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## **IMPORTANT POLICY NOTICE**

**To:** Transplant Professionals

**From:** James B. Alcorn  
Director, Policy

**RE:** Summary of actions taken at the OPTN/UNOS Board of Directors Meeting  
—June 25-26, 2012

**Date:** July 26, 2012

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The attached report summarizes bylaw and policy changes approved by the OPTN/UNOS Board of Directors at its June 2012 meeting. This policy notice also provides the specific bylaw and policy 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. This policy notice, and those reviewing changes from previous Board of Directors meetings, can be found at [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov) (click on “News,” and then select “View all Policy Notices”).

The Evaluation Plan, which reviews specific details regarding how members will be assessed for compliance with OPTN policies and bylaws, has also been updated to reflect the changes resulting from the June 2012 Board of Directors meeting. It can also be found at [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov) (click on “Policy Management,” and then select “Evaluation Plan”).

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

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## Change in OPTN Patient Registration Fee

**Sponsoring Committee:** Finance Committee

**Policy Affected:** 11.0 (Registration Fee)

**Distributed for Public Comment:** No

**Effective Date:** October 1, 2012

<b>Problem Statement</b>
The OPTN needs additional funding for operational expenses during fiscal year 2013 (October 1, 2012 – September 30, 2013).

<b>Changes</b>
The OPTN Board of Directors approved an increase in the OPTN patient registration fee from \$603 to \$651, subject to final approval by the Health Resources and Services Administration (HRSA).

<b>Action Required</b>
Notify your program's finance department of this fee increase.

## OPTN Bylaws Plain Language Rewrite

**Sponsoring Committee:** Membership and Professional Standards Committee

**Bylaws Affected:** Entire Bylaws, except for the current Appendix A: Application and Hearing Procedures for Members and Designated Transplant Programs

**Distributed for Public Comment:** December 2011

**Amended After Public Comment:** Yes

**Effective Date:** September 1, 2012

<b>Problem Statement</b>
Feedback provided during a member survey indicated that the OPTN bylaws are difficult to understand, access, and use.

<b>Changes</b>
The OPTN Bylaws Plain Language Rewrite Project did not include substantive changes to the current content. The changes make the current language easier to understand by using consistent terminology, better organization, and new usability features, including a table of contents.  Additionally, relevant information that was located in the UNOS Bylaws, but not the OPTN Bylaws, has been reorganized and included in the OPTN Bylaws.

<b>Action Required</b>
The rewritten bylaws can be reviewed <a href="#">here</a> . Members should familiarize themselves with the rewritten OPTN bylaws.  For additional background information on the OPTN Bylaws Plain Language Rewrite Project, please access the PowerPoint slides that were used to present these changes during public comment discussions earlier this year. That information can be reviewed <a href="#">here</a> .

## Substantive Rewrite of the OPTN Bylaws Addressing Review, Actions, and Due Process

**Sponsoring Committee:** Membership and Professional Standards Committee

**Bylaw Affected:** Appendix A: Application and Hearing Procedures for Members and Designated Transplant Programs

**Distributed for Public Comment:** February 2012

**Amended After Public Comment:** Yes

**Effective Date:** September 1, 2012

<b>Problem Statement</b>
The OPTN bylaws regarding members' rights and responsibilities, the Secretary of Health and Human Services' (HHS) role in reviewing potential violations of OPTN policies, and the OPTN Contractor's responsibilities and actions when reviewing potential policy violations are not clear.

<b>Changes</b>
The OPTN/UNOS Board of Directors adopted a substantive rewrite of the processes and procedures for reviewing potential violations of non-compliance with OPTN obligations. All content from the former Appendix A also underwent a plain language rewrite and reorganization. This bylaw will now be presented as Appendix L: Reviews, Actions, and Due Process.

<b>Action Required</b>
The rewritten bylaws, including the substantive rewrite of the processes and procedures for reviewing potential violations of non-compliance with OPTN obligations that are included in Appendix L, can be found <a href="#">here</a> . OPTN Members should review and familiarize themselves with the rewritten bylaws.
For additional background information on the substantive rewrite of Appendix A of the OPTN Bylaws, please access the PowerPoint slides that were used to present these changes during public comment discussions earlier this year. That information can be reviewed <a href="#">here</a> .

## OPTN Bylaws Plain Language Rewrite- Moving Bylaws to Policy

**Sponsoring Committee:** Membership and Professional Standards Committee

**Bylaws Affected:** UNOS Bylaws Appendix B, Attachment 1: Designated Transplant Program Criteria, Section XIII Transplant Programs, D.(2) Kidney Transplant Programs that Perform Living Donor Transplants, b. Protocols; UNOS Bylaws Appendix B, Attachment 1: Designated Transplant Program Criteria, Section XIII Transplant Programs D(4) Liver Transplant Programs that Perform Living Donor Liver Transplants, b. Protocols; UNOS Bylaws Appendix B, Section II. Transplant Hospitals, F. Patient Notification; Appendix B, Attachment I(13) Patient Notification, Appendix B, Attachment IIA: Standards for Histocompatibility Testing (D-N); UNOS Bylaws Appendix B, Attachment IID: Preservation of Zero Mismatch Tissue Typing Materials; and Appendix B, Attachment III: Model Elements for DCD Recovery Protocols

**Distributed for Public Comment:** December 2011

**Amended After Public Comment:** Yes

**Effective Date:** September 1, 2012

<b>Problem Statement</b>
Some information in the current OPTN Bylaws would be better organized in OPTN Policy.

<b>Changes</b>
OPTN Bylaws pertaining to required protocols for liver and kidney recovery hospitals, patient notification, histocompatibility laboratory testing requirements, preservation of zero mismatch tissue typing materials, and model elements for controlled DCD recovery protocols have moved to policy as a result of the OPTN Bylaws Plain Language Rewrite. These changes did not impact the content of these bylaws; instead, the information has only be moved and rewritten for clarity.

<b>Action Required</b>
Members should familiarize themselves with the rewritten OPTN bylaws, as well as the rewritten policies addressed in this notice. The rewritten bylaws can be reviewed <a href="#">here</a> .

## Proposal to Clarify and Improve Variance Policies

**Sponsoring Committee:** Policy Oversight Committee

**Policies Affected:** 3.1.7 (Alternative Allocation/Distribution System), 3.1.8 (Variances), 3.1.9 (Committee-Sponsored Alternative System), 3.1.10 (Local and Alternative Local Unit (ALU)), 3.1.11 (Sharing Arrangement and Sharing Agreement), 3.1.12 (Alternative Point Assignment Systems), 3.4.8 (Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems), 3.4.9 (Application, Review, Dissolution and Modification Processes for Variances), 3.4.10 (Development, Application, Review, Dissolution and Modification Processes for Committee-Sponsored Alternative Systems), 3.5.6.1 (Local Allocation), 3.6 (Allocation of Livers), and 3.7.1 (Exceptions)

**Distributed for Public Comment:** September 2011

**Amended After Public Comment:** Yes

**Effective Date:** September 1, 2012

<b>Problem Statement</b>
Policies to create and evaluate variances exist; however, they are difficult to understand.

<b>Changes</b>
The policy language changes: <ul style="list-style-type: none"><li>• make it easier for members to comply with the variance policies</li><li>• enable the OPTN Contractor to evaluate a variance for national use</li><li>• create uniformity in how members apply for any type of variance</li><li>• promote reliability in the category of information provided with each variance application</li></ul>



<b>Action Required</b>
Members should familiarize themselves with the new policy language.  The variance application has also been updated to reflect these policy changes. Please contact your regional administrator to obtain a copy of the new variance application.

Plain Language Modifications to the Adult and Pediatric Heart Allocation Policies, Including the Requirement of Transplant Programs to Report in UNet<sup>SM</sup> a Change in Criterion or Status within Twenty-Four Hours

**Sponsoring Committee:** Thoracic Organ Transplantation Committee

**Policies Affected:** Policies 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status)

**Distributed for Public Comment:** September 2011

**Amended After Public Comment:** No

**Effective Date:** Changes to Policy 3.7.4 Status 1A criterion (e) and Status 1B criterion (a) will be implemented and effective pending programming. The remaining changes will be effective September 1, 2012.

<b>Problem Statement</b>
As part of its site audit criteria, the OPTN Contractor requires adult and pediatric heart transplant programs to record in UNet <sup>SM</sup> any changes to a candidate's status or criterion within 24 hours of that change. This requirement is not in policy.

<b>Changes</b>
If a change in the candidate's medical condition makes the criterion used to justify a candidate's Status 1A or 1B no longer accurate, the transplant program must report the accurate information in UNet <sup>SM</sup> within 24 hours of the change in medical condition.  The OPTN Contractor will change the pediatric heart status justification form to display each inotrope and its dosage that meet Status 1A criterion (e) and Status 1B criterion (a) in Policy 3.7.4.

<b>Action Required</b>
If a change in the candidate's medical condition makes the criterion used to justify a candidate's Status 1A or 1B no longer accurate, the transplant program must <i>continue to</i> report the accurate information in UNet <sup>SM</sup> within 24 hours of the change in medical condition.  The OPTN Contractor will send a system notice when the changes to Policy 3.7.4 Status 1A criterion (e) and Status 1B criterion (a) have been programmed in UNet <sup>SM</sup> .

## Revisions to the Waiting Time Modification Policy

**Sponsoring Committee:** Kidney Transplantation Committee

**Policy Affected:** 3.2.1.8 (Waiting Time Modification)

**Distributed for Public Comment:** September 2011

**Amended After Public Comment:** Yes

**Effective Date:** September 1, 2012

### **Problem Statement**

Current OPTN policies for submitting waiting time modification requests are not clear. This leads to wasted time for the transplant centers that submit requests, for OPTN Contractor staff who process requests, and for the committees that review requests. Required documentation is often missing, which means transplant candidates may not quickly receive the waiting time that they are entitled to under OPTN policy.

### **Changes**

The existing requirements and process for submitting a waiting time modification request have not substantially changed. OPTN Policy 3.2.1.8 (Waiting Time Modification) has primarily been edited to state this process more clearly. The new policy language also explicitly states which committee will review each waiting time modification request. Finally, the new policy language standardizes the processes for the application and implementation of waiting time modifications.

### **Action Required**

Transplant center staff who submit waiting time modification requests to the OPTN Contractor should familiarize themselves with the new policy language. The application to be completed for waiting time modifications can be found under the "Resources" tab in Waitlist<sup>SM</sup>.

Changes to Policy 3.6 (Adult Donor Liver Allocation Algorithm) for Regional Distribution of Livers for Critically Ill Candidates and to Extend the “Share 15” Regional Distribution Policy to “Share 15 National”

**Sponsoring Committee:** Liver and Intestinal Organ Transplantation Committee

**Policy Affected:** 3.6 (Adult Donor Liver Allocation Algorithm)

**Distributed for Public Comment:** September 2011

**Amended After Public Comment:** No

**Effective Date:** Pending programming in UNet<sup>SM</sup>

<b>Problem Statement</b>
Despite improvements in liver allocation and distribution, waitlist mortality remains high for patients with higher MELD/PELD scores.

<b>Changes</b>
The adult donor liver algorithm will be modified so that deceased donor livers (age 18 and older) will be offered to local and regional candidates with MELD/PELD scores of 35 or higher before those livers are offered to local candidates with lower MELD/PELD scores. Livers will also be offered to all candidates with MELD/PELD scores of 15 or higher locally, regionally, and nationally before being offered to candidates with lower MELD/PELD scores. Although these changes are presented in one policy notice, it should be noted that each element was considered separately during public comment and by the OPTN/UNOS Board of Directors.

<b>Action Required</b>
Members should familiarize themselves with the new policy language. The OPTN Contractor will send a system notice when these changes have been programmed in UNet <sup>SM</sup> .

Prohibiting the Use of an “Alternate” Label and Requiring the Use of an OPTN-Distributed, Standardized Label when Transporting Organs on Mechanical Preservation Machines

**Sponsoring Committee:** Organ Procurement Organization Committee

**Policy Affected:** 5.1 (External Packaging Specifications), 5.1.3 (Mechanical preservation machine), and 5.3 (External Labeling Requirements)

**Distributed for Public Comment:** September 2011

**Amended After Public Comment:** No

**Effective Date:** September 1, 2012

<b>Problem Statement</b>
Current OPTN policy allows members to use an alternate label when packaging an organ that will be transported using a mechanical preservation machine. Member-created labels have resulted in inconsistent labeling, specifically the exclusion of important, required information.

<b>Changes</b>
Members will no longer have the option of using alternate shipping labels when transporting organs with mechanical preservation machines. Members will be required to use a new, standardized label when packaging organs that will be transported using mechanical preservation machines. This new label will be a part of the current color-coded labeling system that is now required for organs packaged for transport, and is distributed by the OPTN Contractor.

<b>Action Required</b>
When packaging organs that will be transported using mechanical preservation machines, members must use the new, standardized, color-coded, OPTN-distributed label that corresponds to the organ being shipped. Alternate labels may not be used.
Prior to the September 1, 2012, effective date, these new, color-coded labels for transporting organs on mechanical preservation machines will be available for purchase from the <a href="#">UNOS Store</a> .

Changing the Term “Consent” to “Authorization” Throughout OPTN/UNOS  
Policies and Bylaws When Used in Reference to Organ Donation

**Sponsoring Committee:** Organ Procurement Organization Committee

**Policies and Bylaws Affected:** 2.1 (Host OPO), 2.4 (Obtaining Consent), 3.3.6.1.1, 3.5.3.3 (Sharing), 3.5.5 (Payback Requirements), 5.5.1 (Documentation Accompanying the Organ), 5.10.1 (Vessel recovery and transplant), 6.4.2 (Developmental Protocols in International Organ Exchange), 6.4.3 (Ad Hoc Organ Exchange), 7.0 (Data Submission Requirements), 9.6.6, Attachment III to Appendix B of the OPTN Bylaws, B. (Consent/Approval), and Attachment III to Appendix B of the OPTN Bylaws, C. (Withdrawal of Life Sustaining Measures/ Patient Management)

**Distributed for Public Comment:** September 2011

**Amended After Public Comment:** No

**Effective Date:** September 1, 2012

<b>Problem Statement</b>
Currently, OPTN/UNOS policies and bylaws use the term “consent” to describe the act of making an anatomical gift. The public might associate “consent” with the concept of “informed consent” through which physicians must give patients all the information they need to understand the risks, benefits, and costs of a particular medical treatment.
<b>Changes</b>
The term “consent” has been changed to “authorization” throughout the policies and bylaws when used in reference to organ donation. The purpose of this word substitution is to align policy and bylaw language with terminology used in the transplant community.
<b>Action Required</b>
Members should familiarize themselves with the new policy and bylaw language.

## Revisions to and Reorganization of Policy 6 (Transplantation of Non-Resident Aliens)

**Sponsoring Committees:** Ad Hoc International Relations Committee and Ethics Committee

**Policies Affected:** 1.0 (Member Rights and Obligations), 3.2.1.4 (Prohibition for Organ Offers to Non-Members), and 6.0 (Transplantation of Non-Resident Aliens)

**Distributed for Public Comment:** September 2011

**Amended After Public Comment:** Yes

**Effective Date:** September 1, 2012

<b>Problem Statement</b>
Current Policy 6: <ul style="list-style-type: none"><li>• creates misunderstanding in the transplant community about the audit trigger policy pertaining to the non-residents who receive deceased donor organ transplants in the US</li><li>• lacks transparency regarding non-citizen and non-resident listings and transplants</li><li>• includes some outdated and unenforceable policies.</li></ul>

<b>Changes</b>
The revised Policy 6: <ul style="list-style-type: none"><li>• allows the Ad Hoc International Relations Committee (the Committee) to review all citizenship data reported to the OPTN Contractor</li><li>• allows the Committee to request member transplant centers to voluntarily provide additional information about listings or transplants of non-US citizens/non-US residents</li><li>• allows the Committee to prepare and provide public access to an annual report of transplant center activities related to the listings and transplantation of non-US citizens/non-US residents</li><li>• defines non-US citizen/US resident and non-US citizen/non-US resident</li><li>• eliminates the greater than 5% audit trigger policy (“5% rule”)</li><li>• relocates the policy on valuable consideration and organ export</li><li>• broadens the nondiscrimination policy to include all candidates waiting for transplantation, not just non-residents</li><li>• defines an ad hoc deceased donor import but eliminates the arbitrary rule surrounding six ad hoc deceased donor imports</li><li>• deletes policies that are not enforceable.</li></ul>

<b>Action Required</b>
Members should familiarize themselves with the new policy language.

## Revisions to OPTN/UNOS Bylaws and Policies that Govern HLA Laboratories

**Sponsoring Committee:** Histocompatibility Committee

**Policy and Bylaw Affected:** Attachment IIA to Appendix B of the UNOS Bylaws (Standards for Histocompatibility Testing) and Attachment IIB to Appendix B of the UNOS Bylaws (UNOS Test Data Criteria for New HLA Laboratories and for the Addition of New Techniques)

**Distributed for Public Comment:** September 2011

**Amended After Public Comment:** Yes

**Effective Date:** September 1, 2012

<b>Problem Statement</b>
The OPTN/UNOS bylaws and policies that govern histocompatibility laboratories are outdated. In addition to aligning the policies and bylaws with current practice, consolidation and reorganization were also necessary.

<b>Changes</b>
The existing requirements have been updated to more closely align with current laboratory practices. Additionally, technical changes clarify the bylaws and policies regarding histocompatibility laboratories. Specifically, the bylaw and policy changes address the following: <ul style="list-style-type: none"><li>• how laboratories must test proficiency samples</li><li>• the requirements for subcontractors</li><li>• the requirement for transplant programs to report potentially sensitizing events to laboratories for all candidates</li><li>• the frequency that screen serum samples must be collected</li><li>• the requirement that laboratories use techniques compliant with Federal regulations when performing blood group determination</li><li>• the requirement for new laboratories to submit a copy of procedures and test validation data to the Histocompatibility Committee has been deleted; however, new laboratories are still required to submit these materials to an OPTN approved histocompatibility laboratory accrediting agency.</li></ul>

<b>Action Required</b>
Members should familiarize themselves with the new language.

**Affected Policy Language:****11.0 REGISTRATION FEE**

The OPTN Patient Registration Fee, as provided in Article I, Section 1.13 of the Bylaws for the listing of candidates as required by Policy 3.2.1 for listing a potential recipient in UNet<sup>SM</sup>, shall be ~~\$603~~ \$651.

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

**Affected Bylaw Language:**

The OPTN Bylaws Plain Language Rewrite affects all of the bylaws, except the current Appendix A: Application and Hearing Procedures for Members and Designated Transplant Programs. This section underwent a substantive rewrite which was also approved at the June 2012 OPTN/UNOS Board of Directors meeting. The substantive rewrite of Appendix A will be included in the bylaws as the new Appendix L: Reviews, Actions, and Due Process.

The rewritten bylaws have not been included in this policy notice due to the large file size that would result. Please access the rewritten bylaws [here](#).

To read the current bylaws, which are in effect until September 1, 2012, visit [www.unos.org](http://www.unos.org) or [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov). From the UNOS website, select "Bylaws" from the "I am looking for:" box in the upper left hand corner. From the OPTN website, select the "Policy Management" tab, then select "OPTN Bylaws."

**Affected Bylaw Language:**

These changes affect the current Appendix A: Application and Hearing Procedures for Members and Designated Transplant Programs, which will become Appendix L: Reviews, Actions, and Due Process, to fit with the new organization of the OPTN Bylaws Plain Language Rewrite that was also approved at the June 2012 OPTN/UNOS Board of Directors meeting

The rewritten bylaws have not been included in this policy notice due to the large file size that would result. Please access the rewritten bylaws, including the new Appendix L: Reviews, Actions, and Due Process, [here](#).

To read the current bylaws, which are in effect until September 1, 2012, visit [www.unos.org](http://www.unos.org) or [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov). From the UNOS website, select "Bylaws" from the "I am looking for:" box in the upper left hand corner. From the OPTN website, select the "Policy Management" tab, then select "OPTN Bylaws."

**Affected Policy/Bylaw Language:**

*\*Please note: At its June 2012 meeting, the OPTN/UNOS Board of Directors approved separate resolutions to Attachment IIA (Standards for Histocompatibility Testing) and Attachment IIB (UNOS Test Data Criteria for New HLA Laboratories and for the Addition of New Techniques) to Appendix B of the UNOS Bylaws, and Attachment III to Appendix B of the OPTN Bylaws (Model Elements for Controlled DCD Recovery Protocols). As a part of the OPTN Bylaws Plain Language Rewrite that the Board of Directors also adopted at its June 2012 meeting, these bylaws were also moved to policy. Below, in addition to the changes that resulted from the OPTN Bylaws Plain Language Rewrite- Moving Bylaws to Policy, Appendix D to Policy 3 also reflects the Board of Directors' approved changes from the Revisions to OPTN/UNOS Bylaws and Policies that Govern HLA Laboratories (sponsored by the Histocompatibility Committee). Similarly, Policy 2.8 (Model Elements for Controlled DCD Recovery Protocols) also reflects the Board of Directors' approved changes from Changing the Term "Consent" to "Authorization" Throughout OPTN/UNOS Policies and Bylaws When Used in Reference to Organ Donation (sponsored by the Organ Procurement Organization Committee).*

**UNOS Bylaws Appendix B, Attachment 1: Designated Transplant Program Criteria, Section XIII, (D) Transplant Programs**

- (4) Liver Transplant Programs that Perform Living Donor Liver Recovery.** Liver transplant programs that perform living donor liver recovery ("liver recovery hospital") must demonstrate the following:
- a. Personnel and Resources: Liver recovery hospitals must demonstrate the following:
    - (i) That the liver recovery hospital meets the qualifications of a liver transplant program as set forth above; and.
    - (ii) That the liver recovery hospital has on site no fewer than two surgeons who qualify as liver transplant surgeons under UNOS Bylaws Appendix B, Attachment I, and who have demonstrated experience as the primary surgeon or first assistant in 20 major hepatic resectional surgeries (to include living donor operations, splits, reductions, resections, etc.), 7 of which must have been live donor procedures, within the prior 5-year period. These cases must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, and the role of the surgeon in the operative procedure. It is recognized that in the case of pediatric living donor transplantation, the live organ donation may occur at a center that is distinct from the approved transplant center;
    - (iii) The liver recovery hospital must have the resources available to assess the medical condition of and specific risks to the potential living donor;
    - (iv) The psychosocial assessment should include an assessment of the potential living donor's capacity to make an informed decision and confirmation of the voluntary nature of proceeding with the evaluation and donation; and

- (v) That the liver recovery hospital has an independent donor advocate (IDA) who is not involved with the potential recipient evaluation, is independent of the decision to transplant the potential recipient and, consistent with the protocol referred to below, is a knowledgeable advocate for the potential living donor.

