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IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: James B. Alcorn
Director, Policy

RE: Summary of actions taken at OPTN/UNOS Board of Directors Meetings (June 24-25, 2013; November 11-12, 2013) and OPTN/UNOS Kidney Transplantation Committee Meeting (August 26, 2013)

Date: December 12, 2013

The attached report summarizes changes to OPTN Policy and Bylaws approved by the OPTN/UNOS Board of Directors, and changes to the OPTN KPD Pilot Program Operational Guidelines approved by the OPTN/UNOS Kidney Transplantation Committee. This policy notice provides the specific Policy, Bylaws, and OPTN KPD Pilot Program Operational Guidelines language changes and the corresponding implementation dates. When reviewing the language changes, please note that underlined language is new and what will be in effect upon implementation and language that is ~~struck~~ will be deleted upon implementation. The policy language used to denote the approved changes reflects the most recent version of policy that has been approved, but not necessarily what is currently implemented.

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

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

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

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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, 2013

Problem Statement
The OPTN needs additional funding for operational expenses during fiscal year 2014 (October 1, 2013 – September 30, 2014).

Changes
At its June 2013 meeting, the OPTN Board of Directors approved an increase in the OPTN patient registration fee from \$651 to \$810.

Member Actions
Notify your program's finance department of this fee increase.

[Click here to view the modified policy language.](#)

Addition of KPD Associate Disclosure Agreement to the OPTN KPD Pilot Program Operational Guidelines

Sponsoring Committee: Kidney Transplantation Committee

OPTN KPD Pilot Program Operational Guidelines Affected: Requirements for Participation

Distributed for Public Comment: No

Effective Date: December 12, 2013

Problem Statement

In the OPTN KPD Pilot Program, transplant hospitals often sign associate disclosure agreements that allow them to share information about pairs after they have been matched. These agreements often go through hospital legal departments and have the potential to delay exchanges.

Changes

The KPD Financial Subcommittee has developed standard language for this type of agreement. This language has been added to the OPTN KPD Pilot Program Operational Guidelines for all programs in the pilot. The purpose of including this language in the Operational Guidelines is to set a standard for participating transplant hospitals without requiring them to re-execute a contract agreement. Each participating transplant hospital has already signed a contract stating that they will abide by the Operational Guidelines.

Member Actions

Participating transplant hospitals should review the KPD Associate Disclosure Agreement language in the Operational Guidelines and abide by this language when participating in an OPTN KPD exchange.

[Click here to view the modified policy language](#)

OPTN Policies Plain Language Rewrite

Sponsoring Committee: Policy Oversight Committee

Policies Affected: Complete OPTN Policies

Distributed for Public Comment: July 2012, August 2013

Amended After Public Comment: Yes

Effective Date: February 1, 2014

Problem Statement

A member survey indicated the need for OPTN Policies to be written in plain language with information that was easier to understand, access, and use.

Changes

This rewrite does not make any substantive changes to the content of the current Policies. The changes make the current language easier to understand with more consistent terminology, better organization, and new usability features.

Action Required

On February 1, 2014, the [new Policies](#) will be in effect. Members should review and familiarize themselves with the rewritten Policies.

While the new Policies do not change the substance of any member responsibilities, they do reorganize the Policies. Therefore, Members should update any of their own materials that reference specific Policy sections or contain specific Policy language. A crosswalk of the old and new policy numbers to assist you with this task is included on the [OPTN web page](#) with the new rewritten policies.

[Click here to view the modified policy language.](#)

Effective Date Change - Modifications to the Imminent and Eligible Neurological Death Data Reporting Definitions

Sponsoring Committee: Organ Procurement Organization Committee

Policies Affected: 7.1.6 (Eligible Death Definition) and 7.1.7 (Imminent Neurological Death)

Distributed for Public Comment: September 2012

Amended After Public Comment: Yes

Effective Date: January 1, 2015

Problem Statement

The OPTN/UNOS Board of Directors approved changes to the Imminent and Eligible Death Neurological Data Definitions during its June 2013 meeting and set an effective date of December 1, 2013. Implementing these policy changes on December 1, 2013, would result in organ procurement organizations (OPOs) having to report two separate sets of imminent and eligible neurological death data because of differences in the way the OPTN and CMS define imminent and eligible neurological death data reporting.

Changes

The effective date has been changed from December 1, 2013, to January 1, 2015.

The OPO Committee requested that the effective date be delayed until January 1, 2015, to give the OPTN and CMS enough time to align their definitions for imminent and eligible neurological death. As a result, OPOs will not be required to report separate sets of imminent and eligible neurological death data to accommodate two different sets of definitions.

Member Actions

OPO staff must review these policy changes and, once implemented, apply the new definitions when reporting imminent and eligible death data on the Death Notification Registration form.

Please note that the imminent and eligible definitions are “reporting” definitions only. They are not intended to be inclusive of all actual donors; therefore, they should not be used for screening donors, or affect allocation or acceptance of organs. These criteria are not used to exclude potential organ donors and do not prevent an OPO from pursuing a donor candidate that is not classified as an eligible death.

[Click here to view the modified policy language.](#)

Changes to Update and Clarify Language in the Donation after Circulatory Death Model Elements

Sponsoring Committee: Organ Procurement Organization Committee

Policy Affected: 2.8 (Model Elements for Controlled DCD Recovery Protocols)

Distributed for Public Comment: March 2011 and March 2012

Amended After Public Comment: Yes

Effective Date: February 1, 2014

Problem Statement
In 2010, the Organ Procurement Organization (OPO) Committee began reviewing donation after circulatory death (DCD) policies and determined they were outdated and required modification in order to update DCD protocols and terminology that are consistent with industry practice.

Changes
The policy changes reflect DCD protocols and terminology that are consistent with current industry practice.

Member Actions
Members need to review the new policy language and modify their DCD protocols, if necessary, to include all required elements contained in the new policy.

[Click here to view the modified policy language.](#)

Changes to Policy 3.1.14 (PHS Guideline) to Require the Exclusive Use of the 2013 PHS Guideline for Medical-Social Evaluation

Sponsoring Committee: Ad Hoc Disease Transmission Advisory Committee

Policy Affected: 3.1.14 (PHS Guideline)

Distributed for Public Comment: No

Effective Date: February 1, 2014

Problem Statement

The Executive Committee approved policy on August 28, 2013 (implemented on October 1, 2013), that allowed organ procurement organizations (OPOs) and living donor transplant programs to use either the PHS' 1994 [Guidelines for Preventing Transmission of HIV through Transplantation of Human Tissue and Organs](#) or its new 2013 [Guideline for Reducing Human Immunodeficiency Virus \(HIV\), Hepatitis B Virus \(HBV\), and Hepatitis C Virus \(HCV\) Through Organ Transplantation](#) for medical-social questions posed during evaluation of potential donors. This choice gave members time to update their internal policies and educate staff regarding the June 19, 2013, release of the updated PHS Guideline. The Executive Committee consciously did not specify when OPOs had to use exclusively the 2013 PHS Guideline, since it felt the entire OPTN/UNOS Board of Directors would be better suited to make that determination.

Changes

The change now specifies when OPOs must exclusively use the 2013 PHS Guideline to determine whether a potential organ donor is at increased risk for transmitting HIV, HBV, and HCV.

Programming is already underway to remove the reference to "CDC high risk" donors in DonorNet[®] and replace it with "increased risk" terminology used in the 2013 PHS Guideline. The label change will be implemented in DonorNetSM on December 18, 2013.

Member Actions

As of February 1, 2014, **OPOs** must use the 2013 PHS Guideline for medical-social evaluation questions to determine if a potential deceased donor is at increased risk for HIV, HBV, or HCV transmission. OPOs must note in DonorNetSM whether a donor meets the increased risk criteria outlined in the 2013 PHS Guideline.

Living Donor Recovery Hospitals must use the 2013 PHS Guideline for medical-social evaluation questions to determine if a potential living donor is at increased risk for HIV, HBV, or HCV transmission.

[Click here to view the modified policy language](#)

Redefining the Role of the Vice President of the OPTN/UNOS Board of Directors

Sponsoring Committee: Executive Committee

Bylaws Affected: 6.2 (Vice President) and 7.2 (Standing Committee Chairs)

Distributed for Public Comment: March 2013

Amended After Public Comment: No

Effective Date: February 1, 2014

Problem Statement

The Bylaws require the vice president of the OPTN/UNOS Board of Directors to serve as the Chair of the Membership and Professional Standards Committee (MPSC). Since the responsibilities of the MPSC Chair have increased over time, it can be challenging for the vice president to get sufficient exposure to the broader governance issues that he or she will encounter as president.

Changes

Instead of chairing the MPSC, the vice president now serves as an *ex-officio*, non-voting member. The MPSC Chair will be appointed for a two-year term consistent with the processes for appointing the chairs of other standing committees.

Member Actions

Members should make themselves familiar with the Bylaws changes. There are no actions required of members as a result of these changes.

Click here to view the modified bylaws language.

