At-a-Glance

- **Revision of the UNOS Bylaws, the OPTN Bylaws and the OPTN Policies that Govern HLA Laboratories**

- **Affected/Proposed Policy:**
  Attachment II to Appendix B of the UNOS Bylaws – Criteria for Histocompatibility Laboratory Designation
    - Key Personnel Qualifications
    - A.1. Director Credentials
    - A2. Director Candidates
    - B.1. Responsibilities of a Director of a Histocompatibility Laboratory

  Attachment IIA to Appendix B of the UNOS Bylaws -Standards for Histocompatibility Testing
    - C5.000 Proficiency Testing and Competency Evaluation
    - C9.000 Subcontracting
    - F2.000 HLA Typing
    - F3.000 Antibody Screening
    - I ABO Blood Group Determination
    - J Chimerism Analysis

  Attachment IIB to Appendix B of the UNOS Bylaws; UNOS Test Data Criteria for New HLA Laboratories ….Data

- **Histocompatibility Committee**

  This proposal revises the UNOS Bylaws and Policies that apply to histocompatibility laboratories to more closely align OPTN/UNOS requirements for member laboratories with current laboratory practices.

- **Affected Groups**
  Lab Directors/Supervisors
  PR/Public Education Staff
  General Public

- **Number of Potential Candidates Affected**
  All candidates and potential candidates.

- **Compliance with OPTN Strategic Goals and Final Rule**
  The suggested changes would improve patient safety, assure the best use of donated organs, help to achieve equitable organ allocation, maximize the number of donors, and improve operational effectiveness.

Revision of the UNOS Bylaws, the OPTN Bylaws and the OPTN Policies that Govern HLA Laboratories

Affected/Proposed Policy:

Attachment II to Appendix B of the UNOS Bylaws – Criteria for Histocompatibility Laboratory Designation

- Key Personnel Qualifications
- A.1. Director Credentials
- A2. Director Candidates
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Histocompatibility Committee

Summary and Goals of the Proposal:

UNOS staff has begun the process of consolidating, reorganizing, and simplifying the language of the OPTN Policies and OPTN and UNOS Bylaws. (These updates are not substantive in nature; they are not intended to change the meaning of the policyes and bylaws.) These changes to the language are scheduled to go out for public comment; the Bylaws in the winter of 2012 and the Policies in the summer of 2012.

The Histocompatibility Committee reviewed the documents from the Rewrite Project pertaining to histocompatibility (HLA) laboratories at their July 2011 meeting and identified several challenges. The Committee defined these areas as major defects that are not in line with current practice. The Committees voted to make these updates within the current UNOS Bylaws, the OPTN Bylaws and the OPTN Policies in an effort to improve the review process that will happen later next year within the Rewrite Project.

Background and Significance of the Proposal:

The UNOS bylaws, the OPTN Bylaws and the OPTN Policies that govern HLA laboratories are antiquated. Many of the required tests and methods are out of date and are no longer useful. These requirements should become more succinct and must reflect current lab practices.

In addition, HLA laboratories are not accredited or monitored directly by UNOS, but through agencies that have deemed status with UNOS (American Society of Histocompatibility and Immunogenetics-ASHI and College of American Pathologists -CAP). The Membership and Professional Standards Committee (MPSC) depends on the information given to it by ASHI and/or CAP to validate if UNOS standards are met. The MPSC is beginning to look into complaints pertaining to HLA laboratories. It must rely on the

data supplied by these agencies to make their determinations. Therefore, the contracts with these agencies must be up to date to protect the public.

The UNOS Plain Language Rewrite project is currently consolidating, reorganizing, and simplifying the language of the UNOS, and OPTN Policies and Bylaws. Substantive changes are not part of this phase of the project. The revised documents are scheduled to go out for public comment in 2012. The Committee examined the sections of the documents from the rewrite project that pertained to HLA labs at their July 2011 meeting. The Committee voted to make amendments to the existing requirements in an effort to improve the review process that will happen later next year within the Rewrite Project. They are as follows:

Current Language.

UNOS BYLAWS ATTACHMENT II TO APPENDIX B OF THE UNOS BYLAWS

I. Key Personnel Qualifications

A.1. Director Credentials

(i) The Director must be an MD, DO, or PhD in science, and must meet the qualifications of director of high complexity testing according to Federal CLIA requirements defined in 42CFR 493.1441.

(ii) In addition to A1 (i), at least two of the years of the Director's training and/or experience must be in histocompatibility testing in a OPTN/UNOS approved training program or three years experience under a qualified OPTN/UNOS Histocompatibility Director.

Proposed Revision

UNOS BYLAWS ATTACHMENT II TO APPENDIX B OF THE UNOS BYLAWS

I. Key Personnel Qualifications

(i) The Director must be an MD, DO, or PhD in science, and must meet the qualifications of 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.