The goals of the IDA are:

- (1) to promote the best interests of the potential living donor;
- (2) to advocate the rights of the potential living donor; and
- (3) to assist the potential living donor in obtaining and understanding information regarding the:
  - (a) consent process;
  - (b) evaluation process;
  - (c) surgical procedure; and
  - (d) benefit and need for follow-up.

~~b. Protocols: Liver recovery hospitals must demonstrate that they have the following protocols:~~

- ~~(i) Living Donation Process: Liver recovery hospitals must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative, post-operative care, and submission of required follow up forms at 6 months, one year, and two year post donation.~~

~~Liver recovery hospitals must document that all phases of the living donation process were performed in adherence to the center's protocol. This documentation must be maintained and made available upon request.~~

- ~~(ii) Independent Donor Advocate: Liver recovery hospitals must develop, and once developed, must comply with written protocols for the duties and responsibilities of the Independent Donor Advocate that include, but are not limited, to the following elements:~~

- ~~(1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure that the IDA:~~

- ~~(a) promotes the best interests of the potential living donor;~~

- ~~(b) advocates the rights of the living donor; and~~

- (c) ~~assists the potential donor in obtaining and understanding information regarding the:~~
  - (i) ~~consent process;~~
  - (ii) ~~evaluation process;~~
  - (iii) ~~surgical procedure; and~~
  - (iv) ~~benefit and need for follow up.~~
  
- (iii) ~~Medical Evaluation: Liver recovery hospitals must develop, and once developed, must comply with written protocols for the medical evaluation of the potential living donors must include, but are not limited to the following elements:~~
  - (1) ~~a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post donation, which shall include a screen for any evidence of occult liver disease;~~
  - (2) ~~a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I) must also be provided to assess decision making capacity, screen for any pre-existing psychiatric illness, and evaluate potential coercion;~~
  - (3) ~~screening for evidence of transmissible diseases such as cancers and infections; and~~
  - (4) ~~a radiographic assessment to ensure adequate anatomy and volume of the donor and of the remnant liver.~~
  
- (iv) ~~Informed Consent: Liver recovery hospitals must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Hepatectomy, which include, at a minimum, the following elements:~~
  - (1) ~~discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;~~

- ~~(2) — assurance that all communication between the potential donor and the transplant center will remain confidential;~~
- ~~(3) — discussion of the potential donor's right to opt out at any time during the donation process;~~
- ~~(4) — discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;~~
- ~~(5) — disclosure by the liver recovery hospital that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one year, and two years post donation. The protocol must include a plan to collect the information about each donor; and~~
- ~~(6) — the telephone number that is available for living donors to report concerns or grievances through the OPTN.~~
- ~~(7) — documentation of disclosure by the liver recovery hospital to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.~~

e.b. Conditional Approval Status: If the liver recovery hospital does not have on site a second surgeon who can meet the requirement for having performed 7 live donor liver procedures within the prior 5-year period, but who has completed the requirement for obtaining experience in 20 major hepatic resection surgeries (as described above), as well as all of the other requirements to be designated as a primary liver transplant surgeon, the liver recovery hospital may be eligible for Conditional Approval Status. The liver recovery hospital can be granted one year to fully comply with applicable membership criteria with a possible one year extension. This option shall be available to new programs as well as previously approved programs that experience a change in key personnel. During this period of conditional approval, both of the designated surgeons must be present at the donor's operative procedure.

The liver recovery hospital shall comply with such interim operating policies and procedures as shall be required by the Membership and Professional Standards Committee (MPSC).

This may include the submission of reports describing the surgeon's progress towards meeting the requirements and such other operating conditions as may be required by the MPSC to demonstrate ongoing quality and efficient patient care. The liver recovery hospital must provide a report prior to the conclusion of the first year of conditional approval, which must document that the surgeon has met or is making sufficient progress to meet the objective of performing 7 live donor liver procedures or that the program is making sufficient progress in recruiting and bringing to the program a transplant surgeon who meets this criterion as well as all other criteria for a qualified live donor liver surgeon. Should the surgeon meet the requirements prior to the end of the period of conditional approval, the program may submit a progress report and request review by the MPSC.

**Policy 12.11: Required Protocols for Liver Recovery Hospitals**

Liver recovery hospitals must demonstrate that they have the following protocols:

- (i) Living Donation Process: Liver recovery hospitals must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative, post-operative care, and submission of required follow-up forms at 6 months, one-year, and two-year post donation.

Liver recovery hospitals must document that all phases of the living donation process were performed in adherence to the center's protocol. This documentation must be maintained and made available upon request.

- (ii) Independent Donor Advocate: Liver recovery hospitals must develop, and once developed, must comply with written protocols for the duties and responsibilities of the Independent Donor Advocate that include, but are not limited, to the following elements:

- (1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure that the IDA:

(a) promotes the best interests of the potential living donor;

(b) advocates the rights of the living donor; and

(c) assists the potential donor in obtaining and understanding information regarding the:

(i) consent process;

(ii) evaluation process;

(iii) surgical procedure; and

(iv) benefit and need for follow-up.

(iii) Medical Evaluation: Liver recovery hospitals must develop, and once developed, must comply with written protocols for the medical evaluation of the potential living donors must include, but are not limited to the following elements:

- (1) a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which shall include a screen for any evidence of occult liver disease;
- (2) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I) must also be provided to assess decision making capacity, screen for any pre-existing psychiatric illness, and evaluate potential coercion;
- (3) screening for evidence of transmissible diseases such as cancers and infections; and
- (4) a radiographic assessment to ensure adequate anatomy and volume of the donor and of the remnant liver.

(iv) Informed Consent: Liver recovery hospitals must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Hepatectomy, which include, at a minimum, the following elements:

- (1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;
- (2) assurance that all communication between the potential donor and the transplant center will remain confidential;
- (3) discussion of the potential donor's right to opt out at any time during the donation process;
- (4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;
- (5) disclosure by the liver recovery hospital that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor; and
- (6) the telephone number that is available for living donors to report concerns or grievances through the OPTN.
- (7) documentation of disclosure by the liver recovery hospital to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.

**UNOS Bylaws Appendix B, Section II. Transplant Hospitals, F. Patient Notification and Appendix B, Attachment I(13) Patient Notification**

~~**F. Patient Notification.** Transplant Hospitals are expected to notify patients in writing: (i) within ten business days (a) of the patient's being placed on the Waiting List including the date the patient was listed, or (b) of completion of the patient's evaluation as a candidate for transplantation, that the evaluation has been completed and that the patient will not be placed on the Waiting List at this time, whichever is applicable; and (ii) within ten business days of removal from the Waiting List as a transplant candidate for reasons other than transplantation or death that the patient has been removed from the Waiting List. Each such written notification must reference and include the OPTN contractor's "Patient Information Letter," which provides the telephone number that is available to patients and others to report concerns or grievances through the OPTN. All candidates currently on the waiting list should be notified by their listing center about the patient notification hotline, or other information as directed by the Executive Committee. Transplant Hospitals are further expected to maintain documentation of these notifications and make it available to the OPTN Contractor upon request for purposes of monitoring compliance with this provision. If the Member fails voluntarily to comply with this provision, the Membership and Professional Standards Committee may recommend that the Board of Directors notify the Secretary of HHS of the situation in the case of transplant programs approved by the Secretary of HHS for reimbursement under Medicare or transplant programs in Federal hospitals, or take appropriate action in accordance with Appendix A of these Bylaws in all other cases.~~

**Policy 3.2.8:**

Patient Notification. Transplant Hospitals are expected to notify patients in writing: (i) within ten business days (a) of the patient's being placed on the Waiting List including the date the patient was listed, or (b) of completion of the patient's evaluation as a candidate for transplantation, that the evaluation has been completed and that the patient will not be placed on the Waiting List at this time, whichever is applicable; and (ii) within ten business days of removal from the Waiting List as a transplant candidate for reasons other than transplantation or death that the patient has been removed from the Waiting List. Each such written notification must reference and include the OPTN contractor's "Patient Information Letter," which provides the telephone number that is available to patients and others to report concerns or grievances through the OPTN. All candidates currently on the waiting list should be notified by their listing center about the patient notification hotline, or other information as directed by the Executive Committee. Transplant Hospitals are further expected to maintain documentation of these notifications and make it available to the OPTN Contractor upon request for purposes of monitoring compliance with this provision. If the Member fails voluntarily to comply with this provision, the Membership and Professional Standards Committee may recommend that the Board of Directors

notify the Secretary of HHS of the situation in the case of transplant programs approved by the Secretary of HHS for reimbursement under Medicare or transplant programs in Federal hospitals, or take appropriate action in accordance with Appendix A of these Bylaws in all other cases.

## **UNOS Bylaws Appendix B, Attachment IIA: Standards for Histocompatibility Testing (D-N)**

### **~~D~~ HLA Typing**

~~**D1.000** HLA A, B, Bw4, Bw6, C, DR, and DQB antigens. When reporting DR antigens, DRB1 and DRB3/4/5 must be reported. The lab is encouraged to report splits for all loci as shown in Appendix 3A. Laboratories that perform deceased donor typing to be used in kidney, kidney-pancreas, pancreas, or pancreas islet allocation must report molecular typing results (at the level of serological splits) for all required antigens prior to organ offers.~~

~~D1.100 Laboratories performing HLA typing using cytotoxicity techniques must conform to all pertinent standards in Section H–Cytotoxicity Methods.~~

~~D1.200 Laboratories performing HLA typing using nucleic acid analysis must conform to all pertinent standards in Section K–Nucleic Acid Analysis.~~

~~D1.300 If alternative methods are used for HLA typing, procedures must be defined and validated, and must include sufficient controls to ensure accurate assignment of types. All relevant standards from the above sections must be applied.~~

### **~~D2.000~~ Typing Assignment**

~~D2.100 Each HLA antigen must be defined by a sufficient number of reagents to clearly define each antigen or allele group for which the laboratory tests.~~

~~D2.200 The level of resolution of HLA typing must be appropriate for the clinical application.~~

~~D2.300 The method of assignment of HLA phenotypes must be documented for each technique used.~~

~~D2.400 The laboratory must have and adhere to a written policy that establishes when antigen redefinition and retyping are required.~~

~~D2.500 The laboratory must maintain a list of antigens and/or alleles defined by each test used in the laboratory.~~

### **~~D3.000~~ Reagent Validation**

~~D3.100 Cell or DNA panels of known HLA class I and class II phenotype must be available to validate new typing reagents.~~

~~D3.200 The specificity of typing reagents obtained locally or from other sources and used for preparation of local trays must be documented and confirmed by external and/or internal QC testing.~~

~~D3.300 Each lot and/or shipment of new commercial reagents must be evaluated. The laboratory must establish and employ detailed policies and procedures for such evaluations~~

~~D3.400 Techniques used must be validated to optimally define HLA class I and/or class II antigens and/or alleles.~~

#### ~~**D4.000 HLA Typing by Nucleic Acid Analysis**~~

~~D4.100 The HLA alleles detected by each primer, probe or template primer combination must be defined. Primers and probes must be tested with all alleles that are recognized by the W.H.O. Nomenclature Committee for Factors of the HLA System, provided that nucleotide sequences and reference DNA are readily available.~~

~~D4.200 The laboratory must have a process to recognize and document ambiguous combination(s) of alleles for each template/primer or probe combination.~~

#### ~~**D4.300 Typing by Sequenced Based Typing (SBT)**~~

~~D4.310 Templates must have sufficient specificity for a locus or allele to provide interpretable primary sequencing data.~~

~~D4.320 Each unknown sequence must be compared with the sequences of all alleles that are recognized by the W.H.O. Nomenclature Committee for Factors of the HLA System provided that the nucleotide sequences are readily available.~~

~~D4.330 The laboratory must maintain records that define the sequence database utilized to interpret the primary data. This database must be updated at least annually. If a determined sequence is ambiguous (i.e., more than one possible interpretation of available data) the report must indicate all possible allele combinations.~~

#### ~~**E Antibody Screening**~~

~~E1.000 Laboratories performing assays using cytotoxicity must conform to standards in Section H – Cytotoxicity Methods.~~

~~E1.100 Laboratories performing assays using flow cytometry based methods must conform to the standards in Section L1.000 Instrument Standardization/Calibration and in Section L2.000 Flow Cytometric Crossmatch Technique.~~

~~E1.200 Laboratories using ELISA techniques for antibody screening must conform to Standards in Section M – Enzyme Linked Immuno Sorbent Assay (ELISA).~~

~~E1.300 Laboratories using solid phase multichannel arrays for antibody screening must conform to Standards in Section N.~~

**E2.000 Techniques**

~~E2.100 The laboratory must determine the antibody specificities that can be identified by the technique(s) used. The technique(s) must be appropriate for the clinical application.~~

~~E2.200 To detect antibodies to HLA class II antigens, a method must be used that distinguishes them from antibodies to HLA class I antigens.~~

~~E2.300 There must be a procedure in place to monitor and adjust for non-specific binding of antibody.~~

~~E2.400 Appropriate methods or controls must be used to assess the impact of xenogeneic and/or monoclonal therapeutic antibodies.~~

**E3.000 Sera**

~~E3.100 Sera must be tested at a concentration(s) determined to be optimal for detection of antibody(ies) to HLA antigens. The dilution(s) must be documented in the test records.~~

~~E3.200 All tests must include an appropriate positive and negative control.~~

**E4.000 Panel and Target Selection**

~~E4.100 The panel of antigens must be sufficient in number and phenotypic distribution with respect to individual antigens and/or crossreactive groups (CREGs) for the population served and for the intended use of the test results.~~

~~E4.200 For assays intended to provide information on HLA antibody specificity, documentation of the HLA class I and/or class II phenotypes of the panel must be maintained.~~

~~E4.300 Target cells or purified HLA molecules must be appropriate. The concentration, condition and phenotype of target cells or purified HLA molecules must be sufficient to ensure the antibodies being tested for (either HLA class I or class II) can be detected.~~

**F—Renal and Pancreas Organ Transplantation**

~~F1.000 If deceased donor transplants are performed, personnel for the required histocompatibility testing must be available 24 hours a day, seven days a week.~~

**F2.000 HLA Typing**

~~F2.100 Prospective typing of donors and recipients for HLA-A, B, Bw4, Bw6, and DR antigens is mandatory.~~

~~F2.200 Prospective typing of donors and recipients for HLA-C, and DQ antigens and for DR51, DR52, DR53, is highly recommended.~~

**F3.000 Antibody Screening**

~~F3.100 Laboratories must have a policy in place to evaluate the extent of sensitization of each patient at the time of initial evaluation and following potentially sensitizing events, based on the antibody characteristics that are clinically relevant to each transplant center's protocols.~~

~~F3.200 Laboratories must have a program to periodically screen serum samples from each patient for antibody to HLA antigens. The laboratory must have a documented policy establishing the frequency of screening serum samples and must have data to support this policy. It is recommended that samples be collected monthly.~~

~~F3.300 It is highly recommended that serum samples be tested for antibody to HLA antigens and that 1) information about antibody specificity be considered when evaluating the patient for transplant and, 2) that serum samples having defined class I and/or class II specificities be used in crossmatch testings.~~

~~F3.400 It is highly recommended that the HLA class I and class II specificity of antibodies be identified and reported and be distinguished from antibodies to non-HLA antigens.~~

#### **F4.000 Crossmatching**

~~F4.100 The laboratory must be capable of performing a prospective crossmatch and must do so when requested by a physician or other authorized individuals. Histocompatibility laboratories must have a joint written policy with their transplant program(s) on transplant candidate crossmatching strategies.~~

#### **F4.200 Techniques**

~~F4.210 Although the laboratory may use the basic complement-dependent microlymphocytotoxicity test for determining donor recipient compatibility, it must also use a crossmatching technique with increased sensitivity.~~

~~F4.220 Crossmatches must be performed with potential donor T lymphocytes. It is recommended that crossmatches be performed with B lymphocytes using a method that distinguishes between reactions with T and reactions with B lymphocytes.~~

~~F4.230 The laboratory must have and adhere to a written policy determining the serum(a) used in the final crossmatch. The relevance of the policy must be supported by published data or data generated in the laboratory. The policy must consider or include historic and current sensitizing events.~~

#### **F4.300 Samples**

~~F4.310 Sera must be tested at a dilution that is optimal for each assay.~~

~~F4.320 The laboratory must have a policy for storage and maintenance of recipient sera. The policy must define the samples to be retained and the duration of storage.~~

#### **G Other Organ and Islet Cell Transplantation**

~~G1.000 The laboratory must HLA type all potential transplant recipients and donors when requested by a physician or other authorized individuals.~~

~~G2.000 Patients must be screened for the presence of anti-HLA antibodies at initial evaluation and following sensitizing events when requested by a physician or other authorized individuals. It is recommended that unacceptable antigens be identified to optimize donor selection.~~

~~G3.000 The laboratory must be capable of performing a prospective crossmatch and must do so when requested by a physician or other authorized individuals.~~

~~G4.000 Histocompatibility laboratories must have a joint written policy with their transplant program(s) on transplant candidate antibody screening/identification and crossmatching strategies.~~

~~G5.000 Techniques with increased sensitivity in comparison with the basic/NIH complement-dependent micro-lymphocytotoxicity test must be used.~~

### ~~H Cytotoxicity Methods~~

~~H1.000 For each cell-serum combination, the results must be recorded in a manner that indicates the approximate percent of cells killed.~~

~~H1.100 Each laboratory must have a written policy that assigns positive or negative results based on percentage of cells killed.~~

### ~~H2.000 Controls~~

~~H2.100 Each tray must include at least one positive control serum that reacts with all cells expressing the class of antigens being tested.~~

~~H2.200 Each tray must include at least one negative control serum documented to be non-reactive under the specified test conditions.~~

~~H2.300 Cell viability in the negative control well at the end of incubation must be sufficient to ensure accurate interpretation of results.~~

~~H2.400 Appropriate methods or controls must be used to assess the impact of xenogeneic and/or monoclonal therapeutic antibodies in patient samples on the cytotoxicity assay.~~

### ~~H3.000 Target Cells~~

~~H3.100 When testing enriched cell populations the level of purity must be sufficient to ensure accurate interpretation of results.~~

### ~~H4.000 Complement~~

~~H4.100 Each lot and/or shipment of complement must be tested to determine that it mediates cytotoxicity in the presence of specific antibody, but is not cytotoxic in the absence of specific antibody. Optimal performance must be established and documented.~~

~~H4.200 Complement must be tested separately for use with each type of target cell (i.e., T cells, B cells, CLL cells) and with each test method used, since a different dilution or preparation may be required for optimal performance.~~

#### ~~I-ABO Blood Group Determination~~

~~I1.000 ABO blood group must be performed by techniques compliant with Federal regulations.~~

~~I2.000 If testing for the A1 subgroup of ABO group A is performed, the extract of Dolichos biflorus must be used at a dilution and with a technique documented not to agglutinate non-A<sub>1</sub> cells. Each assay or batch test run must include known A1 and non-A<sub>1</sub> cells as controls.~~

~~I3.000 If titration of anti-ABO antibodies is performed, the procedure and criteria for interpretation must be established and validated by the laboratory.~~

~~I4.000 Laboratories using molecular techniques for ABO blood grouping must conform to all pertinent standards in Section K- Nucleic Acid Analysis.~~

#### ~~J-Chimerism Analysis~~

~~J1.000 Laboratories performing engraftment and chimerism testing using nucleic acid analysis must conform to all pertinent standards in Section K- Nucleic Acid Analysis.~~

~~J2.000 The specificity and sequence of primers must be defined. The genetic designation (e.g., locus) of the target amplified by each set of primers must be defined and documented. For each locus analyzed, the laboratory must have documentation that includes the chromosome location, the approximate number of known alleles, and the distinguishing characteristics (e.g., sizes, sequences) of the alleles that are amplified.~~

~~J3.000 If sample processing involves the isolation of cell subsets or specific hematopoietic cell lineages, the laboratory should document the purity obtained whenever possible. If purity is not documented for a given sample, then this information must be provided on the patient report.~~

~~J4.000 For each locus tested, patient and donor samples collected pre transplant, and/or control samples demonstrated to have similar performance characteristics (e.g., sensitivity, competition in PCR) must be amplified and analyzed concurrently with patient samples collected post transplant.~~

#### ~~J5.000 Analysis and Reports~~

~~J5.100 Potential for preferential amplification of different sized alleles must be assessed and considered in the analysis.~~

~~J5.200 If more than one locus is amplified in a single amplification (multiplex), the effects of such amplification on each system must be assessed and considered in the analysis.~~

~~J5.300 Reports must identify the genetic loci analyzed according to standard nomenclature or published reference. For RFLP testing, the restriction endonuclease used and the fragment size must be identified.~~

~~J5.400 If results are reported in a quantitative or semi-quantitative manner, criteria for evaluating the relative amounts of recipient and donor in a mixed chimeric sample must be established.~~

~~J5.500 When mixed chimerism is not detected, reports must state the sensitivity level of the assay.~~

## ~~K Nucleic Acid Analysis~~

~~K1.000 Universal Standards (The standards in K1 apply to all nucleic acid testing).~~

### ~~K1.100 Nucleic Acid Extraction~~

~~K1.110 Nucleic acids must be purified by standard methods that have been validated in the laboratory and have written guidelines specifying the minimal acceptable sample (e.g., volume, number of cells, type of cells). If tests are performed without prior purification of nucleic acids, the method(s) used must specify the minimum acceptable sample and must fulfill all of the criteria set forth in A5.000.~~

~~K1.120 If nucleic acids are not used immediately after purification, samples must be stored under conditions that preserve their integrity.~~

~~K1.130 Nucleic acids must be of sufficient quality (e.g., purity, concentration) to ensure reliable test results.~~

### ~~K1.200 Electrophoresis~~

~~K1.210 Each electrophoretic run must include negative and positive controls that are processed with each assay to verify adequate and appropriate PCR amplification of target DNA.~~

~~K1.220 If size of the resulting nucleic acid fragment is a critical factor in the analysis of the data, the following steps must be undertaken: 1) the amount of DNA loaded in each lane must be within a range that ensures equivalent migration of DNA in all samples, including size markers, and 2) size markers that produce discrete electrophoretic bands spanning and flanking the entire range of expected fragment sizes must be included in each gel.~~

~~K1.230 The laboratory must establish criteria for accepting validity of each gel and of each lane of the gel and must determine and validate acceptable electrophoretic conditions for each assay.~~

### ~~K1.300 Analysis~~

~~K1.310 Acceptable limits of signal intensity must be specified for positive and negative results. If these are not achieved, corrective action is required.~~