Clarifying Requirements for Independent Donor Advocates at Living Kidney Donor Recovery Centers

Sponsoring Committee: Living Donor Committee

Policies Affected: 12.4 (Independent Donor Advocates); 12.4.1 (IDA Role); 12.4.2 (IDA Responsibilities); and 12.4.3 (IDA Protocols)

Distributed for Public Comment: March 2013

Amended After Public Comment: Yes

Effective Date: February 1, 2014

Problem Statement

Since September 2007, living donor programs have been required to develop and follow center-specific protocols for the responsibilities of the independent donor advocate (IDA).

The results of site surveys conducted for routine living donor programs since 2011 reveal that non-compliance with IDA requirements is common. The site surveys identified wide variability in IDA protocols regarding:

- training
- qualifications
- required documentation
- the IDA's function within the living donor evaluation process
- individual IDAs versus donor advocate teams

Changes

The revised policy outlines specific elements which will be evaluated during site surveys, including specificity on:

- what the IDA must review with the potential living donor
- what the IDA must document pertaining to the potential living donor's psychosocial and medical evaluations
- what the member program must document in their own internal protocols in regards to:
 - the IDA's required qualifications, duties, and responsibilities
 - their grievance process to be used by the IDA if needed

Member Actions

Upon implementation, living kidney donor programs must develop, follow, and document the use of their hospital-specific protocols that address IDA qualifications, training, duties, and responsibilities. Programs must also develop protocols to address any grievance raised by an IDA that concerns the rights and best interest of a living donor. These policy changes are specific to living kidney donor programs; other living donor programs are not required to change their practices at this time.

[Click here to view the modified policy language.](#)

Changes to the OPTN Bylaws Governing Histocompatibility Laboratories

Sponsoring Committee: Histocompatibility Committee

Bylaws Affected: Article 1.4 (Histocompatibility Laboratory Member); Appendix C.1 (Histocompatibility Laboratory Compliance); Appendix C.2 (Facilities and Resources); Appendix C.3 (Histocompatibility Laboratory Personnel); Appendix C.4 (Changes in Key Laboratory Personnel); and Appendix M (Definitions)

Distributed for Public Comment: March 2013

Amended After Public Comment: Yes

Effective Date: February 1, 2014

Problem Statement
<p>The current OPTN Bylaws do not reflect the role that histocompatibility laboratories play in organ allocation. In addition, the Bylaws create duplicative requirements between the OPTN, ASHI, CAP, and federal CLIA regulations. Finally, the current Bylaws are vague about how laboratories should notify the OPTN and document when there are key personnel changes, resulting in laboratories submitting insufficient information about key personnel coverage and delays in notification.</p>

Changes
<ul style="list-style-type: none">• The definition and service area requirements of OPTN histocompatibility laboratories have changed.• OPTN histocompatibility laboratories will be required to comply with the applicable solid organ and islet requirements outlined in the 2012 American Society for Histocompatibility and Immunogenetics (ASHI) Revised Standards for Accredited Laboratories, or the College of American Pathologists (CAP) Histocompatibility Checklist, Laboratory General Checklist, Flow Cytometry Checklist, and Team Leader Assessment of Director and Quality Checklist as of September 25, 2012.• OPTN histocompatibility laboratories will be required to have written agreements (containing certain elements outlined in the Bylaws) with every organ procurement organization (OPO) and transplant program the laboratory serves.• OPTN histocompatibility laboratories will be required to submit to the OPTN Contractor upon request a Laboratory Coverage Plan (containing certain elements outlined in the Bylaws).• OPTN histocompatibility laboratories will now be required to notify the OPTN Contractor within seven business days of learning of a change in key personnel. A change in key laboratory personnel has been expanded to include instances when a laboratory director, technical supervisor, or clinical consultant accepts additional key personnel responsibilities at another histocompatibility laboratory.• Additional documentation will now be required from laboratories seeking approval of a change in key laboratory personnel.

Member Actions

Upon implementation, all OPTN histocompatibility laboratories will need to:

- Provide evidence, upon request, of compliance with the 2012 ASHI or CAP documents referenced above. Current ASHI or CAP accreditation is sufficient to meet this standard; otherwise, laboratories will be required to provide other evidence of compliance. Documentation will also be required after any change in the histocompatibility laboratory director.
- Have a written agreement with every OPO and transplant program the laboratory serves that contains the required elements listed in the Bylaws.
- Notify UNOS within seven business days after learning that a laboratory director, technical supervisor, or clinical consultant is leaving. The laboratory will then be required to submit a personnel change application and a laboratory coverage plan 30 days before the departure date or within 30 days of the departure date if the laboratory received less than 60 days notice.
- Provide a Laboratory Coverage Plan to the OPTN Contractor upon request, and with applications for laboratory key personnel changes. The Laboratory Coverage Plan must contain all of the information stipulated by the OPTN Bylaws.

[Click here to view the modified bylaws language.](#)

Changes to the HLA Equivalency Tables

Sponsoring Committee: Histocompatibility Committee

Policy Affected: Appendix A to Policy 3 (HLA Antigen Values and Split Equivalence)

Distributed for Public Comment: March 2013

Amended After Public Comment: Yes

Effective Date: To be determined, implementation pending programming

Problem Statement

The following problems were identified with the current Appendix A to Policy 3 (HLA Antigen Values and Split Equivalence):

- There are several broad antigen equivalences still listed in the “Matching Antigen Equivalences” table, despite the fact that OPTN Policy Appendix 3D, D.2. (Histocompatibility Laboratory Testing Requirements) requires histocompatibility laboratories to perform HLA typing using molecular methods for deceased kidney, pancreas, and kidney-pancreas donors.
- There are numerous broad antigen equivalences listed in the “Unacceptable Antigen Equivalences” table that should no longer be considered equivalent to a candidate’s unacceptable antigens. Currently, due to the outdated equivalency table, some sensitized candidates are screened from donors from whom they could safely accept an organ.
- In 2010, the Board of Directors approved changes to the unacceptable antigen equivalences that are only used in the calculation of CPRA. These changes have yet to be implemented, but to do so would yield the unintended consequence of inaccurate CPRA score calculations for certain sensitized candidates.
- The current version of the Equivalency Tables is not displayed in a user-friendly format.

Changes

There are several changes to the policy:

- In the “Matching Antigen Equivalences” tables, eight broad antigens have been deleted in order to better define a zero-HLA mismatch and an HLA-DR mismatch level for kidney, kidney-pancreas, and pancreas candidates in deceased donor allocation.
- In the “Unacceptable Antigen Equivalences” tables, four equivalences have been added and 57 deleted in order to ensure greater accuracy in the equivalences used in the screening process for eliminating candidates based on donor HLA.
- Previously approved changes to the list of “Additional Unacceptable Antigen Equivalences to be used in CPRA Only” have been reversed in order to ensure accurate CPRA score calculation for patients with certain unacceptable antigens.
- The antigen Cw13 has been deleted because it is no longer listed in IMGT-HLA Database.
- The tables appear in a new, more user friendly format.

Member Actions

Members should familiarize themselves with the updates to Appendix A to Policy 3. When computer programming is complete, UNOS will send a UNetSM System Notice.

[Click here to view the modified policy language.](#)

** Please note: At its June 2013 meeting, the OPTN/UNOS Board of Directors approved the policy changes denoted below. At its November 2013 meeting, the Board adopted a plain language rewrite of all OPTN Policies. Both sets of policy language related to this specific change are provided below for reference; the policy language in the rewritten policy format will be effective on February 1, 2014.

Affected Policy Language in the *Current* Format:

11.0 REGISTRATION FEE

The OPTN Patient Registration Fee, as provided in *Article I, Section 1.2.D: Registration Fees* of the OPTN Bylaws for the listing of candidates as required by Policy 3.2.1 for listing a potential recipient in UNetSM, shall be ~~\$654~~ \$810.

Affected Policy Language in the *Plain Language* Format (effective February 1, 2014):

3.4.A Registration Fee

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

To read the all of the current policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the "Policy Management" tab, then select "Policies." From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner. Please click [here](#) to read the entire body of rewritten policies in the plain language format, which will be implemented on February 1, 2014.

Affected OPTN KPD Pilot Program Operational Guidelines Language:

Requirements for Participation

1. Purpose: To outline the prerequisites that centers must meet to be eligible to participate in the Kidney Paired Donation (KPD) Pilot Program and to outline the criteria that candidates and donors must meet before they are entered in the Program by the transplant center.

a. Transplants centers:

- i. Must be Organ Procurement and Transplantation Network (OPTN) and UnitedNetwork for Organ Sharing (UNOS) approved to perform kidney transplants and living donor kidney recovery (see UNOS Bylaws, Appendix B, Attachment I, Section XIII on kidney transplant programs)
- ii. Must have a designated contact for the KPD Pilot Program (See KPD Contact Responsibilities Operational Guideline)
- iii. Must agree to abide by all rules set forth in the Kidney Paired Donation Pilot Program Operational Guidelines and the OPTN/UNOS Bylaws and Policies, unless explicitly stated otherwise in the KPD Pilot Program Operational Guidelines. Any potential violations of the KPD Operational Guidelines or any potential violations of policies and bylaws could be referred to the Membership and Professional Standards Committee.

iv. **KIDNEY PAIRED DONATION PROGRAM INFORMATION
DISCLOSURE AND CONFIDENTIALITY AGREEMENT**

WHEREAS, the OPTN operates a national kidney paired donation (KPD) program to aid participants in the system with identifying optimal matches for potential living donor kidney transplants.

