for all organs	For all deceased donors and authorized but not recovered potential deceased donors
Recovery Hospitals	<i>Living donor feedback</i>	The time prior to donation surgery	For each potential living donor organ recovered at the hospital
<u>Recovery Hospital</u>	<u><i>Living Donor Feedback</i></u> <u>Members must amend the form or contact the OPTN Contractor to amend this form according to <i>Policy 18.6: Reporting of Liver Donor Adverse Events</i></u>	<u>72 hours after the donor organ recovery procedure</u>	<u>For any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient</u>
Recovery Hospitals	<i>Living donor registration (LDR)</i>	60 days after the Recovery Hospital submits the <i>living donor feedback</i> form	For each living donor organ recovered at the hospital
Recovery Hospitals	<i>Living donor follow-up (LDF)</i>	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

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

18.6 Reporting of Living Donor Adverse Events

18.6.A Reporting of Living Donor Adverse Events through the Improving Patient Safety Portal

Recovery hospitals must report these living donor adverse or unanticipated events through the Improving Patient Safety Portal or OPTN Contractor according to Table 18-4.

Table 18-4: Living Donor Adverse Event Reporting

The recovery hospital must report to the Patient Safety System when:	To the:	To the Improving Patient Safety Portal Within 72 hours after:
A living donor organ recovery procedure is aborted after the donor has begun to receive general anesthesia.	<u>Improving Patient Safety Portal and the OPTN Contractor</u>	The aborted organ recovery procedure
A living donor dies within 2 years after organ donation	<u>Improving Patient Safety Portal</u>	The program hospital becomes aware
A living liver donor is listed on the liver waitlist within 2 years after organ donation	<u>Improving Patient Safety Portal</u>	The program hospital becomes aware
A living kidney donor is listed on the kidney wait list or begins dialysis within 2 years after organ donation	<u>Improving Patient Safety Portal</u>	The program hospital becomes aware
A living donor organ is recovered but not transplanted <u>into any recipient</u>	<u>Improving Patient Safety Portal and the OPTN Contractor</u>	Organ recovery
A living donor organ is recovered and transplanted into someone other than the intended recipient	<u>Improving Patient Safety Portal</u>	Organ recovery

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

Membership and Personnel Requirements for Intestine Transplant Programs

Sponsoring Committee:	Liver and Intestinal Organ Transplantation Committee
Policy/Bylaws Affected:	Bylaw Appendix F, Membership and Personnel Requirements for Liver Transplant Programs and Intestine Transplant Programs
Distributed for Public Comment:	January 27, 2015
Amended After Public Comment:	No
Effective Date:	Pending implementation and notice to members

Problem Statement

Previously there were no OPTN/UNOS requirements for qualifying intestinal programs, or their associated physicians, and surgeons. Due to this lack of requirements, any transplant program that was approved to perform liver transplants could also perform intestinal transplants.

Summary of Changes

This bylaw defines a designated intestine transplant program and establishes minimum qualifications for primary intestine transplant surgeons and physicians. The intent is to set minimum standards where none previously existed, without compromising quality or restricting new program formation. The bylaw includes a full approval pathway and a conditional approval pathway for intestine transplant programs.

What Members Need to Do

All transplant hospitals with intestine programs with a current status of “Active, Approval Not Required” will receive an OPTN intestine transplant program application. The application will include a submission deadline. If your transplant hospital receives this packet, you will be asked to complete all requisite information to apply for an intestine transplant program and submit the application within 120 days.

If you receive this application but do not intend to apply for an intestine transplant program, you need to document this in writing and submit that documentation to UNOS.

If your transplant hospital does not receive an application but you wish to apply for an intestine transplant program, you should contact the UNOS Membership Analyst for your region to get an application and the necessary instructions once the application period is announced.

The Bylaws will be slated for implementation following the 120-day application submission period. If UNOS receives your application during the submission period, we will act on it before the Bylaws are implemented. If we receive your application after the deadline, we will process it in the order it is received, but we cannot guarantee that we will be able to process it before the

implementation date. We will alert you of the status of your application before the implementation date.

Once the Bylaws are implemented, if your transplant hospital does not have an approved intestine transplant program, but you have intestine or liver-intestine candidates on your waiting list, you must follow the patient notice and transition plan requirements described in OPTN Bylaws Appendix K (Transplant Program Inactivity, Withdrawal, and Termination).

Affected Policy/Bylaw Language:

Appendix F: Membership and Personnel Requirements for Liver Transplant Programs and Intestine Transplant Programs

F.1 Membership and Personnel Requirements for Liver Transplant Programs

F.42 Liver Program Director, Primary Liver Transplant Surgeon and Primary Liver Transplant Physician

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

F.7 Membership and Personnel Requirements for Intestine Transplant Programs

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval as a designated intestine transplant program.
- Completing a Personnel Change Application for a change in key personnel at a designated intestine transplant program.

All intestine transplant programs must also meet general membership requirements, which are described in Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs of these Bylaws.

For more information on the application and review process, see Appendix A: Membership Application and Review of these Bylaws.

F.8 Intestine Program Director, Primary Intestine Transplant Surgeon, and Primary Intestine Transplant Physician

An intestine transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a surgeon or physician who is a member of the transplant hospital staff.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below. The primary surgeon and primary physician, along with the program director, must submit a detailed Program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage Plan, see Appendix D, Section D.5.B: Surgeon and Physician Coverage of these Bylaws.

F.9 Primary Intestine Transplant Surgeon Requirements

A designated intestine transplant program must have a primary surgeon who meets all of the following requirements:

1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The surgeon must have documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing on the hospital's medical staff.
4. The surgeon must have current certification by the American Board of Surgery, the American Board of Osteopathic Surgery, or the foreign equivalent.

In addition, the primary transplant surgeon must have completed at least *one* of the training or experience pathways listed below:

- The primary intestine transplant surgeon full approval pathway, as described in *Section F.9.A* below.
- The primary intestine transplant surgeon conditional pathway, as described in *Section F.9.B* below.

A. Full Intestine Surgeon Approval Pathway

Surgeons can be fully approved as a primary intestine transplant surgeon by completing a formal transplant fellowship or by completing clinical experience at an intestine transplant program if *all* of the following conditions are met:

1. The surgeon performed 7 or more intestine transplants to include the isolated bowel and composite grafts, as primary surgeon or first assistant within the last 10 years. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
2. The surgeon performed 3 or more intestine procurements as primary surgeon or first assistant. These procurements must include selection and evaluation of the donor. These procurements must include 1 or more organ recovery that includes a liver. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
3. The surgeon has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years. This includes the management of patients with short bowel syndrome or intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
4. The training was completed at a hospital with a transplant training program approved by the American Society of Transplant Surgeons (ASTS) or accepted by the OPTN Contractor as described in *Section F.12 Approved Intestine Transplant Surgeon Fellowship Training Programs* that follows. Foreign training programs must be accepted as equivalent by the Membership and Professional Standards Committee (MPSC).
5. The following letters are submitted to the OPTN Contractor:
 - a. A letter from the qualified intestine transplant physician and surgeon who have been directly involved with the surgeon documenting the surgeon's experience and competence.
 - b. A letter of recommendation from the primary surgeon and transplant program director at the fellowship training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request

- additional recommendation letters from the primary surgeon, primary physician surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
- c. A letter from the surgeon that details the training and experience the surgeon gained in intestine transplantation.

B. Conditional Intestine Surgeon Approval Pathway

Surgeons can meet the requirements for conditional approval as primary intestine transplant surgeon through experience gained during or post-fellowship, if *all* of the following conditions are met:

1. The surgeon has performed at least 4 intestine transplants that include the isolated bowel and composite grafts and must perform 3 or more intestine transplants over the next 3 consecutive years as primary surgeon or first assistant at a designated intestine transplant program, or its foreign equivalent. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of intestine transplant candidates, transplants performed as primary surgeon or first assistant and post-operative management of intestine recipients.
2. The surgeon has performed at least 3 intestine procurements as primary surgeon or first assistant. These procurements must include at least 1 procurement of a graft that includes a liver, and selection and evaluation of the donor. This procedure must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years. This includes the management of patients with short bowel syndrome or intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
4. The surgeon develops a formal mentor relationship with a primary intestine transplant surgeon at another approved intestine transplant program. The mentor will discuss program requirements, patient and donor selection, recipient management, and be available for consultation as required until full approval conditions are all met.
5. The following letters are sent to the OPTN Contractor:
 - a. A letter from the director of the transplant program and chair of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct an intestine transplant program.
 - b. A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon, outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and other matters judged appropriate. The MPSC may request additional recommendation letters from the primary surgeon, primary physician, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
 - c. A letter from the surgeon that details the training and experience the surgeon gained in intestine transplantation as well as detailing the plan for obtaining full approval within the 3-year conditional approval period.
 - d. A letter of commitment from the surgeon's mentor supporting the detailed plan developed by the surgeon to obtain full approval.

F.10 Primary Intestine Transplant Physician Requirements

A designated intestine transplant program must have a primary physician who meets all the following requirements:

1. The physician must have an M.D., D.O., or the equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education, and that the physician is currently a member in good standing on the hospital's medical staff.
4. The physician must have current board certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.

In addition, the primary physician must have completed at least one of the training or experience pathways listed below:

- The primary intestine transplant physician full approval pathway, as described in Section F.10.A below.
- The primary intestine transplant physician conditional pathway, as described in Section F.10.B below.

Any physician who meets the criteria as a primary intestine transplant physician can function as the primary intestine transplant physician for a program that serves predominantly pediatric patients, if a pediatric gastroenterologist is also involved in the care of the transplant recipients.

A. Full Intestine Physician Approval Pathway

Physicians can meet the requirements for a primary intestine transplant physician during the physician's adult gastroenterology fellowship, pediatric gastroenterology fellowship, or through acquired clinical experience (including accumulated training during any fellowships) if all of the following conditions are met:

1. The physician has been directly involved within the last 10 years in the primary care of 7 or more newly transplanted intestine recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This clinical experience must be gained as the primary intestine transplant physician or under the direct supervision of a intestine transplant physician and in conjunction with an intestine transplant surgeon at a designated intestine transplant program. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
2. The physician has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years. This includes the management of patients with intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
3. The physician must have observed at least 1 isolated intestine transplant and at least 1 combined liver-intestine or multi-visceral transplant.

4. The following letters are submitted to the OPTN Contractor:
 - a. A letter from the transplant program director documenting the physician's experience and training.
 - b. A letter of recommendation from the primary physician and transplant program director at the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
 - c. A letter from the physician that details the training and experience the physician gained in intestine transplantation.

B. Conditional Intestine Physician Approval Pathway

Physicians can meet the requirements for approval as primary intestine transplant physician through a conditional approval pathway if *all* of the following conditions are met:

1. The physician has current board certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
2. The physician has been involved in the primary care of at least 4 newly transplanted intestine recipients, and has followed these patients for at least 3 months from the time of their transplant. Additionally, the physician must become involved in the care of 3 or more intestine recipients over the next 3 consecutive years. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
3. The physician has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years. This includes the management of patients with intestine failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
4. The physician has 12 months experience as the primary intestine transplant physician or under the direct supervision of a qualified intestine transplant physician along with an intestine transplant surgeon at a designated intestine transplant program, or the foreign equivalent. These 12 months of experience must be acquired within a 2-year period.
5. The physician develops a formal mentor relationship with a primary intestine transplant physician at another approved designated intestine transplant program. The mentor will discuss program requirements, patient and donor selection, recipient management, and be available for consultation as required.
6. The following letters are submitted to the OPTN Contractor:
 - a. A letter from the qualified intestine transplant physician and surgeon who were directly involved with the physician verifying that the physician has satisfactorily met the above requirements to become the primary transplant physician of an intestine transplant program.
 - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional

- recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
- c. A letter from the physician that details the training and experience the physician gained in intestine transplantation as well as a detailed plan for obtaining full approval.
 - d. A letter of commitment from the physician's mentor supporting the detailed plan developed by the physician to obtain full approval.

F.11 Conditional Intestine Program Approval

Either the primary surgeon or primary physician must qualify through one of the full approval pathways described above in sections F.9.A or F.10.A for the program to be eligible for conditional approval status. If either the primary surgeon or primary physician qualify through one of the conditional pathways described above in sections F.9.B or F.10.B, the program must meet the requirements as described below to obtain full approval:

- The transplant program is granted 36 months to fully comply with all membership requirements. This option is available to new programs as well as previously approved programs that experience a change in key personnel.
- The program must comply with all policies and procedures as required by the MPSC. This includes submitting reports describing the surgeon or physician's progress towards meeting the requirements, and any other conditions as requested by the MPSC to demonstrate ongoing quality and efficient patient care.
- During this 36-month period of conditional approval, the surgeon must be present at all intestine transplant surgeries.
- During this 36-month period, the physician must be directly involved in the primary care of all intestine patients, including new recipients.

Prior to the end of each year of conditional approval, the program must provide an annual report documenting at least one of the following:

- The designated surgeon has met or is making sufficient progress toward performing 3 or more intestine transplants
- The designated physician has met or is making sufficient progress toward the direct involvement in the primary care of 3 or more intestine transplant patients
- The program is making sufficient progress in employing a transplant surgeon or physician who meets this, as well as all other criteria, for a primary intestinal transplant surgeon or physician

Should the surgeon or physician meet the requirements before the conditional approval period ends, the program may submit a progress report and request a review by the MPSC.

A. Full Approval Following Conditional Approval

The conditional approval period begins on the first approval date granted to the application, whether it is interim approval granted by the MPSC subcommittee, the MPSC or approval granted by the full Board of Directors. The conditional approval period ends 36 months after the first approval date of the application.

The MPSC may consider on a case-by-case basis granting a 12-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements, but is unable to complete the requirements within the 36-month approval period.

Once the program has met the full approval requirements for both primary surgeon and primary physician, the program may petition the OPTN Contactor in writing for full approval.

B. Rejection of Conditional Approval

If the program is unable to demonstrate that it has a designated surgeon and physician on site who can fully meet the primary surgeon and primary physician requirements as described above at the end of the 36-month conditional approval period, it must stop performing intestine transplants and either:

- Inactivate the intestine transplant program for a period up to 12 months
- Withdraw the intestine transplant program until it can meet the requirements for full approval

The requirements for program inactivation and withdrawal are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

F.12 Approved Intestine Surgeon Transplant Fellowship Programs

Surgeons qualifying as primary transplant surgeon through a formal transplant fellowship must complete their training at a fellowship program approved by the MPSC. Any program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons is automatically accepted by the MPSC, as well as any program that meets *all* of the following criteria:

1. The program is at a hospital that transplants one or more organs, including intestines.
2. The program is at an institution that has a proven commitment to graduate medical education.
3. The program director is a board-certified surgeon who meets the OPTN Contractor requirements for primary intestine transplant surgeon.
4. The program is at a hospital that is affiliated with a histocompatibility laboratory that meets the OPTN Contractor requirements for histocompatibility laboratories.
5. The program is at a hospital that is affiliated with an organ procurement organization (OPO) that meets the OPTN Contractor requirements for OPOs.
6. The program performs at least 10 intestine transplants each year.
7. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.

Establishing a Quality Assessment and Performance Improvement Requirement for Transplant Hospitals and Organ Procurement Organizations

Sponsoring Committee:	Membership and Professional Standards Committee
Bylaws Affected:	Appendix B Membership Requirements for Organ Procurement Organizations and Appendix D Membership Requirements for Transplant Hospitals and Transplant Programs
Distributed for Public Comment:	September 2014
Amended After Public Comment:	Yes
Effective Date:	September 1, 2015

Problem Statement

The MPSC has noted that members having difficulty with compliance or performance often do not have well-developed quality assessment and performance improvement (QAPI) programs. Currently, OPTN Bylaws do not require members to establish and implement a QAPI program. Requiring members to develop and implement a comprehensive QAPI program should help them improve performance and remain in compliance with OPTN obligations.

Summary of Changes

A general requirement that Organ Procurement Organization and Transplant Hospital members develop, implement, and maintain a QAPI program has been added to the Bylaws. The Bylaws also require that these members document that their plan has been implemented.

What Members Need to Do

You should review your QAPI plans before the Bylaws effective date and maintain documentation of implementation. UNOS would only monitor the QAPI requirement in those instances where we have serious concerns about your ability to independently improve and maintain compliance with OPTN obligations; for example, if you repeatedly violate the same or similar policy or bylaw, or have prolonged periods of underperformance. Therefore, routine monitoring of QAPI plans through site surveys or other means will not be implemented.

Affected Bylaw Language:

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

Appendix B: Membership Requirements for Organ Procurement Organizations

B.3 Quality Assessment and Performance Improvement (QAPI) Requirement

- A. OPOs must develop, implement and maintain an ongoing, comprehensive and data-driven QAPI program designed to monitor and evaluate compliance with OPTN requirements and produce measurable process improvement initiatives.
- B. The OPO must document implementation of all elements of the QAPI plan.

B.34 Facilities and Services

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

**Appendix D:
Membership Requirements for Transplant Hospitals and Transplant Programs**

D.3 Quality Assessment and Performance Improvement (QAPI) Requirement

- A. Transplant hospitals must develop, implement and maintain an ongoing, comprehensive and data-driven QAPI program designed to monitor and evaluate compliance with OPTN requirements and produce measurable process improvement initiatives. The QAPI plan must incorporate all designated transplant programs at the transplant hospital.
- B. The hospital must document implementation of all elements of the QAPI plan.

D.34 Facilities and Resources

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

Reducing the Reporting Requirements for the Deceased Donor Registration (DDR) Form

Sponsoring Committee:	OPO Committee
Policy/Bylaws Affected:	Policy 1.2 (Definitions), Policy 18.1 (Data Submission Requirements)
Distributed for Public Comment:	September 2014
Amended After Public Comment:	Yes
Effective Date:	Pending Programming

Problem Statement

Policy 18.1 (Data Submission Requirements) requires all OPOs to complete the deceased donor registration (DDR) form for all *deceased donors* and *authorized but not recovered potential deceased donors*. Since the DDR was never intended to be used for “non-donors,” OPOs have inconsistently reported data on those potential donors that do not proceed to donation. The OPO Committee proposed that we remove the requirement to complete the DDR for non-donors from policy.

Summary of Changes

We removed the policy requirement to complete the DDR for “authorized but not recovered potential deceased donors.”

What Members Need to Do

You should be aware of the label change on the donor organ disposition form. We changed the “Referral Only:” question on the donor organ disposition to “Were any organs recovered:” If yes, you must complete disposition codes for all organs. Only disposition code 5 (recovered for transplant and not transplanted) and disposition code 6 (transplanted) for any organ will generate the DDR, which you must complete.

Affected Policy/Bylaw Language:

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

Policy 1.2 Definitions

Deceased donor

An individual from whom at least one organ is recovered for the purpose of transplantation after declaration of death.

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 accurate 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. Members are responsible for providing documentation upon request to verify the accuracy of all data that is submitted to the OPTN through the use of standardized forms.

This policy does not apply to VCA-only donors or VCA information for donors and recipients; however, for VCA-only procurements, Host OPOs must submit to the OPTN Contractor the Deceased donor registration (DDR) within 30 days after the procurement date.