~~K1.320 Two independent interpretations of primary data are required.~~

~~K1.330 Automated systems and computer programs must be validated prior to use and tested routinely for accuracy and reproducibility of manipulations.~~

## ~~K2.000 Template Amplification~~

**K2.100 Facilities and Equipment**

~~K2.110 Laboratories performing amplification of nucleic acids must establish and employ protocols to prevent DNA contamination using physical and/or biochemical barriers. Pre-amplification procedures must be performed in a work area that excludes amplified nucleic acid that has the potential to serve as a template in any amplification assays performed in the laboratory.~~

~~K2.120 The use of dedicated equipment and reagents as well as physical and/or biochemical barriers must be used to prevent nucleic acid contamination (carry-over).~~

~~K2.130 The laboratory must perform procedures to remove carry-over contamination from work areas used for manipulation of pre-amplification reagents or samples.~~

~~K2.140 When using methods that utilize two consecutive steps of amplification, addition of the template for subsequent amplifications must occur in an area isolated by physical or chemical barriers from both the pre-amplification work area and post-amplification work areas.~~

~~K2.150 Each work area (i.e., pre-amplification, secondary amplification, and post-amplification) must have dedicated pipettors. Positive displacement pipettes or filter barrier tips are recommended for pre-amplification and secondary amplification work areas.~~

~~K2.160 Thermal cycling instruments must precisely and reproducibly maintain the appropriate temperature of samples. Accuracy of temperature control for samples must be verified at least every 6 months.~~

~~K2.170 Incubators and water baths must be monitored for accurate temperature maintenance every time the assay is performed.~~

**K2.200 Reagents**

~~K2.210 All reagents (solutions containing one or multiple components) utilized in the amplification assay must be dispensed in aliquots for single use or reagents can be dispensed in aliquots for multiple use if documented to be free of contamination at each use.~~

~~K2.220 Reagents used for initial amplification must not be exposed to post-amplification work areas. Reagents used for secondary amplification must be stored in an area that prevents carry-over contamination.~~

**K2.300 Primers**

~~K2.310 Primers must be stored under conditions that maintain specificity and sensitivity.~~

~~K2.320. Conditions that influence the specificity or quantity of amplified product must be demonstrated to be satisfactory for each set of primers.~~

~~K2.330 Laboratories must have a policy for quality control of each lot and shipment of primers using reference or well characterized material.~~

~~K2.340 For labeled primers the specificity and robustness of the detection method must be validated. For those laboratories that store these reagents for extended periods, their performance must be periodically confirmed.~~

### ~~K2.400 Amplification Templates~~

~~K2.410 Samples containing nucleic acids that will be amplified (e.g., blood, DNA isolates) must be stored under conditions that do not result in artifacts, inhibition of the amplification reaction, and exposure to post-amplification work areas or any other sources of carry-over contamination.~~

~~K2.420. The acceptable range for the amount of target must be specified and validated.~~

### ~~K2.500 Contamination~~

~~K2.510 Nucleic acid contamination must be monitored for the most common amplification products that are produced in the laboratory. Routine wipe tests of pre-amplification work areas must be performed. Monitoring must be performed using a method that is at least as sensitive as routine test methods. If amplified product is detected, the area must be cleaned to eliminate the contamination and retested. Corrective measures must be taken to prevent future contamination.~~

~~K2.520 At least one negative control (no nucleic acid) must be included in each amplification assay. Testing of open tubes in the work area is recommended.~~

### ~~K2.600 Controls and Quality Assurance~~

~~K2.610 The quantity of specific amplification products must be monitored (e.g., gel electrophoresis, hybridization).~~

~~K2.620 Criteria for accepting or rejecting an amplification assay must be specified.~~

~~K2.630 If presence of an amplified product is used as the end result, controls must be included to detect amplification in every amplification mixture. Amplification specificity must be monitored on a periodic basis.~~

~~K2.640 If an amplified product is used as a nucleic acid target, variation in the amount of amplified product must be monitored (e.g., hybridization with a consensus probe, gel electrophoresis). The acceptable range for the amount of test DNA must be specified.~~

### ~~K3.000 Technique Specific Standards~~

#### ~~K3.100 Oligonucleotide Probe Assays~~

~~K3.110 The specificity and target sequence of oligonucleotide probes must be defined.~~

~~K3.120 Oligonucleotide probes must be stored under conditions that maintain specificity and sensitivity.~~

~~K3.130 Oligonucleotide probes must be utilized under empirically determined conditions that achieve the defined specificity. Laboratories must perform quality control testing to confirm specificity for each lot and shipment of probe. Reference material must be used for quality control whenever possible.~~

~~K3.140 Oligonucleotide probe specificity and detection method sensitivity must be established and must be documented to be reproducible before results are reported.~~

~~K3.150 Hybridization must be carried out under empirically determined conditions that achieve the defined specificity.~~

~~K3.160 The laboratory must have a validated procedure for reuse of nucleic acids (probes or targets) bound to solid supports or in solution. Controls must be included to ensure sensitivity and specificity of the assays are unaltered.~~

### **~~K3.200 Sequence Specific Amplification~~**

~~K3.210 Each amplification reaction must include procedures to detect technical failures (e.g., an internal control such as additional primers or templates that produce a product that can be distinguished from the typing product).~~

### **~~K3.300 Other Techniques~~**

~~K3.310 All methods must be validated in the laboratory, as described under A5.000.~~

~~K3.320 Appropriate controls must be included for each component of the test.~~

## **~~L-Flow Cytometry~~**

### **~~L1.000 Instrument Standardization/Calibration~~**

~~L1.100 An optical standard, consisting of latex beads or other uniform particles, must be run to ensure proper focusing and alignment of all lenses in the path for both the exciting light source and signal (light scatter, fluorescence, etc.) detectors.~~

~~L1.110 Standard(s) must be run for each fluorochrome used to ensure adequate amplification of the fluorescent signal(s). These fluorescent standards may be incorporated in the beads or other particles used for optical standardization (ref. L1.100) or may be a separate bead or fixed cell preparation.~~

~~L1.120 Both the optical and fluorescent standards must be run each time the instrument is turned on and any time maintenance, adjustments, or problems have occurred during operation that could potentially affect instrument function.~~

~~L1.130 The results of optical focusing/ alignment must be recorded in a daily quality control log.~~

~~L1.140 Threshold values for acceptable optical and fluorescent standardization results must be established for all relevant signals for each instrument used.~~

~~L1.150 In the event a particular threshold value cannot be attained, there must be a written protocol detailing the corrective action required.~~

~~L1.200 If performing analyses that require the simultaneous use of two or more fluorochromes, an appropriate procedure must be used to compensate for overlap in their emission spectra.~~

~~L1.300 Laser power output and current input (amps) must be recorded daily for each instrument. Acceptable thresholds and corrective action protocols must be documented.~~

## **~~L2.000 Flow Cytometric Crossmatch Technique~~**

~~L2.100 The laboratory must ensure the appropriate definition and purity of cell populations by the use of either a multi-color technique or other documented method.~~

~~L2.110 The laboratory must assess the binding of human immunoglobulin using a fluorochrome labeled reagent such as either an F(ab')<sub>2</sub> anti-human IgG that is specific for the Fc region of the heavy chain or other documented method.~~

~~L2.120 Crossmatch results for a specific cell population (e.g., T-cells, B-cells and/or monocytes) must be based on the use of a monoclonal antibody that detects an appropriate cluster designated antigen (e.g., CD3 for T cells, CD19 or CD20 for B cells and CD14 for monocytes).~~

~~L2.130 Each laboratory must establish and document the optimum serum/cell ratio.~~

## **~~L2.200 Controls~~**

~~L2.210 The negative control must be human serum documented to be non reactive against the crossmatch target cells.~~

~~L2.220 The positive control must be human antibody of the appropriate isotype for the assays and specific for the antigens that are targeted in the crossmatch. Positive controls must be used at a dilution appropriate for the assay (i.e., a dilution at which moderate changes in assay sensitivity are likely to be detected) and must react with appropriate target cells from all humans.~~

~~L2.230 The anti-human immunoglobulin reagent must be titered to determine the dilution with optimal activity (signal to noise ratio). If a multicolor technique is employed, the reagent must not demonstrate crossreactivity with the other immunoglobulin reagents used to label the cells.~~

~~L2.240 Regardless of the method used for reporting raw data (mean, median, mode channel shifts or quantitative fluorescence measurements), each lab must establish its own threshold for discriminating positive reactions. Any significant change in protocol, reagents, or instrumentation requires repeat determination of the positive threshold.~~

## **~~L2.300 Interpretation~~**

~~L2.310 Each laboratory must define the criteria used to define positive and negative crossmatches.~~

~~L2.320 Appropriate methods or controls must be used to assess the impact of xenogeneic and/or monoclonal therapeutic antibodies on flow crossmatches.~~

**L3.000 Immunophenotyping By Flow Cytometry**

L3.100 Terminology used must conform to the most recent publication of the International Workshop of Differentiation Antigens of Human Leucocytes or other appropriate scientific organizations.

**L3.200 Cell Preparation**

L3.210 The method used for cell preparation must be documented to yield appropriate preparations of viable cells sufficient to ensure accurate test results.

L3.220 For internal labeling, the method used to allow fluorochrome labeled antibodies to penetrate the cell membrane must be documented to be effective.

**L3.300 Quality Control**

L3.310 Specificity controls, consisting of appropriate cell types known to be positive for selected standard antibodies must be run within laboratory defined intervals sufficiently short to assure the proper performance of reagents.

L3.320 A negative reagent control(s) must be identified for each test cell preparation. It is recommended that this control consist of monoclonal antibody(ies) of the same species and subclass and be prepared/purified in the same way as the monoclonal(s) used for phenotyping.

L3.330 For indirect labeling, it is recommended that the negative control reagent be an irrelevant primary antibody and the same secondary antibody(ies) conjugated with the same fluorochrome(s) used.

L3.340 For direct labeling, it is recommended that the negative control reagent be an irrelevant antibody conjugated with the same fluorochrome and at the same fluorochrome: protein ratio used in all relevant test combinations.

L3.350 Each laboratory must define acceptable time periods between processing, labeling and analysis of samples. Control samples must be treated in the same manner.

L3.360 Gating strategies must be employed to assure that the population of interest is being selected without significant contamination.

L3.370 Conclusions about abnormal proportions or abnormal numbers of cells bearing particular internal or cell surface markers must only be drawn in comparison with local 'control' data obtained with the same instrument, reagents and techniques.

L3.380 Determination of percent positives must take into consideration the results of the negative control reagent.

**L3.400 Reagents**

~~L3.410 The laboratory must have a policy to validate the specificity of monoclonal antibodies, either by using appropriate controls or by testing in parallel with previous lots.~~

~~L3.420 The quantities of reagents used for each test sample must be determined by the manufacturers or from published data and whenever possible be verified locally by titration.~~

~~L3.430 Monoclonal antibodies that have been reconstituted from lyophilized powder form for storage at 4°C must be processed according to the manufacturer's instructions or locally documented procedures to remove microaggregates prior to use in preparation of working stains.~~

## **~~M – Enzyme Linked Immuno Sorbent Assay (ELISA)~~**

### **~~M1.000 Instrument Standardization/Calibration~~**

#### **~~M1.100 The ELISA Reader~~**

~~M1.110 The light source and filter must produce the intensity and wavelength of light required for the test system.~~

~~M1.120 Calibration/verification of plate alignment and instrument linearity must be performed according to the manufacturer's instructions or at least once every 6 months and must be documented.~~

~~M1.200 If used, microplate washer performance must be checked monthly and acceptable performance must be documented.~~

#### **~~M2.000 ELISA Technique~~**

~~M2.100 Each assay must contain positive , negative and reagent controls that are appropriate for the intended use of the assay and the test results. The dilution of reagents and test specimens must be documented.~~

~~M2.200 For an assay to be valid it must be documented that all controls meet or exceed established thresholds as specified in the assay procedure.~~

~~M2.300 Sample identity and proper plate orientation must be maintained throughout the procedure.~~

## **~~N – Solid Phase Multi-channel Arrays~~**

### **~~N1.100 Instrument Standardization/Calibration~~**

~~N1.100 Instruments must be standardized and/or calibrated as described under the relevant sections of L1.000 Flow Cytometry: Instrument Standardization/Calibration.~~

~~N1.200 Calibration/verification of plate alignment and instrument linearity must be performed according to the manufacturer's instructions or at least once every 6 months and the precise movement of the tray/plate must be documented.~~

~~N1.300 If used, microplate washer performance must be checked monthly and acceptable performance must be documented.~~

### ~~N2.000 Reagents~~

~~N2.100 Assays must use positive, negative and reagent controls that are appropriate for the intended use of the assay and the test results. Any dilution or optimization of reagents and/or test specimens must be documented.~~

~~N2.200 For an assay to be valid it must be documented that all controls meet or exceed established thresholds specified in the assay procedure.~~

### ~~N3.000 Testing~~

~~N3.100 Sample identity and proper plate orientation must be maintained throughout the procedure.~~

### ~~N3.200 PRA Determination~~

~~N3.210 The quality control of the new system's reagents must adhere to the standards described in M3.300, M3.400, and N2.100.~~

### ~~N3.300 Histocompatibility Typing~~

~~N3.310 If the typing system is probe based, all standards relating to SSO procedures (Section K3.100) are applicable and must be adhered to.~~

## Appendix D to Policy 3

### D.1. GUIDELINES FOR THE DEVELOPMENT OF JOINT WRITTEN AGREEMENTS BETWEEN HISTOCOMPATIBILITY LABORATORIES AND TRANSPLANT PROGRAMS

*(No other changes to this section.)*

[At the end of the Appendix.]

### D.2. Histocompatibility Laboratory Testing Requirements

#### HLA Typing

D1.000 HLA A, B, Bw4, Bw6, C, DR, and DQB antigens. When reporting DR antigens, DRB1 and DRB3/4/5 must be reported. The lab is encouraged to report splits for all loci as shown in Appendix 3A. Laboratories that perform deceased donor typing to be used in kidney, kidney-pancreas, pancreas, or pancreas islet allocation must report molecular typing results (at the level of serological splits) for all required antigens prior to organ offers.

D1.100 Laboratories performing HLA typing using cytotoxicity techniques must conform to all pertinent standards in Section H- Cytotoxicity Methods.

D1.200 Laboratories performing HLA typing using nucleic acid analysis must conform to all pertinent standards in Section K- Nucleic Acid Analysis.

D1.300 If alternative methods are used for HLA typing, procedures must be defined and validated, and must include sufficient controls to ensure accurate assignment of types. All relevant standards from the above sections must be applied.

### **D2.000 Typing Assignment**

D2.100 Each HLA antigen must be defined by a sufficient number of reagents to clearly define each antigen or allele group for which the laboratory tests.

D2.200 The level of resolution of HLA typing must be appropriate for the clinical application.

D2.300 The method of assignment of HLA phenotypes must be documented for each technique used.

D2.400 The laboratory must have and adhere to a written policy that establishes when antigen redefinition and retyping are required.

D2.500 The laboratory must maintain a list of antigens and/or alleles defined by each test used in the laboratory.

### **D3.000 Reagent Validation**

D3.100 Cell or DNA panels of known HLA class I and class II phenotype must be available to validate new typing reagents.

D3.200 The specificity of typing reagents obtained locally or from other sources and used for preparation of local trays must be documented and confirmed by external and/or internal QC testing.

D3.300 Each lot and/or shipment of new commercial reagents must be evaluated. The laboratory must establish and employ detailed policies and procedures for such evaluations

D3.400 Techniques used must be validated to optimally define HLA class I and/or class II antigens and/or alleles.

### **D4.000 HLA Typing by Nucleic Acid Analysis**

D4.100 The HLA alleles detected by each primer, probe or template primer combination must be defined. Primers and probes must be tested with all alleles that are recognized by the W.H.O. Nomenclature Committee for Factors of the HLA System, provided that nucleotide sequences and reference DNA are readily available.

D4.200 The laboratory must have a process to recognize and document ambiguous combination(s) of alleles for each template/primer or probe combination.

**D4.300 Typing by Sequenced Based Typing (SBT)**

D4.310 Templates must have sufficient specificity for a locus or allele to provide interpretable primary sequencing data.

D4.320 Each unknown sequence must be compared with the sequences of all alleles that are recognized by the W.H.O. Nomenclature Committee for Factors of the HLA System provided that the nucleotide sequences are readily available.

D4.330 The laboratory must maintain records that define the sequence database utilized to interpret the primary data. This database must be updated at least annually. If a determined sequence is ambiguous (i.e., more than one possible interpretation of available data) the report must indicate all possible allele combinations.

**E Antibody Screening**

E1.000 Laboratories performing assays using cytotoxicity must conform to standards in Section H - Cytotoxicity Methods.

E1.100 Laboratories performing assays using flow cytometry based methods must conform to the standards in Section L1.000 Instrument Standardization/Calibration and in Section L2.000 Flow Cytometric Crossmatch Technique.

E1.200 Laboratories using ELISA techniques for antibody screening must conform to Standards in Section M- Enzyme Linked Immuno Sorbent Assay (ELISA).

E1.300 Laboratories using solid phase multichannel arrays for antibody screening must conform to Standards in Section N.

**E2.000 Techniques**

E2.100 The laboratory must determine the antibody specificities that can be identified by the technique(s) used. The technique(s) must be appropriate for the clinical application.

E2.200 To detect antibodies to HLA class II antigens, a method must be used that distinguishes them from antibodies to HLA class I antigens.

E2.300 There must be a procedure in place to monitor and adjust for non-specific binding of antibody.

E2.400 Appropriate methods or controls must be used to assess the impact of xenogeneic and/or monoclonal therapeutic antibodies.

**E3.000 Sera**

E3.100 Sera must be tested at a concentration(s) determined to be optimal for detection of antibody(ies) to HLA antigens. The dilution(s) must be documented in the test records.

E3.200 All tests must include an appropriate positive and negative control.

#### **E4.000 Panel and Target Selection**

E4.100 The panel of antigens must be sufficient in number and phenotypic distribution with respect to individual antigens and/or crossreactive groups (CREGs) for the population served and for the intended use of the test results.

E4.200 For assays intended to provide information on HLA antibody specificity, documentation of the HLA class I and/or class II phenotypes of the panel must be maintained.

E4.300 Target cells or purified HLA molecules must be appropriate. The concentration, condition and phenotype of target cells or purified HLA molecules must be sufficient to ensure the antibodies being tested for (either HLA class I or class II) can be detected.

#### **F Renal and Pancreas Organ Transplantation**

F1.000 If deceased donor transplants are performed, personnel for the required histocompatibility testing must be available 24 hours a day, seven days a week.

#### **F2.000 HLA Typing**

##### **F2.000 HLA Typing**

F2.100 Prospective typing of deceased donors for HLA-A, B, C, Bw4, and Bw6, and DR, DR51, DR52, DR53 and DQB antigens is mandatory.

F2.200 Prospective typing of candidates for HLA-A, B, Bw4, Bw6 and DR is mandatory, and the typing of C, DR51, DR52, DR53, and DQB is highly recommended.

#### **F3.000 Antibody Screening**

F3.100 Laboratories must have a policy in place to evaluate the extent of sensitization of each patient at the time of initial evaluation and following potentially sensitizing events, based on the antibody characteristics that are clinically relevant to each transplant center's protocols. The transplant program must provide this information to the laboratory.

F3.200 Laboratories must have a program to periodically screen serum samples from each patient for antibody to HLA antigens. The laboratory must have a documented policy establishing the frequency of screening serum samples and must have data to support this policy. It is recommended that samples be collected monthly. Samples must be collected at time intervals outlined in the joint agreement between the laboratory and the transplant program.

F3.300 It is highly recommended that serum samples be tested for antibody to HLA antigens and that 1) information about antibody specificity be considered when evaluating the patient for transplant and, 2) that serum samples having defined class I and/or class II specificities be used in crossmatch testings.

F3.400 It is highly recommended that the HLA class I and class II specificity of antibodies be identified and reported and be distinguished from antibodies to non-HLA antigens.

**F4.000 Crossmatching**

F4.100 The laboratory must be capable of performing a prospective crossmatch and must do so when requested by a physician or other authorized individuals. Histocompatibility laboratories must have a joint written policy with their transplant program(s) on transplant candidate crossmatching strategies.

**F4.200 Techniques**

F4.210 Although the laboratory may use the basic complement-dependent microlymphocytotoxicity test for determining donor-recipient compatibility, it must also use a crossmatching technique with increased sensitivity.

F4.220 Crossmatches must be performed with potential donor T lymphocytes. It is recommended that crossmatches be performed with B lymphocytes using a method that distinguishes between reactions with T and reactions with B lymphocytes.

F4.230 The laboratory must have and adhere to a written policy determining the serum(a) used in the final crossmatch. The relevance of the policy must be supported by published data or data generated in the laboratory. The policy must consider or include historic and current sensitizing events.

**F4.300 Samples**

F4.310 Sera must be tested at a dilution that is optimal for each assay.

F4.320 The laboratory must have a policy for storage and maintenance of recipient sera. The policy must define the samples to be retained and the duration of storage.

**G Other Organ and Islet Cell Transplantation**

G1.000 The laboratory must HLA type all potential transplant recipients and donors when requested by a physician or other authorized individuals.

G2.000 Patients must be screened for the presence of anti-HLA antibodies at initial evaluation and following sensitizing events when requested by a physician or other authorized individuals. It is recommended that unacceptable antigens be identified to optimize donor selection.

G3.000 The laboratory must be capable of performing a prospective crossmatch and must do so when requested by a physician or other authorized individuals.

G4.000 Histocompatibility laboratories must have a joint written policy with their transplant program(s) on transplant candidate antibody screening/identification and crossmatching strategies.

G5.000 Techniques with increased sensitivity in comparison with the basic/NIH complement-dependent micro-lymphocytotoxicity test must be used.

**H1.000 Cytotoxicity Methods**

1.000 For each cell-serum combination, the results must be recorded in a manner that indicates the approximate percent of cells killed.

1.100 Each laboratory must have a written policy that assigns positive or negative results based on percentage of cells killed.

## **H2.000 Controls**

2.100 Each tray must include at least one positive control serum that reacts with all cells expressing the class of antigens being tested.

2.200 Each tray must include at least one negative control serum documented to be non-reactive under the specified test conditions.

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

2.400 Appropriate methods or controls must be used to assess the impact of xenogeneic and/or monoclonal therapeutic antibodies in patient samples on the cytotoxicity assay.

## **H3.000 Target Cells**

3.100 When testing enriched cell populations the level of purity must be sufficient to ensure accurate interpretation of results.

## **H4.000 Complement**

H4.100 Each lot and/or shipment of complement must be tested to determine that it mediates cytotoxicity in the presence of specific antibody, but is not cytotoxic in the absence of specific antibody. Optimal performance must be established and documented.