WHEREAS, participants in the KPD system have agreed to abide by certain KPD Program Operating Guidelines as a condition of participation in the OPTN KPD Program, in addition to obligations of OPTN membership.

WHEREAS, participants in the KPD Program must share Protected Health Information with and among other participants in the KPD Program to facilitate safe, effective, and efficient transplantation of living donor organs. Participants must also ensure that Protected Health

Information shared as part of the KPD Program is treated with the same degree of care and protections provided by Business Associates of Covered Entities under the Health Insurance Portability and Accountability Act (“HIPAA”).

NOW THEREFORE, the parties agree to abide by the provisions of this Agreement with respect to any Protected Health Information or Electronic Protected Health Information (as defined below) disclosed to other participants in the OPTN KPD Program.

1. Definitions. Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the Privacy Rule and Security Rule.
 - a. KPD Program. The OPTN KPD Program (“KPD Program”) matches living donor/ candidate pairs with other living donor candidate pairs or non-directed donors (donors who do not require that a specific candidate be matched in order for the donor to be matched through KPD) to create transplant opportunities for candidates entered in KPD. It is an opt-in program available to any transplant hospital with an OPTN/UNOS approved kidney and living donor kidney program.
 - b. KPD Program Participant or Participant. A “Participant” is an OPTN/UNOS approved transplant hospital who is participating in the OPTN KPD Program.
 - c. Disclosing KPD Program Participant. “Disclosing KPD Program Participant” shall mean a participant in the OPTN KPD Program who is sharing Protected Health Information with other participants of the OPTN KPD Program.
 - d. Protected Health Information. “Protected Health Information” or PHI shall have the same meaning as the term “protected health information” in 45 C.F.R.164.501, limited to the information created or received by Participant from or on behalf of Disclosing KPD Program Participant. “Protected Health

Information” shall also include “electronic protected health information” as defined in 45 C.F.R. 160.103, limited to the information created or received by Participant from or on behalf of Disclosing KPD Program Participant.

- e. Individual. “Individual” means a living donor/candidate pair or non-directed donor in the KPD Program.
- f. Breach. “Breach” shall have the meaning given to such terms under Health Information Technology for Economic and Clinical Health (HITECH) Act (42 U.S.C. Section 17921).

2. Obligations of Participant

- a. Participant agrees not to use or disclose Protected Health Information under this Agreement other than as permitted or required by this Agreement or as required by law.
- b. Participant agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement. Participant agrees to implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of EPHI that Participant creates, receives, maintains, or transmits on behalf of Disclosing KPD Program Participant.
- c. In the event of any use or disclosure of PHI in violation of this Agreement, the Participant agrees to, in consultation with the Disclosing KPD Program Participant, mitigate, to the extent practicable, any harmful effect that is known to Participant of a use or disclosure of Protected Health Information by Participant of such improper use or disclosure.
- d. Participant agrees to, as soon as practicable, but in no event later than within five (5) days of becoming aware of any use or disclosure of PHI in violation of

this Agreement report any such disclosure to the Disclosing KPD Program Participant. Participant shall promptly report to Disclosing KPD Program Participant any security incident of which it becomes aware in the following time and manner: (i) any security incident will be reported to Disclosing KPD Program Participant in writing, within five (5) business days of the date on which Participant first becomes aware of such security incident; and (ii) any Breach of Protected Health Information (whether electronic, oral or in any other medium and whether secure or unsecured) shall be reported to Disclosing KPD Program Participant within five (5) days of such Breach. For purposes of this paragraph, "security incident" shall mean the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with systems operation in an information system.

- e. Participant agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Participant on behalf of Disclosing KPD Program Participant agrees to the same restrictions and conditions that apply through this Agreement to Participant with respect to such information. Participant agrees to ensure that any agent to whom it provides EPHI, including a subcontractor, agrees to implement reasonable and appropriate safeguards to protect such EPHI.
- f. Participant agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for Disclosing KPD Program Participant to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R.164.528.
- g. Participant agrees to provide to Disclosing KPD Program Participant or an Individual, in a reasonable time and manner, information collected in accordance

with this Agreement, to permit Disclosing KPD Program Participant to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. 164.528.

3. Obligations of UNOS. Upon request, UNOS shall make available to all Participants in the KPD Program a list of all Participants who have executed this Information Disclosure and Confidentiality Agreement, to facilitate the sharing of essential information by and among KPD Program Participants.

4. Permitted Uses and Disclosures by Participant

a. General Use and Disclosure Provisions. Except as otherwise limited in this Agreement, Participant may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, Disclosing KPD Program Participant as specified in this Agreement

b. Specific Use and Disclosure Provisions

i. Except as otherwise limited in this Agreement, Participant may use Protected Health Information for the proper management and administration of the Participant or to carry out the legal responsibilities of the Participant.

ii. Except as otherwise limited in this Agreement, Participant may disclose Protected Health Information for the proper management and administration of the Participant or to carry out the legal responsibilities of the Participant, provided that disclosures are Required By Law, or Participant obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies the Participant of any instances of which it is

aware in which the confidentiality of the information has been breached.

- iii. Participant may use Protected Health Information to report violations of law to appropriate Federal and State authorities.

5. Obligations of Disclosing KPD Program Participant- Provisions for Disclosing KPD Program Participant To Inform Participant of Privacy Practices and Restrictions

- a. Disclosing KPD Program Participant shall notify Participant of any limitation(s) in its notice of privacy practices of Disclosing KPD Program Participant in accordance with 45 C.F. .R.164.520, to the extent that such limitation may affect Participant's use or disclosure of Protected Health Information.
- b. Disclosing KPD Program Participant shall notify Participant of any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, to the extent that such changes may affect Participant's use or disclosure of Protected Health Information.
- c. Disclosing KPD Program Participant shall notify Participant of any restriction to the user disclosure of Protected Health Information that Disclosing KPD Program Participant has agreed to in accordance with 45 C.F.R. 164.522, to the extent that such restriction may affect Participant's use or disclosure of Protected Health Information.
- d. Disclosing KPD Program Participant shall obtain any consent, authorization or permission that may be required by the Privacy Rule or applicable state laws and/or regulations prior to furnishing Participant the Protected Health Information pertaining to an individual.

6. Term and Termination

- a. Term. This Agreement shall be effective as of the Effective Date set forth above, and shall terminate when all of the Protected Health Information provided by Disclosing KPD Program Participant to UNOS or provided to another Disclosing KPD Program Participant, is destroyed or returned to Disclosing KPD Program Participant, or, if it is infeasible to return or destroy Protected Health Information, protections are extended to such information, in accordance with the termination provisions in this Section.
- b. Termination for Cause. Upon a material breach of these obligations of confidentiality by Participant, UNOS or Disclosing KPD Program Participant shall provide an opportunity for Participant to cure the breach. If Participant has breached a material term of this Agreement and cure is not possible, then UNOS may immediately terminate this Agreement and remove Participant from further participation in the KPD Program.
- c. Effect of Termination. Upon termination of this Agreement, for any reason, Participant shall return or destroy all Protected Health Information received from any and all Disclosing KPD Program Participants. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Participant. Participant shall retain no copies of the Protected Health Information. In the event that Participant determines that returning or destroying the Protected Health Information is infeasible, Participant shall provide to Disclosing KPD Program Participant notification of the conditions that make infeasible. If Disclosing KPD Program Participant agrees that such return is infeasible, Participant shall extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as

Participant maintains such Protected Health Information.

- d. Removal from List. Upon termination of this Agreement, for any reason, UNOS shall remove Participant from the list of all Participants who have executed this Information Disclosure and Confidentiality Agreement, which is maintained by UNOS and provided to KPD Program participants.

7. Miscellaneous

- a. Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for either Party or both Parties to comply with the requirements of the Privacy Rule and the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191.
- b. Survival. The respective rights and obligations of Participant of this Agreement shall survive the termination of this Agreement.
- c. Third Party Beneficiaries. This Agreement between Participant and UNOS is intended to confer assurances of confidentiality and protections only to other participants in the OPTN KPD Program who have also executed this Information Disclosure and Confidentiality Agreement. It is acknowledged and agreed that Disclosing KPD Program Participants are intended beneficiaries of the protections of this Agreement in order to facilitate the safe, effective, and efficient transplantation of human organs.

b. Candidates:

- i. Must consent in writing to participate in the Kidney Paired Donation Pilot Program.

c. Potential Living Donors:

- i. Must meet the evaluation requirements set forth in OPTN/UNOS Policy 12.3.1(ABO Identification); Policy 12.3.2 (ABO Subtype Identification); and Policy 12.3.4.

- ii. Must be consented according to the consent process outlined in OPTN/UNOS Policy 12.3.3 (Psychosocial Evaluation of the Living Kidney Donor) and in the Informed Consent Requirements Section of the KPD Pilot Program Operational Guidelines.
- iii. Must be evaluated according to the medical evaluation outlined in OPTN/UNOS Policy 12.3.4 (Medical Evaluation of the Kidney Living Donor).
- iv. Must consent in writing to participate in the Kidney Paired Donation Pilot Program.