Table 18-1: Data Submission Requirements

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For the following groups:
Host OPO	Deceased donor feedback <u>Donor organ disposition</u> (feedback)	5 business days after the procurement date	<u>Individuals, except living donors, from whom at least one organ is recovered</u>
Host OPO	Deceased donor registration (DDR)	30 days after the deceased donor feedback donor organ disposition (feedback) form is submitted and disposition is reported for all organs	For all deceased donors and authorized but not recovered potential deceased donors

Addressing Requirements in the HIV Organ Policy Equity Act

Sponsoring Committee:	OPO Committee
Policies Affected:	Policies 2.7.A (Exceptions to HIV Screening Requirement), 5.3.C (Liver Acceptance Criteria), 5.4.B (Order of Allocation), 5.4.F (Allocation to Candidates Not on the Match Run), 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors), 14.4.E (Living Donor Exclusion Criteria), 15.3 (Informed Consent of Transmissible Disease Risk), 15.4.A (Transplant Program Requirements), 15.6 (Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors), 16.7.B (Vessel Recovery, Transplant, and Storage), 16.7.C (Blood Type Verification Prior to Transplant of Deceased Donor Vessels), and 16.7.E (Blood Type Verification Prior to Transplant of Living Donor Vessels)
Distributed for Public Comment:	September 2014 and January 2015
Amended After Public Comment:	Yes
Effective Date:	Pending programming

Problem Statement

Current federal rules and OPTN policy prohibit recovering and transplanting organs from deceased donors who are human immunodeficiency virus (HIV) positive. The HIV Organ Policy Equity Act (HOPE Act), enacted on November 21, 2013, will allow us to develop and publish criteria for conducting research related to transplanting organs from HIV-positive donors into individuals who are infected with HIV before receiving the organ.

Summary of Changes

- Create an open variance for the allocation and transplantation of HIV+ organs into HIV+ recipients
- Establish specific requirements for OPOs and transplant hospitals to participate in the variance
- Require second verification of HIV+ candidates' willingness to participate in the study
- Create an exception to the exclusion criteria for living donors
- Prohibit storage of extra vessels from HIV+ donors

What Members Need to Do

Transplant hospitals must:

- Notify UNOS if you are participating in an IRB approved research protocol that meets the requirements in the Final Rule regarding the recovery and transplantation of HIV positive organs.

Documentation must include IRB approval that indicates the transplant hospital has met all the requirements outlined in the HOPE Act Safeguards and Research Criteria for Transplantation of Organs Infected with HIV. Note: The research criteria is currently out for public comment¹.

- Notify UNOS in writing if you are no longer participating in an IRB approved research protocol that meets the requirements in the OPTN Final Rule regarding the recovery and transplantation of organs from HIV positive individuals.
- Complete a two-person reporting and verification process in order for HIV positive candidates to appear on the match run
- Obtain specific informed consent before you transplant HIV positive organs

OPOs may:

- Allocate organs only after they determine if the potential deceased donor is HIV positive and the HIV positive candidate is willing to accept an HIV positive organ as part of a research protocol.

OPO and transplant hospital must also do *both* of the following when allocating HIV positive organs to HIV positive candidates who do not appear on the match run:

1. Verify that the potential recipient is registered as a HIV positive candidate at a transplant hospital that meets the requirements in *Policy 15.6.C Transplant Hospital Requirements for Transplantation of HIV Positive Organs*
2. Meet the requirements in *Policy 15.6: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors*.

Affected Policy/Bylaw Language:

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

2.7.A Exceptions to HIV Screening Requirement

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

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

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

In this case the receiving transplant hospital must:

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

5.3.C Liver Acceptance Criteria

The responsible transplant surgeon must determine the acceptable deceased donor weight for each of its liver candidates, and the determined acceptable weight must be reported to the OPTN Contractor.

Liver transplant programs may also specify additional liver acceptance criteria, including *any* of the following:

¹ <https://www.federalregister.gov/articles/2015/06/18/2015-15034/human-immunodeficiency-virus-hiv-organ-policy-equity-hope-act-safeguards-and-research-criteria-for>

1. The maximum number of mismatched antigens it will accept for any of its liver candidates
2. Minimal acceptance criteria for livers
3. If a blood type O candidate will accept a liver from a deceased donor with non-A₁ blood type
4. For status 1A or 1B candidates, if they will accept a liver from a deceased donor with any blood type
5. If a candidate with a Model for End-Stage Liver Disease (MELD) or Pediatric End Stage Liver Disease (PELD) score of at least 30 will accept a liver from a deceased donor with any blood type
6. If a candidate will accept a liver for other methods of hepatic support
7. If a candidate is willing to accept a segmental graft
8. If a candidate is willing to accept an HIV positive liver as part of an institutional review board approved research protocol that meets the requirement in the OPTN Final Rule

5.4.F Allocation to Candidates Not on the Match Run

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

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

1. The reason for transplanting an organ into a candidate who did not appear on the match run
2. The reason the candidate did not appear on the match run
3. Whether the transplant hospital is willing to accept a kidney from a deceased donor with a KDPI score greater than 85% or from a donation after circulatory death (DCD) donor, if applicable
4. Prior to transplant, the transplant hospital must verify the medical suitability between the deceased donor organ and recipient prior to transplant in at least, but not limited to, *all* the following areas according to organ type:
 - Blood type
 - Blood subtype, when used for allocation
 - Donor HLA and candidate's unacceptable antigens
 - Donor height
 - Donor weight
 - Infectious disease test results
 - For HIV positive deceased donor kidneys and livers, the OPO and transplant hospital must also do both of the following:
 1. Verify that the potential recipient is registered as a HIV positive candidate at a transplant hospital that meets the requirements in *Policy 15.6.C Transplant Hospital Requirements for Transplantation of HIV Positive Organs*
 2. Meet the requirements in *Policy 15.6: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors*.

The transplant hospital must maintain all related documentation.

14.4.E Living Donor Exclusion Criteria

Table 14-9: Living Donor Exclusion Criteria

<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Exclusion criteria for all Living Donors</p>	<p>Living donor recovery hospitals may exclude a donor with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation.</p> <p>Living donor recovery hospitals must exclude all donors who meet any of the following exclusion criteria:</p> <ul style="list-style-type: none"> • Is both less than 18 years old and mentally incapable of making an informed decision • HIV, <u>unless the requirements for a variance are met, according to <i>Policy 15.6: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors</i></u> • Active malignancy, or incompletely treated malignancy • High suspicion of donor coercion • High suspicion of illegal financial exchange between donor and recipient • Evidence of acute symptomatic infection (until resolved) • Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Additional Exclusion Criteria for Living Kidney Donors</p>	<p>Kidney recovery hospitals must exclude all donors who meet <i>any</i> of the following additional exclusion criteria:</p> <ul style="list-style-type: none"> • Uncontrollable hypertension or history of hypertension with evidence of end organ damage • Diabetes
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Additional Exclusion Criteria for Living Liver Donors</p>	<p>Liver recovery hospitals must exclude all donors who meet <i>any</i> of the following additional exclusion criteria:</p> <ul style="list-style-type: none"> • HCV RNA positive • HBsAg positive • Donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes • Expected donor remnant volume less than 30% of native liver volume • Prior living liver donor

15.3 Informed Consent of Transmissible Disease Risk

Transplant programs must obtain specific informed consent before transplant of any organ when *any* of the following occurs:

- The donor has a known medical condition that may, in the transplant hospital's medical judgment, be transmissible to the recipient, ~~including HIV, with the exception of HIV, which must be handled according to *Policy 2.7: HIV Screening of Potential Deceased Donors* or exclusionary criteria in *Table 14-2 (Requirements for Living Donor Kidney Medical Evaluations)*.~~

- The deceased donor meets the guidelines for an increased-risk of transmissible disease as specified in the *U.S. Public Health Services (PHS) Guideline*.
- When a hemodiluted specimen is used for deceased donor HIV, hepatitis B, or hepatitis C screening, according to *Policy 2.5: Hemodilution Assessment*.

Transplant programs must also inform potential candidates of the general risks of potential transmission of malignancies and disease from organ donors, including *all* of the following information:

1. Deceased donors are evaluated and screened as outlined in *Policy 2.3: Evaluating and Screening Potential Deceased Donors*.
2. Living Donors are only required to undergo screening for the diseases listed in *Policy 14.4: Medical Evaluation Requirements for Living Donors*.
3. That there is no comprehensive way to screen potential deceased and living donors for all transmissible diseases.
4. That transmissible diseases and malignancies may be identified after transplant.

The transplant program must do *both* of the following:

1. Explain these risks and obtain informed consent from the potential candidate or candidate's agent before transplant.
2. Document consent in the potential candidate's medical record.

15.4.A Transplant Program Requirements

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

1. Notify the institution that recovered the organ (OPO or living donor recovery hospital), without waiting for all medical documentation that may eventually become available. The transplant program must notify the living donor hospital or host OPO by phone and provide documentation as soon as possible but no later than 24 hours after learning of the event.
2. Report the event through the OPTN Improving Patient Safety Portal.

Any transplant program treating recipients that received organs from a donor who is the subject of a potential disease transmission report is responsible for *all* of the following:

1. Responding to host OPO, living donor recovery hospital, and OPTN patient safety staff requests for information regarding all recipients in a timely fashion and communicating updated information regarding recipient condition, test results, diagnosis, and plans for treatment and follow up.
2. Submitting copies of any relevant test results including cultures, ~~serologies~~ infectious disease testing results, imaging studies, or autopsy results to OPTN patient safety staff.
3. Notifying recipients involved in cases of confirmed disease transmissions and documenting this notification in the recipient medical record according to *15.3.A: Requirements for Identified Increased Risk of Transmissible Disease*.
4. If requested by the Ad Hoc Disease Transmission Advisory Committee, submission of a *Potential Disease Transmission Recipient Follow-Up Report* within 45 days of the initial date the potential transmission was reported.

OPTN patient safety staff may request additional information related to the recipient beyond 45 days, in an effort to determine the probability of donor-derived disease transmission, depending on the potentially transmitted disease or malignancy.

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

This variance applies to members participating in an institutional review board approved research protocol that meets the requirements in the OPTN Final Rule (including Health and Human Services (HHS) research criteria pertaining to transplantation of organs from HIV positive donors, as applicable) regarding the recovery of organs from donors that test positive for human immunodeficiency virus (HIV) and the transplantation of these organs into HIV positive recipients.

15.6.A Requirements for Allocating HIV Positive Deceased Donor Organs

In addition to the requirements of the OPTN Final Rule, the OPO may allocate organs only after determining the potential deceased donor is HIV positive and the HIV positive candidate is willing to accept an HIV positive organ as part of a research protocol. In the case of a directed donation and prior to transplant, the OPO must verify that the potential recipient is registered as a HIV positive candidate at a transplant hospital that meets the requirements in *Policy 15.6.C Transplant Hospital Requirements for Transplantation of HIV Positive Organs*.

15.6.B Requirements for Allocating HIV Positive Living Donor Organs

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

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

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

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

In order for an HIV positive candidate to appear on a match run for HIV positive donor kidneys or livers, the transplant hospital must complete a two-person reporting and verification process. This process must include two different individuals who each make an independent report to the OPTN Contractor that the candidate is willing to accept an HIV positive organ as part of a research protocol.

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

The OPTN Contractor may release to the public the names of members participating in this variance.

16.7.B Vessel Recovery, Transplant, and Storage

Transplant hospitals may not store for later use any extra vessels from donors who are HIV positive by antibody, antigen, or nucleic acid test (NAT), hepatitis C antibody positive (HCV), hepatitis C (HCV) NAT positive, or hepatitis B surface antigen positive (HBsAg), or hepatitis B (HBV) NAT positive. If the transplant hospital stores vessels and later uses the vessels for the intended recipient or another recipient, it must notify the OPTN Contractor.

16.7.C Blood Type Verification Prior to Transplant of Deceased Donor Vessels

The transplant hospital must verify the blood type, all serology infectious disease testing results, container contents, date of expiration, and the Donor ID of the vessels with the blood type and all serology infectious disease testing results of the recipient prior to transplant. These verifications must be documented and maintained in the recipient medical record.

16.7.E Blood Type Verification Prior to Transplant of Living Donor Vessels

Prior to transplant, the recovery hospital must verify *all* of the following:

1. The living donor's blood type
2. The living donor's blood subtype, if used for allocation
3. All serology infectious disease testing results
4. Container contents
5. Date of expiration
6. Donor ID

The transplant hospital must also verify the blood type and subtype of the intended recipient, if used for allocation, and all serology infectious disease testing results of the recipient prior to transplant. The documentation of these verifications must be maintained in the recipient medical record.

Allowing Collective Patient and Wait Time Transfers

Sponsoring Committee:	Operations and Safety
Policy/Bylaws Affected:	Policy 3.6.C (Waiting Time Transfers), Policy 3.8 (New: Collective Patient Transfers), Bylaw K.3.B (Notice to the Patients of Long-term Inactive Status), Bylaw K.4.B (Notice to the Patients), Bylaw K.6 (Transferred Candidates Waiting Time)
Distributed for Public Comment:	September 29, 2014
Amended After Public Comment:	Yes
Effective Date:	September 1, 2015

Problem Statement

Processing the transfer of large groups of patients to another program for an extended period has been challenging historically. A manual process requiring individual forms was not the safest or most efficient route to restore an opportunity for transplant. Transplant hospitals may now choose to use the collective transfer process, if needed. The new process involves submitting both an agreement between transferring and accepting program(s) and a plan for processing newly transferred patients. The accepting program will report to UNOS on the status of transferred patients until all evaluations are complete.

Summary of Changes

Transplant programs who face long-term inactivity, withdrawal of membership, or termination of membership should familiarize themselves with this transfer option.

Existing requirements outlined in the *OPTN Bylaws Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* still apply. This action will require existing patient notifications to have an additional element. Notice to patients must include language that prior to being listed as a candidate at an accepting program, the patient will be evaluated according to the accepting program's selection and listing criteria.

The collective patient and wait time transfer may be used in other circumstances if requested and approved by the OPTN.

What Members Need to Do

Transplant programs need to know that a collective transfer process is an option in certain circumstances. If your program chooses to use this process, then you must follow the requirements outlined.

Affected Policy/Bylaw Language:

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

3.6.C Individual Waiting Time Transfers

A candidate may transfer primary waiting time from one transplant hospital to another if it meets the requirements below:

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

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

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

3.8 Collective Patient Transfers

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

3.89 Removing Candidates from the Waiting List

OPTN Bylaws:

K.3.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. Prior to being registered as an active candidate at another transplant program, the accepting transplant program will complete an evaluation to determine suitability for registration.
5. 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.

K. 4. B. Notice to the Patients

When a transplant hospital intends to withdraw its designated transplant program status, or its designated transplant program status is terminated, it must provide written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently receiving care.

Written notice should be provided at least 30 days prior to the anticipated date of withdrawal or termination 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 following withdrawal or termination and include:

1. The reasons for loss of designated transplant program Status.
2. Explanation that although the patient is still on the waiting list, the candidate cannot receive an organ offer through this program.
3. Options for potential candidates, candidates, recipients, and living donors to transfer to another transplant program.
4. Prior to being registered as an active candidate at another transplant program, the accepting transplant program will complete an evaluation to determine suitability for registration.
5. The phone number of the program's administrative office that can help with transferring the candidate or potential candidate to another 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.

K.6 Transferred Candidates Waiting Time

To ensure equity in waiting times and ease the transfer of candidates from the waiting list, the candidates at programs that voluntarily inactivate, withdraw or lose designated transplant program status will:

1. Retain existing waiting time.
2. Continue to accrue waiting time according to their status on the waiting list at the time of the program's inactivation, withdrawal, or termination of designated transplant program status.

This total accrued waiting time can be transferred to the candidate's credit when the candidate is listed with a new transplant program.

The OPTN Contractor may collectively transfer patients from a transplant program, with a status of long-term inactive, withdrawal, or termination, and in other circumstances upon request to one or more active transplant programs.

The transferring transplant program must complete *all* of the following before a collective transfer:

1. All required patient notifications according to *Section K.3 Long-term Inactive Transplant*

Program Status or Section K.4 Withdrawal or Termination of Designated Transplant Program Status.

2. A written agreement with each accepting transplant program that includes all of the following:
 - a. Request for collective transfer of candidates' waiting times
 - b. List of patient names and identifiers to be transferred
 - c. Mutually agreed upon transfer date
 - d. Assurance of notification and patient consent to transfer according to Section K.5 Transition Plan during Long-term Inactivity, Termination, or Withdrawal
 - e. List of active candidates that the transferring program agrees to change to inactive status if requested by the accepting transplant program
 - f. Acknowledgement that all patient information and records available to the OPTN Contractor will be transferred without modification
 - g. Acknowledgement that the transplant program accepting the patients accepts responsibility for patient notification and management according to all applicable OPTN Policies and Bylaws

Each accepting transplant program must develop and implement a plan that includes all of the following:

1. Procedure and timeline for reviewing the status on each collectively transferred candidate and amending this status as appropriate until an evaluation is completed in accordance with the accepting program's selection and listing protocol.
2. If the transferred candidate's status is changed from active to inactive as part of the collective transfer agreement or part of implementing the accepting transplant program's plan, then the accepting transplant hospital must notify the candidate about the status change. The notification must include what the candidate must do to be considered for an active status at the accepting transplant program. The notification must be completed within 14 days after the collective transfer date or after the status change date if it occurs post-collective transfer as part of this plan.
3. Expected timeline for completing evaluations and subsequent waiting list status adjustments on collective transfer candidates according to the accepting program's selection and listing protocol.

Upon receipt of the written agreement and plan, the OPTN Contractor will review the information and provide an expected collective transfer completion date to all the transplant programs involved. After the collective transfer process has been completed, the OPTN Contractor will provide written notification to the transplant programs.

The accepting hospital must submit a progress report to the OPTN Contractor that contains an update on the evaluation status of each collective transfer candidate at day 90 following the collective transfer. The accepting hospital must submit this report within 14 days after day 90 following the collective transfer. Additional updates may be requested from the OPTN Contractor to monitor progress until all collective transfer candidates are evaluated and accepted on the waiting list by a transplant program or removed from the waiting list.

If the transferring transplant program no longer qualifies as a designated transplant program and does not complete the requirements according to Appendix K, the OPTN Contractor may approve and complete a collective transfer of candidates' registrations and waiting times if the accepting transplant program requests in writing to complete the transfer.

Modifying the Sterile Internal Vessels Label

Sponsoring Committee: Operations and Safety
Policy/Bylaws Affected: Policy 16.4.D (Internal Labeling of Vessels)
Distributed for Public Comment: January 2015
Amended After Public Comment: Yes
Effective Date: September 1, 2015

Problem Statement

Completing the sterile internal vessels label has been problematic and prone to error. Transplant professionals must complete fifteen data fields in a sterile field with a sterile pen on a two by four inch label that sometimes gets wet and runs. If pending results change, then the sterile internal vessels label and the hangtag polyplastic label may have discrepant results. Also, the sterile vessels label can only be updated using a sterile technique.