H4.200 Complement must be tested separately for use with each type of target cell (i.e., T-cells, B-cells, CLL cells) and with each test method used, since a different dilution or preparation may be required for optimal performance.

## **I ABO Blood Group Determination**

I1.000 ABO blood group must be performed by techniques compliant with Federal regulations.

I2.000 If testing for the A<sub>1</sub> subgroup of ABO group A is performed, the extract of Dolichos biflorus must be used at a dilution and with a technique documented not to agglutinate non-A<sub>1</sub> cells. Each assay or batch test run must include known A<sub>1</sub> and non-A<sub>1</sub> cells as controls.

I3.000 If titration of anti-ABO antibodies is performed, the procedure and criteria for interpretation must be established and validated by the laboratory.

J4.000 Laboratories using molecular techniques for ABO blood grouping must conform to all pertinent standards in Section K- Nucleic Acid Analysis.

### **J Chimerism Analysis**

J1.000 Laboratories performing engraftment and chimerism testing using nucleic acid analysis must conform to all pertinent standards in Section K- Nucleic Acid Analysis.

J2.000 The specificity and sequence of primers must be defined. The genetic designation (e.g., locus) of the target amplified by each set of primers must be defined and documented. For each locus analyzed, the laboratory must have documentation that includes the chromosome location, the approximate number of known alleles, and the distinguishing characteristics (e.g., sizes, sequences) of the alleles that are amplified.

J3.000 If sample processing involves the isolation of cell subsets or specific hematopoietic cell lineages, the laboratory should document the purity obtained whenever possible. If purity is not documented for a given sample, then this information must be provided on the patient report.

J4.000 For each locus tested, patient and donor samples collected pre-transplant, and/or control samples demonstrated to have similar performance characteristics (e.g., sensitivity, competition in PCR) must be amplified and analyzed concurrently with patient samples collected post-transplant.

### **J5.000 Analysis and Reports**

J5.100 Potential for preferential amplification of different sized alleles must be assessed and considered in the analysis.

J5.200 If more than one locus is amplified in a single amplification (multiplex), the effects of such amplification on each system must be assessed and considered in the analysis.

J5.300 Reports must identify the genetic loci analyzed according to standard nomenclature or published reference. For RFLP testing, the restriction endonuclease used and the fragment size must be identified.

J5.400 If results are reported in a quantitative or semi-quantitative manner, criteria for evaluating the relative amounts of recipient and donor in a mixed chimeric sample must be established.

J5.500 When mixed chimerism is not detected, reports must state the sensitivity level of the assay.

### **K Nucleic Acid Analysis**

**K1.000 Universal Standards** (The standards in K1 apply to all nucleic acid testing).

#### **K1.100 Nucleic Acid Extraction**

K1.110 Nucleic acids must be purified by standard methods that have been validated in the laboratory and have written guidelines specifying the minimal acceptable sample (e.g., volume, number of cells,

type of cells). If tests are performed without prior purification of nucleic acids, the method(s) used must specify the minimum acceptable sample and must fulfill all of the criteria set forth in A5.000.

K1.120 If nucleic acids are not used immediately after purification, samples must be stored under conditions that preserve their integrity.

K1.130 Nucleic acids must be of sufficient quality (e.g., purity, concentration) to ensure reliable test results.

### **K1.200 Electrophoresis**

K1.210 Each electrophoretic run must include negative and positive controls that are processed with each assay to verify adequate and appropriate PCR amplification of target DNA.

K1.220 If size of the resulting nucleic acid fragment is a critical factor in the analysis of the data, the following steps must be undertaken: 1) the amount of DNA loaded in each lane must be within a range that ensures equivalent migration of DNA in all samples, including size markers, and 2) size markers that produce discrete electrophoretic bands spanning and flanking the entire range of expected fragment sizes must be included in each gel.

K1.230 The laboratory must establish criteria for accepting validity of each gel and of each lane of the gel and must determine and validate acceptable electrophoretic conditions for each assay.

### **K1.300 Analysis**

K1.310 Acceptable limits of signal intensity must be specified for positive and negative results. If these are not achieved, corrective action is required.

K1.320 Two independent interpretations of primary data are required.

K1.330 Automated systems and computer programs must be validated prior to use and tested routinely for accuracy and reproducibility of manipulations.

## **K2.000 Template Amplification**

### **K2.100 Facilities and Equipment**

K2.110 Laboratories performing amplification of nucleic acids must establish and employ protocols to prevent DNA contamination using physical and/or biochemical barriers. Pre-amplification procedures must be performed in a work area that excludes amplified nucleic acid that has the potential to serve as a template in any amplification assays performed in the laboratory.

K2.120 The use of dedicated equipment and reagents as well as physical and/or biochemical barriers must be used to prevent nucleic acid contamination (carry-over).

K2.130 The laboratory must perform procedures to remove carry-over contamination from work areas used for manipulation of pre-amplification reagents or samples.

K2.140 When using methods that utilize two consecutive steps of amplification, addition of the template for subsequent amplifications must occur in an area isolated by physical or chemical barriers from both the pre-amplification work area and post-amplification work areas.

K2.150 Each work area (i.e., pre-amplification, secondary amplification, and post-amplification) must have dedicated pipettors. Positive displacement pipettes or filter-barrier tips are recommended for pre-amplification and secondary amplification work areas.

K2.160 Thermal cycling instruments must precisely and reproducibly maintain the appropriate temperature of samples. Accuracy of temperature control for samples must be verified at least every 6 months.

K2.170 Incubators and water baths must be monitored for accurate temperature maintenance every time the assay is performed.

### **K2.200 Reagents**

K2.210 All reagents (solutions containing one or multiple components) utilized in the amplification assay must be dispensed in aliquots for single use or reagents can be dispensed in aliquots for multiple use if documented to be free of contamination at each use.

K2.220 Reagents used for initial amplification must not be exposed to post- amplification work areas. Reagents used for secondary amplification must be stored in an area that prevents carry-over contamination.

### **K2.300 Primers**

K2.310 Primers must be stored under conditions that maintain specificity and sensitivity.

K2.320. Conditions that influence the specificity or quantity of amplified product must be demonstrated to be satisfactory for each set of primers.

K2.330 Laboratories must have a policy for quality control of each lot and shipment of primers using reference or well-characterized material.

K2.340 For labeled primers the specificity and robustness of the detection method must be validated. For those laboratories that store these reagents for extended periods, their performance must be periodically confirmed.

### **K2.400 Amplification Templates**

K2.410 Samples containing nucleic acids that will be amplified (e.g., blood, DNA isolates) must be stored under conditions that do not result in artifacts, inhibition of the amplification reaction, and exposure to post-amplification work areas or any other sources of carry-over contamination.

K2.420. The acceptable range for the amount of target must be specified and validated.

**K2.500 Contamination**

K2.510 Nucleic acid contamination must be monitored for the most common amplification products that are produced in the laboratory. Routine wipe tests of pre-amplification work areas must be performed. Monitoring must be performed using a method that is at least as sensitive as routine test methods. If amplified product is detected, the area must be cleaned to eliminate the contamination and retested. Corrective measures must be taken to prevent future contamination.

K2.520 At least one negative control (no nucleic acid) must be included in each amplification assay. Testing of open tubes in the work area is recommended.

**K2.600 Controls and Quality Assurance**

K2.610 The quantity of specific amplification products must be monitored (e.g., gel electrophoresis, hybridization).

K2.620 Criteria for accepting or rejecting an amplification assay must be specified.

K2.630 If presence of an amplified product is used as the end result, controls must be included to detect amplification in every amplification mixture. Amplification specificity must be monitored on a periodic basis.

K2.640 If an amplified product is used as a nucleic acid target, variation in the amount of amplified product must be monitored (e.g., hybridization with a consensus probe, gel electrophoresis). The acceptable range for the amount of test DNA must be specified.

**K3.000 Technique-Specific Standards****K3.100 Oligonucleotide Probe Assays**

K3.110 The specificity and target sequence of oligonucleotide probes must be defined.

K3.120 Oligonucleotide probes must be stored under conditions that maintain specificity and sensitivity.

K3.130 Oligonucleotide probes must be utilized under empirically determined conditions that achieve the defined specificity. Laboratories must perform quality control testing to confirm specificity for each lot and shipment of probe. Reference material must be used for quality control whenever possible.

K3.140 Oligonucleotide probe specificity and detection method sensitivity must be established and must be documented to be reproducible before results are reported.

K3.150 Hybridization must be carried out under empirically determined conditions that achieve the defined specificity.

K3.160 The laboratory must have a validated procedure for reuse of nucleic acids (probes or targets) bound to solid supports or in solution. Controls must be included to ensure sensitivity and specificity of the assays are unaltered.

**K3.200 Sequence Specific Amplification**

K3.210 Each amplification reaction must include procedures to detect technical failures (e.g., an internal control such as additional primers or templates that produce a product that can be distinguished from the typing product).

**K3.300 Other Techniques**

K3.310 All methods must be validated in the laboratory, as described under A5.000.

K3.320 Appropriate controls must be included for each component of the test.

**L Flow Cytometry****L1.000 Instrument Standardization/Calibration**

L1.100 An optical standard, consisting of latex beads or other uniform particles, must be run to ensure proper focusing and alignment of all lenses in the path for both the exciting light source and signal (light scatter, fluorescence, etc.) detectors.

L1.110 Standard(s) must be run for each fluorochrome used to ensure adequate amplification of the fluorescent signal(s). These fluorescent standards may be incorporated in the beads or other particles used for optical standardization (ref. L1.100) or may be a separate bead or fixed cell preparation.

L1.120 Both the optical and fluorescent standards must be run each time the instrument is turned on and any time maintenance, adjustments, or problems have occurred during operation that could potentially affect instrument function.

L1.130 The results of optical focusing/ alignment must be recorded in a daily quality control log.

L1.140 Threshold values for acceptable optical and fluorescent standardization results must be established for all relevant signals for each instrument used.

L1.150 In the event a particular threshold value cannot be attained, there must be a written protocol detailing the corrective action required.

L1.200 If performing analyses that require the simultaneous use of two or more fluorochromes, an appropriate procedure must be used to compensate for overlap in their emission spectra.

L1.300 Laser power output and current input (amps) must be recorded daily for each instrument. Acceptable thresholds and corrective action protocols must be documented.

**L2.000 Flow Cytometric Crossmatch Technique**

L2.100 The laboratory must ensure the appropriate definition and purity of cell populations by the use of either a multi-color technique or other documented method.

L2.110 The laboratory must assess the binding of human immunoglobulin using a fluorochrome labeled reagent such as either an F(ab')<sub>2</sub> anti-human IgG that is specific for the Fc region of the heavy chain or other documented method.

L2.120 Crossmatch results for a specific cell population (e.g., T-cells, B-cells and/or monocytes) must be based on the use of a monoclonal antibody that detects an appropriate cluster designated antigen (e.g., CD3 for T cells, CD19 or CD20 for B cells and CD14 for monocytes).

L2.130 Each laboratory must establish and document the optimum serum/cell ratio.

### **L2.200 Controls**

L2.210 The negative control must be human serum documented to be non-reactive against the crossmatch target cells.

L2.220 The positive control must be human antibody of the appropriate isotype for the assays and specific for the antigens that are targeted in the crossmatch. Positive controls must be used at a dilution appropriate for the assay (i.e., a dilution at which moderate changes in assay sensitivity are likely to be detected) and must react with appropriate target cells from all humans.

L2.230 The anti-human immunoglobulin reagent must be titered to determine the dilution with optimal activity (signal to noise ratio). If a multicolor technique is employed, the reagent must not demonstrate crossreactivity with the other immunoglobulin reagents used to label the cells.

L2.240 Regardless of the method used for reporting raw data (mean, median, mode channel shifts or quantitative fluorescence measurements), each lab must establish its own threshold for discriminating positive reactions. Any significant change in protocol, reagents, or instrumentation requires repeat determination of the positive threshold.

### **L2.300 Interpretation**

L2.310 Each laboratory must define the criteria used to define positive and negative crossmatches.

L2.320 Appropriate methods or controls must be used to assess the impact of xenogeneic and/or monoclonal therapeutic antibodies on flow crossmatches.

### **L3.000 Immunophenotyping By Flow Cytometry**

L3.100 Terminology used must conform to the most recent publication of the International Workshop of Differentiation Antigens of Human Leucocytes or other appropriate scientific organizations.

### **L3.200 Cell Preparation**

L3.210 The method used for cell preparation must be documented to yield appropriate preparations of viable cells sufficient to ensure accurate test results.

L3.220 For internal labeling, the method used to allow fluorochrome labeled antibodies to penetrate the cell membrane must be documented to be effective.

### **L3.300 Quality Control**

L3.310 Specificity controls, consisting of appropriate cell types known to be positive for selected standard antibodies must be run within laboratory-defined intervals sufficiently short to assure the proper performance of reagents.

L3.320 A negative reagent control(s) must be identified for each test cell preparation. It is recommended that this control consist of monoclonal antibody(ies) of the same species and subclass and be prepared/purified in the same way as the monoclonal(s) used for phenotyping.

L3.330 For indirect labeling, it is recommended that the negative control reagent be an irrelevant primary antibody and the same secondary antibody(ies) conjugated with the same fluorochrome(s) used.

L3.340 For direct labeling, it is recommended that the negative control reagent be an irrelevant antibody conjugated with the same fluorochrome and at the same fluorochrome: protein ratio used in all relevant test combinations.

L3.350 Each laboratory must define acceptable time periods between processing, labeling and analysis of samples. Control samples must be treated in the same manner.

L3.360 Gating strategies must be employed to assure that the population of interest is being selected without significant contamination.

L3.370 Conclusions about abnormal proportions or abnormal numbers of cells bearing particular internal or cell surface markers must only be drawn in comparison with local 'control' data obtained with the same instrument, reagents and techniques.

L3.380 Determination of percent positives must take into consideration the results of the negative control reagent.

### **L3.400 Reagents**

L3.410 The laboratory must have a policy to validate the specificity of monoclonal antibodies, either by using appropriate controls or by testing in parallel with previous lots.

L3.420 The quantities of reagents used for each test sample must be determined by the manufacturers or from published data and whenever possible be verified locally by titration.

L3.430 Monoclonal antibodies that have been reconstituted from lyophilized powder form for storage at 4°C must be processed according to the manufacturer's instructions or locally documented procedures to remove microaggregates prior to use in preparation of working stains.

## **M Enzyme Linked Immuno Sorbent Assay (ELISA)**

**M1.000 Instrument Standardization/Calibration****M1.100 The ELISA Reader**

M1.110 The light source and filter must produce the intensity and wavelength of light required for the test system.

M1.120 Calibration/verification of plate alignment and instrument linearity must be performed according to the manufacturer's instructions or at least once every 6 months and must be documented.

M1.200 If used, microplate washer performance must be checked monthly and acceptable performance must be documented.

**M2.000 ELISA Technique**

M2.100 Each assay must contain positive , negative and reagent controls that are appropriate for the intended use of the assay and the test results. The dilution of reagents and test specimens must be documented.

M2.200 For an assay to be valid it must be documented that all controls meet or exceed established thresholds as specified in the assay procedure.

M2.300 Sample identity and proper plate orientation must be maintained throughout the procedure.

**N Solid Phase Multi-channel Arrays****N1.100 Instrument Standardization/Calibration**

N1.100 Instruments must be standardized and/or calibrated as described under the relevant sections of L1.000 Flow Cytometry: Instrument Standardization/Calibration.

N1.200 Calibration/verification of plate alignment and instrument linearity must be performed according to the manufacturer's instructions or at least once every 6 months and the precise movement of the tray/plate must be documented.

N1.300 If used, microplate washer performance must be checked monthly and acceptable performance must be documented.

**N2.000 Reagents**

N2.100 Assays must use positive, negative and reagent controls that are appropriate for the intended use of the assay and the test results. Any dilution or optimization of reagents and/or test specimens must be documented.

N2.200 For an assay to be valid it must be documented that all controls meet or exceed established thresholds specified in the assay procedure.

**N3.000 Testing**

N3.100 Sample identity and proper plate orientation must be maintained throughout the procedure.

### **N3.200 PRA Determination**

N3.210 The quality control of the new system's reagents must adhere to the standards described in M3.300, M3.400, and N2.100.

### **N3.300 Histocompatibility Typing**

N3.310 If the typing system is probe based, all standards relating to SSO procedures (Section K3.100) are applicable and must be adhered to.

## **UNOS Bylaws Appendix B, Attachment IID: Preservation of Zero Mismatch Tissue Typing Materials**

### **PRESERVATION OF ZERO MISMATCH TISSUE TYPING MATERIALS**

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

### **Appendix D to Policy 3**

### **D.3. PRESERVATION OF ZERO MISMATCH TISSUE TYPING MATERIALS**

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

## **~~ATTACHMENT III TO APPENDIX B OF THE UNOS BYLAWS~~**

### **~~Model Elements for Controlled DCD Recovery Protocols~~**

~~*Introduction:* Donation after Cardiac Death (DCD) has been accepted by the Institute of Medicine and the transplant community as an ethically and medically acceptable option for patients and families making end of life decisions.~~

~~The intent of developing model elements for OPO and transplant hospital DCD recovery protocols is to establish model elements for OPOs and transplant hospitals to meet in developing, reviewing and improving their respective DCD recovery protocols. This outline is intended to set standards of what must be addressed in a DCD recovery protocol by OPOs and hospitals without being prescriptive regarding practice; each hospital and each DSA is specific in its practice, culture, and resources. The continuing collaboration between OPOs and transplant hospitals is encouraged to allow for the~~

constant development of DCD best practices. The joint OPO Committee/MPSC Working Group is available as a continuing resource for OPTN member hospitals that experience delay or difficulty in adopting a DCD recovery protocol.

### **Controlled Donation after Cardiac Death Recovery Protocol Model Elements**

#### **A. Suitable Candidate Selection:**

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

#### **B. Consent/Approval**

1. The legal next of kin may elect to consent to procedures or drug administration for the purposes of organ donation (e.g. heparin, regitine, femoral line placement, lymph node excision, ECMO, and bronchoscopy). No donor related medications shall be administered or donation related procedures performed without consent.
2. Clearance from medical examiner/coroner must be obtained when applicable.
3. There should be a plan for patient care if death does not occur within the established timeframe after the withdrawal of life-sustaining measures. This plan should include logistics and provisions for continued end-of life care, including immediate notification of the family.
4. For purposes of these model elements, "legal next of kin" shall also include the patient, a designated health care representative, legal next of kin, or appropriate surrogate.

#### **C. Withdrawal of Life Sustaining Measures/ Patient Management**

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

#### **D. Pronouncement of Death**

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

**~~E. Organ Recovery~~**

1. ~~Following the declaration of death by the hospital patient care team, the organ recovery may be initiated.~~

**~~F. Financial Considerations~~**

1. ~~OPO policy shall ensure that no donation related charges are passed to the donor family.~~

**Policy 2.8 Model Elements for Controlled DCD Recovery Protocols**

Introduction: Donation after Cardiac Death (DCD) has been accepted by the Institute of Medicine and the transplant community as an ethically and medically acceptable option for patients and families making end of life decisions.

The intent of developing model elements for OPO and transplant hospital DCD recovery protocols is to establish model elements for OPOs and transplant hospitals to meet in developing, reviewing and improving their respective DCD recovery protocols. This outline is intended to set standards of what must be addressed in a DCD recovery protocol by OPOs and hospitals without being prescriptive regarding practice; each hospital and each DSA is specific in its practice, culture, and resources. The continuing collaboration between OPOs and transplant hospitals is encouraged to allow for the constant development of DCD best practices. The joint OPO Committee/MPSC Working Group is available as a continuing resource for OPTN member hospitals that experience delay or difficulty in adopting a DCD recovery protocol.

In order to recover organs from a DCD donor, an OPO must follow an established protocol that contains the standards of the DCD Model Elements as adopted below in the OPTN Bylaws, Appendix B, Attachment III.

**Controlled Donation after Cardiac Death Recovery Protocol Model Elements**

**A. Suitable Candidate Selection:**

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

5. An assessment should be made as to whether death is likely to occur (after the withdrawal of life-sustaining measures) within a time frame that allows for organ donation.

**B. Consent Authorization /Approval**

1. The legal next of kin may elect to consent to authorize procedures or drug administration for the purposes of organ donation (e.g. heparin, regitine, femoral line placement, lymph node excision, ECMO, and bronchoscopy). No donor related medications shall be administered or donation related procedures performed without consent authorization.
2. Clearance from medical examiner/coroner must be obtained when applicable.
3. There should be a plan for patient care if death does not occur within the established timeframe after the withdrawal of life sustaining measures. This plan should include logistics and provisions for continued end of life care, including immediate notification of the family.
4. For purposes of these model elements, "legal next of kin" shall also include the patient, a designated health care representative, legal next of kin, or appropriate surrogate.

**C. Withdrawal of Life Sustaining Measures/ Patient Management**

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

**D. Pronouncement of Death**

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

**E. Organ Recovery**

Following the declaration of death by the hospital patient care team, the organ recovery may be initiated.

**F. Financial Considerations**

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

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

To read the current UNOS language visit [www.unos.org](http://www.unos.org) and select "UNOS bylaws" in the "I am looking for:" box in the upper left hand corner. To read the complete OPTN bylaw language visit [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov), select the "Policy Management" tab, then select "OPTN Bylaws." These versions of the bylaws will be in effect until September 1, 2012.