2. Records Required:

- All records below must be maintained and submitted to the OPTN contractor upon request:
 - Record of candidate's informed consent in writing to participate in the Kidney Paired Donation Pilot Program in the candidate's medical record
 - Record of the potential living donor's informed consent in writing to participate in the Kidney Paired Donation Pilot Program in the potential living donor's medical record
 - Record of the potential living donor's informed consent according to OPTN/UNOS Policy 12.2 (Informed Consent of Living Kidney Donors) in the potential living donor's medical record.

To read the complete OPTN Kidney Paired Donation Pilot Program Operational Guidelines visit optn.transplant.hrsa.gov, select the "Resources" tab, then select "Kidney Paired Donation Pilot Program." On this page, select "KPDPP Operational Guidelines."

Affected Policy Language:

This rewrite affects the entire body of OPTN Policies. The rewritten Policies have not been included in this policy notice due to the large files size that would result. Please access the rewritten Policies [here](#).

To read the current Policies, which are in effect until February, 1, 2014, visit www.unos.org or 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 "OPTN Policies."

Affected Policy Language:

** Please note: The OPTN/UNOS Board of Directors approved the policy changes denoted below at its [June 2013 meeting](#). At its November 2013 meeting, the Board did not change any of this previously approved language, *only* the implementation date. The policy changes below are provided for your reference and reflect what the Board approved at its June 2013 meeting, to be implemented on January 1, 2015.

At its November 2013 meeting the Board also adopted a plain language rewrite of all OPTN Policies. The policy language that will be effective on January 1, 2015, has also been provided as it will appear in the new, rewritten policy format.

7.1.6 ~~Imminent Neurological Death is defined as a patient who is 70 years old or younger with severe neurological injury and requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has an absence of at least three brain stem reflexes but does not yet meet the OPTN definition of an eligible death, specifically that the patient has not yet been legally declared brain dead according to hospital policy. Persons with any condition which would exclude them from being reported as an eligible death would also be excluded from consideration for reporting as an imminent death. For the purposes of submitting data to the OPTN, the OPO shall apply the definition of imminent neurological death to a patient that meets the definition of imminent death at the time when the OPO certifies the final disposition of the organ donation referral.~~

~~Brain Stem Reflexes:~~

- ~~• _____ Pupillary reaction~~
- ~~• _____ Response to iced caloric~~
- ~~• _____ Gag Reflex~~
- ~~• _____ Cough Reflex~~
- ~~• _____ Corneal Reflex~~
- ~~• _____ Doll's eyes reflex~~
- ~~• _____ Response to painful stimuli~~
- ~~• _____ Spontaneous breathing~~

7.1.76 ~~Although it is recognized that **Eligible Death Definition**. The OPO must maintain documentation used to exclude any patient from the eligible data definition. †This definition does not include all potential donors, for reporting purposes for DSA performance assessment, an eligible death for organ donation is defined as the death of a patient 70 years old or younger who ultimately is legally declared brain dead according to hospital policy independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice, who exhibits the following: with all the following characteristics:~~

- ~~• 75 years old or younger;~~
- ~~• Is legally declared dead by neurologic criteria in accordance with current standards of accepted medical practice and state or local law;~~
- ~~• Body Weight 5 kg or greater;~~

- Body Mass Index (BMI) of 50 kg/m² or less;
- Has at least one kidney, liver, heart or lung that is “deemed to meet the eligible data definition as defined below:
 - The kidney would be initially deemed to meet the eligible data definition unless the donor has one of the following:
 - > 70 years of age
 - Age 50-69 years with history of Type 1 diabetes for >20 years
 - Polycystic kidney disease
 - Glomerulosclerosis ≥ 20 % by kidney biopsy
 - Terminal serum creatinine greater than 4.0 mg/dl
 - Chronic Renal Failure
 - No urine output ≥ 24 hours
 - The liver would be initially deemed to meet the eligible data definition unless the donor has one of the following:
 - Cirrhosis
 - Terminal total bilirubin ≥ 4 mg/dl
 - Portal hypertension
 - Macrosteatosis ≥ 50% or fibrosis ≥ stage II
 - Fulminant hepatic failure
 - Terminal AST/ALT > 700 U/L
 - The heart would be initially deemed to meet the eligible data definition unless the donor has one of the following:
 - > 60 years of age
 - ≥ 45 years of age with a history of ≥10 years of HTN or ≥10 years of type 1 diabetes
 - History of Coronary Artery Bypass Graft (CABG)
 - History of coronary stent/intervention
 - Current or past medical history of myocardial infarction (MI)
 - Severe vessel diagnosis as supported by cardiac catheterization (i.e. >50% occlusion or 2+ vessel disease)
 - Acute myocarditis and/or endocarditis
 - Heart failure due to cardiomyopathy
 - Internal defibrillator or pacemaker
 - Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair
 - Serial echo results showing severe global hypokinesis
 - Myxoma
 - Congenital defects (whether surgically corrected or not)
 - The lung would be initially deemed to meet the eligible data definition unless the donor has one of the following:
 - Age > 65 years of age
 - Diagnosed COPD (eg: emphysema)
 - Terminal PaO₂/FiO₂ <250 mmHg
 - Asthma (with daily prescription)
 - Asthma is the cause of death
 - Pulmonary Fibrosis

- Previous lobectomy
- Multiple blebs documented on Computed Axial Tomography (CAT) Scan
- Pneumonia as indicated on Computed Tomography (CT), X-ray, bronchoscopy, or cultures
- Bilateral severe pulmonary contusions as per CT

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

- The donor has no suitable organ for transplant (as defined above), or;
- the donor goes to the operating room with intent to recover organs for transplant and all organs are deemed not medically suitable for transplantation, or;
- if the donor exhibits any of the following:
 - Active infections (with a specific diagnoses;) ~~[Exclusions to the Definition of Eligible]~~
 - Bacterial: Tuberculosis, Gangrenous bowel or perforated bowel and/or intra-abdominal sepsis, ~~See "sepsis" below under "General"~~
 - Viral: HIV infection by serologic or molecular detection, Rabies, Reactive Hepatitis B Surface Antigen, Retroviral infections including HTLV-III, Viral Encephalitis or Meningitis, Active Disseminated Herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia, Acute Epstein Barr Virus (mononucleosis), West Nile Virus infection, SARS
 - Fungal: Active infection with Cryptococcus, Aspergillus, Histoplasma, Coccidioides, Active candidemia or invasive yeast infection
 - Parasites: Active infection with Trypanosoma cruzi (Chagas'), Leishmania, Strongyloides, or Malaria (Plasmodium sp.)
 - Prion: Creutzfeldt-Jacob Disease
 - General [Exclusions to the Definition of Eligible]: Aplastic Anemia, Agranulocytosis
 - ~~Extreme Immaturity (<500 grams or gestational age of <32 weeks)~~
 - Current malignant neoplasms except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease
 - Previous malignant neoplasms with current evident metastatic disease
 - A history of melanoma
 - Hematologic malignancies: Leukemia, Hodgkin's Disease, Lymphoma, Multiple Myeloma
 - ~~Multi-system organ failure (MSOF) due to overwhelming sepsis or MSOF without sepsis defined as 3 or more systems in simultaneous failure for a period of 24 hours or more without response to treatment or resuscitation~~
 - Active Fungal, Parasitic, ~~Viral~~, or Bacterial Meningitis or Encephalitis
 - No discernable cause of death

7.1.7 Imminent Neurological Death. The OPO must maintain documentation used to exclude any patient from the imminent neurological death data definition.

Imminent Neurological Death is defined as a death of a patient:

- who meets the eligible death definition with the exception that the patient has not been declared legally dead by neurologic criteria in accordance with current standards of accepted medical practice and state or local law, and
- who has a severe neurological injury requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has no observed spontaneous breathing and has an absence of at least two additional brain stem reflexes.