Summary of Changes

We've reduced the infectious disease information required on this label to critical data only. The critical information will include whether the vessels are from a donor with positive results for HIV, HBV (HBsAg), or HCV, including NAT results. Based on public comment feedback, the HBcAb (core antibody) results will be on a separate line. The last question will be whether the donor is an increased risk donor according to the PHS Guideline.

The hangtag poly-plastic label will not change and will still be required to have all infectious disease results.

INFECTIOUS DISEASE TEST RESULTS
 Vessels are from a donor:

1. With positive results (NAT included) for HIV, HBV (HBsAg) or HCV*
 YES NO PENDING

2. With positive results for HBcAb
 YES NO PENDING

3. At PHS Increased Risk for HIV, HBV, or HCV
 YES NO

What Members Need to Do

OPOs:
 You will need to stop using the current label and start using the new label. You need to train staff on how to complete the label properly. For question number one, it will be important to educate your staff that they can only check "No" if they have received all of the results and all of them are negative. If any result is still pending, they must check "Yes" or "Pending."

UNOS will not sell the labels from its online store. You will access a .pdf file of these labels from our website that you can print and sterilize or forward to a vendor to have the sterile labels printed.

Transplant hospitals:
 You need to be aware that the label is changing and understand how to interpret it. Use the source documents posted in DonorNet to check on pending results.

Affected Policy/Bylaw Language:

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

16.4.D Internal Labeling of Vessels

The rigid container holding the vessels and the outermost layer of the triple sterile barrier must each have a completed OPTN vessel label. The OPTN Contractor distributes a standardized labels

that must be used for this purpose. The labels must contain *all* of the following information according to Table 16-1 below:

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. Public Health Services (PHS) Guideline.~~
8. ~~That the vessel is for use in organ transplantation only~~

Table 16-1: Required Information on Internal Labels for Vessels

<u>This information must be included:</u>	<u>On the rigid container:</u>	<u>On the outermost layer of the triple sterile barrier:</u>
1. <u>Donor ID</u>	● —	● —
2. <u>Donor blood type</u>	● —	● —
3. <u>Donor blood subtype, if used for allocation</u>	● —	● —
4. <u>Recovery date</u>	● —	● —
5. <u>Description of the container contents</u>	● —	● —
6. <u>That the vessel is for use in organ transplantation only</u>	● —	● —
7. <u>All infectious disease testing results</u>		● —
8. <u>Whether the vessels are from a donor with a positive result (including NAT) for any of the following:</u> <ul style="list-style-type: none"> • <u>Human Immunodeficiency Virus (HIV), Hepatitis C virus (HCV), or Hepatitis B Virus (HBsAg or NAT)</u> • <u>Hepatitis B virus (HBcAb)</u> 	● —	
9. <u>Whether the vessels are from a donor that meets the increased risk for disease transmission criteria in the U.S. Public Health Service (PHS) Guideline</u>	● —	● —

Proposal to Modify ABO Determination, Reporting, and Verification Requirements

Sponsoring Committee:

Operations and Safety

Policy/Bylaws Affected:

Policies 1.2 (Definitions), 2.6 (Deceased Donor Blood Type Determination and Reporting), 2.6.A (Deceased Donor Blood Type Determination), 2.6.B (Deceased Donor Blood Subtype Determination), 2.6.C (Primary Reporting of Deceased Donor Blood Type and Subtype), 2.6.D. (Secondary Reporting of Deceased Donor Blood Type and Subtype), 2.15.B (New: Pre-Recovery Verification), 3.3 (Candidate Blood Type Determination and Reporting before Waiting List Registration), 3.3.A (Blood Type Determination before Registration on the Waiting List), 3.3.B (Secondary Reporting of Candidate Blood Type), 5.4.B (Order of Allocation), 5.5.A (Receiving and Reviewing Organ Offers), 5.6 (Blood Type Verification Upon Receipt), 5.7 (New: Pre-Transplant Verification), 5.7.A (New: Pre-Transplant Verification Prior to Organ Receipt), 5.7.B (New: Pre-Transplant Verification Upon Organ Receipt), 13.6.A (Requirements for Match Run Eligibility for Candidates), 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors), 14.4 (Medical Evaluation Requirements for Living Donors), 14.4.A (Living Donor Blood Type Determination), 14.4.Ai (Living Donor Blood Subtype Determination), 14.4.B (Living Donor Medical Evaluation Requirements) 14.5 (Registration and Blood Type Verification of Living Donors before Donation), 14.5.A (New: Living Donor Blood Type Determination), 14.5.B (New: Living Donor Blood Subtype Determination) 14.5.C (New: Reporting of Living Donor Blood Type and

Subtype), 14.7 (New: Living Donor Pre-Recovery Verification), 14.9 (New: Living Donor Organ Check-In), 14.10 (New: Living Donor Pre-Transplant Verification), 16.1 (Organs Not Requiring Transport), and 16.4.C (Internal Labeling of Blood and Tissue Typing Materials) Policy 16.4.D (Internal Labeling of Vessels)

Distributed for Public Comment: January 2015
Amended After Public Comment: Yes
Effective Date: February 1, 2016

Problem Statement

The transplant community has had many questions regarding ABO policies and their interpretation. The rules have been misunderstood or unclear resulting in compliance issues. In some areas, OPTN and CMS rules differ creating further confusion and requests to align the two where possible. ABO policies have been one of the most frequently cited issues from both the OPTN and CMS.

Accidental ABO incompatible transplants have occurred as well as surgeries where the wrong organ was given to the wrong person, or the organ laterality was confused. Also, there are reports of organ discards due to wrong ABO blood type or discovery of the wrong organ upon arrival.

Summary of Changes

Definitions:

Definitions for *intended incompatible*, *qualified health care professional*, and *source document* have been added to policies.

Determination of ABO blood type and subtype:

- The option for OPOs to draw blood samples at one time and send to two different labs has been removed.
- Living donor blood type determination must be completed prior to generation of the living donor ID. This is earlier in the process than prior to incision.
- OPOs, recovery hospitals, and transplant hospitals must have a process included in their written protocols for how to handle conflicting primary blood type results.

Reporting of ABO blood type and subtype:

Reporting of blood type must be based on both blood type determinations. The initial report and second user verification must be completed prior to the match run for deceased donors. This is earlier in the process than prior to incision.

For living donors, the above changes apply and the timing must be completed prior to registration UNOS using the Living Donor Feedback Form.

Reporting of all blood types and subtypes must be conducted by a qualified health care professional. A qualified health care professional must be defined by the organization (OPO, recovery hospital, or transplant hospital) in their individual protocol.

Match Run:

Policy has been changed to require re-execution of the match run versus the option to re-execute the match run when an organ has not been accepted on a match run and the transplant hospital updates data following notification by the OPO.

Verification (Pre-Surgical):

Adjustments and additions to pre-surgical verifications (some previously referred to as time-outs) in policies have been made. These include:

- Verification of donor ID, donor blood type and subtype (if used for allocation), and organ type (with laterality if applicable), for all deceased donors prior to incision completed by a qualified health care professional who is an OPO employee and the recovering surgeon.
- When the intended recipient is known, verification of the unique intended recipient identifier, intended recipient blood type, and donor and intended recipient are blood type compatible or intended incompatible by two qualified health care professionals, one of which must be an OPO staff member.
- Verification of specified data elements on all living donors, not just those within the same facility. The verification timing has been moved up to prior to administration of general anesthesia on the day of the recovery versus prior to leaving the OR. The elements to be verified are the living donor ID, organ type and laterality (if applicable), donor blood type and subtype (if used for ensuring transplant compatibility or allocation), intended recipient unique identifier, intended recipient blood type, that the donor and intended recipient are blood type compatible or intended incompatible, and that the correct donor organ has been identified for the correct intended recipient. The verification will be completed by the recovery surgeon and another licensed health care provider.
- An organ check-in process has been added for all organs received from outside facilities.
- An additional pre-transplant verification has been added if surgery starts prior to organ arrival. The elements to be verified include the expected donor ID, expected organ (and laterality if applicable), expected donor blood type and subtype (if used for allocation), recipient unique identifier, recipient blood type, and that the expected donor and recipient are blood type compatible (or intended incompatible).
- For all verifications, the policy specifies acceptable sources that can be used to verify each required data element.

Miscellaneous:

Policy has been modified to allow ABO to be labeled on additional red top blood tubes sent with the organ. This is not a requirement. The ABO blood type result may or may not be labeled on the tube.

What Members Need to Do

Definitions:

OPOs, recovery hospitals, and transplant hospitals need to familiarize themselves with definitions for *intended incompatible*, *qualified health care professional*, and *source document*.

Determination of ABO blood type and subtype:

OPOs need to ensure that two separate draws have been completed to determine deceased donor blood type. The option to draw blood at one time and send to two different labs has been removed. Historical blood type results can be used for one of the typings if source documentation of these results is available.

Recovery hospitals must complete living donor blood type determination prior to generation of the living donor ID.

OPOs, recovery hospitals, and transplant hospitals must develop and include a process in their written protocols for how they will handle conflicting primary blood type results.

Reporting of ABO blood type and subtype:

OPOs, recovery hospitals, and transplant hospitals must complete blood type reporting to UNOS based on at least two blood type determinations. The initial report and second user verification must be completed prior to the match run for deceased donors. For living donors, the above changes apply and the timing must be completed prior to registration with UNOS using the Living Donor Feedback Form.

A qualified health care professional must be used to report all blood types and subtypes. A qualified health care professional is defined by the OPO, recovery hospital, or transplant hospital in their individual protocol.

Match Run:

If an organ has not been accepted on a match run and the transplant hospital updates data following notification by the OPO, then the OPO must re-execute the match run prior to allocation.

Verification (Pre-Surgical):

OPOs must perform a verification of the donor ID; donor blood type and subtype (if used for allocation), and organ type (with laterality if applicable) to be recovered on all deceased donors prior to incision. This must be completed by an OPO staff person that is a qualified health care professional and the recovering surgeon.

When the intended recipient is known, the OPO must verify the intended recipient's unique identifier, intended recipient's blood type, and that the donor and intended recipient are blood type compatible or intended incompatible. This must be done using two qualified health care professionals, and one must be an OPO staff member.

Recovery hospitals must conduct a pre-recovery verification on all living donors prior to administration of general anesthesia on the day of the recovery. The verification must include the living donor ID, organ type and laterality (if applicable), donor blood type and subtype (if used for ensuring transplant compatibility or allocation), intended recipient unique identifier, intended recipient blood type, that the donor and intended recipient are blood type compatible or intended incompatible, and that the correct donor organ has been identified for the correct intended recipient. This must be done by the recovery surgeon and another licensed health care provider.

Transplant hospitals must check-in all organs received from outside facilities. The check-in must include confirmation that the external package donor ID and organ type (including laterality if applicable) were as expected.

Transplant hospitals must conduct an additional pre-transplant verification if surgery starts prior to organ arrival. This verification must include the expected donor ID, expected organ (and laterality if applicable), expected donor blood type and subtype (if used for allocation), recipient unique identifier, recipient blood type, and that the expected donor and recipient are blood type compatible (or intended incompatible).

OPOs, recovery hospitals, and transplant hospitals must use acceptable sources, as defined in the policies, to verify each data element.

Miscellaneous:

OPOs may or may not label additional red top blood tubes sent with the organ with the ABO blood type.

Affected Policy/Bylaw Language:

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

1.2 Definitions

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

Intended incompatible

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

Qualified health care professional

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

Source document

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

2.6 Deceased Donor Blood Type Determination and Reporting

~~The host OPOs must ensure that each deceased donor's blood type is accurately determined, report the blood type to the OPTN Contractor, and then verify that the correct blood type was reported.~~ develop and comply with a written protocol for blood type determination and reporting that includes all of the requirements below.

2.6.A Deceased Donor Blood Type Determination

~~The host OPO must ensure that each deceased donor's blood type is accurately determined by testing at least two donor blood samples prior to incision the match run. The host OPO must develop and comply with a written protocol to resolve conflicting primary blood type results. If the two samples are from the same blood draw, then the samples must be tested by two different laboratories.~~

Deceased donor blood samples must:

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

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

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

2.6.B Deceased Donor Blood Subtype Determination

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

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

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

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

<u>If the donor's primary blood type is:</u>	<u>Then subtyping is:</u>	<u>A second subtyping must be completed if the first subtype result is:</u>
<u>A</u>	<u>Required</u>	<u>Blood type A, non-A₁</u>
<u>AB</u>	<u>Optional</u>	<u>Blood type AB, non-A₁B</u>

Deceased donor blood samples for subtyping must:

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

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

For all blood type A donors, The the host OPO must document *either* that blood subtype determination tests have been completed to determine the deceased donor's blood subtype subtyping was completed or the reason it could not be completed.

2.6_C Primary Reporting of Deceased Donor Blood Type and Subtype

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

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

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

~~In order to verify that the correct blood type and subtype is reported to the OPTN Contractor, each OPO must establish and then implement a protocol for secondary reporting of blood type that is completed by someone:~~

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

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

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

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

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

The OPO must ~~maintain documentation~~ document that ~~secondary~~ reporting was completed using ~~both sub-typing according to the OPO's protocol and the above requirements.~~

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

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

2.15 Organ Procurement

2.15.A Conflicts of Interest

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

- The potential deceased donor's attending physician at the time of death
- The physician who declares the time of the potential deceased donor's death

2.15.B ~~Organ Procurement Procedures~~ Pre-Recovery Verification

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

The host OPO must conduct a verification prior to organ recovery according to *Table 2.1* below. Assistance using an OPTN-approved electronic method is permitted.

Table 2.1: Pre-Recovery Verification Requirements

<u>The host OPO must verify all of the following information:</u>	<u>Using at least one of these sources:</u>	<u>By the following individuals:</u>
<u>Donor ID</u>	<ul style="list-style-type: none"> <u>Donor's identification band</u> <u>OPTN computer system</u> 	<ol style="list-style-type: none"> <u>On-site recovering surgeon</u> <u>Qualified health care professional</u>
<u>Organ (and laterality, if applicable)</u>	<ul style="list-style-type: none"> <u>Donor medical record</u> <u>OPTN computer system</u> 	<ol style="list-style-type: none"> <u>On-site recovering surgeon</u> <u>Qualified health care professional</u>
<u>Donor blood type and subtype (if used for allocation)</u>	<ul style="list-style-type: none"> <u>Donor blood type and subtype source documents</u> 	<ol style="list-style-type: none"> <u>On-site recovering surgeon</u> <u>Qualified health care professional</u>

When the intended recipient is known prior to organ recovery, the host OPO must verify all of the additional information according to Table 2.2 below.

Table 2.2: Additional Pre-Recovery Verification Requirements When the Intended Recipient is Known Prior to Organ Recovery

<u>The host OPO must verify all of the following information:</u>	<u>Using at least one of these sources:</u>	<u>By the following individuals:</u>
<u>Intended recipient unique identifier</u>	<ul style="list-style-type: none"> <u>OPTN computer system</u> 	<u>Two qualified health care professionals</u>
<u>Intended recipient blood type</u>	<ul style="list-style-type: none"> <u>OPTN computer system</u> 	<u>Two qualified health care professionals</u>
<u>Donor and intended recipient are blood type compatible (or intended incompatible).</u>	<ul style="list-style-type: none"> <u>OPTN computer system</u> 	<u>Two qualified health care professionals</u>

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

2.15.BC Organ Procurement Procedures

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

3.3 Candidate Blood Type Determination and Reporting before Waiting List Registration

Transplant programs must determine and report each transplant candidate's actual blood type before registering them on the waiting list develop and comply with a written protocol for blood type determination and reporting that includes all of the requirements below.

3.3.A Candidate Blood Type Determination before Registration on the Waiting List

The Transplant transplant programs must determine ensure that each candidate's blood type is determined by testing at least two candidate blood samples prior to registration on the waiting list. The transplant program must develop and comply with a written protocol to resolve conflicting primary blood type results. Transplant programs must test at least two blood samples from two separate blood draws taken at two different times.

Candidate blood samples must:

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

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

3.3.B Secondary Reporting of Candidate Blood Type

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

~~Each transplant program must develop and comply with a written protocol for secondary reporting of blood type that is completed by someone:~~

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

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

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

~~The transplant program must maintain documentation of this verification document that reporting was completed according to the program's protocol and the above requirements.~~

5.4.B Order of Allocation

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

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.
3. OPOs must first offer organs to potential recipients in the order that the potential recipients appear on a match run.
4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update their candidates' data with the OPTN Contractor. The host OPO ~~may must run an updated re-execute the match run and to~~ allocate the organ ~~according to the updated candidate data.~~
5. If no transplant program within the DSA or through an approved regional sharing arrangement accepts the organ, the Organ Center will allocate an abdominal organ first regionally and then nationally, according to allocation Policies. The Organ Center will allocate

thoracic organs according to *Policy 6: Allocation of Hearts and Heart-Lungs* and *Policy 10: Allocation of Lungs*.

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

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

5.5 Receiving and Accepting Organ Offers

5.5.A Receiving and Reviewing Organ Offers

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

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

5.6 ~~Blood Type Verification upon Receipt~~ Organ Check-In

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

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

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

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

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

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

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

5.7 Released Organs Pre-Transplant Verification

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

5.7.A Pre-Transplant Verification Prior to Organ Receipt

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

1. Two licensed health care professionals must participate in the verification
2. The intended recipient must be present in the operating room
3. The verification must occur *either*:
 - a. Prior to induction of general anesthesia
 - b. Prior to incision if the patient has been receiving continuous sedation prior to arrival in the operating room
4. Transplant hospitals must use at least one of the acceptable sources during the pre-transplant verification prior to organ receipt to verify all of the following information in *Table 5.1* below. Assistance using an OPTN-approved electronic method is permitted.