**Affected Policy Language:**

- 3.1.7 Alternative Allocation/Distribution System.** A type of variance that allows Members to allocate organs differently than the OPTN policies. The term “Alternative Allocation System” or “Alternative Distribution System” (AAD System) refers to any system, with the exception of “Variances” and “Committee-Sponsored Alternative Systems” as described in Policies 3.1.8 and 3.1.9, respectively below, used for local organ allocation or distribution, as applicable, that is different from the standard allocation or distribution system for that organ as defined by policy. Such systems are designed for the purpose of increasing organ availability and/or organ quality, reducing or addressing an inequity in organ allocation/distribution unique to the local area, and/or examining a policy variation intended to benefit the allocation/distribution system overall. They exist in the forms of (i) alternative local units (ALUs), (ii) sharing arrangements and agreements, (iii) alternative point assignment systems, and (iv) systems that may include components of more than one of these AAD Systems. Liver payback provisions currently listed within existing Alternative Allocation/Distribution Systems will be eliminated.
- 3.1.8 Variances.** An experimental policy that tests methods of improving allocation. The term “Variance” refers to any system for organ allocation and/or distribution that meets the criteria for a “Variance” as described in the Final Rule for operation of the Organ Procurement and Transplantation Network, 42 C.F.R. §121.8(g). Such systems may be designed pursuant to policy-making processes and the Final Rule, §121.4, as potentially temporary policies for the purpose of previewing methods for improving organ allocation or distribution. They must include a plan for data collection and analysis and have a defined time limit for the policy variation.
- 3.1.9 Open and Closed Variances.** An open variance is a variance that allows other Members to join it. A closed variance is a variance that is not open for other Members to join it. ~~Committee-Sponsored Alternative System.~~ The term “Committee-Sponsored Alternative System” refers to an Alternative Allocation System or Alternative Distribution System developed by the relevant Committee(s) and approved by the Board of Directors to address issues in organ allocation/distribution applicable to multiple local areas but not nationally, or for which consensus to modify standard policy for the nation as a whole has not been achieved.
- 3.1.10 Local and Alternative Local Unit (ALU).** A local unit is the geographic area for organ procurement and distribution. An alternative local unit is a type of variance that creates a distinct geographic area for organ procurement and distribution. The Local Unit will be the OPO in most cases. Alternative Local Units (Alternative Local Units or ALUs) such as subdivisions of the OPO which function as distinct areas for organ procurement and distribution, entire states,

Regions or other appropriate units are acceptable if they can be demonstrated to the satisfaction of the Board of Directors to fulfill the principles below and ALU application requirements, as well as adhere to applicable laws and regulations.

The principles for defining local, all of which should be addressed and appropriately balanced in each instance, are as follows:

**3.1.10.1** There should be a single waiting list for each organ within each Local Unit. Any deviation from this principle must be submitted for approval.

**3.1.10.2** There should be Local Unit review. The OPO or OPOs involved shall collect and review data on organ procurement, organ distribution, organ quality, and organ function for the Local Unit.

**3.1.10.3** There should be a demonstrated inequity in organ distribution within the OPO or OPOs involved that is addressed by the ALU and corrected or at least improved within a specified period of years as shown through objective criteria. The purpose of the ALU should be to provide a system of equitable organ distribution. Equitable organ distribution should attempt to balance justice and medical utility.

**3.1.10.4** There should be monitorable organ distribution. Data collection and review are necessary to be certain that the distribution system is being followed and that it is achieving its goals.

**3.1.10.5** There should be no organ distribution predicated on the procuring transplant center or individual.

**3.1.10.6** There should be effective organ procurement throughout the Local Unit. Enhancement of the organ supply should be a primary goal of any organ distribution system.

In cases where a subdivision of an OPO is the Local Unit, organs recovered, but not used within that segment of the OPO will be used in the remainder of the OPO before regional or national distribution. Cooperative working relationships within and among OPOs are encouraged to serve the best interests of transplant candidates, in a manner that is consistent with the principles set forth in the Policy 3.1.10.

Once an ALU is approved, Members participating in the ALU are required to fulfill all stipulations agreed to in their application and comply with the data submission and other requirements included in Policy 3.4.6.

**3.1.11 ~~Sharing Arrangement and Sharing Agreement.~~ A type of variance that permits two or more OPOs to share organs.** The term sharing arrangement refers to an

arrangement entered into by two or more OPOs to share organs, interregionally or intraregionally, between or among the OPOs. OPOs may distribute organs pursuant to a sharing arrangement after fulfilling the Sharing Arrangement/Sharing Agreement application requirements and obtaining approval by the Board of Directors. Organs must be distributed within the sharing area on the basis of a common Waiting List unless an appropriate Alternative Local Unit for the area is approved by the Board of Directors. Unless specifically required for examining the effectiveness of the Sharing Agreement, as required by its evaluation plan, OPOs participating in a sharing arrangement must have geographically contiguous service areas. The term sharing agreement refers to the written document that defines the sharing arrangement.

Once a Sharing Arrangement is approved, Members participating in the Sharing Arrangement are required to fulfill all stipulations agreed to in their application and comply with the data submission and other requirements included in Policy 3.4.6.

**3.1.12 Alternative Point Assignment Systems.** A type of variance that permits Members to assign points differently than the OPTN policies. An OPO, Members participating in an approved Alternative Local Unit or Members participating in an approved sharing arrangement may assign to each of the point system criteria set forth in Policies 3.5 through 3.11 a number of points other than the number of points set forth in such policies for allocation of local organs after fulfilling the alternative point assignment system application requirements and obtaining approval by the Board of Directors. Members participating in an approved alternative point assignment system shall be obligated to: (a) stay aware of all applicable provisions of the organ allocation policies and any amendments thereto ("policy requirements") (as well as all other Bylaws and Policies), (b) evaluate the continued benefit of the system in light of the policy requirements and (c) request Committee and Board of Director approval for any adjustment to the alternative point assignment system deemed appropriate and desirable by the Member(s) following such evaluation. No approved alternative point assignment system will automatically be modified in light of or to incorporate in any way any policy requirement adopted by the Board of Directors following approval of the system unless otherwise specifically provided by the Board of Directors. Any modification of an approved alternative point assignment system shall require application by the applicable Member(s) in accordance with Policy 3.4.6.4.

Once an alternative point assignment protocol is approved, Members participating in the protocol are required to fulfill all stipulations agreed to in

~~their application and comply with the data submission and other requirements included in Policy 3.4.6.~~

### **3.4.8 Variances**

#### **3.4.8.1 Acceptable Variances**

Permissible variances include, but are not limited to:

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

The following principles apply to all variances:

- Variances must comply with the National Organ Transplant Act and the Final Rule.
- Members participating in a variance must follow all rules and requirements of the OPTN Policies and Bylaws.
- If the Board later amends a policy containing a variance, the policy amendment will not affect the existing variance.
- There must be a single waiting list for each organ within each local unit.
- Where the local unit is a subdivision of the OPO's Donation Service Area (DSA), the OPO will allocate organs to the remainder of the DSA after allocating organs to the local unit.
- If a Member's application to create, amend, or join a variance will require other Members to join the variance, the applicant must solicit their support.
- The Board of Directors may extend, amend, or terminate a variance at any time.

#### **3.4.8.2 Application**

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

1. The purpose for which the variance is proposed and how the variance will further this purpose.
2. If a Member's application to create, amend, or join a variance will require other Members to join the variance, the applicant must solicit their support. Committees will not review a Member's variance application unless the applicant receives affirmative support from at least 75% of the Members required to join by the application.
3. A defined expiration date or period of time after which the variance will conclude, the participating Members will report results, and the sponsoring Committee will evaluate the impact of the variance.
4. An evaluation plan with objective criteria to measure the variance's success achieving the variance's stated purpose.

5. Any anticipated difficulties in demonstrating whether the variance is achieving its stated purpose.
6. Whether this is an open variance or closed variance and, if this is an open variance, any additional conditions for Members to join this variance.

Members wishing to join an existing open variance must submit an application as dictated by the specific variance. If a Member's application will require other Members to join the variance, the applicant must solicit support from them. When an open variance is created, it may set conditions for the OPTN contractor to approve certain applications. The OPTN contractor may approve an application to join an open variance when all Members required to join the variance support the application. When all Members do not support the application, only the sponsoring Committee may approve the application.

#### **3.4.8.3 Reporting Requirements**

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

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

Participating Members must also submit a final report to the sponsoring Committee at least six months before the variance's expiration date.

The sponsoring Committee must actively monitor and evaluate these reports to review the variance's achievements toward its stated purpose.

#### **3.4.8.4 Final Evaluation**

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

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

#### **3.4.8.5 Terminating Variances**

Members participating in a variance may apply to the sponsoring Committee to withdraw from or terminate a variance. The applicant must solicit feedback from all other Members participating in the variance. The sponsoring Committee must

recommend to the Board of Directors whether to approve or deny the request. The Board of Directors may approve, modify, or deny the request.

#### **3.4.8.6 Appeals**

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

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

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

#### **3.4.9 Reserved**

#### **3.4.10 Reserved**

~~**3.4.8 Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems.** The following policies define the processes for applying for a new or modified AAD System, review of such systems and withdrawal from such systems by any one or more of the participants.~~

~~**3.4.8.1 Application.** Applications to allocate organs locally using alternative point assignment systems may be submitted by OPOs, Members participating in a Board approved ALU or Members participating in a Board approved sharing arrangement. In each case, the application must indicate for each OPO and transplant center that is to take part in the alternative point assignment system whether or not the institution supports the system. Applications to distribute organs according to sharing arrangements or ALUs may be submitted by OPOs; any such application must indicate for each applicant OPO whether or not the~~

OPO's Board of Directors supports the sharing arrangement or ALU, as applicable. In cases where unanimity cannot be achieved at the local level, applications to allocate organs using either an alternative point assignment system, sharing agreement or ALU must have approval of 75% of the Member OPOs and or transplant centers.

Applications to allocate organs using alternative point assignment systems or to distribute organs using sharing arrangements or ALUs are submitted to the appropriate organ-specific committees for consideration before being issued for public comment according to processes for public comment. Such applications are then reconsidered by the relevant Committee in light of public comment. Final applications to allocate organs locally using alternative point assignments or to distribute organs using sharing arrangements or ALUs must be presented to and approved by the Board of Directors before they can be implemented or used in organ allocation/distribution. An application to allocate organs locally using an AAD System must specify the purpose for which it is proposed, how the system is intended to accomplish this purpose, and an evaluation plan by which the participating Members will assess the system's success in achieving its stated purpose. The evaluation plan must include objective criteria for measuring the AAD System's results, including, for example, (a) candidate waiting time (stratified by candidate populations), (b) graft survival (stratified by recipient populations), and (c) organ availability and/or organ quality. Applicants are encouraged to explain in the evaluation plan any difficulties they anticipate in demonstrating results from the AAD system that would assist the reviewing committees in assessing the system. This might include, for example, low volumes and difficulties in establishing statistical significance even over relatively long periods of time in the case of a system intended to adjust priority for pediatric candidates. The relevant reviewing committees and/or Board of Directors may specify criteria in addition to those proposed by the Members for the Members to address in assessing the ongoing operations of the AAD System.

Applications shall comply with other application requirements as may be established by the appropriate committees and Board of Directors. Once approved, notice of the AAD System will be included in the policies. Initial approval by the Board of Directors of any AAD System shall be on a provisional basis for a period of 3 years. By the end of this period, the applicable Members must have demonstrated through objective criteria that the purpose for which the system was approved has been achieved or at least that progress considered adequate and demonstrated to the satisfaction of the reviewing committee(s)/Board to this end has been accomplished. At the end of the provisional approval period, the appropriate reviewing committees will recommend to the Board of Directors that the AAD System be: (a) finally approved,

(b) approved on a continued provisional basis for a specific period of time, or (c) terminated.

When an alternative point assignment system, sharing arrangement or ALU is proposed to permit participation of a distribution unit in a scientific study to test a stated hypothesis with defined parameters under controlled conditions, such an alternative point assignment system, sharing arrangement or ALU may be approved by the Board of Directors for implementation if it (a) is of scientific merit (The Board may consider prior approval of such national agencies as the National Institutes of Health, Veterans Administration or national voluntary health agencies in making this determination); (b) extends for a defined, limited time period not greater than the initial 3-year provisional period, plus 2 years; and, (c) will have no net effect on the number of organs available for transplant within the applicable distribution unit, or potentially affected larger distribution units which include the applicable distribution unit. Such proposals will be considered in accordance with the standard process for consideration of alternative point assignment systems, sharing arrangements or ALUs, as applicable.

**3.4.8.2 Data Submission Requirements.** ~~Members receiving permission of the Board of Directors for evaluating alternative point assignment systems, sharing arrangements and ALUs, including those denied with conditions and those approved on a provisional basis, shall submit, at one year intervals, or more frequently upon request, relevant data and status reports that assess the impact of the AAD System, relative to the system's stated objectives and using the performance measures proposed in the participating Members' application, address any organ allocation problems that may have arisen as a result of the system and, in the case of ALUs, demonstrate adherence to the principles for defining local (Policy 3.1.9) and progress toward correcting or at least reducing the inequity that the ALU is intended to address. From time to time, these Members may be provided with data reports (from UNet<sup>SM</sup>) showing the experience of the alternative organ distribution\allocation system as well as the national system for various risk factors. Any such reports will be available for use by the Members, along with any other information the Members would like to provide, in assessing and/or explaining the impacts of the system. Members receiving approval by the Board of Directors to participate in an alternative point assignment system, sharing arrangement or ALU as part of a limited duration scientific study shall be subject to the data submission requirements stipulated above in addition to submission of a final report within six months following completion of the study.~~

The appropriate committee(s) shall actively monitor these data and status reports to provide consistency to efforts to assist the

participating OPOs and transplant centers in dealing with each of their special circumstances; to make recommendations to the Board of Directors for continuation, modification or termination of the AAD Systems; and, in the case of alternative point assignment systems to review the alternative system in light of standard organ allocation policies. This provision shall not be interpreted to limit or otherwise affect the Board of Directors' authority to revoke or suspend operation of any AAD System as deemed appropriate by the Board of Directors.

**~~3.4.8.3 Dissolution of Alternative Assignment Systems~~** Sharing Arrangements and ALUs. Members operating with an approved (a) alternative point assignment system who unanimously elect to withdraw from that system and use the standard point system criteria pursuant to Policies 3.5 through 3.11, (b) sharing arrangement who unanimously elect to withdraw from that arrangement and define the OPOs as the Local Units for purposes of organ distribution or (c) ALU who unanimously elect to withdraw from that ALU and use the OPO, or larger sharing area under a Board approved sharing arrangement, as the Local Unit pursuant to Policy 3.1.7, shall provide timely written notification of such withdrawal and resulting dissolution of the alternative point assignment system, sharing arrangement or ALU, as applicable, to the relevant Region, appropriate committees and the Board of Directors. Dissolution of the alternative point assignment system, sharing arrangement or ALU, as applicable, shall be effective after appropriate re-programming on UNet<sup>SM</sup>. A request to withdraw from an alternative point assignment system, sharing arrangement or ALU that is not unanimous among the parties who obtained approval of the system shall be considered a proposal to modify the system in accordance with the process described in Policy 3.4.6.4 below.

**~~3.4.8.4 Modifications of Alternative Point Assignment Systems, Sharing Arrangements and ALUs.~~** Any proposed modification of an approved alternative point assignment system, sharing arrangement or ALU, other than a proposal to dissolve the system agreed to unanimously by the parties, shall require application by the participating Member(s) in the case of an alternative point assignment system, or participating OPOs in the case of a sharing arrangement or ALU, and approval by the Board in accordance with the application process described in Policy 3.4.6.1 above.

**~~3.4.8.5 AAD Systems Approved Prior to March 15, 2005.~~** Members using an approved AAD System as of March 15, 2005, that meets the criteria for such system in effect prior to that date, shall be permitted to continue the system for 3 years from March 2005, at which time they will be

required to re-apply to continue their systems under the requirements and criteria of applicable policies for AAD Systems then in effect.

**3.4.8.6 Appealing A Decision on An Alternative Organ Distribution or Allocation System.** A participating Member can appeal a committee's or a Board of Directors' decision on an alternative organ distribution or allocation system. To appeal a decision on an alternative organ distribution or allocation system, the participating Member must follow the process described below.

*a. Appealing A Committee's Decision*

The committee will notify the participating Member in writing of its decision within 10 business days, inclusive, of the meeting in which it determined the outcome of the alternative organ distribution or allocation system.

To express its intent to appeal a committee's decision on an alternative organ distribution or allocation system, the participating Member must do so in writing and within 30 days, inclusive, of the committee's communication of its decision. The participating Member must appeal a committee's decision *before* the Policy Oversight Committee (POC) reviews this recommendation. The participating member should contact the OPTN Contractor for the POC meeting schedule.

In considering the appeal, the committee will *only review evidence not considered previously*. The committee will evaluate the appeal as it would the application (see Policy 3.4.7.1 – Application). The participating Member may choose to take part in this appeal discussion. The committee may request additional information from the participating Member. Once the committee makes its final decision on the alternative organ distribution or allocation system, the participating Member *cannot request another appeal* until the POC *and* the Board of Directors decide on the alternative organ distribution or allocation system.

In its evaluation of the alternative organ distribution or allocation system, the POC may request additional information from the committee, who will communicate this query to the participating Member. The committee will submit any information received from the participating Member to the POC. The POC will then decide on the alternative organ distribution or allocation system and submit its recommendation to the Board of Directors. The Board of Directors will consider the alternative organ distribution or

allocation system, including the decisions of the committee and POC. The participating Member may choose to take part in this meeting of the Board of Directors.

If the Board of Directors decides in favor of the alternative organ distribution or allocation system, then the alternative organ distribution or allocation system is approved for the trial period requested by the participating Member. If the Board of Directors decides against the alternative organ distribution or allocation system, then the alternative organ distribution or allocation system is not approved.

*b. —Appealing a Board of Directors' Decision*

To appeal the decision of the Board of Directors on an alternative organ distribution or allocation system, the participating Member of the alternative organ distribution or allocation system may appeal directly to the Secretary of the Health and Human Services (HHS), in accordance with the OPTN Final Rule, 42 CFR § 121.4 (OPTN policies: Secretarial review and appeals).

***NOTE: —Policy 3.4.8.6 (Appealing A Decision on An Alternative Organ Distribution or Allocation System) shall be effective following notice to the membership. (Approved at the June 21-22, 2010 Board of Directors Meeting.)***

**3.4.9 —Application, Review, Dissolution and Modification Processes for Variances.**

The following policies define the processes for applying for a new or modified Variance, review of such systems by, and withdrawal from such systems by any one or more participants.

**3.4.9.1 Application.** Applications to allocate or distribute organs using a Variance may be submitted by OPOs, Members participating in a Board approved ALU or Members participating in a Board approved Sharing Arrangement. In each case, the application must indicate for each OPO and transplant center that is to take part in the Variance whether or not the institution supports the system. Unanimity among participants is encouraged but not required. In cases where unanimity cannot be achieved, Variance applications must include statements of support or opposition on behalf of each potential participant explaining their position. Variance applications are submitted to the appropriate organ-specific committees for consideration before being issued for public comment according to processes for public comment. Variance applications are then reconsidered by the relevant Committee in light of public comment. Final Variance applications must be presented to and approved by the Board of Directors before they can be implemented on UNet<sup>SM</sup> or used in organ allocation/distribution. Once approved, notice of the Variance will be included in the policies.

A Variance must comply with application requirements as may be established by the appropriate committees and Board of Directors and specify the purpose for which it is proposed, incorporating a review of the method for improving organ allocation or distribution; how the system is intended to accomplish this purpose; and a plan for data collection and analysis for assessment of the system's success in achieving its stated purpose. The relevant reviewing committees and/or Board of Directors may specify criteria in addition to those proposed by the Members for the Members to address in assessing the ongoing operations of the policy variance. The plan must include a defined end point by which the Variance will be completed and results reported.

Once a Variance is approved, Members participating in the variance are required to fulfill all stipulations agreed to in their application and comply with the data submission and other requirements included in Policy 3.4.7.2. Participants in an approved Variance are further required to stay aware of all applicable provisions of the organ allocation policies and any amendments thereto as well as other bylaws and policies.

**3.4.9.2 Data Requirements.** Members receiving permission of the Board of Directors for evaluating Variances shall submit, at one-year intervals, or more frequently upon request, relevant data and status reports that: (i) assess the impact of the Variance relative to the system's proposed effect and in accordance with the plan for data collection and analysis defined in the participating Members' application, and (ii) address any organ allocation problems that may have arisen as a result of the system. From time to time, these Members may be provided with data reports (from UNet<sup>SM</sup>) showing the experience of the variance as well as the national system for various risk factors. Any such reports will be available for use by the Members, along with any other information the Members would like to provide, in assessing and/or explaining the impacts of the system. In addition to the periodic reports stipulated above, Variance participants must submit a final report within six months following completion of the plan.

The appropriate committee(s) shall actively monitor these data and status reports to review the Variance and any potential for improving standard national organ allocation policies. This provision shall not be interpreted to limit or otherwise affect the Board of Directors' authority to revoke or suspend operation of any Variance as deemed appropriate by the Board of Directors.

~~**3.4.9.3 Appeal to Secretary.** Decisions of the Board of Directors to approve a Variance may be appealed to the Secretary of HHS in accordance with the OPTN Final Rule, 42 CFR § 121.4.~~

~~**3.4.9.3 Appealing A Variance Decision.** The participating Member can appeal a committee's or Board of Directors' decision on a variance. To appeal a decision on a variance, the participating Member must follow the process described below.~~

~~*a. — Appealing a Committee's Decision*~~

~~The committee will notify the participating Member in writing of its decision within 10 business days, inclusive, of the meeting in which it determined the outcome of the variance.~~

~~To express its intent to appeal, the participating Member must do so in writing and within 30 days, inclusive, of the committee's communication of its decision. The participating Member must appeal a committee's decision *before* the Policy Oversight Committee (POC) reviews this recommendation. The participating member should contact the OPTN Contractor for the POC meeting schedule.~~

~~In considering the appeal, the committee will *only review evidence not considered previously*. The committee will evaluate the appeal as it would a variance application (see Policy 3.4.8.1 — Application). The participating Member may choose to take part in this appeal discussion. The committee may request additional information from the participating Member. Once the committee makes its final decision on the variance, the participating Member *cannot request another appeal* until the POC *and* the Board of Directors decide on the variance.~~

~~In its evaluation of the variance, the POC may request additional information from the committee, who will communicate this query to the participating Member. The committee will submit any information received from the participating Member to the POC. The POC will then decide on the variance and submit its recommendation to the Board of Directors. The Board of Directors will consider the variance, including the decisions of the committee and POC. The participating Member may choose to take part in this meeting of the Board of Directors.~~

~~If the Board of Directors decides in favor of the variance, then the variance is approved for the trial period requested by the~~

participant. If the Board of Directors decides against the variance, then the variance is not approved.

*b. —Appealing a Board of Directors' Decision*

To appeal the decision of the Board of Directors, the variance applicant may appeal directly to the Secretary of the Health and Human Services (HHS), in accordance with the OPTN Final Rule, 42 CFR § 121.4 (OPTN policies: Secretarial review and appeals).

***NOTE: —Policy 3.4.9.3 (Appealing A Variance Decision) shall be effective following notice to the membership. (Approved at the June 21-22, 2010 Board of Directors Meeting.)***

**~~3.4.9.4 Termination of Member Participation in Variance.~~** Members operating with an approved Variance who unanimously elect to withdraw from the variance and use the standard allocation and distribution system criteria pursuant to applicable policies shall provide timely written notification of such withdrawal and resulting termination of Variance to the relevant Region(s), appropriate committees and the Board of Directors. Termination of the Variance shall be effective after appropriate re-programming on UNet<sup>SM</sup>. A request to withdraw from a Variance that is not unanimous among the parties who obtained approval of the system shall be considered a proposal to modify the system in accordance with the process described in Policy 3.4.7.5 below.