Brain Stem Reflexes:

- Pupillary reaction
- Response to iced caloric
- Gag Reflex
- Cough Reflex
- Corneal Reflex
- Doll's eyes reflex
- Response to painful stimuli

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

Affected Policy Language in the *Plain Language* Format (effective January 1, 2015):

1.2 Definitions

Eligible death

For reporting purposes of DSA performance assessments, an eligible death for deceased organ donation is defined as the death of a patient who meets *all* the following characteristics:

- Is 75 years old or less
- Is legally declared dead by neurologic criteria according to the current standards of accepted medical practice and state or local law
- Has body weight of 5 kg or greater
- Has a body mass index (BMI) of 50 kg/m² or less
- Has at least one kidney, liver, heart or lung that is deemed to meet the eligible data definition as defined below:
 - The kidney would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
 - Greater than 70 years old
 - Age 50-69 years with history of type 1 diabetes for more than 20 years
 - Polycystic kidney disease
 - Glomerulosclerosis greater than or equal to 20% by kidney biopsy

- Terminal serum creatinine greater than 4.0 mg/dL
- Chronic renal failure
- No urine output for 24 hours or longer
- The liver would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
 - Cirrhosis
 - Terminal total bilirubin greater than or equal to 4 mg/dL
 - Portal hypertension
 - Macrosteatosis greater than or equal to 50%
 - Fibrosis greater than or equal to stage II
 - Fulminant hepatic failure
 - Terminal AST/ALT greater than 700 U/L
- The heart would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
 - 60 years old or older
 - 45 years old or older with a history of 10 or more years of HTN or 10 or more years of type 1 diabetes
 - History of coronary artery bypass graft (CABG)
 - History of coronary stent/intervention
 - Current or past medical history of myocardial infarction (MI)
 - Severe vessel diagnosis as supported by cardiac catheterization
 - Acute myocarditis or endocarditis, or both
 - Heart failure due to cardiomyopathy
 - Internal defibrillator or pacemaker
 - Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair
 - Serial echo results showing severe global hypokinesis
 - Myxoma
 - Congenital defects (surgically corrected or not)
- The lung would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
 - Age 65 years or older
 - Diagnosed with COPD
 - Terminal PaO₂/FiO₂ less than 250 mmHg
 - Asthma (with daily prescription)
 - Asthma is the cause of death
 - Pulmonary fibrosis
 - Previous lobectomy
 - Multiple blebs documented on computed axial tomography (CAT) scan
 - Pneumonia as indicated on computed tomography (CT), X-ray, bronchoscopy, or cultures
 - Bilateral severe pulmonary contusions as per CT

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

- The donor has no suitable organ for transplant (as defined above)
- The donor goes to the operating room with intent to recover organs for transplant and all organs are deemed not medically suitable for transplant

- The donor exhibits *any* of the following:
 - Active infections (with a specific diagnosis)
 - Bacterial: tuberculosis, gangrenous bowel or perforated bowel or intra-abdominal sepsis
 - Viral: HIV infection by serologic or molecular detection, rabies, reactive hepatitis B surface antigen, retroviral infections including viral encephalitis or meningitis, active herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia, acute epstein barr virus (mononucleosis), West Nile virus infection, SARS
 - Fungal: active infection with cryptococcus, aspergillus, histoplasma, coccidioides, active candidemia or invasive yeast infection
 - Parasites: active infection with trypanosoma cruzi (Chagas'), Leishmania, strongyloides, or malaria (*plasmodium sp.*)
 - Prion: Creutzfeldt-Jacob disease
 - General [Exclusions to the Definition of Eligible]: aplastic anemia, agranulocytosis
 - Current malignant neoplasms, except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease
 - Previous malignant neoplasms with current evident metastatic disease
 - A history of melanoma
 - Hematologic malignancies: leukemia, Hodgkin's disease, lymphoma, multiple myeloma
 - Active fungal or parasitic meningitis or encephalitis
 - No discernible cause of death

Imminent neurological death

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

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

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

To read the all of the current policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the "Policy Management" tab, then select "Policies." From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner. Please click [here](#) to read the entire body of rewritten policies in the plain language format, which will be implemented on February 1, 2014.

** Please note: At its November 2013 meeting, the OPTN/UNOS Board of Directors approved the policy changes denoted below. As a separate action, the Board adopted a plain language rewrite of all OPTN Policies. Accordingly, the Board also approved a resolution to incorporate the policy changes it had previously adopted at the November 2013 meeting into the new, rewritten policy format. Both sets of policy language related to this specific change are provided below for reference; the policy language in the rewritten policy format will be effective on February 1, 2014.

Affected Policy Language in the *Current* Format:

2.8 ~~Model Elements~~ Requirements for Controlled Donation after Circulatory Death Recovery (DCD) 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.~~

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

state and local statutes or regulation. A DCD donor may also be called a non-heartbeating, asystolic, or donation after cardiac death donor.

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

A. Agreement

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

B. Protocols

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

C. ~~A. Suitable Candidate Selection~~ Potential DCD Donor Evaluation

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

- ~~1. A patient (from age newborn to the 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.~~

D B. Authorization/Approval Consent for DCD

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

- ~~4. The OPO must confirm that consent has been obtained for any DCD related procedures or drug administration that occur prior to patient death. 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.~~

E. Authorization for DCD

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

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

F. G. Withdrawal of Life Sustaining Medical Treatment/Support Measures/Patient Management

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

1. the patient's identification.
 2. the process for withdrawing life-sustaining treatment or ventilated support.
 3. roles and responsibilities of the primary patient care team, the OPO team, and the organ recovery team.
 4. the hospital's plan for continued patient care in the event that the patient does not become a donor and appropriate communication with the next of kin.
- ~~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 recovery personnel (surgeons and other recovery practitioners) member of the transplant team may shall be present for the withdrawal of life-sustaining measures. medical treatment or ventilated support.~~

- ~~3. No member of the organ recovery team or OPO staff may guide or administer participate in the guidance or administration of palliative care, or declare 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.~~

G. D. Pronouncement of Death

- ~~6. The patient care team member that is authorized to declare death must not be a member of the OPO or organ recovery team.~~
- ~~7. 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.~~

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

H. E. Organ Recovery

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

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

F. Financial Considerations

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

Affected Policy Language in the *Plain Language* Format (effective February 1, 2014):

2.13 Donation after Circulatory Death (DCD)

Donation after Circulatory Death (DCD) describes the organ recovery process that may occur following death by irreversible cessation of circulatory and respiratory functions. Potential DCD donors are limited to patients who have died, or whose death is imminent, and whose medical

treatment no longer offers a medical benefit to the patient as determined by the patient, the patient's authorized surrogate, or the patient's advance directive if applicable, in consultation with the healthcare team. Any planned withdrawal of life sustaining medical treatment/support will be carried out in accordance with hospital policy. Prior to the OPO initiating any discussion with the legal next-of-kin about organ donation for a potential DCD donor, the OPO must confirm that the legal next-of-kin has elected to withdraw life sustaining medical treatment. The timing of a potential DCD donor evaluation and donation discussion shall be coordinated with the OPO and the patient's healthcare team, in accordance with hospital policy. Death is declared by a healthcare team member in accordance with hospital policy and applicable state and local statutes or regulation. A DCD donor may also be called a non-heartbeating, asystolic, or donation after cardiac death donor.

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

2.13.A Agreement

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

2.13.B Protocols

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

2.13.C Potential DCD Donor Evaluation

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

2.13.D Consent for DCD

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

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

2.13.E Authorization for DCD

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

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

2.13.F Withdrawal of Life Sustaining Medical Treatment or Support

Prior to the donor hospital withdrawing life-sustaining medical treatment or ventilated support,

the OPO is required to conduct a timeout to confirm:

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

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

2.13.G Pronouncement of Death

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

2.13.H Organ Recovery

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

To read the all of the current policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the "Policy Management" tab, then select "Policies." From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner. Please click [here](#) to read the entire body of rewritten policies in the plain language format, which will be implemented on February 1, 2014.

** Please note: At its November 2013 meeting, the OPTN/UNOS Board of Directors approved the policy changes denoted below. As a separate action, the Board adopted a plain language rewrite of all OPTN Policies. Accordingly, the Board also approved a resolution to incorporate the policy changes it had previously adopted at the November 2013 meeting into the new, rewritten policy format. Both sets of policy language related to this specific change are provided below for reference; the policy language in the rewritten policy format will be effective on February 1, 2014.

Affected Policy Language in the *Current* Format:

3.1.14 PHS Guideline. For requirements that reference the “PHS Guideline,” members must use either the ~~United States Public Health Service (PHS) *Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissues and Organs* (1994)~~ or the *PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation* (2013). For the purposes of the PHS Guideline, “increased risk of disease transmission” is used interchangeably with “high risk.” For each organ donor, OPOs must document in the donor highlights section of DonorNet which set of guidelines it used to evaluate that particular donor.

Affected Policy Language in the *Plain Language* Format (effective February 1, 2014):

1.2 Definitions

United States Public Health Service (PHS) Guideline

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

To read the all of the current policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the “Policy Management” tab, then select “Policies.” From the UNOS website, select “Policies” from the “I am looking for:” box in the upper left hand corner. Please click [here](#) to read the entire body of rewritten policies in the plain language format, which will be implemented on February 1, 2014.

Affected Bylaws Language:

6.2 Vice President

The vice president is the president-elect of the OPTN and serves as an *ex officio*, non-voting member~~Chair~~ of the Membership and Professional Standards Committee (MPSC). If the president is absent, the vice president performs all duties required of the president, as well as any other duties required by the Board of Directors or these Bylaws. The vice president serves for a term of one year, and may not serve consecutive terms.

7.2 Standing Committee Chairs

Committee Chairs inform the OPTN president and the Executive Director of the activities of their Committees and report to the Board of Directors upon request.

The treasurer of the OPTN serves as the Chair of the Finance Committee ~~and the vice president serves as the Chair of the Membership and Professional Standards Committee (MPSC)~~. The vice president, with approval of the Board of Directors, appoints the Chair of the other standing Committees.

Chairs of the standing Committees have the following terms:

- ~~▪ The vice president serves a one-year term as the Chair of the MPSC.~~
- The Patient Affairs, Ethics and Transplant Administrator Chairs serve three year terms.
- Other Chairs serve two year terms.