Table 5.1: Pre-Transplant Verification Prior to Organ Receipt Requirements

<u>The transplant hospital must verify all of the following information:</u>	<u>Using at least <i>one</i> of these sources:</u>
<u>Expected donor ID</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>Recipient medical record</u>
<u>Expected organ (and laterality if applicable)</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>Recipient medical record</u>
<u>Expected donor blood type and subtype (if used for allocation)</u>	<ul style="list-style-type: none"> • <u>Donor blood type and subtype source documents</u> • <u>OPTN computer system</u>
<u>Recipient unique identifier</u>	<ul style="list-style-type: none"> • <u>Recipient identification band</u>
<u>Recipient blood type</u>	<ul style="list-style-type: none"> • <u>Recipient blood type and subtype source documents</u> • <u>Recipient medical record</u>
<u>Expected donor and recipient are blood type compatible (or intended incompatible).</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>Recipient medical record</u> • <u>Attestation following verification of donor and recipient blood types</u>

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

5.7.B Pre-Transplant Verification Upon Organ Receipt

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

1. The transplant surgeon and another licensed health care professional must participate in the verification
2. The intended recipient must be present in the operating room
3. The verification must occur after the organ arrives in the operating room, but prior to anastomosis of the first organ
4. Transplant hospitals must use at least one of the acceptable sources during the pre-transplant verification upon organ receipt to verify all of the following information in *Table 5.2* below. Assistance using an OPTN-approved electronic method is permitted

Table 5.2: Pre-Transplant Verification Upon Organ Receipt Requirements

<u>The transplant hospital must verify all of the following information:</u>	<u>Using at least one of these sources:</u>
<u>Donor ID</u>	<ul style="list-style-type: none"> • <u>External and internal organ package labels</u> • <u>Documentation with organ</u>
<u>Organ (and laterality if applicable)</u>	<ul style="list-style-type: none"> • <u>Organ received</u>
<u>Donor blood type and subtype (if used for allocation)</u>	<ul style="list-style-type: none"> • <u>Donor blood type and subtype source documents</u>
<u>Recipient unique identifier</u>	<ul style="list-style-type: none"> • <u>Recipient identification band</u>
<u>Recipient blood type</u>	<ul style="list-style-type: none"> • <u>Recipient blood type source documents</u> • <u>Recipient medical record</u>
<u>Donor and recipient are blood type compatible (or intended incompatible)</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>Recipient medical record</u> • <u>Attestation following verification of donor and recipient blood types</u>
<u>Correct donor organ has been identified for the correct recipient</u>	<ul style="list-style-type: none"> • <u>Recipient medical record</u> • <u>OPTN computer system</u>

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

5.78 Released Organs

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

13.6.A Requirements for Match Run Eligibility for Candidates

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

1. The candidate's transplant hospital must comply with *Policies 5.5.A: Receiving and Reviewing Organ Offers* and *5.5.D: Blood Type Verification upon Receipt*, *5.6: Organ Check-In*, and *5.7: Pre-Transplant Verification*.
2. The candidate's transplant hospital must complete the informed consent process according to KPD Operational Guidelines
3. The candidate's transplant hospital must submit *all* the information for these required fields to the OPTN Contractor:
 - a. Candidate details, including *all* of the following:
 - Last name
 - First name
 - SSN
 - Date of birth
 - Gender
 - Ethnicity
 - ABO
 - Whether the candidate has signed an agreement to participate in the OPTN KPD program

- Whether the candidate has signed a release of protected health information
 - Whether the candidate is a prior living donor
 - KPD status: active, inactive or removed
- b. Candidate choices, including *all* of the following
- Whether the candidate would be willing to travel, and, if so, the transplant hospitals to which a candidate would be willing to travel
 - Whether the candidate is willing to accept a shipped kidney, and, if so, from which transplant hospitals the candidate would be willing to accept a shipped kidney
 - Minimum and maximum acceptable donor age
 - Minimum acceptable donor creatinine clearance
 - Maximum acceptable donor BMI
 - Maximum acceptable systolic and diastolic blood pressure
 - Whether the candidate is willing to accept a hepatitis B core antibody positive KPD donor, a CMV positive KPD donor, and an EBV positive KPD donor
 - Whether the candidate would be willing to accept a left kidney, right kidney, or either kidney
- c. Candidate HLA as defined in *Policy 13.5.A: Histocompatibility Requirements for KPD Candidates*
4. The candidate must have current active status in the OPTN KPD program
 5. The candidate must have at least one active and eligible potential KPD donor registered in the OPTN KPD program
 6. The candidate's transplant hospital must submit a response for all previous match offers for the candidate in the OPTN KPD program
 7. The candidate must not be in a pending exchange in the OPTN KPD program

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

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

1. The transplant hospital registering the potential KPD donor must perform blood typing and subtyping as required by *Policy 44.4.A 14.5: Living Donor Blood ~~type~~ Type Determination and Reporting* with the following modifications:
 - a. The transplant hospital registering the potential KPD donor must report the potential KPD donor's ~~actual~~ blood type to the OPTN Contractor
 - b. ~~Someone, other than the person~~ A qualified health care professional, other than the qualified health care professional who initially reported the potential KPD donor's blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential KPD donor's ~~actual~~ blood type to the OPTN Contractor
 - c. The potential KPD donor is not eligible for a KPD match run until the transplant hospital verifies and reports two identical blood types
2. The transplant hospital registering the potential KPD donor must complete the informed consent process according to KPD Operational Guidelines
3. The transplant hospital registering the potential KPD donor must complete the medical evaluation process according to *Policy 14: Living Donation*
4. The transplant hospital registering the potential KPD donor must submit the information for the required fields below to the OPTN Contractor:

- a. Donor details, including *all* of the following:
 - Last name
 - First name
 - SSN
 - Date of birth
 - Gender
 - Ethnicity
 - ABO
 - Height and weight
 - Whether the potential KPD donor is a non-directed donor or a paired donor
 - If the potential KPD donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential KPD donor's relationship to the candidate
 - Whether the potential KPD donor has signed an agreement to participate in the OPTN KPD program
 - Whether the potential KPD donor has signed a release of protected health information
 - Whether the potential KPD donor has signed an informed consent as required in policy
 - Whether the potential KPD donor has undergone a medical evaluation as required in *Policy 14: Living Donation*
 - Whether the potential KPD donor has had all age appropriate cancer screenings as defined by the American Cancer Society
 - KPD status: active, inactive or removed
 - b. Clinical information, including *all* of the following:
 - The number of anti-hypertensive medications the potential KPD donor is currently taking
 - Systolic and diastolic blood pressure with date (either 24-hour monitoring or two measurements)
 - Creatinine clearance, date, and method
 - Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results
 - c. Donor choices, including *all* of the following:
 - Whether the potential KPD donor would be willing to travel, and, if so, the transplant hospitals to which the potential KPD donor would be willing to travel
 - Whether the potential KPD donor is willing to ship a kidney
 - Whether the potential KPD donor is willing to donate a left kidney, right kidney, or either kidney
 - Whether the KPD candidate-donor pair and the transplant hospital are willing to participate in a three-way exchange or a donor chain
 - Whether the potential KPD donor and the transplant hospital are willing for the potential KPD donor to be a bridge donor
 - d. Donor HLA as defined in *Policy 13.5.C: Histocompatibility Requirements for KPD Donors*
5. The potential KPD donor must have current active status in the OPTN KPD program
 6. The potential KPD donor must be paired to an active and eligible candidate registered in the OPTN KPD program or be a non-directed donor
 7. The transplant hospital registering the potential KPD donor must submit a response for all previous match offers for the potential KPD donor in the OPTN KPD program

- 8. The potential KPD donor must not be in a pending exchange in the OPTN KPD program

14.4 Medical Evaluation Requirements for Living Donors

~~14.4.A Living Donor Blood type Determination~~

~~The recovery hospital must ensure that blood typing of each living donor is performed on two separate occasions before the recovery. Two separate occasions are defined as two blood samples taken at different times, and sent to the same or different laboratories.~~

~~14.4.A.i Living Donor Blood Subtype Determination~~

~~The recovery hospital subtyping a living donor whose initial subtype test indicates the donor to be non A₁ (negative for A₁) or non A₁B (negative for A₁B), must ensure a second determination test is performed prior to living donation to assess the accuracy of the result. Blood samples for subtype testing must be taken on two separate occasions, defined as two samples taken at different times. Samples tested must not be taken after a blood transfusion. When the initial and second determination subtypings are the same result, the result can be used to determine transplant compatibility with the intended recipient or any other potential recipient. If the initial and second determination subtyping results are not the same, the donor must be allocated based on the primary blood type, A or AB.~~

14.4.BA Living Donor Medical Evaluation Requirements

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

Table 14-6: 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	<ol style="list-style-type: none"> 1. A personal history of significant medical conditions which include but are not limited to: <ol style="list-style-type: none"> a. Hypertension b. Diabetes c. Lung disease d. Heart disease e. Gastrointestinal disease f. Autoimmune disease g. Neurologic disease h. Genitourinary disease i. Hematologic disorders j. Bleeding or clotting disorders k. History of cancer including melanoma 2. History of infections 3. Active and past medications with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medication 4. Allergies 5. An evaluation for coronary artery disease

This evaluation must be completed:	Including evaluation for and assessment of this information:
General family history	<ul style="list-style-type: none"> • Coronary artery disease • Cancer
Social history	<ul style="list-style-type: none"> • Occupation, employment status, health insurance status, living arrangements, and social support • Smoking, alcohol and drug use and abuse • Psychiatric illness, depression, suicide attempts • Increased risk behavior as defined by the <i>U.S. Public Health Services (PHS) Guideline</i>
Physical Exam	<ul style="list-style-type: none"> • Height • Weight • BMI • Vital signs • Examination of all major organ systems
General laboratory and imaging tests	<ul style="list-style-type: none"> • Complete blood count (CBC) with platelet count • Blood type and subtype as specified in <i>Policy 14.4.A5: Living Donor Blood Type Determination and Reporting</i> and its subsections • Prothrombin Time (PT) or International Normalized Ratio (INR) • Partial Thromboplastin Time (PTT) • Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin) • HCG quantitative pregnancy test for premenopausal women without surgical sterilization • Chest X-Ray • Electrocardiogram (ECG)

This evaluation must be completed:	Including evaluation for and assessment of this information:
Transmissible disease screening	<p>Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using FDA-licensed, approved, or cleared tests. Testing must include <i>all</i> the following:</p> <ol style="list-style-type: none"> 1. CMV (Cytomegalovirus) antibody 2. EBV (Epstein Barr Virus) antibody 3. HIV antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination test as close as possible, but within 28 days prior to organ recovery 4. Hepatitis B surface antigen (HBsAg) testing as close as possible, but within 28 days prior to organ recovery 5. Hepatitis B core antibody (anti-HBc) testing as close as possible, but within 28 days prior to organ recovery 6. Hepatitis C antibody (anti-HCV) testing as close as possible, but within 28 days prior to organ recovery 7. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 8. Syphilis testing <p>If a living donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to <i>the U.S. Public Health Services (PHS) Guideline</i>, testing must also include HIV ribonucleic acid (RNA) by NAT or HIV antigen/antibody (Ag/Ab) combination test. This does not apply to donors whose only increased risk factor is receiving hemodialysis within the preceding 12 months, as they are at risk only for HCV according to the <i>U.S. Public Health Services (PHS) Guideline</i>.</p> <p>For tuberculosis (TB), living donor recovery hospitals must determine if the donor is at increased risk for this infection. If TB risk is suspected, testing must include screening for latent infection using <i>either</i>:</p> <ul style="list-style-type: none"> • Intradermal PPD • Interferon Gamma Release Assay (IGRA)
Endemic transmissible diseases	<p>Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation.</p>
Cancer screening	<p>Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) or the U.S. Preventive Services Task Force to screen for:</p> <ul style="list-style-type: none"> • Cervical cancer • Breast cancer • Prostate cancer • Colon cancer • Lung cancer

14.5 Registration and Blood Type Verification of Living Donors before Donation
Living Donor Blood Type Determination and Reporting

~~Recovery hospitals must use source documents from both an initial and second determination blood typings and subtypings (when used to determine transplant compatibility), to enter the living donor's blood type data on the *Living Donor Feedback Form*. Additionally, each living donor program must develop and comply with a protocol to verify that the living donor's blood type and type was correctly entered on the *Living Donor Feedback Form* with both the initial and second determination blood typing and subtyping source documents by an individual other than the person initially entering the donor's blood type data.~~

~~Recovery hospitals must document that each blood typing and subtyping entry was performed according to the program's protocol and must maintain this documentation.~~

~~This policy does not apply to VCA transplants.~~

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

14.5.A Living Donor Blood Type Determination

The recovery hospital must ensure that each living donor's blood type is determined by testing at least two donor blood samples prior to generation of the living donor ID. The recovery hospital must develop and comply with a written protocol to resolve conflicting primary blood type results.

Living donor blood samples must:

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

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

14.5.B Living Donor Blood Subtype Determination

Subtyping is optional for living donors.

If the recovery hospital chooses to subtype *and* pre-red blood cell transfusion samples are available, then subtyping must be completed according to *Table 14-2*.

Table 14-2: Subtyping Requirements by First Subtype Result

<u>If the donor's primary blood type is:</u>	<u>A second subtyping must be completed if the first subtype result is:</u>
<u>A</u>	<u>Blood type A, non-A₁</u>
<u>AB</u>	<u>Blood type AB, non-A₁B</u>

Living donor blood samples for subtyping must:

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

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

If subtype is determined and reported, the recovery hospital must document that subtyping was conducted according to the above requirements.

14.5.C Reporting of Living Donor Blood Type and Subtype

The recovery hospital must report and verify the living donor blood type prior to registration with the OPTN Contractor using the *Living Donor Feedback Form* as required below:

1. Two different qualified health care professionals, as defined in the recovery hospital's protocol, must each make an independent report to the OPTN Contractor for blood type. For VCA recoveries, the blood type verification and reporting must be recorded in the living donor's medical record.
2. If blood subtype is used for ensuring transplant compatibility or allocation, a qualified health care professional must report blood subtype to the OPTN Contractor. This report must be verified by a different qualified health care professional according to the recovery hospital's protocol. For VCA recoveries, the blood subtype verification and reporting must be recorded in the living donor's medical record.
3. Both qualified health care professionals must use all blood type and subtype determination source documents to verify they:
 - a. Contain blood type and subtype (if used for ensuring transplant compatibility or allocation) results for the donor
 - b. Indicate the same blood type and subtype (if used for ensuring transplant compatibility or allocation) on the two test results
 - c. Match the result reported to the OPTN Contractor or VCA donor medical record

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

14.7 Living Donor Pre-Recovery Verification

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

The recovery hospital must conduct a pre-recovery verification that meets *all* of the following requirements:

1. The recovery surgeon and another licensed health care professional must participate in the verification.
2. The verification must occur prior to the induction of general anesthesia on the day of the living donor recovery.
3. Recovery hospitals must use at least one of the acceptable sources during the pre-recovery verification to verify all of the following information in *Table 14.3* below. Assistance using an OPTN approved electronic method is permitted.

Table 14.3: Pre-Recovery Verification Requirements

<u>The recovery hospital must verify <i>all</i> of the following information:</u>	<u>Using at least <i>one</i> of these sources:</u>
<u>Donor ID</u>	<ul style="list-style-type: none"> • <u>Donor identification band</u>
<u>Organ type and laterality (if applicable)</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u>

<u>The recovery hospital must verify <i>all</i> of the following information:</u>	<u>Using at least <i>one</i> of these sources:</u>
<u>Donor blood type and subtype (if used for ensuring transplant compatibility or allocation)</u>	<ul style="list-style-type: none"> • <u>Donor blood type and subtype source documents</u>
<u>Intended recipient unique identifier</u>	<ul style="list-style-type: none"> • <u>Recipient medical record</u> • <u>OPTN computer system</u>
<u>Intended recipient blood type</u>	<ul style="list-style-type: none"> • <u>Recipient medical record</u> • <u>OPTN computer system</u>
<u>Donor and intended recipient are blood type compatible (or intended incompatible).</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>Recipient medical record</u> • <u>Attestation following verification of donor and recipient blood types</u>
<u>Correct donor organ has been identified for the correct intended recipient</u>	<ul style="list-style-type: none"> • <u>Donor medical record</u> • <u>OPTN computer system</u>

The recovery hospital must document that the verification was completed according to the hospital's protocol and the above requirements.

14.78 Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials

14.9 Living Donor Organ Check-In

Transplant hospitals must perform organ check-ins as required by *Policy 5.6: Organ Check-In*.

14.10 Living Donor Pre-Transplant Verification

Transplant hospitals must perform pre-transplant verifications as required by *Policy 5.7: Pre-Transplant Verification*.

14.8-11 Reporting Requirements

16.1 ~~Organs Not Requiring Transport~~

~~The transplant hospital and host OPO (if applicable) must develop and follow a protocol to ensure that the correct living or deceased donor organ is transplanted into the correct recipient when either of the following occurs:~~

- ~~• Organs are recovered from a deceased donor and remain in the same operating suite as the intended recipient~~
- ~~• Organs are recovered from a living donor and remain in the same facility as the intended recipient~~

~~Time-outs must occur:~~

- ~~1. Before the organ leaves the deceased or living donor operating room~~
- ~~2. Again when the organ arrives at the potential recipient's operating room~~

~~During these time outs and before the transplant occurs, the transplant hospital must confirm and document that a member of the transplant team identified the correct organ for the correct potential recipient prior to transplant according to *Policy 5.6: Blood Type Verification upon Receipt*.~~

16.4.C Internal Labeling of Blood and Tissue Typing Materials

Each separate specimen container of blood or tissue typing material must have a label that will

remain secured to the container under normal conditions of transport. The label must include the donor ID and at least *one* of the following identifiers:

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

Additionally each specimen should be labeled with *both* of the following:

1. The date and time the sample was procured
2. The type of tissue

The donor blood type and subtype, if used for allocation, should be included on tissue typing material ~~but must not be included on~~ and blood samples if known. If the donor ID or blood type is not available during the preliminary evaluation of a donor, a locally assigned unique ID and one other identifier for the transportation of initial screening specimens may be used. The OPO must document in the OPO donor record all unique identifiers used to label tissue typing specimens.

Clarify Policy Language and Process for Individual Wait Time Transfer

Sponsoring Committee:	Patient Affairs Committee
Policy/Bylaws Affected:	Policy 3.6.C (Waiting Time Transfers)
Distributed for Public Comment:	January 2015
Amended After Public Comment:	Yes
Effective Date:	September 1, 2015

Problem Statement

Current policy does not completely describe all of the situations in which candidates request to transfer primary waiting time from one transplant program to another. It also does not provide waiting time calculations for various transfer scenarios, including transfer between two current registrations and transfer from a removed registration.

Summary of Changes

Policy will now describe the individual waiting time transfer process in greater detail. This process is initiated when the program submits the Wait Time Transfer form that the candidate has signed. This form indicates whether the candidate chooses to have multiple registrations. If the candidate chooses to have multiple registrations, then UNOS will exchange the primary qualifying date and accrued waiting time from the earlier program to the new program. If the candidate does not choose to have multiple registrations, then UNOS will exchange the primary qualifying date and accrued waiting time from the earlier program to the new program and remove the candidate from the earlier program's waiting list.

Policy will now provide guidance on how to calculate waiting time in various transfer scenarios. If a candidate is transferring time between two current registrations and chooses to be multiply-listed, their time should be exchanged between the two programs. Otherwise, any time accrued before registering at the new program will be transferred. Time accrued concurrently is only counted once.

A candidate may also transfer time from a removed registration. In this instance, it does not matter if the time accrued during the earlier registration is less than time accrued at the new registration; any amount of time gained before they are removed from the waiting list and registered at the newer program may be transferred. However, the interval of time in between registrations, commonly referred to as "gap time," is ineligible for transfer.

What Members Need to Do

This policy clarifies, but does not significantly change, the process for waiting list transfer. The only new requirement is that the program requesting the transfer must notify the candidate of the outcome of the request within 10 business days of receiving notification from UNOS, and document that the notification occurred.

Affected Policy/Bylaw Language:

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

3.6.C Waiting Time Transfers

A candidate may transfer primary waiting time from one transplant ~~hospital program~~ to another if ~~it meets all of the following requirements are met below:~~

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

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

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

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

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

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

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

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

Definition of Pancreas Graft Failure

Sponsoring Committee:	Pancreas Transplantation
Policy/Bylaws Affected:	Policies 1.2 Definitions, 3.6 Waiting Time
Distributed for Public Comment:	September 29th, 2014
Amended After Public Comment:	No
Effective Date:	Upon implementation and notice to members

Problem Statement

Currently, there is no specific definition for pancreas graft failure in OPTN Policy. Consequently, transplant programs report graft failure at varying degrees. This variability limits the OPTN's ability to analyze and compare pancreas programs' outcomes. This proposal establishes a definition within policy that will help transplant professionals identify when pancreas allograft failure has occurred, and explain how these professionals should document pancreas graft failure events.