**~~3.4.9.5 Modification of Variance.~~** Any proposed modification of an approved Variance, other than a proposal to dissolve the variance agreed to unanimously by the parties, shall require application by the participating Member(s), and approval by Board of Directors in accordance with the application process described in Policy 3.4.7.1 above.

**~~3.4.10 Development, Application, Review, Dissolution and Modification Processes for Committee Sponsored Alternative Systems.~~** The following policies define the processes for developing a new or modified Committee Sponsored Alternative System, application to participate in such systems, review of such systems, and withdrawal from such systems by any one or more participants.

**~~3.4.10.1 Development and Application.~~** Committee Sponsored Alternative Systems are developed by the applicable reviewing Committee(s), submitted for public comment according to processes for public comment, and reconsidered by the sponsoring Committee in light of public comment. Final proposals for Committee Sponsored Alternative Systems must be presented to and approved by the Board of Directors prior to implementation on UNet<sup>SM</sup>. Once approved, notice of the Committee Sponsored Alternative System will be included in the policies. A Committee Sponsored Alternative System must specify the purpose for which it is proposed, how the system is

intended to accomplish this purpose, and an evaluation plan by which the sponsoring Committee will assess the system's success in achieving its stated purpose. The evaluation plan must include objective criteria for measuring the Committee-Sponsored Alternative System's results, including, for example, (a) candidate waiting time (stratified by candidate populations), (b) graft survival (stratified by candidate populations), and (c) organ availability and/or organ quality. Committees are encouraged to explain in the evaluation plan any difficulties they anticipate in demonstrating results from the Committee-Sponsored Alternative System that would assist the reviewing committees in assessing the system. This might include, for example, low volumes and difficulties in establishing statistical significance even over relatively long periods of time in the case of a system intended to adjust priority for pediatric candidates. The system must be established for a defined period of time, during which the sponsoring Committee must collect and evaluate relevant data to assess whether the system is achieving its objectives and should be continued, modified, or terminated. By the end of this period, the sponsoring Committee must have demonstrated through objective criteria that the purpose for which the system was approved has been accomplished or at least that progress considered adequate and demonstrated to the satisfaction of the reviewing committee(s)/Board to this end has been attained. Based upon this assessment, the sponsoring Committee shall recommend to the Board of Directors whether the Committee-Sponsored Alternative System should be continued without change, modified, or terminated.

OPOs and their affiliated transplant centers may apply to participate in an approved Committee-Sponsored Alternative System by demonstrating unanimous agreement to such participation among the OPO(s) and their transplant centers with programs for transplantation of the applicable organ(s). For those OPOs with multiple units (ALUs), signatures must be obtained from each transplant center within the OPO (with programs for transplantation of the applicable organ(s)) indicating that they agree to participate in the system. Applicants also must provide Member contact and other information as may be determined by the appropriate Committees and Board of Directors. Once the Board of Directors has approved a Committee-Sponsored Alternative System, individual participant applications do not require Committee or Region review or Board approval prior to implementation on UNet<sup>SM</sup>. Participants in Committee-Sponsored Alternative Systems are required to stay aware of all applicable provisions of the organ allocation policies and any amendments thereto as well as other bylaws and policies.

**3.4.10.2 Data Requirements.** Members participating in a Board-approved Committee-Sponsored Alternative System are not required to submit

alternative system data other than any specific data submission requirements of the system.

**3.4.10.3 Termination of Member Participation in Committee Sponsored Alternative System.** ~~An OPO and its affiliated transplant centers participating in an approved Committee Sponsored Alternative System may unanimously elect to withdraw from the alternative system and use the standard allocation and distribution system criteria pursuant to applicable policies upon providing timely written notification of such withdrawal and resulting termination of participation in the alternative system to the relevant Region(s), appropriate committees and the Board of Directors. Termination of the Members' participation in the alternative system shall be effective after appropriate re-programming in UNet<sup>SM</sup>.~~

**3.4.10.4 Modification of Committee Sponsored Alternative System.** ~~Any proposed modification of an approved Committee Sponsored Alternative System, other than withdrawal by individual participant(s), shall require application by the sponsoring Committee, and approval by Board of Directors in accordance with the application process described in Policy 3.4.8.1 above.~~

**3.4.10.5 Committee Sponsored Alternative Systems Approved Prior to March 15, 2005.** ~~Committee Sponsored Alternative Systems approved by the Board of Directors as of March 15, 2005, shall be permitted to continue to operate for 3 years from March 2005, at which time the applicable sponsoring Committees will be required to re-apply to continue the systems under the requirements and criteria of applicable policies for Committee Sponsored Alternative Systems then in effect.~~

**3.4.10.6 Appealing A Decision on A Committee Sponsored Alternative System.**

The committee sponsoring a Committee Sponsored Alternative System may appeal the decision of the Policy Oversight Committee (POC), but cannot appeal a decision of the Board of Directors.

*a. — Appealing the POC's Decision*

The POC will notify the sponsoring committee in writing of its decision within 10 business days, inclusive, of the meeting in which it determined the outcome of the variance.

To express its intent to appeal, the sponsoring committee must do so in writing and within 30 days, inclusive, of the POC's communication of its decision. The sponsoring committee must appeal the POC's decision *before* the Board of Directors reviews the POC's recommendation.

~~In considering the appeal, the POC will only review evidence not considered previously. The POC will evaluate the appeal as it would an application for a Committee-Sponsored Alternative System (see Policy 3.4.9.1—Development and Application). The sponsoring committee may choose to take part in this appeal discussion. The POC may request additional information from the sponsoring committee. Once the POC makes its final decision on the variance, the sponsoring committee cannot request another appeal until the Board of Directors decide on the Committee-Sponsored Alternative System.~~

~~In its evaluation of the Committee-Sponsored Alternative System, the POC may request additional information from the sponsoring committee. Once the sponsoring committee submits any information requested by the POC, the POC will then decide on the Committee-Sponsored Alternative System and submit its recommendation to the Board of Directors. The Board of Directors will consider the Committee-Sponsored Alternative System. The sponsoring committee may choose to take part in this meeting of the Board of Directors.~~

~~If the Board of Directors decides in favor of the Committee-Sponsored Alternative System, then the Committee-Sponsored Alternative System is approved for the trial period requested by the committee. If the Board of Directors decides against the Committee-Sponsored Alternative System, then the Committee-Sponsored Alternative System is not approved.~~

*b.—Appealing the Board of Directors' Decision*

~~Only a member participating in an existing Committee-Sponsored Alternative System can appeal the Board of Directors' decision on a Committee-Sponsored Alternative System.~~

~~To appeal the decision of the Board of Directors on a Committee-Sponsored Alternative System, the member participating in an approved Committee-Sponsored Alternative System may appeal directly to the Secretary of the Health and Human Services (HHS), in accordance with the OPTN Final Rule, 42 CFR § 121.4 (OPTN policies: Secretarial review and appeals).~~

***NOTE: Policy 3.4.10.6 (Appealing A Decision on A Committee-Sponsored Alternative System) shall be effective following notice to the membership. (Approved at the June 21-22, 2010 Board of Directors Meeting.)***

*No further changes to this policy*

**3.5.6.1** Local Allocation. With the exception of kidneys that are 1) shared as a result of a zero antigen mismatch, 2) offered as payback as defined in Policy 3.5.5 or 3) are allocated according to a voluntary organ sharing arrangement as provided in Policy 3.4.6, all kidneys will be allocated first to ~~local~~ candidates within the local unit as defined in Policy 3.1.7 ~~the locale~~ where the kidneys are procured.

*No further changes to this policy*

### **3.6 ALLOCATION OF LIVERS.**

Unless otherwise approved according to ~~Policy 3.4.8 (Variances)~~ ~~Policies 3.1.7 (Local and Alternative Local Unit), 3.1.8 (Sharing Arrangement and Sharing Agreement), 3.1.9 (Alternate Point Assignments (Variances), Policy 3.4.6 (Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems),~~ Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates) and Policy 3.11.4 (Combined Intestine-Liver Organ Candidates), the allocation of livers according to the following system is mandatory. For the purpose of enabling physicians to apply their consensus medical judgment for the benefit of liver transplant candidates as a group, each candidate will be assigned a status code or probability of candidate death derived from a mortality risk score corresponding to the degree of medical urgency as described in Policy 3.6.4 below. Mortality risk scores shall be determined by the prognostic factors specified in Tables 1 and 2 and calculated in accordance with the Model for End-Stage Liver Disease (MELD) Scoring System and Pediatric End Stage Liver Disease (PELD) Scoring System described in Policy 3.6.4.1 and 3.6.4.2, respectively. Candidates will be stratified within MELD or PELD score by blood type similarity as described in Policy 3.6.2. No individual or property rights are conferred by this system of liver allocation.

*No further changes to Policy 3.6.*

#### **3.7.1 Exceptions.**

Unless otherwise approved according to ~~Policy 3.4.8 (Variances)~~ ~~Policies 3.1.7 (Local and Alternative Local Unit), 3.1.8 (Sharing Arrangement and Sharing Agreement), 3.1.9 (Alternate Point Assignments (Variances)), and 3.4.6 (Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems),~~ or specifically allowed by the exceptions described in this Policy 3.7.1, all thoracic organs must be allocated in accordance with Policy 3.7.

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

**Affected Policy Language:**

**3.7.3 Adult Candidate Status.**— Each candidate awaiting heart transplantation is ~~assigned~~receives a status code ~~which corresponds~~ corresponding to ~~how medically urgent it is that the candidate's medical urgency receive a~~for transplant. ~~Medical urgency is assigned to a heart transplant candidate who is greater than or equal to 18 years of age at the time of listing as follows~~A heart transplant candidate at least 18 years of age at the time of listing receives a status code as follows:

Status Definition

**Status 1A** A candidate listed as Status 1A is admitted to the listing transplant center hospital (with the exception for a 1A(b) candidates) and has at least one of the following devices or therapies in place:

- (a) Mechanical circulatory support for acute hemodynamic decompensation that includes at least one of the following:
  - (i) left and/or right ventricular assist device implanted  
Candidates listed under this criterion, may be listed for 30 days at any point after being implanted as Status 1A once the treating physician determines that they are clinically stable. Admittance to the listing transplant center hospital is not required.
  - (ii) total artificial heart;
  - (iii) intra-aortic balloon pump; or
  - (iv) extracorporeal membrane oxygenator (ECMO).

Qualification for Status 1A under criterion 1A(a)(ii), (iii) or (iv) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1A for 30 days at any point in time after the discharge.

- (b) Mechanical circulatory support with objective medical evidence of significant device-related complications, such as thromboembolism, device infection, mechanical failure or life-threatening ventricular arrhythmias. A transplant center can report a complication not listed here. The report of an “other” complication will result in a review by the respective heart regional review board. (Candidate sensitization is not an appropriate device-related complication for qualification as Status 1A under this criterion. The applicability of sensitization to thoracic organ allocation is specified by Policy 3.7.1.1 (Exception for Sensitized Candidates).)

Admittance to the listing center transplant hospital is not required. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

- (c) Continuous Mechanical ventilation. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.
- (d) Continuous infusion of a single high-dose intravenous inotrope or multiple intravenous inotropes, in addition to continuous hemodynamic monitoring of left ventricular filling pressures.

Qualification for Status 1A under this criterion is valid for 7 days and may be renewed for an additional 7 days for each occurrence of a Status 1A listing under this criterion for the same candidate. The OPTN contractor shall maintain in the heart status justification form in UNet<sup>SM</sup> a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.

#### **Status 1A by-Exception**

A candidate who does not meet ~~criteria~~criterion (a), (b), (c), or (d) may nevertheless be Status 1A upon application by his or her transplant physician. The transplant physician must justify~~and justification~~ to the applicable Regional Review Board ~~that why~~ the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit ~~comparable to that of~~as other candidates in Status 1A~~this status as defined above~~. The justification must be for a candidate admitted to his or her listing transplant center hospital and must include a rationale for incorporating the exceptional case as part of Status 1A~~the status criteria~~. The justification must be reviewed and approved by the Regional Review Board. Timing of the review of these cases, whether prospective or retrospective, will be left to the discretion of each Regional Review Board. ~~A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation Committee to determine consistency in application among and within Regions and continued appropriateness of the candidate status.~~

A candidate's listing under this exceptional provision is valid for 14 days. Any further extension of the Status 1A listing ~~under this criterion~~ by exception requires prospective review and approval by a majority of the Regional Review Board Members. If Regional Review Board approval is

not given, the candidate's transplant physician may list the candidate as Status 1A, subject to automatic referral to the Thoracic Organ Transplantation Committee. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation ~~Committee and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria.~~ The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

#### **Submission of Status 1A Justification Form**

A completed Heart Status 1A Justification Form must be submitted ~~to~~ in UNet<sup>SM</sup> in order to list a candidate as Status 1A, or extend his or her listing as Status 1A in accordance with the criteria listed above. When a candidate's time at Status 1A expires, the candidate will automatically be classified as Status 1B ~~unless the attending physician recertifies the candidate's qualification for a Status 1A criterion. Note: This automatic downgrade will not require submission of a Status 1B Justification Form.~~ The attending physician must classify the candidate as Status 2 or 7 if the candidate's medical condition does not qualify for Status 1A or Status 1B.

#### **Status 1B**

A candidate listed as Status 1B has at least one of the following devices or therapies in place:

- (aa) left and/or right ventricular assist device implanted; or
- (bb) continuous infusion of intravenous inotropes.

A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1B at any point in time after the discharge.

#### **Status 1B- by Exception**

A candidate who does not meet the criteria for Status 1B may nevertheless be ~~assigned to such status~~ listed as Status 1B upon application by his or her transplant physician. ~~The transplant physician must and justification justify~~ to the applicable Regional Review Board that why the candidate is considered, using ~~accepted~~ acceptable medical criteria, to have an urgency and potential for benefit ~~comparable to that of as other Status 1B candidates in this status as defined above.~~ The justification must include a rationale for incorporating the exceptional case as part of ~~Status 1B~~ the status criteria. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation ~~Committee and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria.~~ The Thoracic Organ

Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

**Submission of Status 1B Justification Form**

A completed Heart Status 1B Justification Form must be submitted ~~to~~ in UNet<sup>SM</sup> in order to list a candidate as Status 1B.

**Status 2** A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.

**Status 7** A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

**Change in Status 1A or 1B Criterion or Eligibility**

If a change in the candidate's medical condition makes the criterion used to justify a candidate's Status 1A or 1B no longer accurate, the transplant program must report the accurate information in UNet<sup>SM</sup> within 24 hours of the change in medical condition.

~~Prior to downgrading any candidates upon expiration of any limited term for any listing category, the OPTN contractor shall notify a responsible member of the relevant transplant team.~~

**3.7.4 Pediatric Candidate Status.** Each candidate awaiting heart transplantation ~~is assigned~~ receives a status code ~~which corresponds~~ corresponding to ~~how medically urgent it is~~ that the candidate's medical urgency for ~~receive~~ a transplant. Medical urgency is assigned to a heart transplant candidate who is less than 18 years of age at the time of listing ~~as follows~~: Pediatric heart transplant candidates who ~~have not received a heart transplant~~ remain on the Waiting List at the time of ~~before~~ their 18<sup>th</sup> birthday ~~without receiving a transplant~~, shall continue to qualify for medical urgency status based ~~upon~~ the criteria set forth in ~~on~~ Policy 3.7.4. A heart transplant candidate who is less than 18 years of age at the time of listing receives a status code as follows:

Status Definition

**Status 1A** A candidate listed as Status 1A meets at least one of the following criteria:

- (a) Requires assistance with a ventilator;
- (b) Requires assistance with a mechanical assist device (e.g., ECMO);
- (c) Requires assistance with a balloon pump;

- (d) A candidate less than six months old with congenital or acquired heart disease exhibiting reactive pulmonary hypertension at greater than 50% of systemic level. Such a candidate may be treated with prostaglandin E (PGE) to maintain patency of the ductus arteriosus;
- (e) Requires infusion of high dose ~~(e.g., dobutamine > / = 7.5 mcg/kg/min or milrinone > / = .50 mcg/kg/min)~~ or multiple inotropes ~~(e.g., addition of dopamine at > / = 5 mcg/kg/min)~~ (The OPTN contractor shall maintain in the heart status justification form in UNet<sup>SM</sup> a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.); or,
- (f) A candidate who does not meet the criteria specified in (a), (b), (c), (d), or (e) may be listed as Status 1A if the candidate has a life expectancy without a heart transplant of less than 14 days, such as due to refractory arrhythmia. Qualification for Status 1A under this criterion is valid for 14 days and may be recertified by an attending physician for one additional 14-day period. Any further extension of the Status 1A listing under this criterion requires a conference with the applicable Regional Review Board. If Regional Review Board approval is not given, the candidate's transplant physician may list the candidate as Status 1A, subject to automatic referral to the Thoracic Organ Transplantation Committee. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Qualification for Status 1A under criteria (a) through (e) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

**Submission of Status 1A Justification Form**

~~For all pediatric candidates listed as Status 1A, a completed Heart Status 1A Justification Form must be received on UNet<sup>SM</sup> in order to list a candidate As as Status 1A, or extend their listing as Status 1A in accordance with the criteria listed above in Policy 3.7.4. Candidates who are listed as Status 1A will automatically revert back to Status 1B after 14 days unless these candidates are re-listed on UNet<sup>SM</sup> as Status 1A by an attending physician within the time frames described in the definitions of status 1A(a)-(e) above~~

A completed Heart Status 1A Justification Form must be submitted in UNet<sup>SM</sup> in order to list a candidate as Status 1A, or extend his or her listing as Status 1A in accordance with the criteria listed above in Policy 3.7.4. When a candidate's time at Status 1A expires, the candidate will automatically be classified as Status 1B. The attending physician must classify the candidate as Status 2 or 7 if the candidate's medical condition does not qualify for Status 1A or Status 1B.

**Status 1B**

A candidate listed as Status 1B meets at least one of the following criteria:

- (a) Requires infusion of low dose single inotropes ~~(e.g., dobutamine or dopamine < / =7.5 mcg/kg/min)~~(The OPTN contractor shall maintain in the heart status justification form in UNet<sup>SM</sup> a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.);
- (b) Less than six months old and does not meet the criteria for Status 1A; or
- (c) Growth failure *i.e.*, +less than 5<sup>th</sup> percentile for weight and/or height, or loss of 1.5 standard deviations of expected growth (height or weight) based on the National Center for Health Statistics for pediatric growth curves.

Note: This criterion defines growth failure as either < 5<sup>th</sup> percentile for weight and/or height, or loss of 1.5 standard deviation score of expected growth (height or weight). The first measure looks at relative growth as of a single point in time. The second alternative accounts for cases in which a substantial loss in growth occurs between two points in time. –Assessment of growth failure using the standard deviation score decrease can be derived by, first, measuring (or using a measure of) the candidate's growth at two different times, second, calculating the candidate's growth velocity between these times, and, third, using the growth velocity to calculate the standard deviation score (*i.e.*, (candidate's growth rate - mean growth rate for age and sex) divided by standard deviation of growth rate for age and sex).

**Status 1B by Exception**

A candidate who does not meet the criteria for Status 1B may be listed as Status 1B upon application by his transplant physician to the applicable Regional Review Board. The transplant physician must justify why the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit as other candidates listed as Status 1B. The justification must include a rationale for incorporating the exceptional case as part of Status 1B. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation Committees. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

~~For all pediatric candidates listed as Status 1B, a completed Heart Status 1B Justification Form must be received on UNet<sup>SM</sup> in order to list a candidate as Status 1B. A candidate who does not meet the criteria for Status 1B may nevertheless be assigned to such status upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates in this status as defined above. The justification must include a rationale for incorporating the exceptional case as part of the status criteria. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria.~~

#### **Submission of Status 1B Justification Form**

A completed Heart Status 1B Justification Form must be submitted in UNet<sup>SM</sup> to list a candidate as Status 1B.

**Status 2** A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.

**Status 7** A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

#### **Change in Status 1A or 1B Criterion or Eligibility**

If a change in the candidate's medical condition makes the criterion used to justify a candidate's Status 1A or 1B no longer accurate, the transplant program must report the accurate information in UNet<sup>SM</sup> within 24 hours of the change in medical condition.

~~Prior to downgrading any candidates upon expiration of any limited term for any listing category, the OPTN contractor shall notify a responsible member of the relevant transplant team.~~

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

**Affected Policy Language:****3.2.1.8 Waiting Time Modification****3.2.1.8.1 Permissible Modifications**

Applications for waiting time modifications that meet any of the following qualifications must follow the procedures for expedited modifications of waiting time in Policy 3.2.1.8.3 below.

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

Applications to modify a candidate's registration date and all other applications for waiting time modifications must follow the procedures for modifications of waiting time in Policy 3.2.1.8.4 below. Additionally, applications must meet any additional requirements stipulated in the organ-specific allocation policies. If an application does not comply with the requirements of Policy 3.2.1.8, then the OPTN Contractor will neither implement the requested waiting time modifications nor forward the application for review.

**3.2.1.8.2 Application**

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

1. The requested listing date and documentation showing an intent to register the candidate at the requested listing date.
2. That the candidate met applicable waiting time qualifying criteria in the organ specific policies (Policy 3.0 *et seq.*).
3. A corrective action plan, if the application is due to an error.
4. The name and signature of the candidate's physician or surgeon.
5. Signatures indicating agreement from all applicable transplant programs in the OPO. If a signature cannot be obtained from a transplant program, the submitting program must explain the efforts it made to obtain a signature and include any stated reasons for disagreement with the request.

**3.2.1.8.3 Expedited Modifications of Waiting Time**

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

1. Upon receipt of a complete application, the OPTN Contractor will implement the waiting time modification.

2. The OPTN Contractor will report the modification, without person-identified data, to the relevant organ specific Committee.
3. The Committee will report the modification, without person-identified data, to the Board of Directors.

**3.2.1.8.4 Modifications of Waiting Time**

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

1. Upon receipt of a complete application and approval or explanation of disagreements from all applicable Transplant Programs within the local unit where the candidate is registered, the OPTN Contractor will forward the application, without person-identified data, as follows:

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

**Review of Waiting List Modification Applications**

2. The reviewer will determine if it is appropriate to modify the candidate’s waiting time as requested in the application and notify the OPTN Contractor of the decision.
3. Upon notice, the OPTN Contractor will implement the waiting time modification.
4. The reviewer will report the modification, without person-identified data, to the relevant organ specific Committee.
5. The Committee will report the modification, without person-identified data, to the Board of Directors.