The vice president may appoint one or more Committee Chairs for a one-year term so that a staggered rotation is achieved. Committee Chairs may be appointed to consecutive terms.

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

** Please note: At its November 2013 meeting, the OPTN/UNOS Board of Directors approved the policy changes denoted below. As a separate action, the Board adopted a plain language rewrite of all OPTN Policies. Accordingly, the Board also approved a resolution to incorporate the policy changes it had previously adopted at the November 2013 meeting into the new, rewritten policy format. Both sets of policy language related to this specific change are provided below for reference; the policy language in the rewritten policy format will be effective on February 1, 2014.

Affected Policy Language in the *Current* Format:

12.4 Independent Donor Advocates- (IDA)

12.4.1 IDA Role

For any potential living kidney donor who is undergoing evaluation for donation, the living kidney donor recovery hospital must designate and provide an independent donor advocate (IDA) who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient. The IDA may be one person or an independent living donor advocate team with multiple members. The IDA team must designate one person from the team as the key contact for each potential living donor.

12.4.2 IDA Responsibilities

~~12.4.1 The IDA must assist the potential living kidney donor with the evaluation process and focus on their needs and questions. The IDA must be knowledgeable about risks and benefits associated with all phases of the donation process. The IDA responsibilities include, but are not limited to the following must:~~

- ~~1. Function independently from the transplant candidate's team~~
 - ~~• Promote the best interests of the potential living donor~~
- ~~2. •Advocate for the rights of potential living donor and the living donor~~
- ~~3. Fulfill the qualifications and training requirements specified in the hospital's protocols regarding knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressures on the potential living donor's decision about whether to donate. Document that each requirement has been met.~~
- ~~4. •Review whether the potential donor has received information on each of the following areas, and assist the potential donor in obtaining additional and understanding information as needed regarding the:~~
 - ~~• i. Informed Consent process as described in policy 12.2 and its subsections;~~

- ~~ii-~~ Evaluation process as described in policies 12.2.1, 12.3.3, and 12.3.4 and its subsections;
- ~~iii-~~ Surgical procedure;
- ~~iv-~~ Medical and psychosocial risks as described in policy 12.2.1;
- ~~v-~~ Follow-up requirements, and the Bbenefit and need for participating in follow-up as described in policies 7.2, 12.8.2, 12.8.3 and 12.8.4.
- ~~vi-~~ Document that each topic was reviewed.

12.4.3 IDA Protocols

The living kidney donor recovery hospital must develop, and once developed must comply with, written protocols for:

1. The composition of the IDA team, if the hospital uses a team
2. The qualifications and training (both initial and ongoing) required for the IDA. Minimum qualifications must include knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressures on the potential living donor's donation decision.
3. The duties and responsibilities of the IDA, which must include at least the functions and duties listed throughout Policy 12.4
4. The process the living donor recovery hospital will provide for the IDA to file a grievance when necessary to protect the rights or best interests of the living donor.
5. The process the living donor recovery hospital will use to address any grievance raised by the IDA concerning the rights or best interests of the living donor.

Affected Policy Language in the *Plain Language* Format (effective February 1, 2014):

14.2.A ILDA Requirements for Kidney Recovery Hospitals

For any potential living kidney donor who is undergoing evaluation for donation, the living kidney donor recovery hospital must designate and provide each potential living donor with an ILDA who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient. The ILDA may be one person or an independent living donor advocate team with multiple members. An ILDA team must designate one person from the team as the key contact for each potential living donor.

The ILDA must:

1. Function independently from the transplant candidate's team.
2. Advocate for the rights of the potential living donor and the living donor.
3. Fulfill the qualification and training requirements specified in the recovery hospital's protocols regarding knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressure on the potential living donor's decision about whether to donate. Document that each requirement has been met.
4. Review whether the potential living donor has received information on each of the following areas and assist the potential donor in obtaining additional information from other professionals as needed about the:
 - a. Informed consent process as described in *Policy 14.3* and its subsections
 - b. Evaluation process according to *Policies 14.3.A.ii, 14.4.B and 14.5.A* and its subsections
 - c. Surgical procedure
 - d. Medical risks according to *Policy 14.3.A.ii*
 - e. Psychosocial risks according to *Policy 14.3.A.ii*
 - f. Follow-up requirements, and the benefit and need for participating in follow-up according to *Policies 18.1: Data Submission Requirements, 18.5.A: Reporting Requirements after Donation and 18.5.B: Submission of Living Donor Death and Organ Failure*
5. Document that each topic was reviewed.

14.2.B ILDA Protocols for Kidney Recovery Hospitals

The living kidney donor recovery hospital must develop, and once developed must comply with, written protocols for:

- a. The composition of the ILDA team, if the hospital uses a team
- b. The qualifications and training (both initial and ongoing) required for the ILDA. Minimum qualifications must include knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressures on the potential living donor's donation decision.
- c. The duties and responsibilities of the ILDA, which must include at least the functions and duties listed throughout *Policies 14.2.A*.
- d. The process the living donor recovery hospital will provide for the ILDA to file a grievance when necessary to protect the rights or best interests of the living donor.
- e. The process the living donor recovery hospital will use to address any grievance raised by the ILDA concerning the rights or best interests of the living donor.

14.2.C ILDA Protocols for Liver Recovery Hospitals

Liver recovery hospitals must develop and comply with written protocols for the duties and responsibilities of the ILDA that include, but are not limited to, *all* of the following elements:

1. Promoting the best interests of the potential living donor
2. Advocating for the rights of the living donor
3. Assisting the potential donor in obtaining and understanding information about the:
 - a. Consent process
 - b. Evaluation process

- c. Surgical procedure
- d. Benefit of follow up
- e. Need for follow up

To read the all of the current policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the "Policy Management" tab, then select "Policies." From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner. Please click [here](#) to read the entire body of rewritten policies in the plain language format, which will be implemented on February 1, 2014.

Affected Bylaws Language:

Article I: Membership

1.4 Histocompatibility Laboratory Members

A histocompatibility laboratory member is any histocompatibility laboratory that performs histocompatibility testing, including but not limited to, HLA typing, antibody screening, compatibility testing, or crossmatching, and serves at least one transplant hospital member or OPO within its service area.

A. Histocompatibility Laboratory Member Representatives

Independent histocompatibility laboratory members have the following responsibilities:

1. Appoint a representative to vote and act for the member on all OPTN business.
2. Appoint an alternate representative who will have authority if the representative is unable to vote or act.
3. Submit in writing to the Executive Director the name and address of its representative and alternative representative to receive all meeting notices.

B. Histocompatibility Laboratory Membership Terms

Histocompatibility laboratory members have unlimited terms.

C. Histocompatibility Laboratory Membership Voting Privileges

Each histocompatibility laboratory member has one vote provided that the histocompatibility laboratory is independent. An independent histocompatibility laboratory is defined as one that has a distinct governing body separate from any transplant hospital or commonly controlled group of transplant hospitals it serves.

Appendix C:

Membership Requirements for Histocompatibility Laboratories

~~A histocompatibility laboratory member is any histocompatibility laboratory that serves at least one transplant hospital member or OPO member within its Donation Service Area (DSA).~~

~~An independent histocompatibility laboratory has a distinct governing body separate from any transplant hospital or commonly controlled group of transplant hospitals it serves. Only independent histocompatibility laboratories have voting privileges in the OPTN. For more information on the terms, voting privileges, and responsibilities of histocompatibility laboratories, see Article I: *Membership* of these Bylaws.~~

C.1 Histocompatibility Laboratory Compliance

~~By accepting membership in the OPTN, e~~Each histocompatibility laboratory member must agree to comply with all applicable provisions of the following:

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

C.2 Facilities and Resources

Histocompatibility laboratories ~~require~~ must have considerable facilities, equipment, and resources to ensure accurate, reliable, and efficient testing. ~~The following sections describe the minimum required facilities and resources required for a histocompatibility laboratory.~~

A. Facilities Size, Lighting, Ventilation and Temperature

The laboratory must have:

1. Enough space and equipment so that procedures and tests can be performed accurately and efficiently.
2. Adequate facilities to store medical and test records for candidates, recipients, and donors.
3. ~~Adequate lighting and ventilation.~~
4. ~~The proper temperature as specified in the laboratory's procedure manual so that procedures are completed in the optimal temperature range.~~

B. Records Access

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

C. Transplant Program Affiliation

Histocompatibility laboratories must have written agreements with every transplant program the laboratory serves, unless clinical urgency prevents such

an agreement. Written agreements between histocompatibility laboratories and transplant programs must include *all* of the following:

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

D. OPO Affiliation

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

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

B. Refrigeration

~~Refrigerators and freezers must be monitored to ensure the optimal storage temperature for samples and reagents. Refrigerators and freezers must be equipped with an audible or centrally located temperature alarm system. If a refrigerator or freezer fails, an emergency storage plan must be in place and followed.~~

C. Liquid Nitrogen Storage

~~If liquid nitrogen is used for storage of frozen cells, the liquid nitrogen level in the freezers must be monitored to ensure an adequate supply at all times.~~