Summary of Changes

We'll establish policy for when a pancreas graft has failed (modifications to Policy 1.2: *Definitions*), which will streamline TIEDI help documentation about how professionals should document pancreas graft failure, and we'll update the graft status section in the OPTN Pancreas and Kidney Pancreas Transplant Recipient Registration and Transplant Recipient Follow-Up Forms ("OPTN pancreas forms").

What Members Need to Do

Transplant hospitals should become familiar with the new policy definition for pancreas graft failure, be aware of the changes to the pancreas data collection forms, and understand how the two changes interact. You also need to understand what constitutes a pancreas graft failure, and know how to fill out the graft status section of the pancreas OPTN data collection forms. You will be expected to accurately report graft failure based upon the proposed language.

You should also be aware of additional fields in the pancreas data collection forms. You will be required to complete these additional fields when filling out your forms.

Affected Policy/Bylaw Language:

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

1.2 Definitions

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

Graft failure

For all organs except pancreas, graft failure ~~o~~Occurs when any of the following occurs:

- ~~a~~ A recipient's transplanted organ is removed,
- ~~a~~ A recipient dies,
- ~~or a~~ A recipient is placed on a chronic allograft support system.

Pancreas graft failure occurs when any of the following occurs:

- A recipient's transplanted pancreas is removed
- A recipient re-registers for a pancreas
- A recipient registers for an islet transplant after receiving a pancreas transplant
- A recipient's total insulin use is greater than or equal to 0.5 units/kg/day for a consecutive 90 days
- A recipient dies

3.6.B.ii Non-function of a Transplanted Pancreas

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

Pancreas waiting time will be reinstated when the OPTN Contractor receives a completed *Pancreas Waiting Time Reinstatement Form* and *either* of the following:

- An operative report of the removal of the pancreas.
- A statement of intent from the transplant hospital to remove the transplanted pancreas, and a statement that there is documented, radiographic evidence indicating that the transplanted pancreas has failed.

The transplant hospital must maintain this documentation. The OPTN Contractor will send a notice of waiting time reinstatement to the transplant hospital involved.

Automatically Transferring Pediatric Classification for Registered Liver Candidates Turning 18

Sponsoring Committee:	Pediatric Transplantation Committee
Policy/Bylaws Affected:	Policies 9.1 (Status and Score Assignments), 9.1.B (Pediatric Status 1A Requirements), 9.1.C (Pediatric Status 1B); 9.3.A (Pediatric Status Exception for Candidates 18 Years or Older)
Distributed for Public Comment:	August 2014
Amended After Public Comment:	No
Effective Date:	September 1, 2015

Problem Statement

Under current liver policy, if a candidate turns 18 years old while waiting for an organ, that candidate does not automatically retain pediatric classification. Instead, the transplant program must request a pediatric classification exception from the Regional Review Board (RRB). Additionally, if a candidate was ever registered as a pediatric patient and was later removed from the waiting list, but returns to the waiting list as an adult, the transplant program may apply to the RRB for a pediatric classification exception for this candidate. What this means operationally is that the affected candidate is prioritized as a 12 to 17 year old candidate on the liver match run. Both of these exception processes are inconsistent with allocation policy for most other organs.

Summary of Changes

Policy modifications to align liver allocation policy with that of other organs include:

1. Automatically transferring pediatric classification for all candidates who turn 18 while waiting for a liver transplant.
2. Eliminating the pediatric classification process for an adult candidate who was ever on the waiting list before age 18 but has since been removed and reregistered.

What Members Need to Do

No action is required of liver programs; however, you will want to ensure your donor acceptance criteria is up to date. This policy will not require any changes to the Regional Review Board guidelines.

Affected Policy/Bylaw Language:

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

9.1 Status and Score Assignments

Each liver transplant candidate is assigned a score that reflects the probability of death within a 3-month period as determined by the Model for End-Stage Liver Disease (MELD) scoring system or the Pediatric

End Stage Liver Disease (PELD) scoring system. Liver candidates can also be assigned a priority status if the candidate meets the requirements for that status.

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

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

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

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

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

- *Policy 9.6.F: Allocation of Livers from Deceased Donors 11 to 17 Years Old*
- *Policy 9.6.G: Allocation of Livers from Deceased Donors Less than 11 Years Old*
- *Policy 9.6.J: Allocation of Liver-Intestines from Donors Less than 11 Years Old*

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

9.1.B Pediatric Status 1A Requirements

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

The candidate's transplant program may assign the candidate pediatric status 1A if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of initial registration. This includes candidates who are currently 18 years old and greater but remain on the waiting list, or have returned to the waiting list after initial registration less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, but does not include candidates removed from the waiting list at any time who then return to the waiting list after turning 18 years old.
2. The candidate has at least *one* of the following conditions:
 - a. Fulminant liver failure without pre-existing liver disease, defined as the onset of hepatic encephalopathy within 8 weeks of the first symptoms of liver disease and has at least *one* of the following criteria:
 - i. Is ventilator dependent

- ii. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
 - iii. Has an international normalized ratio (INR) greater than 2.0
- b. Diagnosis of primary non-function of a transplanted liver within 7 days of transplant, evidenced by at least *two* of the following:
- i. Alanine aminotransferase (ALT) greater than or equal to 2,000 U/L
 - ii. INR greater than or equal to 2.5
 - iii. Total bilirubin greater than or equal to 10 mg/dL
 - iv. Acidosis, defined as *one* of the following:
 - Arterial pH less than or equal to 7.30
 - Venous pH less than or equal to 7.25
 - Lactate greater than or equal to 4 mmol/L
- All laboratory results reported for any tests required for the primary non-function of a transplanted liver diagnosis above must be from the same blood draw taken between 24 hours and 7 days after the transplant.
- c. Diagnosis of hepatic artery thrombosis (HAT) in a transplanted liver within 14 days of transplant
- d. Acute decompensated Wilson's disease

9.1.C Pediatric Status 1B

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

The candidate's transplant program may assign the candidate pediatric status 1B if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of ~~initial~~ registration. This includes candidates ~~who are currently 18 years old and greater but remain on the waiting list or have returned to the waiting list after initial registration less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, but does not include candidates removed from the waiting list at any time who then return to the waiting list after turning 18 years old.~~
2. The candidate has *one* of the following conditions:
 - a. The candidate has a biopsy-proven hepatoblastoma without evidence of metastatic disease.
 - b. The candidate has an organic acidemia or urea cycle defect and a MELD or PELD exception score of 30 points for at least 30 days.
 - c. Chronic liver disease with a MELD greater than 25 for adolescent candidates 12 to 17 years old, or a PELD greater than 25 for candidates less than 12 years old, and has at least *one* of the following criteria:
 - i. Is on a mechanical ventilator
 - ii. Has gastrointestinal bleeding requiring at least 30 mL/kg of red blood cell replacement within the previous 24 hours
 - iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)

- iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension.
- d. Chronic liver disease and is a combined liver-intestine candidate with an adjusted MELD or PELD score greater than 25 according to *Policy 9.1.F: Liver-Intestine Candidates* and has at least *one* of the following criteria:
 - i. Is on a mechanical ventilator
 - ii. Has gastrointestinal bleeding requiring at least 10 mL/kg of red blood cell replacement within the previous 24 hours
 - iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
 - iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension.

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

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

9.3.BA MELD/PELD Exception Applications

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

Clarifying Multi-organ Policies

Sponsoring Committee:	Policy Oversight Committee
Policy/Bylaws Affected:	Policies 2.12.F (Multiple Organ Procurement), 3.4.C (Candidate Registrations), 3.4.F (Multi-Organ Candidate Registrations), 5.4.D (Multiple Organ Procurement and Offers), 5.8 (Allocation of Multi-Organ Combinations), and 6.4.A (Waiting Time for Multi-organ Candidates)
Distributed for Public Comment:	September 2014
Amended After Public Comment:	No
Effective Date:	September 1, 2015

Problem Statement

OPTN Policies regarding multi-organ procurement, allocation, and waiting time are unclear and sometimes inconsistent. Some of these issues were raised during the 2011 plain language rewrite of the OPTN policies. The multi-organ policies were not clarified during the 2011 rewrite because the rewrite focused on plain language changes and there was substantial confusion regarding the meaning of some of the multi-organ policies.

Summary of Changes

- We edited Policy 2.12.F for clarity and to better explain what is required when organs are recovered. This is *not* an issue of multi-organ procurement, but organ procurement in general, so we changed the title to reflect that.
- Information in Policy 3.4.F was similar in content with Policy 3.4.C so we combined these two policies. With these changes, Policy 3.4.C now includes the multi-organ candidate registration requirements so that all the information is in one place.
- Policy 5.4.D says the same thing as Policy 2.12.F so we deleted it. The first sentence in the original language is vague — “OPO’s medical judgment” and not a true requirement as written and therefore justifies deletion.
- The first sentence in Policy 5.8 is very similar to Policy 3.4.F and is not needed here.
- New section 5.8.A highlights different allocation scheme for Heart-Lung candidates and includes a cross-reference. This is not new, but we moved it out of the paragraph below to give it emphasis.
- New section 5.8.B clarifies multi-organ allocation and eliminates the language about paybacks that was not a true requirement and only “recommended” and is in keeping with the removal of paybacks since the new Kidney Allocation System (KAS) has been implemented.
- Policy 6.4.A is better located in Policy 3.7 with the other waiting time modifications as new Policy 3.7.C. We updated Table 6-4 since most of these waiting time modifications cannot operationally be done since this is currently not programmed and there is currently no automated process to do these modifications. In addition, you cannot transfer status to different organ types. For example, there is no way to equate a status 1a heart candidate’s time to an LAS score, so these sorts of waiting time modifications do not logically make sense and have never been put into practice as currently written.

What Members Need to Do

This proposal only clarifies and reorganizes current policy language and does not require that you change how you currently deal with multi-organ transplantation at your institution. You should review and become familiar with the new policy language.

Affected Policy/Bylaw Language:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (example).

12.15.F ~~Multiple Start Time for Organ Procurement~~

After ~~a member indicates its initial acceptance of an organ~~ have been offered and accepted, the ~~transplant hospitals and OPOs involved~~ recovery teams must agree on the time ~~the~~ that multiple organ procurement will begin. If ~~the members~~ they cannot agree on the ~~procurement start time for the procurement~~, the host OPO has the authority to ~~may~~ withdraw the offer from the transplant hospital or OPO that cannot ~~unable to agree on the start time for procurement to begin~~.

3.4.C Candidate Registrations

Recipients of deceased and living donor organs must be registered as candidates on the waiting list prior to their transplant, including recipients receiving directed donations from deceased donors. All multi-organ candidates must be registered on the waiting list for each required organ.

Transplant programs must complete all candidate registrations, modifications, and removals in the waiting list.

~~3.4.F Multi organ Candidate Registrations~~

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

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

~~3.4.GF Multiple Transplant Program Registrations~~

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

Transplant hospitals may access a report from the OPTN Contractor that identifies any candidates that have multiple registrations for the same organ. This report will not include the identities of the other hospitals where the candidates are registered.

Policy 3.7.C6-4.A Waiting Time Modifications for Multi-organ Heart, Lung, and Heart-Lung Candidates

The OPTN Contractor may assign ~~multi-organ~~ heart, lung, and heart-lung candidates waiting time from one waiting list to another waiting list according to ~~Table 6-4~~ 3-6 below.

Table 6-4-3-6: Waiting Time Assignments Modifications for ~~Multi-organ~~ Heart, Lung, and Heart-Lung Candidates

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

5.4.D Multiple Organ Procurement and Offers

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

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

5.4.ED Backup Organ Offers

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

Policy 5.8 Allocation of Multi-Organ Combinations

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

5.8.A Allocation of Heart-Lungs

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

5.8.B Other Multi-Organ Combinations

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

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

Policy Rewrite Parking Lot “Quick Fixes”

Sponsoring Committee:	Policy Oversight Committee
Policy/Bylaws Affected:	Policies 1 (Administrative Rules and Definitions), 2.5 (Hemodilution Assessment), 2.7.B (Informing Personnel), 2.11.A (Required Information for Deceased Kidney Donors), 2.14 (Deceased Donor Management), 3.6.B.i (Non-function of a Transplanted Kidney), 3.8.B (Removing Pancreas Islets Candidates from the Waiting List), 5.3.A (Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA)), 5.4.C (Liver Offers), 5.4.E (Backup Organ Offers), 8.2.B (Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings), 8.3 (Points), 9.1.A (Adult Status 1A Requirements), 9.1.B (Pediatric Status 1A Requirements), 9.1.C (Pediatric Status 1B), 9.1.D (MELD Score), 9.1.F (Liver-Intestine Candidates), 9.3.D (Specific MELD/PELD Exceptions), 9.3.F (Candidates with Cholangiocarcinoma), 9.5 (Points), 9.5.A (Points for Waiting Time), 9.6.H (Allocation of Liver-Intestines), 9.7.C (Rights Conferred by the Allocation System), 11.2 (Points), 14.3 (Informed Consent Requirements), 14.3.A.ii (Living Kidney Donor Informed Consent Requirements), 14.7.B (Placement of Non-directed Living Donor Kidneys), 14.8 (Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials), 15.1 (Patient Safety Contact), 15.2 (Potential Candidate Screening Requirements), 15.4.B (Requirements for Living Donor Recovery Hospital and Host OPOs), 16.2 (Organs Recovered by Living Donor Recovery Hospitals), 16.4.A (Internal Packaging), 18.1 (Data Submission Requirements), 18.2 (Timely Collection of Data), 19.9 (Access to Recipient Outcomes Data), 20.2.A (Booking Travel), 20.4.B (Transportation To and From the Airport), 20.4.C (Rental Cars), 20.8.A (Expense Reimbursement Form), 20.8.B (Receipts)

Distributed for Public Comment: September 2014

Amended After Public Comment: Yes

Effective Date: September 1, 2015

Problem Statement

In 2013 the POC sponsored the OPTN/UNOS Policies Plain Language Rewrite, which was passed by the Board and subsequently, the rewritten Policies became effective February 1, 2014. The plain language rewrite included plain language changes and reorganization only, and did not involve making any substantive changes to the policies. As a result, during the rewrite, the many reviewers identified a number of issues that would require substantive changes to the policies; these issues were recorded in the rewrite “parking lot” to be addressed in the future. This proposal identifies the “quick fixes” or easy, non-controversial changes that are currently in the parking lot and offers the corrected policy language to further clarify the OPTN/UNOS policies.

Summary of Changes

Specifically, we made the following changes:

- Changed “shoulds” to “must” where applicable and where we were able to identify the policy as a true requirement and not just a recommendation
- Standardized periods, including stating periods in days rather than weeks or months
- Streamlined the administrative rules and definitions, including deleting unnecessary or duplicative definitions.
- Made necessary changes to more consistently and appropriately use common terms in policies (for example, the use of transplant program versus transplant hospital or transplant center).
- Made simple, non-controversial changes to increase language clarity
- Made some headings more descriptive
- Clarified Policy 9.1. (Status Scores and Assignments) by reorganizing lists
- Deleted 9.6.H (Allocation of Liver-Intestines) since it is a repeat of language in 9.1.F (Liver-Intestine Candidates)
- Deleted other outdated or superfluous sections including 9.7.C (Rights Conferred by the Allocation System) and 11.2 (Points)
- Made minor clerical and punctuation changes, including formatting

What Members Need to Do

This proposal only clarifies and reorganizes current policy language and does not require any changes from members. Members should review and familiarize themselves with the new policy language.

Affected Policy/Bylaw Language:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (example).

Policy 1: Administrative Rules and Definitions

1.1.A Time

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

~~1.1.B Gender~~

~~A word used in the masculine includes the feminine.~~

1.1.CB Headings, Notes, and History

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

1.1.DC Reporting of Information to the OPTN Contractor

Members must report requested information to the OPTN Contractor to fulfill membership requirements and to ensure compliance with OPTN Policies and Bylaws. The OPTN Contractor will determine the required method and format for reporting any information required by OPTN Policies and Bylaws, including the requirement to submit specific forms at defined times.

1.2 Definitions

Histocompatibility Laboratory

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

Match run

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

Receiving transplant program

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

Recipient

A candidate that has received an organ transplant.

Recipient transplant hospitals

~~Transplant hospitals that perform living donor transplants.~~

Recovery hospital

A healthcare facility that recovers living donor organs.

1.4.D Telecommunications Outage

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

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

1.4.E OPTN Computer Match Program Outages

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

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

Policy 2: Deceased Donor Organ Procurement

2.5 Hemodilution Assessment

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

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

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

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

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

2.7.B Informing Personnel

The host OPO ~~should~~ must only 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.

2.11.A Required Information for Deceased Kidney Donors

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

1. Date of admission for the current hospitalization
2. Donor name
3. Donor ID
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, DQA, DQB, and DPB antigens prior to organ offers.
11. Indications of sepsis
12. Injuries to or abnormalities of ~~the blood~~ vessels, ureters, or kidney
13. Assurance that final blood and urine cultures
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

2.12.A Kidney

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

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

2.14 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.

Policy 3: Candidate Registrations, Modifications, and Removals

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

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

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

Kidney waiting time will be reinstated when the OPTN Contractor receives a completed *Renal Waiting Time Reinstatement Form* and the supporting documentation required above. The Estimated Post Transplant Survival (EPTS) score will also be calculated without interruption. The OPTN Contractor will send a notice of waiting time reinstatement to the transplant hospital involved.

3.8.B Removing Pancreas Islets Candidates from the Waiting List

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

Policy 5: Organ Offers, Acceptance, and Verification

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

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

- Define the criteria for unacceptable antigens that are considered as contraindications for transplant. This may include clarification of unacceptable antigens based on solid phase testing, consideration of prior donor antigens or non-self antigens involved in pregnancies, prior blood transfusion, and unexpected positive crossmatches.
- Base unacceptable antigens on laboratory detection of human leukocyte antigen (HLA) specific antibodies using at least one solid phase immunoassay with purified HLA molecules.

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

5.4.C Liver Offers

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

- A previously accepted liver is later refused because there is a change in ~~specific~~ specific medical information or infectious disease test results related to the deceased liver donor
- The deceased donor liver has not been allocated within two hours of procurement

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

5.4.E Backup Organ Offers

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

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

Policy 8: Allocation of Kidneys

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

Allocation of deceased donor kidneys is based on the HLA typing identified by the donor histocompatibility laboratory. If the recipient HLA laboratory identifies a different HLA type for the deceased donor, the kidney may be allocated according to the original HLA typing, or the ~~recipient transplant hospital~~ receiving transplant program may reallocate the kidney locally, according to *Policy 8: Allocation of Kidneys*.