. (ii) In addition to A1 (i), ~~at least two of the years of the Director's training and/or experience must be in histocompatibility testing in a OPTN/UNOS an approved training program or Three years experience~~ if the candidate is also the technical supervisor of the laboratory, they must have completed two years general immunology plus two years histocompatibility experience under a qualified OPTN/UNOS Histocompatibility Director doing histocompatibility testing for solid organ transplantation.

Committee Rationalfor Revision

These corrections must be made to be compliant with Federal CLIA requirements. It is also important to note that the OPTN/UNOS does not approve training programs.

Current Language

A2. Director Candidates

(ii) The director candidate must provide documentation of appropriate training and experience through submission of a portfolio of cases (see iii and iv, below) covered during the training in a OPTN/UNOS approved transplant center or must have certification by the American Board of Histocompatibility and Immunogenetics. Evidence of active laboratory involvement and interaction with transplant groups must also be documented and submitted.

Proposed Revision

(ii) The director candidate must provide documentation of appropriate training and

experience through submission of a portfolio of cases (see iii and iv, below) covered during the training in a OPTN/UNOS approved transplant center or must have certification by the American Board of Histocompatibility and Immunogenetics or other CMS approved board certification....

Committee Rational for Revision
This correction is important because it is now possible for a lab director to be qualified using other CMS approved certifications and there are currently several directors that do.

Current Language
B.1. Responsibilities of a Director of a Histocompatibility Laboratory
(i) Ensure that the laboratory facilities are adequate and safe from physical, chemical, and biological hazards.
(ii) Provide consultation to clients on test results.
(iii) Must be accessible to the laboratory to provide onsite, telephone or electronic consultation, as needed.
(iv) Ensure that an approved procedure manual is available to all technical personnel.
(v) Ensure and monitor that all delegated duties are properly performed.
(vi) Determine that a laboratory has a qualified general supervisor. is on-site for all routine testing.
(vii) Ensure…….

Proposed Revision
B.1. Responsibilities of a Director of a Histocompatibility Laboratory
(i) Ensure that the laboratory facilities are adequate and safe from physical, chemical, and biological hazards.
(ii) Provide consultation to clients on test results.
(iii) Must be accessible to the laboratory to provide onsite, telephone or electronic consultation, as needed.
(iv) Ensure that an approved procedure manual is available to all technical personnel.
(v) Ensure and monitor that all delegated duties are properly performed.
(vi) Determine that a laboratory has a qualified general supervisor. ~~is on-site for all routine testing.~~
(vii) Ensure…….

Committee Rational for Revision
The Committee said this bylaw was unrealistic and that no laboratory requires that the general lab supervisor be on site 24 hours a day, seven days a week.

Current Language
UNOS Bylaws Appendix B Attachment IIA - Standards for Histocompatibility Testing
C. Quality Assurance
C5.000 Proficiency Testing and Competency Evaluation
C5.300 The laboratory must test proficiency samples in a manner comparable to that for testing clinical samples.

Proposed Revision
UNOS Bylaws Appendix B Attachment IIA - Standards for Histocompatibility Testing
C. Quality Assurance
C5.000 Proficiency Testing and Competency Evaluation

C5.300 The laboratory must test proficiency samples in the same manner ~~comparable~~ to that for testing clinical samples.

Committee Rational for Revision
It is important that this bylaw be changed because this is a CLIA standard and must be adhered to by law.

Current Language
C9.000 Subcontracting
C9.100 A UNOS approved laboratory may engage another laboratory to perform testing by subcontracting the work to that laboratory. In that event, if histocompatibility and/or transplantation immunology testing is referred, the subcontracting laboratory must be CLIA certified/exempt and either UNOS approved or ASHI accredited for that testing…

Proposed Revision
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C9.100 A UNOS approved laboratory may engage another laboratory to perform testing by subcontracting the work to that laboratory. In that event, if histocompatibility and/or transplantation immunology testing is referred, the subcontracting laboratory must be CLIA certified/exempt and either UNOS approved or ASHI / CAP accredited for that testing…

Committee Rational for Revision
CAP also has deemed status with UNOS and currently there are several HLA laboratories that are CAP certified.

Current Language
F. Renal and Pancreas Organ Transplantation
F2.000 HLA Typing
F2.100 Prospective typing of donors and recipients for HLA-A, B, Bw4, Bw6, and DR antigens is mandatory.
F2.200 Prospective typing of donors and recipients for HLA-C, and DQ antigens and for DR51, DR52, DR53, is highly recommended.

Proposed Revision
~~F2.100 Prospective typing of donors and recipients for HLA-A, B, Bw4, Bw6, and DR antigens is mandatory.~~
~~F2.200 Prospective typing of donors and recipients for HLA-C, and DQ antigens and for DR51, DR52, DR53, is highly recommended~~
F.2.100 Prospective typing of deceased donors for HLA-A, B, C, Bw4, and Bw6, and DR, DR51, DR52, DR53 and DQ antigens is mandatory.
F2.200 Prospective typing of candidates of A, B, Bw4, Bw6 and DR is mandatory, and the typing of C, DR51, DR52, DR53, and DQ is highly recommended.