D. Equipment Maintenance

~~The laboratory must establish and adhere to policies and procedures for the proper maintenance of equipment, instruments and test systems by:~~

- ~~1. Defining and performing the preventive maintenance program for each instrument and piece of equipment.~~
- ~~2. Performing and documenting function checks on equipment with at least the frequency specified by the manufacturer.~~
- ~~3. Verifying that the equipment is calibrated at least every six months.~~

E. Records Storage and Access

~~The laboratory must have adequate facilities to store medical and test records. Records must be available onsite for at least two years and readily accessible after that for at least the period specified by local, state and federal regulations.~~

F. Health and Safety Compliance

~~The laboratory must comply with all applicable federal, state and local health and safety regulations including:~~

- ~~1. Fire safety regulations.~~
- ~~2. Regulations for the storage, handling and disposal of hazardous chemical, biological and radioactive materials.~~

G. Software Validation

~~The laboratory must have documented validation of all software used for patient data analysis to ensure that computer-assisted analyses are accurate.~~

C.3 Histocompatibility Laboratory Key Personnel

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

The size and training of the histocompatibility laboratory staff must be enough to carry out the volume and variety of tests required to ensure accuracy and prompt completion of tests. All personnel must be licensed or meet the standards required by federal, state and local regulations. ~~These personnel requirements are consistent with the current Clinical Laboratory Improvement Act (CLIA) regulations, which outline the requirements for all histocompatibility laboratories.~~

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

A. Laboratory Director

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

Laboratory Director Qualifications

The laboratory director must meet *all* of the following requirements:

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

Laboratory Director Candidate Requirements

Any professional being considered for the position of laboratory director must also provide *one* of the following:

- Proof of certification by the American Board of Histocompatibility and Immunogenetics.
- A portfolio of cases covered during training in an OPTN approved transplant hospital. If a portfolio is submitted, the portfolio may be also reviewed by an OPTN approved accrediting agency as part of their application process. The portfolio must include:
 1. A log of 50 cases reviewed in each histocompatibility testing technique used in organ transplantation. Each case should include the date and a record identification number, along with a brief description and the testing technology used. A minimum of ten of these cases must include all the related worksheets and notes.
 2. Cases that demonstrate the applicant's analytical skills, including the ability to recognize and resolve difficult testing and interpretation issues.

These cases should also include instances when the applicant made recommendations for additional testing or clinical care.

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

1. Proof of active laboratory interaction with transplant professionals.
2. A letter that describes all experience in immunology and clinical histocompatibility testing.
3. A summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks performed.
4. A current curriculum vitae or resume.
5. A demonstrated knowledge of the fundamentals of immunology, genetics, and histocompatibility testing and this knowledge should be reflected by participation in professional conferences and publications in peer reviewed journals. An American Board of Histocompatibility and Immunogenetics Diplomat (ABHI D) certification is highly recommended.

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

Laboratory Director Responsibilities

A histocompatibility laboratory director has the following responsibilities:

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

~~Laboratories must document if any of the director's responsibilities will be performed by other Laboratory staff. This documentation must include a list of the duties delegated, the times when these duties will be delegated, the qualifications of the staff that will perform the delegated duties, and the quality systems in place to ensure the duties are correctly performed.~~

B. Technical Supervisor Qualifications and Responsibilities

The technical supervisor must meet all the qualifications for laboratory director as outlined in C.3.A. *Laboratory Director* above and for technical supervisor as specified in 42CFR493. In addition, the supervisor must have at least two years of training in an OPTN approved training program or three years experience under a qualified OPTN histocompatibility laboratory director.

A technical supervisor has the following responsibilities:

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

~~Laboratories must document any technical supervisor responsibilities that will be delegated, including a list of the duties delegated, the times when these duties will be delegated, the qualifications of the staff that will perform the delegated duties, and the quality systems in place to ensure each duty is correctly performed.~~

C.4 Laboratory Coverage Plan

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

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

1. The laboratory must document that qualified key personnel are providing coverage at all times, including during the entire application process for changes in key personnel, regardless of the status of the application.
2. The laboratory must document that the clinical consultant and technical supervisor are available to provide onsite, telephone, or electronic consultation to facilitate organ acceptance and transplantation.

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

C. 5C.4 Changes in Key Laboratory Personnel

~~To maintain a histocompatibility laboratory's OPTN membership approval, the laboratory must have a qualified director, technical supervisor and clinical consultant on staff at all times. When the laboratory learns that a director, technical supervisor or clinical consultant plans to leave, it must notify the OPTN contractor immediately, within 30 days if possible, of departure. At this time, the laboratory must submit to the OPTN Contractor the name of the replacement, curriculum vitae, and information required for compliance with OPTN criteria for Histocompatibility Laboratory Membership. Failure to inform the OPTN Contractor of changes in key personnel may result in disciplinary action as described in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.~~

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

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

1. Notify the OPTN Contractor in writing within seven business days of when the laboratory becomes aware of the change in key personnel.
2. Submit a completed Personnel Change Application to the OPTN Contractor no less than 30 days before the end of the individual's active employment or change in status. The Personnel Change Application must document that the new or acting laboratory director, technical supervisor, and clinical consultant meet the requirements of these Bylaws.
3. Submit an updated Laboratory Coverage Plan no less than 30 days before the date of departure that specifies how continuous coverage will be provided at the laboratory by all key personnel during and after the transition period to a new or acting laboratory director, technical supervisor, or clinical consultant.
4. If the histocompatibility laboratory receives less than 60 days notice of the key personnel change, then the laboratory must submit a completed Personnel Change Application and updated Laboratory Coverage Plan to the OPTN Contractor within 30 days of the date of departure.

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

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

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

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

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

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

C.6 G-5 Histocompatibility Laboratory Policies and Procedures

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

A. Criteria for Mandatory Performance Review of Director, Technical Supervisor or Clinical Consultant

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

- Less than 100% successful performance in an ABO external proficiency testing program.
- For programs other than ABO, a less than 80% successful performance in an external proficiency testing program within a year.
- Accreditation revoked by any OPTN approved histocompatibility regulatory agency.

- A focused re-inspection by any OPTN approved histocompatibility regulatory agency.
- Restrictions imposed on the laboratory by any OPTN approved histocompatibility regulatory agency.

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

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

B. Information Required from Laboratories with Unsatisfactory Performance

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

- Letters from transplant program physicians or coordinators describing the level of interaction and involvement of the director, technical supervisor and clinical consultant.
- Interviews with transplant program staff.
- Laboratory complaint log and documentation of resolutions from other healthcare professionals.
- Samples of laboratory reports that demonstrate the review of patient history, notation of unusual results, and recommendations for additional testing.

- Documentation of any extracurricular commitments, including estimates of time required, for director, technical consultant and clinical consultant outside of the histocompatibility laboratory. This may include other employment, current committee assignments, teaching commitments, students mentored, research commitments, grants, and all other patient care responsibilities.
- Other material as requested.

C. Periodic Reviews

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

D. Regulatory Agency Adverse Actions

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

E. Inactive Status

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

C.7C.6 Histocompatibility Laboratory Testing Requirements

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

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

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

A. Handling of Specimens

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

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

B. Handling of Reagents

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

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

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

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

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

C. Testing Standards

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

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

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

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

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

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

Proficiency Testing and Competency Evaluation

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

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

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

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

D. Quality Assurance

Laboratories must have ongoing procedures for monitoring and evaluating its quality assurance program including procedures to evaluate corrective action taken. Laboratories must document and assess problems identified during quality assurance reviews, discuss them with the staff, and take corrective action to prevent recurrences. Ineffective policies and procedures must be revised based on the outcome of the evaluation.

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

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

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

Laboratories must also have a process for addressing any discrepancies in HLA typing results for the same individual as reported by different laboratories or at different times as described in *OPTN Policy, Appendix 3C*.

E. Procedure Manual

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

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

F. Records and Test Reports

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

1. Test requisition.
2. Subject identification number.
3. Accession number or unique identification of the specimen.
4. The tissue source of the specimen.

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

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

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

All test reports must contain:

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

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

Waiting List Data Verification

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

G. Service Requirements

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

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

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

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, 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.

J. Submission Requirements for Laboratories Using New Techniques

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

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

Laboratories adding or changing test methods must submit procedures and test validation data for the new tests and methods to an OPTN approved histocompatibility laboratory accrediting agency, with a copy to the OPTN Histocompatibility Committee. The laboratory must also submit the curriculum vitae for the Director documenting experience in the new testing.

The curriculum vitae should include qualifications such as publications and years of experience as the Director of another laboratory approved for the new techniques. A summary of the Director review of five cases for each type of test, including the testing and interpretation, may be submitted instead if the Director does not have documented experience in the new techniques.