8.3 Kidney Allocation Points

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

Table 8-1: Kidney Points

If the candidate is:	And the following allocation sequence is used:	Then the candidate receives this many points:
Registered for transplant and meets the qualifying criteria described in <i>Policy 8.4: Waiting Time</i>	8.5.H, 8.5.I, 8.5.J, or 8.5.K	1/365 points for each day since the qualifying criteria in <i>Policy 8.4: Waiting Time</i>
Aged 0-10 at time of match and a 0-ABDR mismatch with the donor	8.5.H, 8.5.I, or 8.5.J	4 points

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

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

Table 8-2: Points for CPRA

If the candidate’s CPRA score is:	Then the candidate receives this many points:
0	0.00
1-9	0.00
10-19	0.00
20-29	0.08
30-39	0.21
40-49	0.34
50-59	0.48
60-69	0.81
70-74	1.09
75-79	1.58
80-84	2.46
85-89	4.05
90-94	6.71
95	10.82
96	12.17
97	17.30
98	24.40
99	50.09
100	202.10

Policy 9: Allocation of Livers and Liver-Intestines

9.1.A Adult Status 1A Requirements

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

The candidate's transplant program may assign the candidate adult status 1A if *all* the following conditions are met:

1. The candidate is at least 18 years old at the time of registration
 2. The candidate has a life expectancy without a liver transplant of less than 7 days and has at least *one* of the following conditions:
 - a. Fulminant liver failure, without pre-existing liver disease and currently in the intensive care unit (ICU), defined as the onset of hepatic encephalopathy within ~~8-weeks~~ 56 days of the first signs or symptoms of liver disease, and has at least *one* of the following criteria:
 - i. Is ventilator dependent
 - ii. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
 - iii. Has an international normalized ratio (INR) greater than 2.0
 - b. Anhepatic
 - c. ~~b.~~ Primary non-function of a transplanted whole liver within 7 days of transplant, with evidenced by at least one of the following:
 - ~~i.~~ Anhepatic Aspartate aminotransferase (AST) greater than or equal to 3,000 U/L and at least *one* of the following:
 - International normalized ratio (INR) greater than or equal to 2.5
 - Arterial pH less than or equal to 7.30
 - Venous pH less than or equal to 7.25
 - Lactate greater than or equal to 4 mmol/L
- All laboratory results reported for the tests required above must be from the same blood draw taken 24 hours to 7 days after the transplant.
- ~~d.~~ e. Primary non-function within 7-days of transplant of a transplanted liver segment from a deceased or living donor, evidenced by at least *one* of the following:
 - ~~i.~~ Anhepatic
 - ~~ii.~~ INR greater than or equal to 2.5
 - ~~iii.~~ Arterial pH less than or equal to 7.30
 - ~~iv.~~ Venous pH less than or equal to 7.25
 - ~~v.~~ Lactate greater than or equal to 4 mmol/L
 - ~~e.~~ d. Hepatic artery thrombosis (HAT) within 7-days of transplant, with evidenced by either of the following:
 - ~~i.~~ Anhepatic
 - ~~ii.~~ Aspartate aminotransferase (AST) greater than or equal to 3,000 U/L and at least *one* of the following:
 - INR greater than or equal to 2.5
 - Arterial pH less than or equal to 7.30
 - Venous pH less than or equal to 7.25

- Lactate greater than or equal to 4 mmol/L

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

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

- f. ~~e.~~ Acute decompensated Wilson's disease

9.1.B Pediatric Status 1A Requirements

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

The candidate's transplant program may assign the candidate pediatric status 1A if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of initial registration. This includes candidates who are currently 18 years old and greater but remain on the waiting list, or have returned to the waiting list after initial registration.
2. The candidate has at least *one* of the following conditions:
 - a. Fulminant liver failure without pre-existing liver disease, defined as the onset of hepatic encephalopathy within ~~8 weeks~~ 56 days of the first signs and symptoms of liver disease and has at least *one* of the following criteria:
 - i. Is ventilator dependent
 - ii. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
 - iii. Has an international normalized ratio (INR) greater than 2.0
 - b. Diagnosis of primary non-function of a transplanted liver within 7 days of transplant, evidenced by at least *two* of the following:
 - i. Alanine aminotransferase (ALT) greater than or equal to 2,000 U/L
 - ii. INR greater than or equal to 2.5
 - iii. Total bilirubin greater than or equal to 10 mg/dL
 - iv. Acidosis, defined as *one* of the following:
 - Arterial pH less than or equal to 7.30
 - Venous pH less than or equal to 7.25
 - Lactate greater than or equal to 4 mmol/L

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

- c. Diagnosis of hepatic artery thrombosis (HAT) in a transplanted liver within 14 days of transplant
- d. Acute decompensated Wilson's disease

9.1.C Pediatric Status 1B Requirements

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

The candidate's transplant program may assign the candidate pediatric status 1B if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of initial registration. This includes candidates who are currently 18 years old and greater but remain on the waiting list or have returned to the waiting list after initial registration.
2. The candidate has *one* of the following conditions:
 - a. The candidate has a biopsy-proven hepatoblastoma without evidence of metastatic disease.
 - b. The candidate has an organic acidemia or urea cycle defect and a MELD or PELD exception score of 30 points for at least 30 days.
 - c. Chronic liver disease with a calculated MELD greater than 25 for adolescent candidates 12 to 17 years old, or a calculated PELD greater than 25 for candidates less than 12 years old, and has at least *one* of the following criteria:
 - i. Is on a mechanical ventilator
 - ii. Has gastrointestinal bleeding requiring at least 30 mL/kg of red blood cell replacement within the previous 24 hours
 - iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
 - iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension
 - d. Chronic liver disease and is a combined liver-intestine candidate with an adjusted MELD or PELD score greater than 25 according to *Policy 9.1.F: Liver-Intestine Candidates* and has at least *one* of the following criteria:
 - i. Is on a mechanical ventilator
 - ii. Has gastrointestinal bleeding requiring at least 10 mL/kg of red blood cell replacement within the previous 24 hours
 - iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
 - iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension

9.1.D MELD Score

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

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

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~~-7 days

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

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

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

$$\text{MELD} = \text{MELD}_{(i)} + 1.32 \cdot (137 - \text{Na}) - [0.033 \cdot \text{MELD}_{(i)} \cdot (137 - \text{Na})]$$

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

9.1.E PELD Score

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

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

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

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

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

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

9.1.F Liver-Intestine Candidates

Candidates awaiting a liver-intestine transplant who are registered and active on both waiting lists will automatically receive an additional increase in their MELD or PELD score equivalent to a 10 percentage point increase in risk of 3-month mortality. Candidates less than 18 years old will receive 23 additional points to their calculated MELD or PELD score instead of the 10 percentage point increase. The transplant hospital must ~~verify~~ document in the candidate's medical record the medical justification for the combined liver-intestine transplant and that an intestinal the transplant is required and took place was completed.

9.3.D Specific MELD/PELD Exceptions

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

Table 9-2: Specific Standardized MELD/PELD Exceptions

If the candidate has:	And submits to the OPTN Contractor evidence that includes:	Then the candidate:
Cholangiocarcinoma	The information required according to <i>Policy 9.3.F: Candidates with Cholangiocarcinoma</i> .	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.
Cystic Fibrosis	The candidate has signs of reduced pulmonary function with forced expiratory volume at one second (FEV ₁) that falls below 40 percent.	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.
Familial Amyloid Polyneuropathy (FAP)	<i>All of the following:</i> <ol style="list-style-type: none"> 1. Clear diagnosis of FAP. 2. Echocardiogram showing the candidate has an ejection fraction greater than 40 percent. 3. Ambulatory status. 4. Identification of transthyretin (TTR gene) mutation (Val30Met vs. non-Val30Met). 5. Biopsy- proven amyloid in the involved organ. 	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.
Hepatic Artery Thrombosis (HAT)	Candidate has HAT within 14 days of transplant but does not meet criteria for status 1A in <i>Policy 9.1.A: Adult Status 1A Requirements</i> .	Will receive a MELD score of 40.
Hepatocellular Carcinoma (HCC)	The information required according to <i>Policy 9.3.G: Candidates with Hepatocellular Carcinoma (HCC)</i> .	<i>See Policy 9.3.G: Candidates with Hepatocellular Carcinoma (HCC)</i> .
Hepatopulmonary Syndrome (HPS)	<i>All of the following:</i> <ol style="list-style-type: none"> 1. Clinical evidence of portal hypertension. 2. Evidence of a shunt. 3. PaO₂ less than 60 mmHg on room air. 4. No significant clinical evidence of underlying primary pulmonary disease. 	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months that the candidate's PaO ₂ remains under 60 mmHg.
Metabolic Disease	The information required according to <i>Policy 9.3.E: Pediatric Liver Candidates with Metabolic Diseases</i> .	<i>See Policy 9.3.E: Pediatric Liver Candidates with Metabolic Diseases</i> .

If the candidate has:	And submits to the OPTN Contractor evidence that includes:	Then the candidate:
Portopulmonary Hypertension	<p>The candidate has a mean pulmonary arterial pressure (MPAP) below 35 mmHg following intervention.</p> <p>The diagnosis should must also include <i>all</i> of the following:</p> <ol style="list-style-type: none"> 1. Initial mean pulmonary arterial pressure (MPAP) level. 2. Initial pulmonary vascular resistance (PVR) level. 3. Initial transpulmonary gradient to correct for volume overload. 4. Documentation of treatment. 5. Post-treatment MPAP less than 35 mmHg. 6. Post treatment PVR less than 400 dynes/sec/cm⁻⁵. 	<p>Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months if a repeat heart catheterization confirms that the mean pulmonary arterial pressure (MPAP) remains below 35 mmHg.</p>
Primary Hyperoxaluria	<p>The candidate has <i>all</i> of the following:</p> <ol style="list-style-type: none"> 1. Is registered for a combined liver-kidney transplant. 2. Alanine glyoxylate aminotransferase (AGT) deficiency proven by liver biopsy using sample analysis or genetic analysis. 3. Glomerular filtration rate (GFR) less than or equal to 25 mL/min, by six variable Modification of Diet in Renal Disease formula (MDRD6) or direct measurement of iothalamate or iohexol, for six weeks 42 or more days. 	<p>Will receive a MELD score of 28 or PELD score of 41; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.</p>

9.3. F Candidates with Cholangiocarcinoma

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

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

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

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

3. If cross-sectional imaging studies demonstrate a mass, the mass ~~should~~ must be less than three cm.
4. Intrahepatic and extrahepatic metastases ~~should~~ must be excluded by cross-sectional imaging studies of the chest and abdomen at the time of the initial application for the MELD/PELD exception and every three months before the MELD/PELD score increases.
5. Regional hepatic lymph node involvement and peritoneal metastases ~~should~~ must be assessed by operative staging after completion of neoadjuvant therapy and before liver transplantation. Endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable to exclude patients with obvious metastases before neo-adjuvant therapy is initiated.
6. Transperitoneal aspiration or biopsy of the primary tumor (either by endoscopic ultrasound, operative or percutaneous approaches) ~~should~~ must be avoided because of the high risk of tumor seeding associated with these procedures.

9.5 Liver Allocation Points

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

9.5.A Points for Waiting Time

Points are assigned so that the status 1A or 1B candidate with the longest waiting time receives the most points as follows:

- 10 points for the candidate with the greatest total status 1A or status 1B ~~W~~waiting Time within each classification
- A fraction of 10 points divided up among the remaining status 1A or status 1B candidates within each classification, based on the potential recipient's total waiting time

~~9.6.H Allocation of Liver Intestines~~

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

~~9.7.C Rights Conferred by the Allocation System~~

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

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

~~11.2 Points~~

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

~~11.32~~ **Waiting List Registration**

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

Policy 14: Living Donation

14.3 Informed Consent Requirements

Table 14-2: Required Recipient Outcome and Transplanted Organ Survival Data

If the recovery hospital and the recipient hospital:	Then:	Including <i>all</i> the following information:
Are the same	The recovery hospital must provide the living donor with both national and that hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) program hospital-specific reports.	<ul style="list-style-type: none"> • National 1-year patient and transplanted organ survival • The hospital's 1-year patient and transplanted organ survival • Notification about all Centers for Medicare and Medicaid Services (CMS) outcome requirements not being met by the transplant hospital
Will not be the same and the recipient hospital is known	The recovery hospital must provide the living donor with both national and the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR program hospital-specific reports.	<ul style="list-style-type: none"> • National 1-year patient and transplanted organ survival • The recipient hospital's 1-year patient and transplanted organ survival • Notification about all CMS outcome requirements not being met by the recipient hospital

14.6.B Placement of Non-directed Living Donor Kidneys

Prior to determining the placement of a non-directed living donor kidney, the recovery hospital must obtain the match run of its waiting list candidates from its local OPO or the Organ Center. When a non-directed living donor kidney is allocated, the recovery hospital must document how the organ is allocated and the rationale for allocation.

This requirement does not apply to non-directed living kidney donors who donate a kidney through consent to participate in a Kidney Paired Donation (KPD) arrangement.

14.7 Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials

Recovery hospitals are responsible for packaging and labeling any living donor organs, tissue typing specimens, or vessels that are recovered from living donors according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage* when either of the following occurs:

- Living donor organs, tissue typing specimens, or vessels are recovered and must be transported outside the recovery hospital
- A living donor organ, tissue typing specimens, or vessels requires repackaging by a transplant hospital for transport outside the transplant hospital

Policy 15: Identification of Transmissible Diseases

15.1 Patient Safety Contact

Each OPO and transplant program must identify a patient safety contact and develop and comply with a written protocol for the patient safety contact to fulfill all the following responsibilities:

1. Be available 24 hours a day.
2. Receive notifications of potential disease transmission and related communication from the OPTN Contractor.
3. Receive relevant medical information that may affect or change recipient care.
4. Communicate any information regarding potential disease transmissions to the medical staff responsible for the recipient's clinical care at the transplant program as soon as possible, but no later than 24 hours after becoming aware of the potential disease transmission.
5. Facilitate communication about the current clinical status of any recipient when the transplant program is notified of a potential or proven disease transmission that may affect the recipient.

~~Transplant programs and OPOs must make this information available to the OPTN Contractor on request.~~

15.2 Potential Candidate Screening Requirements

To be eligible for an organ transplant, potential transplant candidates must be tested for human immunodeficiency virus (HIV), hepatitis B, and hepatitis C, unless the testing would violate state or federal laws. Potential candidates who test positive for HIV, hepatitis B, or hepatitis C ~~should~~ must be offered appropriate counseling.

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

15.4.B Requirements for Living Donor Recovery Hospital and Host OPOs

The living donor recovery hospital or host OPO is responsible for *all* the following:

1. Communication of the suspected donor's and affected recipient's test results and diagnosis that may be relevant to acute patient care as soon as possible, but no more than 24 hours

after receipt, to any transplant programs, patient safety contacts, and tissue banks that received organs or tissue from the donor. This includes any test results that were not available at the time of procurement or that were performed after recovery. The living donor recovery hospital or host OPO must document that this information is shared with all receiving transplant programs ~~recipient transplant hospitals~~ and tissue banks.

2. Notification of the event to the OPTN Improving Patient Safety Portal as soon as possible, but no later than 24 hours after receipt of test results or diagnosis.
3. Potential disease transmission follow up communication as follows, including:
 - a. For deceased donors, completion and submission of the *Potential Disease Transmission Report Form* no later than 24 hours after reporting the event through the OPTN Improving Patient Safety Portal. This must include:
 - i. The specific ~~recipient~~ receiving transplant program patient safety contact and tissue bank staff that were notified of the potential transmission
 - ii. Disposition of all organs, tissues, and vessels
 - iii. Any preliminary information available regarding any remaining deceased donor samples for additional testing, notification to state or local health department as appropriate for nationally notifiable infectious diseases, and whether an autopsy was performed on the deceased donor.
4. A follow up review of the event, in partnership with OPTN patient safety staff, to determine whether the deceased or living donor was diagnosed with a potentially transmissible disease or condition.

For all living and deceased donors, the Ad Hoc Disease Transmission Advisory Committee may request submission of a *Potential Disease Transmission Donor Follow-Up Report* 45 days after the initial reporting date. Patient safety staff may request additional information related to the living donor beyond 45 days, including pending test results, depending on the potentially transmitted disease or condition.

If a host OPO learns new information regarding a deceased donor as part of its required ~~living~~ donor follow up that indicates risk of potential transmission of disease or malignancy, the host OPO must report the information through the OPTN Improving Patient Safety Portal.

If a recovery hospital learns new information about a living donor during the first two years post donation that indicates risk of potential transmission of disease or malignancy, then the recovery hospital must do at least all of the following:

1. Disclose to the living donor that a potential disease transmission or malignancy must be reported to the ~~recipient transplant hospital~~ receiving transplant program and the OPTN Improving Patient Safety Portal
2. Notify the ~~recipient transplant hospital~~ receiving transplant program
3. Report the potential transmission through the OPTN Improving Patient Safety Portal

The recovery hospital may also need to report the new information to local, state, or federal public health authorities.

Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage

16.2 Organs Recovered by Living Donor Recovery Hospitals

Living donor recovery hospitals must follow all of the requirements for packaging, labeling, and transporting organs, tissue typing material, and vessels according to this Policy, with these differences:

1. While OPOs are responsible for packaging, labeling, and transporting deceased donor organs, vessels, and tissue typing samples, recovery hospitals are responsible for packaging, labeling, and transporting living donor organs, vessels, and tissue typing samples.
2. When a member repackages a living donor organ, they are not required to notify the member that originally packaged the organ.
3. Instead of the list of documents in *Policy 16.5: Documentation Accompanying the Organ or Vessel*, living donor organs must contain the blood type source documents, donor informed consent form, and the complete medical record of the living donor. Vessels that are shipped separately from living donor organs must include the same documents as are required for shipping living donor organs.
4. Blood samples and tissue typing materials must contain the donor ID and *one* of the following three identifiers: donor date of birth, donor initials, or a locally assigned unique ID. Each sample ~~should~~ must contain the donor's blood type and subtype, the type of tissue, and the date and time when the sample was obtained. The recovery hospital must document in the donor record all unique identifiers used to label blood samples and tissue typing materials.
5. The recovery hospital will provide specimens for tissue typing if requested. The minimum typing materials for living donor kidneys are: two ACD (yellow top) tubes per kidney.

16.4.A Internal Packaging

A triple sterile barrier must protect organs and vessels. A ~~sterile rigid container may be used as one layer of the triple sterile barrier for all organs and~~ must be used as one layer when packaging kidneys, pancreas, and vessels that are packaged separately from the organ. If the rigid container is sterile, it can serve as one layer of the required triple sterile barrier. The use of a rigid container is optional for all other organs.

Policy 18: Data Submission Requirements

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 accurate 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.

This policy does not apply to VCA-only donors or VCA information for donors and recipients; however, for VCA-only procurements, Host OPOs must submit to the OPTN Contractor the Deceased donor registration (DDR) within 30 days after the procurement date.