~~**3.2.1.8 Waiting Time Modification.** Transplant candidates on the Waiting List may have waiting time accrued under a previous Waiting List registration reinstated under the following circumstances:~~

- ~~i. The candidate was incorrectly removed from the Waiting List, as a result of errors and/or miscommunication between clinical/clerical personnel. The reinstated waiting time shall include time accrued under the previous registration, in addition to the time interval during which the candidate was removed from the Waiting List.~~
- ~~ii. The candidate was removed from the Waiting List for medical reasons other than having received a transplant and subsequently was relisted for the same organ with the same diagnosis. The reinstated waiting time only shall include time accrued under the previous registration and not the time interval during which the candidate was removed from the Waiting List.~~

~~Upon receipt by the Organ Center of a completed Waiting Time Modification Form (with all required information) and verification of the information through review of the candidate's history, Organ Center staff may reinstate the candidate's waiting time.~~

~~All other requests for waiting time reinstatement that are not specified under Policy 3.2.3.2 (Waiting Time Reinstatement for Kidney Recipients), or other policies which describe permissible waiting time adjustments, shall be first approved by unanimous agreement among the hospitals (with transplant programs for the applicable organ) within the local area in which the candidate is listed, and then submitted to the appropriate organ specific committees and Board of Directors for review with appropriate supporting documentation. Notwithstanding the above, however, upon demonstration to the appropriate organ specific committee that unanimous agreement among the relevant parties cannot be obtained despite efforts to do so, such a request may be submitted with appropriate supporting documentation, including without limitation, reasons provided by the dissenting party(ies) for any disagreement, for consideration despite the lack of unanimous approval. Modification requests for isolated kidney and combined kidney/pancreas waiting time shall indicate and substantiate with supporting documentation that the candidate met waiting time criteria as defined in Policy 3.5.11.1 (Time of Waiting), or Policy 3.5.12.1 (Time of Waiting), or Policy 3.8.4.3 (Waiting time) as of the listing date requested. Under the circumstances described in this paragraph, waiting time modifications will be made, in the case of requests for modifying kidney or pancreas waiting time, after consideration and approval by the Kidney Transplantation Committee (for kidney and kidney/pancrease candidates) or & Pancreas Transplantation Committee (for kidney/pancreas and pancreas candidates), or, in the case of pediatric (i.e., less than 18 years old) kidney candidates, with approval from the Chair of the Kidney & Pancreas Transplantation Committee to proceed to a subcommittee of the full Committee followed by consideration and unanimous approval by this subcommittee. Pediatric candidate cases addressed by a subcommittee of the Kidney & Pancreas Transplantation Committee will subsequently be referred to the full Committee for consideration of final action as determined appropriate by the Committee and in the case of requests for modifying waiting time for organs other than kidney, kidney pancreas, and pancreas (except as provided in Policy 3.2.1.8.1 (Waiting Time Modification for Urgent Status Candidates)) only upon approval by the Board of Directors, or by the Executive Committee subject to ratification by the Board of Directors. Requests for modifying kidney or pancreas waiting time, along with decisions of the~~

~~Kidney Transplantation Committee & Pancreas Transplantation Committee or subcommittee in the case of pediatric candidates and Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.~~

~~**3.2.1.8.1 Waiting Time Modification for Urgent Status Candidates.** Adjustments will be permitted to the waiting time of Status 1 liver transplant candidates, Status 1A heart transplant candidates, and Priority 1 pediatric lung candidates registered on the Waiting List if an error or miscommunication occurred in listing, modification, or accidental removal of the candidate, or in renewing the candidate's status. Supporting documentation must be submitted, including a written request from the physician/surgeon in charge of the candidate's care explaining the circumstance along with the appropriate status justification form and Wait Time Modification Form. Upon receipt of completed documentation, the requested modification will be made. Each case will be reported retrospectively to the appropriate regional review board for consideration.~~

~~**3.2.107 Waiting Time Adjustment for Candidates Needing a Life-Saving Organ Transplant When the Need for a Second Organ Transplant Arises.** Waiting time accrued by a candidate for a transplant of a life-saving organ while waiting on the Waiting List may also be accrued for a second organ, when it is determined that the candidate requires a multiple organ transplant. For purposes of this policy, a life-saving organ shall be defined as the heart, lung or liver. Kidney, pancreas or intestine may qualify as life-saving organs if routine alternative therapies are not possible and demonstrable and after all transplant centers and programs within those centers, the other transplant programs within the OPO and the OPO itself agree to the waiting time adjustment.~~

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

**Affected Policy Language:**

*\*\* Please note: At its June 2012 meeting, the OPTN/UNOS Board of Directors approved two separate resolutions that modified Policy 3.6 (Allocation of Livers). Below, Policy 3.6 reflects the changes from both of these proposals: Changes to Policy 3.6 (Adult Donor Liver Allocation Algorithm) for Regional Distribution of Livers for Critically Ill Candidates and to Extend the "Share 15" Regional Distribution Policy to "Share 15 National" (sponsored by the Liver and Intestinal Organ Transplantation Committee) and Proposal to Clarify and Improve Variance Policies (sponsored by the Policy Oversight Committee).*

*Additionally, amendments to the Adult Donor Liver Allocation Algorithm in Policy 3.6 that the Board of Directors approved at its November 2011 meeting are still awaiting programming for implementation. The complete allocation algorithm for adult donor livers upon the implementation of the approved policy changes from both the November 2011 and June 2012 meetings is provided below. To distinguish the changes to Policy 3.6 approved by the Board of Directors, policy language changes from the November 2011 meeting are marked with a ~~single strikethrough~~ or a single underline and those policy changes from the June 2012 meeting are marked with a ~~double strikethrough~~ or double underline.*

**3.6 ALLOCATION OF LIVERS.** Unless otherwise approved according to Policy 3.4.8 (Variances) Policies 3.1.7 (Local and Alternative Local Unit), 3.1.8 (Sharing Arrangement and Sharing Agreement), 3.1.9 (Alternate Point Assignments (Variances)), Policy 3.4.6 (Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems), Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates) and Policy 3.11.4 (Combined Intestine-Liver Organ Candidates), the allocation of livers according to the following system is mandatory. For the purpose of enabling physicians to apply their consensus medical judgement for the benefit of liver transplant candidates as a group, each candidate will be assigned a status code or probability of candidate death derived from a mortality risk score corresponding to the degree of medical urgency as described in Policy 3.6.4 below. Mortality risk scores shall be determined by the prognostic factors specified in Tables 1 and 2 and calculated in accordance with the Model for End-Stage Liver Disease (MELD) Scoring System and Pediatric End Stage Liver Disease (PELD) Scoring System described in Policy 3.6.4.1 and 3.6.4.2, respectively. Candidates will be stratified within MELD or PELD score by blood type similarity as described in Policy 3.6.2. No individual or property rights are conferred by this system of liver allocation.

Livers will be offered to candidates with an assigned Status of 1A and 1B in descending point sequence with the candidate having the highest number of points receiving the highest priority before being offered for candidates listed in other categories within distribution areas as noted below. Following Status 1, livers will be offered to candidates based upon their probability of candidate death derived from assigned MELD or PELD scores, as applicable, in descending point sequence with the candidate having the highest probability ranking receiving the highest priority before being offered to candidates having lower probability rankings. Additionally, Alternative Allocation/ Distribution Systems, as described in Policy 3.1.7, shall no longer contain liver payback provisions.

At each level of distribution, adult livers (i.e., greater than or equal to 18 years old) will be allocated in the following sequence (adult donor liver allocation algorithm):

### Adult Donor Liver Allocation Algorithm

#### Combined Local and Regional

1. Status 1A candidates in descending point order
2. Status 1B candidates in descending order

#### Local and Regional

3. Candidates with MELD/PELD Scores  $\geq 35$  in descending order of mortality risk (MELD) scores, with Local candidates ranked above Regional candidates at each level of MELD score

#### Local

- ~~34.~~ Candidates with MELD/PELD Scores  ~~$\geq 15$~~  29-34 in descending order of mortality risk scores (probability of candidate death)

#### National

45. Liver-Intestine Candidates in descending order of mortality risk scores (probability of candidate death)

#### Local

- ~~56.~~ Candidates with MELD/PELD Scores 15-28 in descending order of mortality risk scores (probability of candidate death)

#### Regional

- ~~46.~~ Candidates with MELD/PELD Scores  ~~$\geq 15$~~  15-34 in descending order of mortality risk scores (probability of candidate death)

#### National

8. Status 1A candidates in descending point order
9. Status 1B candidates in descending point order
10. Candidates with MELD/PELD Scores  $\geq 15$  in descending order of mortality risk scores (probability of candidate death)

#### Local

- ~~57.~~ Candidates with MELD/PELD Scores < 15 in descending order of mortality risk scores (probability of candidate death)

#### Regional

- ~~68.~~ Candidates with MELD/PELD Scores < 15 in descending order of mortality risk scores (probability of candidate death)

#### National

- ~~79.~~ Status 1A candidates in descending point order
- ~~810.~~ Status 1B candidates in descending point order
- ~~911.~~ All other eCandidates with MELD/PELD Scores < 15 in descending order of mortality risk scores (probability of candidate death)

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

**Affected Policy Language:****5.0 STANDARDIZED PACKAGING, LABELING AND TRANSPORTING OF ORGANS, VESSELS, AND TISSUE TYPING MATERIALS**

The purpose of Policy 5.0 and its subsections is to:

- state requirements for packaging and labeling organs, tissue typing specimens, and vessels to prevent wastage (and/or to promote safe and efficient use);
- define terms and responsibilities related to packaging, labeling, and transporting organs, tissue typing specimens, and vessels; and
- state requirements for recovering, storing, and using vessels in solid organ recipients.

The responsibility for packaging and labeling deceased donor organs is assigned to the Host OPO. Transplant Center staff may not leave the operating room without allowing the OPO to package and label the organ in accordance with OPTN policy. The OPO must submit a report through the Patient Safety System when a Transplant Center fails to comply with this policy. The OPO will make all reasonable efforts to package and label the organ in a timely fashion. If an organ is repackaged by a transplant center for transport, the Transplant Center will package, label and ship the organ in accordance with this policy and immediately notify the recovering OPO of the repackaging.

**5.1 EXTERNAL PACKAGING SPECIFICATIONS**

An external transport container is defined as a: disposable shipping box, cooler or mechanical preservation machine. The transplant center or OPO must use both internal and external transport containers to package a deceased donor organ that travels outside of the recovery facility where the organ is recovered.

**5.1.1 – 5.1.2 [No Change]****5.1.3 Mechanical preservation machine**

- Mechanical preservation machines are permitted for transporting an organ.
- The cassette containing the organ must be labeled with the organ type (i.e. left kidney, right kidney), ABO, and UNOS ID.
- The external surface of a mechanical preservation machine must be labeled with:
  - ⊖ the standardized external label distributed by the OPTN contractor, ~~or~~
  - ⊖ ~~an alternate label that contains all information included on the OPTN contractor standardized label.~~
- Before re-using a mechanical preservation machine that was used to transport an organ, all labels from the previous donor organ must be removed.

**5.2 INTERNAL PACKAGING SPECIFICATIONS [No Change]****5.3 EXTERNAL LABELING REQUIREMENTS**

When a disposable shipping box or cooler is used to transport a deceased donor organ, the Host OPO must use the standardized external label distributed by the OPTN contractor. ~~When a mechanical preservation machine is used, the OPO or Transplant~~

~~Center, as applicable, may use an alternative label if the label contains all of the required information.~~

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

## Affected Policy and Bylaw Language:

*\*\* Please note: The public comment proposal for these changes originally recommended edits to Attachment III to Appendix B of the OPTN Bylaws (Model Elements for Controlled DCD Recovery Protocols). As a part of the OPTN Bylaws Plain Language Rewrite that the OPTN/UNOS Board of Directors also adopted at its June 2012 meeting, the information in Attachment III to Appendix B of the OPTN Bylaws moved to OPTN Policy 2.8 (Model Elements for Controlled DCD Recovery Protocols). The changes to Attachment III to Appendix B of the OPTN Bylaws that the Board of Directors adopted are presented below as they will read upon implementation, i.e. incorporated into Policy 2.8 (Model Elements for Controlled DCD Recovery Protocols).*

*The public comment proposal for these changes also recommended edits to Policy 6.4.2 (Developmental Protocols in International Organ Exchange) and Policy 6.4.3 (Ad Hoc Organ Exchange). A resolution sponsored by the Ad Hoc International Relations Committee and the Ethics Committee, and also adopted by the Board at its June 2012 meeting, made significant changes to Policy 6.4.2 and Policy 6.4.3. The policy changes sponsored by the Ad Hoc International Relations and Ethics Committees incorporate the term "authorization" in place of "consent," as appropriate. All the changes to Policy 6.4.2 and 6.4.3 are presented in Exhibit J, which corresponds to the policy changes sponsored by the Ad Hoc International Relations and Ethics Committees.*

## 2.0 MINIMUM PROCUREMENT STANDARDS FOR AN ORGAN PROCUREMENT ORGANIZATION (OPO)

In order to maximize the gift of donation and optimize recipient outcomes and safety, the Organ Procurement Organization (OPO) must comply with the following policies for minimum procurement standards.

**2.1 HOST OPO.** The OPO responding to an organ donor call from a hospital is the "Host OPO" for that particular donor. The Host OPO is responsible for identifying, evaluating and maintaining the donor, obtaining ~~consent~~ authorization for the removal of organs, complying with OPTN policy throughout the donation process, and organ allocation.

Additionally, the Host OPO is responsible for ensuring that donor tissue typing information is entered into UNet<sup>SM</sup> and that the approved OPTN automated organ allocation computer algorithm is executed for each donor organ.

The Host OPO shall make reasonable attempts to obtain a medical/behavioral history from individual(s) familiar with the donor.

The Host OPO is responsible for organ procurement quality including appropriate preservation, and packaging of the organs, and assurance that adequate tissue typing material is procured, divided, and packaged.

The Host OPO is responsible for written documentation of donor evaluation, donor maintenance, ~~consent~~ authorization for donation, death pronouncement, and organ

procurement quality accompanies the organ as described in Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials).

2.2 – 2.3 [No Change].

**2.4 OBTAINING ~~CONSENT~~AUTHORIZATION.** The Host OPO must provide evidence of ~~consent~~ authorization for donation according to applicable legal authority.

2.5 – 2.7 [No Change].

## 2.8 Model Elements for Controlled DCD Recovery Protocols

### B. ~~Consent~~Authorization/Approval

1. The legal next of kin may elect to ~~consent to~~ authorize procedures or drug administration for the purposes of organ donation (e.g. heparin, regitine, femoral line placement, lymph node excision, ECMO, and bronchoscopy). No donor related medications shall be administered or donation related procedures performed without ~~consent~~ authorization.
2. Clearance from medical examiner/coroner must be obtained when applicable.
3. There should be a plan for patient care if death does not occur within the established timeframe after the withdrawal of life sustaining measures. This plan should include logistics and provisions for continued end of life care, including immediate notification of the family.
4. For purposes of these model elements, “legal next of kin” shall also include the patient, a designated health care representative, legal next of kin, or appropriate surrogate.

### C. Withdrawal of Life Sustaining Measures/ Patient Management

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

## 3.3 ACCEPTANCE CRITERIA

**3.3.1– 3.3.5 [No Change].**

**3.3.6 Center Acceptance of Organ Offers.** If an organ is offered and accepted without conditions, the Host OPO and intended recipient’s transplant center shall be bound by this transaction unless there is mutual agreement on an alternative allocation of the organ.

**3.3.6.1** Exception for DCD Donor who Converts to Brain Death After an Organ Offer has been Made. When a DCD donor converts to brain death, the match system must be re-executed and organs must be allocated according to policies 3.5 - 3.11. Policy 3.6.5.1 does not apply when a DCD donor converts to brain death. Additionally, OPOs are encouraged to initiate allocation of organs that may have been ruled out due to the donor’s DCD status (i.e. heart, lungs, pancreas).

**3.3.6.1.1** The Host OPO may choose not to re-allocate organs from a DCD donor who converts to brain death in the following circumstances: 1) lack of donor family approval and ~~consent~~ authorization; 2) donor instability; or 3) other extraordinary circumstances. The Host OPO must document the reason for not re-allocating organs when a DCD donor converts to brain death and make this documentation available upon request.

**3.5 ALLOCATION OF DECEASED KIDNEYS****3.5.1 – 3.5.3.2 [No Change].**

**3.5.3.3 Sharing.** With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors<sup>1</sup> if there is a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List for whom there is a zero antigen mismatch with a standard donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch subject to time limitations for such organ offers set forth in Policy 3.5.3.5. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors<sup>1</sup>, if there is a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List who has agreed to receive expanded criteria donor kidneys for whom there is a zero antigen mismatch with an expanded criteria donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch who has agreed to be transplanted with expanded criteria donor kidneys subject to time limitations for such organ offers set forth in Policy 3.5.3.5. If both donor kidneys are transplantable, the recipient center that was offered the kidney for a candidate with a zero antigen mismatch does not have the implicit right to choose between the two kidneys.

The final decision as to which of the two kidneys is to be shared rests with the Host OPO. In lieu of the four additional points for a candidate with a PRA of

80% or higher and a preliminary negative crossmatch (Policy 3.5.11.3) four additional points will be added to all candidates for whom there is a zero antigen mismatch with a standard donor and whose PRA is 80% or higher regardless of preliminary crossmatch results. For kidneys procured from Donation after Cardiac Death donors, if there is any candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate listed locally with the zero antigen mismatch, by blood group identical and then compatible; then to all other local candidates in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria; then to regional and then national pediatric or sensitized adult candidates (CPRA>20%) in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria. When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:

<sup>1</sup>For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after Cardiac Death donors shall be defined as follows: (1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written ~~consent~~ authorization for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after Cardiac Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before ~~consent~~ authorization for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until ~~consent~~ authorization can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a candidate who is ~~consented~~ authorized for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

### **3.5.3 – 3.5.4 5 [No Change].**

**3.5.5 Payback Requirements.** Except as otherwise provided in Policy 3.5.3.5 (Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.3.4 Organ Offer Limit), 3.5.5.2 (Exception for Prior Living Organ Donors), and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged Less than 35 Years), when a kidney is shared pursuant to: (i) the zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a candidate with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the Organ Center a kidney from the next suitable standard donor that does not meet the criteria for a Donation after Cardiac Death donor<sup>1</sup>, six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after Cardiac Death donor, or (iii) donor is less than six years old and 60 years old or older may be offered for payback at the

discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

<sup>1</sup>For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after Cardiac Death donors shall be defined as follows: (1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written ~~consent~~ authorization for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after Cardiac Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before ~~consent~~ authorization for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until ~~consent~~ authorization can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a candidate who is ~~consented~~ authorized for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

**3.5.6 – 3.5.17 5 [No Change].**

## **5.0 STANDARDIZED PACKAGING, LABELING AND TRANSPORTING OF ORGANS, VESSELS, AND TISSUE TYPING MATERIALS**

**5.1 – 5.4 [No Change].**

### **5.5 DOCUMENTATION ACCOMPANYING THE ORGAN OR VESSEL**

#### **5.5.1 Documentation accompanying the organ**

- Complete donor documentation must be sent in the container with each transported organ. This documentation must include:
  - ABO typing source documentation;
  - Infectious disease testing results;
  - Medical/Behavioral History form;
  - Donor Evaluation;
  - Complete record of the donor;
  - ~~Consent~~Authorization form; and
  - Organ quality information as noted in Policy 2.5
- Donor documentation must be placed in a watertight container.
- Donor documentation may be placed in either:
  - a location specifically designed for documentation, or
  - between the outer and inner containers.
- Whenever a deceased donor organ is transported, the Host OPO or the Transplant Center, as applicable, must include in the donor documentation the source documentation.

#### **5.5.2 Documentation accompanying the vessel**

If the vessels are not shipped in the same package as the organ, the same complete donor documentation, as described in Policy 2.5.6.1, must be included with the vessels.

**5.6 - 5.9 - [No Change].****5.10 VESSEL RECOVERY, TRANSPLANT, AND STORAGE**

The intent of this policy is to permit:

- vessel recovery and immediate use in a solid organ transplant (for example either a current liver or pancreas transplant); and
- vessel recovery and storage for use in a subsequent solid organ transplant from a donor with a different UNOS Donor ID (for example, when the vessel(s) and the liver or pancreas allograft are being transplanted from different donors with different numbers).

**5.10.1 Vessel recovery and transplant**

- The ~~consent~~ authorization forms used by the recovering OPO must include language that indicates that vessels will be used for transplant.
- The vessels cannot be used other than for the implantation or modification of a solid organ transplant.
- Vessels can be shared among transplant programs. If sharing occurs between transplant programs, the implanting program must submit to the OPTN a detailed explanation justifying the sharing. The justification will be reviewed by the Membership and Professional Standards Committee (MPSC). The implanting transplant program must notify the OPTN of subsequent disposition of the vessel(s).
- If the transplant center stores vessels and subsequently uses the vessels for the intended recipient or another transplant recipient, the OPTN must be notified.
- If vascular conduits from donors with positive serology for hepatitis are subsequently used in other than the intended recipient, the implanting transplant center must provide a detailed explanation to the OPTN for the use of this conduit. The explanation will be reviewed by the MPSC.

**5.10.2 – 5.11.3 [No Change].****7.0 DATA SUBMISSION REQUIREMENTS**

Members must submit data to the OPTN through use of standardized forms. Data requirements include submission of information on all deceased and living donors, potential transplant recipients, and actual transplant recipients. All transplant data forms must be submitted through UNet<sup>SM</sup>, beginning January 1, 2003. All OPOs are responsible for submission of patient level data for all ~~consented~~ authorized donors, ~~consent~~ authorized but not recovered potential donors, imminent neurological and eligible deaths in its DSA. All OPOs are also responsible for submission of the total number of reported deaths by donor hospital. The OPO responsible for allocation of the donor organs will be responsible for submission of the Deceased Donor Feedback information, Deceased Donor Registration (DDR) Forms and Potential Transplant Recipient (PTR) Forms. Histocompatibility laboratories will be responsible for submission of the Donor and Recipient Histocompatibility forms for each donor and actual transplant recipient typed by the laboratory.

Recipient transplant centers are responsible for submission of Recipient Feedback information, Living Donor Feedback information, Living Donor Registration Forms, Living Donor Follow-up Forms, Transplant Candidate Registration Forms, organ-specific Transplant Recipient Registration Forms, organ-specific Transplant Recipient Follow-up Forms, and Recipient Malignancy Forms for each recipient on the waiting list, transplanted or followed at the center.