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

1. A summary of the internal validation data and the Director's summary of that data.
2. The step-by-step procedure including worksheets and list of reagents.
3. The clinical protocol that validates the use of the procedure.
4. The program for training staff in the new testing technique.
5. Documentation of the training of staff that will be performing the test and reviewing the test results.
6. Performance requirements, including accuracy, precision, sensitivity, specificity, reportable range of test results, normal values, and any other relevant characteristics.
7. Quality control procedures.
8. Calibration data for necessary equipment.
9. Quality assurance data.
10. Evidence that the laboratory is currently enrolled in a Proficiency Testing (PT) program for the test, if available.
11. Tests results including worksheets and sample reports with interpretation of 10 samples including at least one of each of the test materials that will be used by the laboratory. Laboratories without access to a particular type of

- sample may request that it be supplied by another OPTN accredited laboratory. Multiple samples from the same individual may not be used.
12. Externally blinded side-by-side validation tests using specimens from an OPTN accredited laboratory, or well-characterized reference materials (ASHI repository or commercial panels) equivalent to those provided by the selected PT program, or a complete year of PT. A combination of these may also be used to meet this requirement.

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

Appendix M: Definitions

Histocompatibility Laboratory Member

A histocompatibility laboratory member is a member of the OPTN. A histocompatibility member is any histocompatibility laboratory that performs histocompatibility testing, including but not limited to, HLA typing, antibody screening, compatibility testing, or crossmatching, and serves at least one transplant hospital member or OPO within its service area. Histocompatibility laboratory members are either independent or hospital-based. See also *independent Histocompatibility Laboratory* and *Hospital-based Histocompatibility Laboratory*.

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

** Please note: At its November 2013 meeting, the OPTN/UNOS Board of Directors approved changes to the HLA equivalency tables that are currently located in Appendix A to Policy 3 (HLA Antigen Values and Split Equivalence). As a separate action, the Board adopted a plain language rewrite of all OPTN Policies which included moving all the information located in Appendix A to Policy 3 into the rewritten section of policy that now contains all histocompatibility policies, Policy 4 (Histocompatibility). Because the changes to the HLA equivalency tables will be implemented pending programming, and after February 1, 2014, the changes were presented to the Board in the plain language rewrite format. As such, approved changes to the HLA equivalency tables are denoted below only in the plain language policy rewrite format.

Affected Policy Language in the *Plain Language* Format (effective pending programming):

4.16 Reference Table of HLA Antigen Values and Split Equivalences

Tables 4-6, 4-7, and 4-8 show patient-donor antigen combination and whether they are mismatches. For each candidate antigen, the donor antigens that are not mismatched are listed below. All other combinations are considered mismatches. Antigens with an * indicate an allele that may not have a World Health Organization (WHO)-approved serologic specificity. Antigens given **99 means the patient locus was not tested.

Table 4-6: HLA A Matching Antigen Equivalences

Patient A Locus Antigen	Equivalent Donor Antigens	Patient A Locus Antigen	Equivalent Donor Antigens	Patient A Locus Antigen	Equivalent Donor Antigens
1	1	28	28, 69	68	68
2	2, 203	29	29	69	69, 28
3	3	30	30	74	74
9	9	31	31	80	80
10	10	32	32	203	203, 2
11	11	33	33	210	210, 2
19	19	34	34	2403	2403, 24
23	23	36	36	*6601	*6601, 66
24	24, 2403	43	43	*6602	*6602, 66
25	25	66	66, *6601, *6602	** 99	(No equivalent)
26	26				

Table 4-7: HLA B Matching Antigen Equivalences

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

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

Patient B Locus Antigen	Equivalent Donor Antigens
73	73
75	75, 15
76	76, 15
77	77, 15
78	78
81	81
82	82, *8201
703	703, 7
*0804	*0804, 8
*1304	*1304, 15, 21, 49, 50
2708	2708, 27, 7
3901	3901, 39
3902	3902, 39
*3905	*3905, 39
4005	4005, 50
5102	5102, 51, 53
5103	5103, 51
7801	7801
*8201	*8201, 82
** 99	(No equivalent)

Table 4-8: HLA DR Matching Antigen Equivalence

Patient DR Locus Antigen	Equivalent Donor Antigens	Patient DR Locus Antigen	Equivalent Donor Antigens	Patient DR Locus Antigen	Equivalent Donor Antigens
1	1, 103	9	9	16	16, 2
2	2	10	10	17	17, 3
3	3	11	11	18	18, 3
4	4	12	12	103	103, 1
5	5	13	13	1403	1403, 14, 6
6	6	14	14, 1403, 1404	1404	1404, 14, 6
7	7	15	15	** 99	(No equivalent)
8	8				

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

** Code 99 means not tested

Examples of how “Matching Antigen Equivalences” works:

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

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

Table 4-9: HLA A Unacceptable Antigen Equivalences

Patient Unacceptable A Locus Antigen	Donor Equivalent Antigens	Patient Unacceptable A Locus Antigen	Donor Equivalent Antigens	Patient Unacceptable A Locus Antigen	Donor Equivalent Antigens
1	1	24	24, 2403, 9	68	68, 28
2	2, 203, 210	25	25, 10	69	69, 28
3	3	26	26, 10	74	74
9	9, 23, 24, 2403	28	28, 68, 69	80	80
10	10, 25, 26, 34, 66, *6601, *6602, 43	29	29	203	203
11	11	30	30	210	210
19	19, 29, 30, 31, 32, 33, 74	31	31	2403	2403
23	23, 9	32	32	*6601	*6601, 66
		33	33	*6602	*6602, 66
		34	34		
		36	36		
		43	43		
		66	66, *6601, *6602, 10		

Table 4-10: HLA B Unacceptable Antigen Equivalences

Patient Unacceptable B Locus Antigen	Donor Equivalent Antigens
5	5, 51, 5102 , 5103, 52, 78
7	7, 703, 2708
8	8
12	12, 44, 45
13	13
14	14, 64, 65
15	15, 62, 63, 75, 76, 77
16	16, 38, 39
17	17, 57, 58
18	18
21	21, 49, 50, 4005
22	22, 54, 55, 56
27	27, 2708
35	35
37	37
38	38, 16
39	39, 3901, 3902, *3905, 16
40	40, 60, 61
41	41
42	42
44	44, 12
45	45, 12
46	46
47	47

Patient Unacceptable B Locus Antigen	Donor Equivalent Antigens
48	48
49	49, 21
50	50, 4005, 21
51	51, 5102 , 5103
52	52
53	53
54	54, 22
55	55, 22
56	56, 22
57	57, 17
58	58, 17
59	59
60	60, 40
61	61, 40
62	62, 15
63	63, 15
64	64, 14
65	65, 14
67	67
70	70, 71, 72
71	71, 70
72	72, 70
73	73
75	75
76	76
77	77
78	78
81	81
82	82, *8201

Patient Unacceptable B Locus Antigen	Donor Equivalent Antigens
703	703
*0804	*0804
*1304	*1304
2708	2708
3901	3901
3902	3902
*3905	*3905
4005	4005, <u>50</u>
5102	5102
5103	5103
7801	7801, <u>78</u>
*8201	*8201, <u>82</u>
<u>Bw4</u>	<u>Bw4, 5, 13, 17, 27, 37, 38, 44, 47, 49, 51, 52, 53, 57, 58, 59, 63, 77</u>
<u>Bw6</u>	<u>Bw6, 7, 8, 14, 18, 22, 2708, 35, 39, 40, 41, 42, 45, 48, 50, *4005, 54, 55, 56, 60, 61, 62, 64, 65, 67, 70, 71, 72, 75, 76, 78, 81, 82</u>

Table 4-11: HLA C Unacceptable Antigen Equivalences

Patient Unacceptable C Locus Antigen	Donor Equivalent Antigens
w1	w1
w2	w2
w3	w3, w9, w10
w4	w4
w5	w5
w6	w6

Patient Unacceptable C Locus Antigen	Donor Equivalent Antigens
w7	w7
w8	w8
w9	w9
w10	w10
*12	*12
	*13

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

Table 4-12: HLA DR Unacceptable Antigen Equivalences

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

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

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

Table 4-13: HLA DQB Unacceptable Antigen Equivalences

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

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

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

Examples of how “Unacceptable Antigen Equivalences” works:

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

~~Bw4 should exclude B5, B13, B17, B27, B37, B38, B44, B47, B49, B51, B52, B53, B57, B58, B59, B63, B77, Bw4.~~

~~Bw6 should exclude B7, B8, B14, B18, B22, B35, B39, B40, B41, B42, B45, B48, B50, (B*4005), B54, B55, B56, B60, B61, B62, B64, B65, B67, B70, B71, B72, B75, B76, B78, B81, B46, B73, Bw6~~

Additional Unacceptable Antigen Equivalences to be used in the Calculated PRA Only

DR51 should also include DR2, DR15, DR16.

DR52 should also include DR3, DR5, DR6, DR11, DR12, DR13, DR14, DR17, DR18.

DR53 should also include DR4, DR7, DR9.

NOTE: The remaining amendments to Appendix 3A to Policy 3 (HLA Antigen Values and Split Equivalences) shall be effective pending distribution of appropriate notice and programming in UNetSM. (Approved at the November 8-9, 2010 Board of Directors Meeting)

To read the all of the current policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the "Policy Management" tab, then select "Policies." From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner. Please click [here](#) to read the entire body of rewritten policies in the plain language format, which will be implemented on February 1, 2014.