Table 18-1: Data Submission Requirements

<i>The following member:</i>	<i>Must submit the following materials to the OPTN Contractor:</i>	<i>Within:</i>	<i>For the following groups:</i>
Histocompatibility Laboratory	<i>Donor histocompatibility (DHS)</i>	30_ days after the OPO submits the deceased donor registration	For each donor typed by the laboratory
Histocompatibility Laboratory	<i>Recipient histocompatibility (RHS)</i>	<i>Either of the following:</i> <ul style="list-style-type: none"> • 30_ days after the transplant hospital removes the candidate from the waiting list because of transplant • 30_ days after the transplant hospital submits the <i>recipient feedback</i> 	For each transplant recipient typed by the laboratory
OPOs, all	<i>Death notification records (DNR)</i>	30_ days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	For all imminent neurological deaths and eligible deaths in its DSA
OPOs, all	<i>Monthly Donation Data Report: Reported Deaths</i>	30_ days after the end of the month in which a donor hospital reports a death to the OPO	For all deaths reported by a hospital to the OPO
Allocating OPO	<i>Potential transplant recipient (PTR)</i>	30_ days after the match run date by the OPO or the OPTN Contractor	For each deceased donor organ that is offered to a potential recipient
Host OPO	<i>Deceased donor feedback</i>	5 business days after the procurement date	
Host OPO	<i>Deceased donor registration (DDR)</i>	30 days after the <i>deceased donor feedback</i> form is submitted and disposition is reported for all organs	For all deceased donors and authorized but not recovered potential deceased donors

<i>The following member:</i>	<i>Must submit the following materials to the OPTN Contractor:</i>	<i>Within:</i>	<i>For the following groups:</i>
Recovery Hospitals	<i>Living donor feedback</i>	The time prior to donation surgery	For each potential living donor organ recovered at the hospital
Recovery Hospitals	<i>Living donor registration (LDR)</i>	60 days after the Recovery Hospital submits the <i>living donor feedback</i> form	For each living donor organ recovered at the hospital
Recovery Hospitals	<i>Living donor follow-up (LDF)</i>	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	<i>Organ specific transplant recipient follow-up (TRF)</i>	<u><i>Either of the following:</i></u> <ul style="list-style-type: none"> •30_ days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure •14_ days from notification of the recipient's death or graft failure 	For each recipient followed by the hospital
Transplant hospitals	<i>Organ specific transplant recipient registration (TRR)</i>	60_ days after transplant hospital submits the <i>recipient feedback</i> form	For each recipient transplanted by the hospital
Transplant hospitals	<i>Liver Post-Transplant Explant Pathology</i>	60_ days after transplant hospital submits the <i>recipient feedback</i> form	For each liver recipient transplanted by the hospital
Transplant hospitals	<i>Recipient feedback</i>	24_ hours after the transplant	For each recipient transplanted by the hospital
Transplant hospitals	<i>Recipient malignancy (PTM)</i>	30_ days after the transplant hospital reports the malignancy on the <i>transplant recipient follow-up</i> form	For each recipient, with a reported malignancy, that is followed by the hospital

<i>The following member:</i>	<i>Must submit the following materials to the OPTN Contractor:</i>	<i>Within:</i>	<i>For the following groups:</i>
Transplant hospitals	<i>Transplant candidate registration (TCR)</i>	30_ days after the transplant hospital registers the candidate on the waiting list	For each candidate on the waiting list or recipient transplanted 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.

This policy does not apply to VCA transplants.

Table 18-2: Timely Data Collection

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Transplant hospital	<i>Organ specific transplant recipient registration (TRR)</i>	When the transplant recipient is discharged from the hospital or six weeks <u>42 days</u> following the transplant date, whichever is first
Recovery hospital	<i>Living donor registration (LDR)</i>	When the living donor is discharged from the hospital or six weeks <u>42 days</u> following the transplant date, whichever is first
Recovery hospital	<i>Living donor follow-up (LDF)</i>	60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date

Policy 19: Data Release

19.9 Access to Recipient Outcomes Data

OPOs may receive recipient outcomes data, without permission from the transplant hospital, for each deceased donor organ transplanted. This information would be used in determining the appropriateness of deceased donor selection and management techniques as well as quality assurance of the procurement process. The data would be accessed and downloaded through the OPTN Contractor. The

members that receive the data will not publish or publicly disseminate outcomes of specific recipients, physicians, or institutions. These data fields are located on the *Transplant Recipient Registration* forms and include all of the following:

Recipient status (all organs)

- Living – date of hospital report
- Dead – date and cause of death
- Re-transplanted prior to hospital discharge – date
- Cause of retransplant (thoracic only)

Clinical information at discharge (kidneys only)

- Most recent serum creatinine prior to discharge
- Did kidney produce >40 mL of urine in first 24 hours?
- Did recipient need dialysis within first ~~week~~ 7 days?
- Did creatinine decline by 25% or more in first 24 hours on two separate serum samples taken within first 24 hours?

Transplanted kidney, liver, or pancreas status at discharge

- Functioning or failed
- If failed, date and cause
- Preservation Information (all organs)

Policy 20: Travel Expense and Reimbursement

20.2 Airfare and Rail Reimbursement

20.2.A Booking Travel

OPTN Contractor staff and members must use the approved OPTN Contractor travel agency to arrange all OPTN Contractor related travel and obtain a low-cost coach fare that will accommodate the traveler's needs. If the traveler chooses not to accept those flight arrangements, the OPTN Contractor will reimburse only up to the amount the approved OPTN travel agency would have paid.

~~Travelers should book airline reservations at least one month in advance of travel.~~

20.4.B Transportation To and From the Airport

The OPTN Contractor will reimburse *all* of the following costs:

1. Transportation between the airport and the traveler's home.
2. Transportation between the airport and the meeting location.
3. Parking fees at the airport from which the traveler departs.

Travelers ~~should~~ must use the least expensive, convenient option to travel to and from airports. The OPTN Contractor will not reimburse limousines unless the cost is shared with another traveler and the total cost to the OPTN Contractor is no more expensive than cab fare.

20.4.C Rental Cars

The OPTN Contractor will not reimburse rental cars if less expensive modes of travel are available. The traveler must elect rental car insurance coverage and ~~should~~ must minimize

additional rental car fees. If the traveler elects to rent a car when less expensive modes of travel are available, the OPTN Contractor will reimburse up to the amount of the estimated cab fare needed for the duration of the stay.

20.8 Filing Expense Reports

20.8.A Expense Reimbursement Form

To request reimbursement from the OPTN Contractor, the traveler must complete and submit an OPTN Contractor expense reimbursement form with original receipts. Off-site OPTN members may submit scanned copies of the original receipts. The traveler must sign the expense reimbursement form and must include *all* of the following information:

1. Dates of travel
2. Reason for travel
3. Meeting location and name of event
4. To whom the reimbursement check will be made payable
5. The address to which the reimbursement will be sent
6. The traveler's phone number

20.8.B Receipts

The expense report must have original receipts for expenses attached. Off-site OPTN members may submit scanned copies of the original receipts. If one traveler has a meal receipt that includes other OPTN Contractor travelers, the receipt must include the names of all travelers.

Clarifying Definition of Organ Transplant and Transplant Date

Sponsoring Committee:	Policy Oversight Committee
Policy/Bylaws Affected:	Policy 1.2 (Definitions)
Distributed for Public Comment:	September 2014
Amended After Public Comment:	No
Effective Date:	Upon implementation and notice to members

Problem Statement

UNOS staff routinely receives questions from OPTN/UNOS members about the definition of organ transplant, including what they should report as the transplant date, especially in regards to meeting reporting requirements in UNetSM. Members report a disconnect between current definitions and actual clinical practices. These proposed definitions will help bridge the disconnect and clarify the policy requirements.

Summary of Changes

We have updated and clarified the definitions for both Organ Transplant and Transplant Date so that they more closely align with clinical practice.

What Members Need to Do

You will be expected to accurately report data based on the proposed language. Although the proposed language will not change the fields routinely monitored, you are expected to apply the new definitions of organ transplant and transplant date when you report in UNetSM. Any data you enter in UNetSM may be subject to OPTN review, and our site surveyors may ask you to provide documentation.

Affected Policy/Bylaw Language:

1.2 Definitions

Organ transplant

Organ transplants include solid organ transplants and islet infusions. An organ transplant begins at the start of once any initiation of organ anastomosis has taken place during the intended transplant or the start of an islet cell infusion.

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

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

Transplant date

Determined by the start of the organ anastomosis during transplant or the start of the islet infusion. beginning of organ anastomosis. For a multi organ transplant procedure, the transplant date for each organ is determined by the transplant date of the first organ transplanted.

VCA Data Collection and Submission

Sponsoring Committee:	VCA Committee
Policy/Bylaws Affected:	OPTN Policy 18.1 and 18.2
Distributed for Public Comment:	September 2014 to December 2014
Amended After Public Comment:	No
Effective Date:	Pending programming and notice to members

Problem Statement

There is no systematic, centralized way to collect data for VCA transplants in the U.S. This is the first attempt to collect transplant and follow-up data on VCA recipients so we can evaluate outcomes and ensure patient safety. We have identified the VCA-specific data elements we need to collect at the time of transplant and during follow-up. As the data collection evolves, we may need to add, amend, or delete data elements based on input from the transplant community.

Summary of Changes

This data collection adheres to the OPTN Principles of Data Collection passed by the OPTN/UNOS Board of Directors in 2006. The primary goal of these principles is to improve patient outcomes by:

- Developing transplant, donation, and allocation policies
- Determining if institutional members are complying with policies
- Determining member-specific performance
- Ensuring patient safety when no alternative sources of data exist
- Fulfilling the requirements of the OPTN Final Rule

The changes to *OPTN Policies 18.1* and *18.2* outline the following:

- Member responsibility for submitting VCA organ transplant candidate, recipient, and deceased donor data
- The period that VCA organ transplant candidate, recipient, and deceased donor data must be submitted to the OPTN.

Additionally, new Transplant Recipient Registration (TRR) and Transplant Recipient Follow-up (TRF) forms will need to capture specific data elements on VCA recipients.

What Members Need to Do

Transplant programs:

- Continue to register and remove VCA candidates by using the worksheets provided by UNOS (see *Table 18-1*).
- Complete TRR and TRF forms for VCA recipients and submit completed forms as outlined in (see *Table 18-1*).

OPOs:

- Continue to use DonorNet® to register all deceased donors, including those donors from whom only VCA grafts may be recovered.
- Continue to complete Deceased Donor Feedback and Deceased Donor Registration forms for all donors, including those donors from whom only VCA grafts are recovered (see *Table 18-1*).
- Submit completed VCA Candidate lists to UNOS (see *Table 18-1*).

Affected Policy/Bylaw Language:

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

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 accurate data to the OPTN Contractor ~~using standardized forms according to~~ Table 18-1 below, ~~shows the member responsible for submitting each data form and when the Member must submit the following materials to the OPTN Contractor.~~

~~This policy does not apply to VCA only donors or VCA information for donors and recipients; however, for VCA only procurements, Host OPOs must submit to the OPTN Contractor the Deceased donor registration (DDR) within 30 days after the procurement date.~~

Table 18-1: Data Submission Requirements

<i>This e-following member:</i>	<i>Must submit the following materials to the OPTN Contractor:</i>	<i>Within:</i>	<i>For the following groups:</i>
Histocompatibility Laboratory	Donor histocompatibility (DHS)	30 days after the OPO submits the deceased donor registration	For e <u>Each heart, intestine, kidney, liver, lung, or pancreas</u> donor typed by the laboratory
Histocompatibility Laboratory	Recipient histocompatibility (RHS)	Either of the following: <ul style="list-style-type: none"> • 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 e <u>Each heart, intestine, kidney, liver, lung, or pancreas</u> 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 a <u>All</u> 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	For a <u>All</u> deaths reported by a hospital to the OPO

		hospital reports a death to the OPO	
Allocating OPO	Potential transplant recipient (PTR)	30 days after the match run date by the OPO or the OPTN Contractor	For e Each deceased organ donor heart, intestine, kidney, liver, lung, or pancreas that is offered to a potential recipient
<u>Allocating OPO</u>	<u>VCA Candidate List</u>	<u>30 days after the procurement date</u>	<u>Each deceased donor VCA organ that is offered to a potential VCA recipient</u>
Host OPO	Deceased donor feedback	5 business days after the procurement date	<u>All deceased donors</u>
Host OPO	Deceased donor registration (DDR)	30 days after the deceased donor feedback form is submitted and disposition is reported for all organs	For a All deceased donors and authorized but not recovered potential deceased donors
Recovery Hospitals	Living donor feedback	The time prior to donation surgery	For e Each potential living donor organ recovered at the hospital <u>This does not apply to VCA donor organs</u>
Recovery Hospitals	Living donor registration (LDR)	60 days after the recovery hospital submits the living donor feedback form	For e Each living donor organ recovered at the hospital <u>This does not apply to VCA donor organs</u>
Recovery Hospitals	Living donor follow-up (LDF)	60 days after the six-month, 1-year, and 2-year anniversary of the donation date	For e Each living donor organ recovered at the hospital <u>This does not apply to VCA donor organs</u>

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients is based on recipient status at a time as close as possible to the specified transplant event anniversary. **Error! Reference source not found.** sets standards for when the member must collect the data from the patient.

~~This policy does not apply to VCA transplants.~~

Table 18-2: Timely Data Collection

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Transplant hospital	<i>Organ specific transplant recipient registration (TRR)</i>	When the transplant recipient is discharged from the hospital or six-weeks following the transplant date, whichever is first.

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Recovery hospital	<i>Living donor registration (LDR)</i>	When the living donor is discharged from the hospital or six-weeks following the transplant date, whichever is first. <u>This does not apply to VCA transplants.</u>
Recovery hospital	<i>Living donor follow-up (LDF)</i>	60-days before or after the six-month, 1-year, and 2-year anniversary of the donation date. <u>This does not apply to VCA transplants.</u>

VCA Implementation

Sponsoring Committee:	VCA Committee
Policy/Bylaws Affected:	Policies 11.2 (Definitions), 2.2.12 (OPO Responsibilities), 2.15.C (Authorization Requirement), 5.2 (Maximum Mismatched Antigens), 5.4.B (Order of Allocation), 5.5.A (Receiving and Reviewing Organ Offers), 5.5.B (Time Limit for Acceptance), 12 (Allocation of Vascularized Composite Allografts), 14.5 (Registration and Blood Type Verification of Living Donors Before Donation), and 18.3 (Recording and Reporting Outcomes of Organ Offers) Bylaws: D.2 (Program Requirements), D.4 (Transplant Program Director), D.5 (Transplant Program Key Personnel), D.6 (Changes in Key Transplant Program Personnel), D.9.A (Functional Inactivity), D.10.A (Transplant Program Performance), D.10.B (Notification Requirements for Waiting List Inactivation), D.10.G (Relocation or Transfer of Designated Program), J (Membership Requirements for VCA Transplant Programs), K.1 (Transplant Program Inactivity), K.2 (Short-term Inactive Transplant Program Status), K.3 (Long-term Inactive Transplant Program Status), M (Definitions)
Distributed for Public Comment:	September 2014 to December 2014
Amended After Public Comment:	Yes
Effective Date:	September 1, 2015

Problem Statement

On June 24, 2014, the OPTN/UNOS Board of Directors approved numerous policy and bylaw changes to guide the implementation of VCA recovery and transplantation. These changes were effective at the same time the OPTN Final Rule was amended on July 3, 2014. Substantial updates were required to:

- Define body parts covered by VCA policies.
- Establish VCA donor authorization requirements.
- Establish VCA allocation policies.
- Provide membership requirements for hospitals that perform VCA transplants.

As a result of the timeline and pending regulatory changes, we sought public comment in the fall of 2014 *after* Board approval. The Committee carefully considered all comments received, and amended the policy language as a result. Exemptions for VCAs continue to appear in several policy and bylaws, mostly for technology reasons. Many policy and bylaw exemptions already approved by the Board in June 2014 were then removed when the board approved policy and bylaw language pertaining to VCA recovery and transplantation in June 2015. These include exemptions addressed in separate proposals for VCA Data Collection and Submission, and Membership Requirements for VCA Transplant Programs.

Summary of Changes

We are making the following changes to OPTN Policies and Bylaws to establish requirements for members wishing to participate in VCA recovery and transplantation:

- We amended OPTN Policy 2.15.D on VCA donor authorization to avoid conflicts with the Uniform Anatomical Gift Act, applicable state laws, and the efforts of the donation community. The amended language clarifies that a surrogate decision-maker can only provide authorization for donation from deceased donors.
- Content on VCA Allocation in OPTN Policy 12 ranks VCA candidates by waiting time and compatible blood type. Allocation begins within the OPO's region, then goes beyond the OPO's region.
- Bylaws, Appendix D.2 requires a transplant hospital to have an approved and maintained designated transplant program for another organ in addition to its VCA program designation.
- Bylaws, Appendix D.9.A adds VCA transplant programs to the list of programs that no functional inactivity thresholds currently identified.
- Bylaws, Appendix J outlines specific membership requirements of a VCA transplant program and the program's letter of intent.
- Policy 1.2 and Bylaws Appendix M have been updated to include "vascularized composite allografts" as an organ. Further, to be a VCA organ, a body part must meet all nine criteria from the Final Rule. These criteria appear in the definition of "Vascularized Composite Allograft."
- Policy 18.3 directs members to submit VCA donor, candidate, and recipient data according to Policy 18.1.

What Members Need to Do

You must be familiar with and comply with the policies and bylaws pertaining to VCA recovery and transplantation.

Transplant programs:

- Ensure that a body part they intend to transplant meets the criteria according to OPTN Bylaws, Appendix M and OPTN Policy 1.2. This includes, but is not limited to, upper limbs, grafts from the head and neck, and abdominal wall grafts.
- Before transplanting VCAs, you must submit a letter to UNOS stating your intent to perform these transplants. This letter is in lieu of a formal application for a VCA transplant program designation. OPTN Bylaws, Appendix J lists what must appear in the letter of intent. Your program must not perform VCA transplants until UNOS notifies you that you have been designated to perform your requested VCA transplant.
- After your hospital receives VCA transplant program approval, email UNOS at vca@unos.org and request a worksheet to register and remove candidates on the VCA candidate list. Use this worksheet to register and remove your VCA candidates.

OPOs:

- Discuss and document VCA donor authorization separately from solid organ donor authorization. You must document VCA donor authorization on a separate VCA-specific authorization form. The VCA allocation system resides outside DonorNet®. OPOs must allocate VCA organs from the VCA candidate list in Secure Enterprise and record applicable refusal, bypass, and acceptance reasons for each VCA organ consented. You must return each completed VCA candidate list to UNOS using secure email (vca@unos.org), as set forth in OPTN Policy 18.1.

Affected Policy/Bylaw Language:

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

Appendix D:

Membership Requirements for Transplant Hospitals and Transplant Programs

A transplant hospital member is any hospital that performs organ transplants and has current approval as a designated transplant program for at least one organ.

The following provisions of Appendix D do not apply to VCA transplant programs:

- *D.4: Transplant Program Director*
- *D.5: Transplant Program Key Personnel*
- *D.6: Changes in Key Transplant Program Personnel*
- ~~*D.9: Review of Transplant Program Functional Activity*~~
- ~~*D.10 A: Transplant Program Survival Rates*~~
- ~~*D.10 B: Patient Notification Requirements for Waiting List Inactivation*~~
- ~~*D.10 C: Relocation of Transfer of Designated Transplant Programs*~~

D.2 Designated Transplant Program Requirement

In order to receive organs for transplantation, a transplant hospital member must have current approval as a designated transplant program for at least one organ. Designated transplant programs must meet at least *one* of the following requirements:

- Have approval as a transplant program by the Secretary of the U.S. Department of Health and Human Services (HSS) for reimbursement under Medicare.
- Have approval as a transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital.
- Qualify as a designated transplant program according to the membership requirements of these Bylaws.