Committee Rational for Revision
This correction is important because OPTN policy requires that this level of typing be done. Prospective typing of deceased donors for these antigens is required by OPTN policies 3.5.9.1 (Essential Information for Kidney Offers) and 3.8.2.2 (Essential information for Pancreas Offers).

For kidney and pancreas candidates HLA antigen information (at lease 1A, 1B, and 1DR antigen) is required by OPTN policies 3.2.1.5 (Renal and Renal Pancreas Combination Candidate Listing) and 3.8.2.1 (Inclusion of HLA Data). This requirement does not apply to candidates listed for combined kidney-nonrenal transplantation, with the exception of kidney-pancreas transplantation.

Current Language

F3.000 Antibody Screening

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

Proposed Revision

F3.000 Antibody Screening

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

Committee Rational for Revision

This correction is important because OPTN Policy 3 Appendix D requires a contract between the laboratory and the transplant center and requires that this information be provided.

Current Language

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

Proposed Revision

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

Committee Rational for Revision

This correction is important because OPTN Policy 3 Appendix D requires a contract between the laboratory and the transplant center and requires that the schedule of collection times be specified within that document. It is also important that each transplant center may define that time period depending on their needs.

Current Language

ABO Blood Group Determination

I1.000 Laboratories performing ABO blood group determination, must use be performed by techniques compliant with Federal regulations.

Proposed Revision

I. ABO Blood Group Determination

I1.000 Laboratories performing ABO blood group determination, must use ~~be performed by~~ techniques compliant with Federal regulations.

Committee Rational for Revision

This change is important because not all HLA laboratories do ABO blood group determination.

Current Language

J Chimerism Analysis

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

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

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

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

J5.000 Analysis and Reports

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

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

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

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

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

Proposed Revision

~~**J Chimerism Analysis**~~

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

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Committee Rational for Revision

Chimerism testing is routinely used for blood and marrow transplantation. It is rarely used in solid organ transplantation (predominantly for suspected graft-versus-host disease, which is rare). Since it has never been routinely used for solid organ transplant, the subcommittee suggested removing it.

Current Language

Attachment IIB – UNOS Test Data Criteria for New HLA Laboratories and for the Addition of New Techniques

Data Submission

New Laboratories are required to submit procedures and test validation data for all categories and methods of testing unless such work is performed, without exception, by another approved laboratory… These materials are required to be submitted to an Agency with deemed status for the Accreditation of UNOS Laboratories, with a copy to the UNOS Histocompatibility committee.

Proposed Revision

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Committee Rational for Revision

This material is not shared with the committee at this time nor has it been in at least 5 years.

Collaboration:

The Committee will work with UNOS staff to accomplish the needed revisions.

Alternatives considered:

The only alternative would be to let the documents from the “Rewrite Project” go out as is next year. The Committee is afraid that if this happened, the resulting avalanche of negative comment would be unmanageable and mask the real effort to make the needed revisions.

Strengths and weaknesses:

The major weakness with this proposal is this effort, because of time constraints, is not a comprehensive rewrite of the histocompatibility requirements.

Description of intended and unintended consequences:

An unintended consequence may be that this proposal will call attention to the condition of the current bylaws and policies.

Expected Impact on Living Donors or Living Donation

Not applicable

Expected Impact on Specific Patient Populations:

Not applicable

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

The suggested changes would improve patient safety, assure the best use of donated organs, help to achieve equitable organ allocation, maximize the number of donors, and improve operational effectiveness.

HHS Program Goals	*Strategic Plan Goals*
Patient Safety	The OPTN will promote safe, high-quality care for transplant candidates, transplant recipients, and living donors
Best Use	To achieve the best use of donated organs, the OPTN will refine allocation policies by incorporating objective, measurable criteria related to concepts of donor risk/quality and recipient benefit
Equitable Access	To achieve equitable organ allocation, the OPTN will refine allocation policies to reduce geographic variation in waiting list deaths and access to transplantation
Maximum Capacity	The OPTN will support the HHS Program Goals and maximize the number of donors and transplants
Operational Effectiveness	The OPTN will identify process and system improvements that best support critical network functions, and work to disseminate them to all members who could benefit

Plan for Evaluating the Proposal: N/A

Additional Data Collection: N/A

Expected Implementation Plan: N/A

Communication and Education Plan: N/A

Policy or Bylaw Proposal:

UNOS Bylaws Appendix B Attachment IIA - Standards for Histocompatibility Testing

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UNOS Bylaws Appendix B Attachment IIA - Standards for Histocompatibility Testing
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