**7.1 – 7.9 [No Change].**

**9.0 RELEASE OF INFORMATION TO THE PUBLIC.**

**9.1 – 9.6.5 [No Change].**

**9.6.6** Updated OPO-specific donor procurement volumes, (using data validated by the member through UNet<sup>SM</sup>, including organ-specific ~~consent~~ authorization, procurement, and utilization volumes, by OPO; and numbers of donors by OPO, (using data validated by the member through UNet<sup>SM</sup>, stratified by demographic and medical factors for such period(s) as determined appropriate by the POC.

**9.6.7 – 9.12 [No Change].**

**~~ATTACHMENT III TO APPENDIX B OF THE OPTN BYLAWS~~**

**~~Model Elements for Controlled DCD Recovery Protocols~~**

**~~A. Suitable Candidate Selection [No Change].~~**

**~~B. Consent Authorization/Approval~~**

- ~~1. The legal next of kin may elect to consent to authorize procedures or drug administration for the purposes of organ donation (e.g. heparin, regitine, femoral line placement, lymph node excision, ECMO, and bronchoscopy). No donor related medications shall be administered or donation related procedures performed without consent authorization.~~
- ~~2. Clearance from medical examiner/coroner must be obtained when applicable.~~
- ~~3. There should be a plan for patient care if death does not occur within the established timeframe after the withdrawal of life sustaining measures. This plan should include logistics and provisions for continued end of life care, including immediate notification of the family.~~
- ~~4. For purposes of these model elements, “legal next of kin” shall also include the patient, a designated health care representative, legal next of kin, or appropriate surrogate.~~

**~~C. Withdrawal of Life Sustaining Measures/ Patient Management~~**

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

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

To read the current OPTN bylaws, which will be in effect until September 1, 2012, visit [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov). From the OPTN website, select the "Policy Management" tab, then select "OPTN Bylaws."

**Affected Policy Language:**

~~**6.4.4 Ethical Practices.** No member will engage in practices which might discredit the transplant community. Organs accepted for importation must be from deceased donors and must have been voluntarily donated. Organs imported from living donors or organs for which compensation has been made or promised are not acceptable for exchange or acceptance by members.~~

**1.0 Member Rights and Obligations**

The Organ Procurement and Transplantation Network (OPTN) is a private non-profit entity that has an expertise in organ procurement and transplantation. The purposes for which the OPTN is organized are detailed in the OPTN Charter. Membership in the Corporation is voluntary; rights and obligations of Members of the OPTN are set forth in the OPTN Bylaws and in OPTN Policies adopted by the OPTN Board of Directors.

OPTN Policies govern the various areas of OPTN operations. Amendments and additions to OPTN Policies are adopted by the Board of Directors and may be incorporated into the Bylaws. Policy Amendments and additions are binding upon OPTN Members after adoption by the Board of Directors and after notice to Members, whether or not such amendments and additions are incorporated into the Bylaws. Copies of OPTN Policies are distributed to Members upon request, and policy updates are available subsequent to adoption of policy changes.

By accepting membership in the OPTN, each Member agrees to be bound by all provisions of the OPTN Charter, Bylaws, and Policies, including amendments thereto. A Member who does not comply with such provisions will be afforded the appropriate due process as described in the OPTN Bylaws.

The Membership application and review process is set forth in the OPTN Bylaws. Permanent Standing Committees and Ad Hoc Committees, develop OPTN Policies and propose such Policies, amendments, and additions for consideration and adoption by the Board of Directors. All OPTN Members are invited and encouraged to participate in OPTN activities through OPTN committee service and through consultation with OPTN Committee Members and members of the Board of Directors.

**1.1 Obligation to the National Organ Transplantation Act**

An OPTN member may not knowingly permit donation, recovery, or transplantation of deceased or living donor organs for valuable consideration.

~~**3.2.1.4 Prohibition for Organ Offers to Non-Members.** Members shall not provide organs to non-member transplant centers except to transplant centers in foreign countries as described in Policy 6.4 (Exportation and Importation of Organs—Developmental Status).  
Members must not provide organs to non-Member Transplant Centers except to~~

Transplant Centers in foreign countries. Exportation of organs from the United States or its territories is prohibited unless a well documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List.

**6.0 ~~TRANSPLANTATION OF NON-RESIDENT ALIENS~~ Deceased Donor Organ Transplantation of Non-US Residents/Non-US Citizens, and the Importation of Deceased Donor Organs from Foreign Sources**

**6.1 ~~DEFINITIONS~~ Definitions.** The following definitions apply to this policy:

~~**6.1.1 Non-Resident Alien.** A non-resident alien is an individual granted permission by the United States Government to enter the United States on a temporary basis as a non-immigrant alien for purposes which include tourism, business, education, medical care, or temporary employment.~~

~~**6.1.2 Domestic, American Candidate or Resident Alien.** A domestic, American candidate or resident alien is an individual who is either an American citizen or is an immigrant alien granted permanent resident status by the United States Government or any individual, regardless of immigrant status, qualified for health care entitlement funds from state or federal government sources.~~

**6.1.1 Non-US Citizen/US Resident** – A non-citizen of the United States for whom the United States is the primary place of residence.

**6.1.2 Non-US Citizen/Non-US Resident** – A non-citizen of the United States for whom the United States is not the primary place of residence.

**6.2 ~~Guidelines.~~ Guidelines.** Any member transplant center which agrees to list non-resident aliens on its Waiting List shall adhere to the following guidelines: Any member transplant center that places a non-US citizen/non-US resident on its waiting list shall adhere to the following guidelines:

**6.2.1 ~~Nondiscrimination/Organ Allocation~~ Nondiscrimination in Organ Allocation.** Selection, from the Waiting List, of non-resident alien candidates for transplantation shall be based on the same allocation policies (Section 3.0) mandated by the Board of Directors for selection of domestic candidates. Such selection shall not be influenced by favoritism or discrimination based on political influence, national origin, race, sex, religion or financial status. Deceased donor organ allocation to candidates for transplantation shall not differ on the basis of a candidate's citizenship or residency status in the US. Allocation shall not be influenced by

favoritism or discrimination based on political influence, national origin, race, sex, religion, or financial status.

**6.2.2 ~~Transplant Centers.~~** ~~Transplantation of each non-resident alien should be done in a transplant center with a historical pattern of international referral and a reputation for both treatment of primary and endstage organ disease and transplantation, with regard to the particular organ(s) being transplanted.~~

**6.2.3 ~~Fees.~~** ~~Transplantation of non-resident aliens is a humanitarian act and shall not be done for financial advantage. Transplant centers listing non-resident aliens on their Waiting Lists shall charge non-residents the same fees for service as those charged to domestic candidates and recipients.~~

**6.2.4 ~~Referrals.~~** ~~Members shall not enter into formal contractual arrangements with foreign agencies or governments for the transplantation of non-resident aliens non-US residents/non-US citizens. OPTN members may negotiate the terms and conditions under which any individual candidate would be treated with the understanding that each candidate must be referred on a case-by-case and physician-to-physician basis.~~

**6.2.5 ~~Community Participation.~~** ~~Each member center which lists non-resident aliens on its Waiting List should establish a mechanism for community participation and review of its candidate acceptance criteria.~~

**6.2.6 ~~Training Programs.~~** ~~To enhance transplantation in underserved nations, it is desirable for transplant centers engaged in the transplantation of non-resident aliens to establish training programs which include transplantation training of physicians from underserved nations and educational programs designed for development of transplantation services in those underserved nations.~~

**6.3 AUDIT-Review and Reporting of Non-US Citizen/Non-US Resident Listings and Transplants.** As a condition of membership, all member transplant centers agree to allow the Ad Hoc International Relations Committee to review and audit, at its discretion, all center activities pertaining to transplantation of non-resident aliens. The Committee will review the activities of each member transplant center where non-resident alien recipients constitute more than 5% of recipients of any particular type of deceased organ. At centers where non-resident alien transplant recipients constitute more than 5% of recipients of any particular organ type, circumstances underlying the transplants for non-resident aliens will be reviewed by the Committee. Special consideration will be given to programs served by OPOs with non-resident alien organ donors. The Ad Hoc International Relations Committee will review all citizenship data submitted to the OPTN Contractor. The

Ad Hoc International Relations Committee may request that Member transplant centers voluntarily provide additional information about listings or transplants of non-US citizens/non-US residents.

**6.3.1 Transparency in Reporting Listings and Transplants of Non-US Citizens/Non-US Residents.** The Ad Hoc International Relations Committee shall prepare and provide public access to an annual report of Member transplant center activities related to the listings and transplantation of non-US citizens/non-US residents.

~~**6.4 EXPORTATION AND IMPORTATION OF ORGANS DEVELOPMENTAL STATUS.**~~ International exchange of organs for transplantation is technically feasible but remains an uncommon procedure. The OPTN regards international sharing of organs to be in an early phase of development. **Importation of Deceased Donor Organs from Foreign Sources.** Members may import deceased donor organs from foreign sources, and in doing so, must adhere to the related policies below.

~~**6.4.1 Exportation.**~~ Exportation of organs from the United States or its territories is prohibited unless a well documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List. **Formal Deceased Donor Organ Import Agreement.** Upon approval by the Board of Directors, a Member may enter into formal, deceased donor organ import agreement with a foreign entity. Each formal agreement cannot exceed two years in duration. A Member that wishes to enter into a formal, deceased donor organ import agreement with a foreign entity must submit a proposal to the Ad Hoc International Relations Committee for review. The proposed deceased donor organ import agreement must:

- 1) Describe the basis for the agreement.
- 2) Describe the expected benefits to the foreign and domestic participants.
- 3) Include credentials of the foreign entity.
- 4) State the number and type of deceased donor organs anticipated for import.
- 5) Outline a plan for reporting the results of the agreement.
- 6) Include a requirement for the donor organization to submit documentation certifying the authorization of the donor or his or her legal representative.
- 7) Include a requirement for the donor organization to submit documentation certifying that the donor has met the met brain death or donation after circulatory death (DCD) protocols that are in compliance with recognized US standards for domestic organ procurement.
- 8) Include a requirement for the donor organization to submit

documentation of the donor's ABO.

The Ad Hoc International Relations Committee will review each formal agreement every two years.

Each organ imported through a formal agreement must adhere to the requirements listed in 6.4.1.1.

**6.4.1.1 Requirements for Importing Deceased Donor Organs through a Formal Agreement.** The Member importing any deceased donor organ from a foreign entity must:

- Report the event within 72 hours to the Organ Center.
- Allocate the organ using the Match System in accordance with the allocation policy for that organ.
- Provide the minimum required information about the foreign deceased donor organ, as specified in Policies 2 (Minimum Procurement Standards for an Organ Procurement Organization (OPO), 3.5.9 (Minimum Information/ Tissue for Kidney Offer), 3.6.9 (Minimum Information for Liver Offers), 3.7.12 (Minimum Information for Thoracic Organ Offers, and 3.8.2 (Required Information).
- Comply with the ABO verification requirements in Policies 2 and 3.2.4 (Match System Access).
- Evaluate the organ for transmissible diseases as specified in Policy 4 (Identification of Transmissible Diseases in Organ Recipients).
- Verify that the foreign entity is authorized as a transplant center or organ procurement program by an appropriate agency of its national government.
- Obtain official documentation from the exporting party that it is a medical center authorized to export organs for transplantation.

**6.4.2 ~~Developmental Protocols in International Organ Exchange.~~** ~~After prior approval by the OPTN, members may enter into formal organ exchange arrangements, each not to exceed two years in duration, with a foreign transplant program or programs. Negotiations with foreign transplant programs or foreign agencies which include importing organs must be approved by the Ad Hoc International Relations Committee. Importation of organs is defined in Policy 6.4.5 (Importation). Proposed protocols must be submitted to the OPTN describing the basis for such arrangements, expected benefits to both foreign and domestic participants, credentials of the foreign source, number and type of organs anticipated to be involved, and plans for allocation procedures and~~

reporting of results. Proposed protocols must include a requirement for the donor organization to submit documentation certifying the informed consent of the donor or his or her legal representative. Proposed protocols must also include a requirement for the donor organization to submit documentation certifying that the donor has met the met brain death or donation after cardiac death (DCD) protocols that are in compliance with recognized U.S. standards for domestic organ procurement. Proposed protocols must include a requirement for the donor organization to submit documentation of the donor's ABO. Proposed protocols will be reviewed by the Ad Hoc International Relations Committee, which will then make recommendations to the Board of Directors. **Deceased Donor Organs Imported from outside of the United States.** A Member may import a deceased donor organ recovered outside of the United States without a formal agreement (6.4.1). An imported deceased donor organ must meet all the requirements in 6.4.1.1. The Member must notify the Organ Center immediately so that the OPTN Contractor can allocate the organ using the Match System in accordance with the allocation policy for that organ.

The Member importing the organ must provide the following to the OPTN Contractor:

- Documentation certifying that the donor has met brain death or donation after circulatory death (DCD) protocols that are in compliance with recognized standards for domestic organ procurement;
- Documentation from the donor organization certifying the authorization of the donor or his or her legal representative; and,
- Documentation from the donor organization verifying the donor's ABO.

The Ad Hoc International Relations Committee will review the circumstances of each deceased donor organ imported without a formal agreement.

**6.4.2.1** All foreign organ exchanges must be reported within 72 hours to the Organ Center. All exchanges must satisfy policy that no organs can be exported from the United States without first a determination having been made by the Organ Center that there is no suitable recipient for that organ on the Waiting List. All imported organs will be allocated first within the local area of the OPO that arranged the importation of the organ and in accordance with the allocation policy for that organ. If no recipient is found within the local area of the OPO that arranged

the importation of the organ, then the organ shall be allocated outside the local area in a manner consistent with the policies which apply to that organ.

OPO's are required to execute the Match System (UNet<sup>sm</sup>) for the allocation of all organs. The importing OPO must provide the minimum required information about the foreign donor consistent with Policy 3.5.9 (Minimum Information/ Tissue for Kidney Offer), Policy 3.6.9 (Minimum Information for Liver Offers), Policy 3.7.12 (Minimum Information for Thoracic Organ Offers), and Policy 3.8.5 (Minimum Information for Pancreas Offers) and comply with the ABO verification requirements in accordance with Policy 3.2.3 (Match System Access).

~~6.4.2.2~~ All approved international organ exchange protocols will be reviewed at least annually by the Ad Hoc International Relations Committee. Any additional policies regarding international exchange agreements will be developed by the Committee based on experience acquired pursuant to approved developmental protocols. It is a goal of the OPTN that international exchange of organs between OPTN members and foreign programs will foster the development of international organ sharing. It is hoped that such exchanges will occur through the regular national OPTN system, after feasibility has been established.

~~6.4.2.3~~ Importation of an organ for human transplantation in the United States is appropriate only if the foreign source is an OPTN-recognized source, i.e., organ transplant center or organ procurement program specifically authorized as a transplant center or organ procurement program by an appropriate agency of its national government. The OPO or transplant center responsible for importation of an organ must obtain official documentation from the exporting party that it is a medical center authorized to export organs for transplantation.

~~6.4.3~~ **Ad Hoc Organ Exchange.** Except as provided for in approved international exchange protocols, all offers of organs for human transplantation from foreign sources must be made to the Organ Center. If a member is contacted by a foreign source with an organ offer, that member must notify the Organ Center of that offer. No more than six exchanges by any member with any foreign program(s) will be allowed on an ad hoc basis. Additional exchanges must be made as part of an

~~international organ exchange protocol approved by the Ad Hoc International Relations Committee and Board of Directors.~~

~~Imports of organs from foreign sources on an ad hoc basis must meet the requirements for importing organs and allocation of those organs under organ exchange protocols found in Policy 6.4.2.1. Additionally, organs imported by OPOs must include documentation certifying that the donor has met brain death or donation after cardiac death (DCD) protocols that are in compliance with recognized standards for domestic organ procurement. Organs imported by OPOs must include documentation from the donor organization certifying the informed consent of the donor or his or her legal representative. Organs imported by OPOs must include documentation from the donor organization verifying the donor's ABO.~~

~~**6.4.3.1 Ad Hoc Organ Exchange Review.** Ad hoc organ exchange will be reviewed annually by the Ad Hoc International Relations Committee.~~

~~**6.4.4 Ethical Practices.** No member will engage in practices which might discredit the transplant community. Organs accepted for importation must be from deceased donors and must have been voluntarily donated. Organs imported from living donors or organs for which compensation has been made or promised are not acceptable for exchange or acceptance by members.~~

~~**6.4.5 Importation.** An imported organ is defined as an organ that is procured outside of the United States of America or its territories. Imported organs must meet the requirements of Policy 6.4.2 (Developmental Protocols in International Organ Exchange) and/or Policy 6.4.3 (Ad Hoc Organ Exchange).~~

~~**6.5 VIOLATIONS OF POLICIES.** Violations of import/export policies (6.2.2 through 6.2.4 and 6.4.1 through 6.4.4) will be reported to the Membership and Professional Standards Committee and may result in suspension of membership by the Board of Directors. Persistent violations of Policy 6.3 (Audit) without justification or explanation, or failure to respond to inquiries will be reported to the Membership and Professional Standards Committee.~~

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

**Affected Bylaws and Policy Language:**

*\*\* Please note: The public comment proposal for these changes originally recommended edits to Attachment IIA (Standards for Histocompatibility Testing) and Attachment IIB (UNOS Test Data Criteria for New HLA Laboratories and for the Addition of New Techniques) to Appendix B of the UNOS Bylaws (in addition to changes to Attachment II (Criteria for Histocompatibility Laboratory Designation) that the Histocompatibility Committee did not forward for the OPTN/UNOS Board of Directors' consideration). As a part of the OPTN Bylaws Plain Language Rewrite that the Board of Directors also adopted at its June 2012 meeting, the information in Attachment IIA and Attachment IIB to Appendix B of the UNOS Bylaws has been reorganized in Appendix C: Membership Requirements for Histocompatibility Laboratories of the OPTN/UNOS Bylaws and Appendix D to Policy 3. The changes to Attachment IIA and Attachment IIB to Appendix B of the UNOS Bylaws that the Board of Directors adopted are presented below as they will read upon implementation, i.e. incorporated into Appendix C of the rewritten bylaws and Appendix D to Policy 3.*

**Appendix C: Membership Requirements for Histocompatibility Laboratories****C.6 Histocompatibility Laboratory Testing Requirements****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 a the same manner comparable to ~~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.-G.** [No Change].

#### **H. 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 exempt.
2. OPTN-approved, ~~or~~ ASHI accredited, or CAP accredited for that testing.

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.

## I. 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.

New laboratories are required to submit procedures and test validation data for all categories and methods of testing unless the testing is performed, without exception, by another approved laboratory. These materials must be submitted to an OPTN approved histocompatibility laboratory accrediting agency, ~~with a copy to the OPTN Histocompatibility Committee.~~

### Appendix D to Policy 3:

#### **F2.000 HLA Typing**

F 2.100 Prospective typing of deceased donors for HLA-A, B, C, Bw4, and Bw6, and DR, DR51, DR52, DR53 and DQB antigens is mandatory.

F2.200 Prospective typing of candidates for HLA-A, B, Bw4, Bw6 and DR is mandatory, and the typing of C, DR51, DR52, DR53, and DQB is highly recommended.

#### **F3.000 Antibody Screening**

F3.100 Laboratories must have a policy in place to evaluate the extent of sensitization of each patient at the time of initial evaluation and following potentially sensitizing events, based on the antibody characteristics that are clinically relevant to each transplant center's protocols. The transplant program must provide this information to the laboratory.

F3.200 Laboratories must have a program to periodically screen serum samples from each patient for antibody to HLA antigens. The laboratory must have a documented policy establishing the frequency of screening serum samples and must have data to support this policy. Samples must be collected at time intervals outlined in the joint agreement between the laboratory and the transplant program.

#### **I ABO Blood Group Determination**

I1.000 Laboratories performing ABO blood group determination must use ~~be performed by~~ techniques compliant with Federal regulations.

#### ~~UNOS Bylaws Appendix B Attachment IIA – Standards for Histocompatibility Testing~~

#### ~~C. Quality Assurance~~

#### ~~C5.000 Proficiency Testing and Competency Evaluation~~

~~C5.300 The laboratory must test proficiency samples in the same manner comparable to that for testing clinical samples.~~

#### ~~C9.000 Subcontracting~~

~~C9.100 A UNOS approved laboratory may engage another laboratory to perform testing by subcontracting the work to that laboratory. In that event, if histocompatibility and/or transplantation~~

immunology testing is referred, the subcontracting laboratory must be CLIA certified/exempt and either UNOS approved, or ASHI accredited, / or CAP accredited for that testing...

## **F. Renal and Pancreas Organ Transplantation**

### **F2.000 HLA Typing**

~~F2.100 Prospective typing of donors and recipients for HLA-A, B, Bw4, Bw6, and DR antigens is mandatory.~~

~~F2.200 Prospective typing of donors and recipients for HLA-C, and DQ antigens and for DR51, DR52, DR53, is highly recommended.~~

~~F.2.100 Prospective typing of deceased donors for HLA A, B, C, Bw4, and Bw6, and DR, DR51, DR52, DR53 and DQB antigens is mandatory.~~

~~F2.200 Prospective typing of candidates for of HLA-A, B, Bw4, Bw6 and DR is mandatory, and the typing of C, DR51, DR52, DR53, and DQB is highly recommended.~~

### **F3.000 Antibody Screening**

~~F3.100 Laboratories must have a policy in place to evaluate the extent of sensitization of each patient at the time of initial evaluation and following potentially sensitizing events, based on the antibody characteristics that are clinically relevant to each transplant center's protocols. This information is provided to the laboratory by the transplant program. The transplant program must provide this information to the laboratory.~~

~~F3.200 Laboratories must have a program to periodically screen serum samples from each patient for antibody to HLA antigens. The laboratory must have a documented policy establishing the frequency of screening serum samples and must have data to support this policy. It is recommended that samples be collected monthly. Samples will must be collected at time intervals outlined in the joint agreement between the laboratory and the transplant program.~~

## **I. ABO Blood Group Determination**

~~I1.000 Laboratories performing ABO blood group determination, must use be performed by techniques compliant with Federal regulations.~~

## **Attachment IIB UNOS Test Data Criteria for New HLA Laboratories and for the Addition of New Techniques**

### **Data Submission**

~~New laboratories are required to submit procedures and test validation data for all categories and methods of testing unless such work is performed, without exception, by another approved laboratory...~~

~~These materials are required to be submitted to an Agency with deemed status for the Accreditation of UNOS Laboratories, with a copy to the UNOS Histocompatibility Committee.~~

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

To read the complete UNOS bylaw language visit [www.unos.org](http://www.unos.org) and select “UNOS bylaws” in the “I am looking for:” box in the upper left hand corner. To read the complete OPTN bylaw language visit [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov), select the “Policy Management” tab, then select “OPTN Bylaws.”