The OPTN does not grant designated transplant program approval for any type of vascularized organ transplantation for which the OPTN has not established specific criteria. In order to perform vascularized organ transplantation procedures for which there are no OPTN-established criteria, including multi-visceral transplants, a hospital must be a transplant hospital member and have current approval as a designated transplant program for at least one of the organ types involved in multi-visceral transplant. In the case of abdominal multi-visceral organ transplants, the transplant hospital must have approval as a

designated liver transplant program. In the case of vascularized composite allografts (including, but not limited to, faces and upper extremities), the transplant hospital must have approval for at least one designated transplant program in addition to the vascularized composite allograft program designation.

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 the failure to perform a transplant during the periods defined in the table below:

Program Type	Inactive Period
<i>Kidney, Liver or Heart</i>	<i>3 consecutive months</i>
Pancreas or Lung	6 consecutive months
Stand-alone pediatric transplant programs	12 consecutive months

Functional inactivity thresholds have not been established for pancreatic islet, ~~and~~ intestinal, and VCA transplant programs.

D.10 Additional Transplant Program Requirements

A. Transplant Program Performance

Appendix D.10.A does not apply to VCA transplants.

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, the MPSC will review a transplant program if it has a higher hazard ratio of mortality or graft failure than would be expected 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 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, the 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.

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.

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.

The following provisions of Appendix K do *not* apply to VCA transplant programs:

- *K.1: Transplant Program Inactivity*
- *K.2: Short-term Inactive Transplant Program Status*
- *K.3: Long-term Inactive Transplant Program Status*

Appendix M: Definitions

Designated Transplant Program

An organ-specific program that has been approved by the MPSC to be a part of the transplant hospital membership. A transplant hospital member may have transplant programs for transplantation of hearts, lungs, liver, kidneys, pancreas, pancreas islets, ~~and~~ intestines, and vascularized composite allografts. In order to be a transplant hospital member, the transplant hospital must have current designated transplant program approval for at least one organ. A designated transplant program may also be called a transplant program in these Bylaws.

Organ

A human kidney, liver, heart, lung, pancreas, ~~or~~ intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract), or vascularized composite allograft. Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled "For use in organ transplantation only."

Vascularized Composite Allograft (VCA)

A transplant involving any body parts that meets *all* nine of the following criteria:

1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation.
2. Containing multiple tissue types.
3. Recovered from a human donor as an anatomical/structural unit.
4. Transplanted into a human recipient as an anatomical/structural unit.
5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement).
6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor).

7. Not combined with another article such as a device.
8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

Policy 1.2 Definitions

Organ

A human kidney, liver, heart, lung, pancreas, or intestine (including the esophagus, stomach, small or large intestine, or any portion of the gastrointestinal tract), or vascularized composite allograft. Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled "For use in organ transplantation only."

Organ allocation policies

OPTN Policies: *Policy 6: Allocation of Hearts and Heart-Lungs, Policy 7: Allocation of Intestines, Policy 8: Allocation of Kidneys, Policy 9: Allocation of Livers and Liver-Intestines, Policy 10: Allocation of Lungs, and Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets, and Policy 12: Allocation of Vascularized Composite Allografts.*

Vascularized Composite Allograft (VCA)

A transplant involving any body parts that meet all nine of the following criteria:

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

2.2 OPO Responsibilities

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

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Clinical management of the deceased donor.

8. Assuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, packaging, and transporting the organs.
11. Reporting to the OPTN Contractor all deceased donor information required for organ placement, including the donor's human leukocyte antigen (HLA) type.
12. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to VCA transplants; instead, members must allocate VCAs according to *Policy 12.2: VCA Allocation*.
13. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
14. Ensuring that written documentation of the deceased donor evaluation, donor management, authorization for donation, death pronouncement, and organ procurement quality accompanies the organ as described in *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.

Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

2.15.D Authorization Requirement

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

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

5.2 Maximum Mismatched Antigens

A transplant program may also specify the maximum number of mismatched antigens it will accept and any unacceptable antigens for any of its candidates. If a transplant program specifies these mismatched antigens, the OPTN Contractor will only offer organs from deceased donors with mismatched antigens equal to or less than the maximum specified.

This policy does not apply to VCA transplants.

5.4.B Order of Allocation

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

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.
3. OPOs must first offer organs to potential recipients in the order that the potential recipients appear on a match run.
4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update their candidates' data with the OPTN Contractor. The host OPO may run an updated match run and allocate the organ according to the updated candidate data.

5. If no transplant program within the DSA or through an approved regional sharing arrangement accepts the organ, the Organ Center will allocate an abdominal organ first regionally and then nationally, according to allocation Policies. The Organ Center will allocate thoracic organs according to *Policy 6: Allocation of Hearts and Heart-Lungs* and *Policy 10: Allocation of Lungs*.
6. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all potential recipients on the match run. Members must submit the *Organ Export Verification Form* to the OPTN Contractor prior to exporting deceased donor organs.

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

5.5.A Receiving and Reviewing Organ Offers

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

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

5.5.B Time Limit for Acceptance

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

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

This policy does not apply to VCA transplants.

Policy 12: Allocation of Vascularized Composite Allografts

12.1 Waiting Time

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

12.2 VCA Allocation

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

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

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

When a VCA is allocated, the host OPO must document:

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

14.5 Registration and Blood Type Verification of Living Donors before Donation

Recovery hospitals must use source documents from both an initial and second determination blood typings and subtypings (when used to determine transplant compatibility), to enter the living donor's blood type data on the *Living Donor Feedback Form*. Additionally, each living donor program must develop and comply with a protocol to verify that the living donor's blood type and type was correctly entered on *the Living Donor Feedback Form* with both the initial and second determination blood typing and subtyping source documents by an individual other than the person initially entering the donor's blood type data.

Recovery hospitals must document that each blood typing and subtyping entry was performed according to the program's protocol and must maintain this documentation.

This policy does not apply to VCA transplants.

18.3 Recording and Reporting the Outcomes of Organ Offers

The allocating OPO and the transplant hospitals that received organ offers share responsibility for reporting the outcomes of all organ offers. OPOs are responsible for reporting the outcomes of organ offers to the OPTN Contractor within 30 days of the match run date. OPOs, transplant hospitals, and the OPTN Contractor may report this information. The OPO or the OPTN Contractor must obtain PTR refusal codes directly from the physician, surgeon, or their designee involved with the potential recipient and not from other personnel.

If the OPO reports the refusal code, then the transplant hospital has 45 days from the match run date, to validate the refusal code by either confirming or amending the refusal code. If the OPO and transplant hospital report different refusal codes, then the OPTN Contractor will use the transplant hospital's refusal code for data analysis purposes.

If the OPTN reports the refusal code, then the transplant hospital will not be required to validate the refusal code.

~~This policy does not apply to VCA organ offers; instead, members must document VCA offers according to *Policy 12.2: VCA Allocation*.~~

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

Membership Requirements for VCA Transplant Programs

Sponsoring Committee:	VCA Committee
Policy/Bylaws Affected:	OPTN Bylaws, Appendix J
Distributed for Public Comment:	January 2015 to March 2015
Amended After Public Comment:	Yes
Effective Date:	Pending programming and notice to members

Problem Statement

Current OPTN Bylaws do not include specific training and experience requirements for key personnel at VCA transplant programs. The VCA Committee proposed minimal certification, training, and experience for individuals serving as primary transplant physicians and surgeons at VCA programs.

Summary of Changes

Changes to OPTN Bylaws Appendix J establish abdominal wall, head and neck, upper limb, and other VCA transplant programs and specify requirements for program directors, primary transplant surgeons, and primary transplant physicians at these programs. The new Bylaws outline key personnel certification, training, and experience requirements, and include a:

- Certification requirement, or clinical experience pathway in lieu of certification
- Formal training requirement, or clinical experience pathway in lieu of completing formal training

What Members Need to Do

The approved membership requirements for VCA Transplant Programs represent a significant change from the previous membership requirements. Once effective, transplant hospitals with designated VCA programs will need to reapply for OPTN approval. UNOS will give you advance notice of when these Bylaws changes will be effective. This will allow you to submit your program application and for the MPSC to review it before the implementation date.

These changes will be effective once they have been programmed into the system and you have been notified. Once implemented, your hospital will need to ensure that key VCA program personnel meet or exceed the certification, training, and experience requirements outlined below.

Affected Policy/Bylaw Language:

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

Appendix J:

Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs

This appendix describes the documentation transplant hospitals must provide when requesting approval as a designated VCA transplant program. VCAs include, but are not limited to, faces and upper extremities.

J.1 Letter of Notification

If a transplant hospital member commits to performing VCA transplants the hospital must send written notification of this intent to the OPTN Contractor. The notification to the OPTN Contractor must include a written assurance from the local OPO that it will provide organs for use in vascularized composite allografts.

The letter of notification from the transplant hospital must be signed by *all* of the following individuals:

1. The chief administrative officer for the institution.
2. A reconstructive surgeon with expertise in microsurgical reconstruction, prior experience in VCA, or in lieu of actual VCA experience, extensive experience in the applicable reconstructive procedure as required, such as hand replantation or facial reconstruction.
3. A transplant physician or transplant surgeon at an approved transplant program that has completed an approved transplant fellowship, or qualifies by documented transplant experience, in a medical or surgical specialty.

The OPTN Contractor will then notify the transplant hospital member of the program designation.

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval for each designated VCA transplant program.
- Completing a Personnel Change Application for a change in key personnel at each designated VCA transplant program.

For approval as a designated VCA transplant program, transplant hospitals must also:

1. Meet general membership requirements, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*.
2. Have current approval for and maintain a designated kidney, liver, heart, lung, or pancreas transplant program

For more information on the application and review process, see *Appendix A: Membership Application and Review*.

J.1 Program Director, Primary Transplant Physician, and Primary Transplant Surgeon

A VCA transplant program must identify at least one designated staff member to act as the VCA program director. The director must be a physician or surgeon who is a member of the transplant hospital staff. The same individual can serve as the program director for multiple VCA programs.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below. The primary transplant surgeon, primary transplant physician, and VCA program director for each designated VCA transplant program must submit a detailed Program Coverage Plan to the OPTN Contractor. For information about the Program Coverage Plan, see *Appendix D.5.B, Surgeon and Physician Coverage*.

J.2 Primary VCA Transplant Physician Requirements

Each designated VCA transplant program must have a primary transplant physician who is (1) currently designated as the primary transplant surgeon or primary transplant physician at an active solid organ

transplant program, (2) meets the requirements of a primary transplant surgeon or primary transplant physician in the OPTN Bylaws, or (3) who meets all of the following requirements:

1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be on-site at this hospital.
3. The physician must have documentation from the hospital's credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education, and that the physician is currently a member in good standing of the hospital's medical staff.
4. The physician must have completed an approved transplant fellowship in a medical or surgical specialty. Approved transplant fellowships for each organ are determined according to the requirements in OPTN Bylaws Appendices E through I.

J.3 Primary VCA Transplant Surgeon Requirements

Each designated VCA transplant program must have a primary transplant surgeon that meets all of the following requirements:

1. The primary surgeon must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The primary surgeon must be accepted onto the hospital's medical staff, and be on-site at this hospital.
3. The primary surgeon must have documentation from the hospital's credentialing committee that it has verified the surgeon's state license, training, and continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.
4. The primary surgeon must have observed at least 2 multi-organ procurements.

A. Additional Primary Surgeon Requirements for Upper Limb Transplant Programs

In addition to the requirements as described in J.3 above, the surgeon for an upper limb transplant program must meet the following:

1. Must meet at least one of the following:
 - a. Have current certification by the American Board of Plastic Surgery, the American Board of Orthopedic Surgery, the American Board of Surgery, or the foreign equivalent. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of renewal for an additional 12-month period.
 - b. If the surgeon does not have board certification, the surgeon may qualify by gaining all of the relevant clinical experience as outlined below. As of September 1, 2018, this pathway will no longer be available and all primary surgeons must meet the requirements of paragraph 1A.
 - i. Observation of at least 2 multi-organ procurements and acted as the first-assistant or primary surgeon on at least 1 VCA procurement.
 - ii. Pre-operative evaluation of at least 3 potential upper limb transplant patients.
 - iii. Acted as primary surgeon of a least 1 upper limb transplant.
 - iv. Post-operative follow-up of at least 1 upper limb recipient for 1 year post-transplant.
The multi-organ procurement experience must be documented in a log that includes the Donor ID or other unique identifier that can be verified by the OPTN Contractor. The experience for upper limb transplant procedures must be

documented in a log that includes the dates of procedures and evaluations, the role of the surgeon, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained. If a primary surgeon qualified under 1.b ends his involvement with the transplant program, the program must identify a primary transplant surgeon who meets the requirements under 1.a.

2. Completion of at least one of the following:
 - a. Completion of a fellowship program in hand surgery that is approved by the MPSC. Any Accreditation Council of Graduate Medical Education (ACGME) approved fellowship program is automatically accepted by the MPSC.
 - b. Completion of a fellowship program in hand surgery that meets all of the following criteria will also be accepted:
 - i. The program is located at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.
 - ii. The program is located at an institution that has a proven commitment to graduate medical education.
 - iii. The program director must have current certification in the sub-specialty by the American Board of Orthopedic Surgery, the American Board of Plastic Surgery, or American Board of Surgery.
 - iv. The program should have at least 2 physician faculty members with hand surgery experience and current medical licensure who are actively involved in the instruction and supervision of fellows during the time of accredited education.
 - v. The program at a hospital that has affiliated rehabilitation medicine services.
 - vi. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.
 - c. The surgeon must have at least 2 years of consecutive and independent practice of hand surgery and must have completed a minimum number of upper limb procedures as the primary surgeon shown in Table J.1 below. This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery. These procedures must be documented in a log that includes the date of the procedure and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained. Surgery of the hand includes only those procedures performed on the upper limb below the elbow.

Table J.1: Minimum Procedures for Upper Limb Primary Transplant Surgeons

<u>Type of Procedure</u>	<u>Minimum Number of Procedures</u>
<u>Bone</u>	<u>20</u>
<u>Nerve</u>	<u>20</u>
<u>Tendon</u>	<u>20</u>
<u>Skin or Wound Problems</u>	<u>14</u>
<u>Contracture or Joint Stiffness</u>	<u>10</u>
<u>Tumor</u>	<u>10</u>
<u>Microsurgical Procedures</u>	
<u>Free flaps</u>	<u>10</u>
<u>Non-surgical management</u>	<u>6</u>
<u>Replantation or Transplant</u>	<u>5</u>

B. Additional Primary Surgeon Requirements for Head and Neck Transplant Programs

In addition to the requirements as described in J.3 above, the transplant surgeon for a head and neck transplant program must meet at least *one* of the following:

1. Must meet at least *one* of the following:
 - a. Have current certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, American Board of Oral and Maxillofacial Surgery, the American Board of Surgery, or the foreign equivalent. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of renewal for an additional 12-month period.
 - b. If the surgeon does not have board certification, the surgeon may qualify by gaining all of the relevant clinical experience as outlined below. As of September 1, 2018, this pathway will no longer be available and all primary surgeons must meet the requirements of paragraph 1.a.
 - i. Observe at least 2 multi-organ procurements and acted as the first-assistant or primary surgeon on at least 1 VCA procurement.
 - ii. Pre-operative evaluation of at least 3 potential head and neck transplant patients.
 - iii. Primary surgeon of a least 1 head and neck transplant.
 - iv. Post-operative follow up of at least 1 head and neck recipient for 1 year post-transplant.

The multi-organ procurement experience must be documented in a log that includes the Donor ID or other unique identifier that can be verified by the OPTN Contractor. The experience for head and neck procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained. If a primary surgeon qualified under 1.b ends his involvement with the transplant program, the program must identify a primary transplant surgeon who meets the requirements under 1.a.

2. Completion of at least *one* of the following:
 - a. Completion of a fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery that is approved by the MPSC. Any ACGME–approved fellowship program is automatically accepted by the MPSC.
 - b. Completion of a fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery that meets all of the following criteria:
 - i. The program is at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.
 - ii. The program is at an institution that has a proven commitment to graduate medical education.
 - iii. The program director must have current certification in the sub-specialty by the American Board of Plastic Surgery, the American Board of Otolaryngology, American Board of Oral and Maxillofacial Surgery.
 - iv. The program should have at least two physician faculty members with head and neck surgery experience and current medical licensure who

- are actively involved in the instruction and supervision of fellows during the time of accredited education.
 - v. The program is at a hospital that has affiliated rehabilitation medicine services.
 - vi. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.
- c. The surgeon must have at least 2 years of consecutive and independent practice of head and neck surgery. The surgeon must have completed at least 1 face transplant as primary surgeon or first-assistant, or a minimum number of head and neck procedures as the primary surgeon as shown in Table J.2 below. This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery. These procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon and the medical record number, Donor ID, or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.

Table J.2: Minimum Procedures for Head and Neck Primary Transplant Surgeons

Type of Procedure	Minimum Number of Procedures
Facial trauma with bone fixation	10
Head or neck free tissue reconstruction	10

C. Additional Primary Surgeon Requirements for Abdominal Wall Transplant Programs

The primary surgeon for an abdominal wall transplant program must meet the primary transplant surgeon requirements of a head and neck, intestine, kidney, liver, pancreas, or upper limb transplant program.

D. Additional Primary Surgeon Requirements for Other VCA Transplant Programs

This pathway is only for the primary transplant surgeon at a VCA program intending to transplant body parts other than those that will be transplanted at approved upper limb, head and neck, or abdominal wall transplant programs. In addition to the requirements as described in J.3 above, the primary surgeon for other VCA transplant programs must meet *all* of the following:

1. Specify the type or types of VCA transplant the surgeon will perform.
2. Have current American Board of Medical Specialties certification or the foreign equivalent in a specialty relevant to the type of VCA transplant the surgeon will be performing.
3. Have gained all of the relevant clinical experience as outlined below:
 - a. Observe at least 2 multi-organ procurements.
 - b. Pre-operative evaluation of at least 3 potential VCA transplant patients.
4. Have current working knowledge in the surgical specialty, defined as independent practice in the specialty over a consecutive five-year period.
5. Assembled a multidisciplinary surgical team that includes the primary surgeon with board certification in the relevant surgical specialty and other specialists necessary to complete the VCA transplant including, for example, plastic surgery, orthopedics, otolaryngology, obstetrics and gynecology, urology, or general surgery. This team must include a team member that has microvascular experience such as replantation, revascularization, free tissue transfer, and major flap surgery. These

procedures must be documented in a log that includes the dates of procedures, the role of the surgeon, and the medical record number, Donor ID, or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained. The team must have demonstrated detailed planning and cadaver rehearsals that are specific to the type or types of VCA transplant the program will perform.

A letter from the presiding institutional executive of the institution where the VCA will be performed must provide written notification that requirements 1-5 above have been met.