

At-a-Glance

Proposed Changes to the OPTN Bylaws Governing Histocompatibility Laboratories (Phase II)

- **Affected/Proposed Bylaws and Policies:** Bylaws Appendix C.1 (Histocompatibility Laboratory Compliance); Bylaws Appendix C.2 (Facilities and Resources); Bylaws Appendix C.3 (Histocompatibility Laboratory Key Personnel); Bylaws Appendix C.4 (Laboratory Coverage Plan); Bylaws Appendix C.5 (Changes in Key Laboratory Personnel); Bylaws Appendix C.6 Histocompatibility Laboratory Policies and Procedures; Bylaws Appendix C.7 (Histocompatibility Laboratory Testing Requirements); Policy 4.2 (Requirements for Laboratory Review of Reports); Policy 4.3 (Requirements for Waiting List Data Verification).

- **OPTN/UNOS Histocompatibility Committee**

This proposal represents the second phase of a comprehensive review of the OPTN Bylaws governing histocompatibility laboratories. This proposal contains numerous proposed changes, including a reference update to the requirement that histocompatibility laboratories maintain the standards of the American Society for Histocompatibility and Immunogenetics (ASHI) or the requirements listed in the College of American Pathologists (CAP) checklists as of a date certain, the addition of general supervisor to laboratory key personnel, modifications of education, certification, and experience requirements for laboratory key personnel, and new performance indicators that will trigger mandatory performance review of a laboratory.

- **Affected Groups**

Directors of Organ Procurement
Lab Directors/Supervisors
OPO Executive Directors
OPO Medical Directors
OPO Coordinators
Transplant Administrators
Transplant Data Coordinators
Transplant Physicians/Surgeons
PR/Public Education Staff
Transplant Program Directors
Transplant Social Workers
Organ Recipients
Organ Candidates
Living Donors
Donor Family Members
General Public

- **Number of Potential Candidates Affected**

Histocompatibility testing impacts all transplant candidates. This proposal intends to ensure that histocompatibility laboratories have adequate key personnel and resources to perform high quality histocompatibility testing for the transplant programs and OPOs they serve.

- **Compliance with OPTN Strategic Goals and Final Rule**

This proposal is expected to meet the OPTN Key Goals of increasing access to transplants and promoting the efficient management of the OPTN. The proposal will increase access to transplants by providing a layer of accountability in the event HLA typing errors occur and potentially reducing these typing errors in the future. To the extent that the proposal increases quality histocompatibility testing, it will also improve transplant patient safety. Furthermore, this proposal intends to rewrite the OPTN Bylaws in a manner that conveys clear membership standards for histocompatibility laboratories.

- **Specific Requests for Comment**

None.

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Histocompatibility Committee

Public comment response period: September 29, 2014 – December 5, 2014

Summary and Goals of the Proposal:

Histocompatibility laboratories (“laboratories”) are a vital component to proper organ allocation, acceptance, transplantation, and post-transplant care. Laboratories perform high complexity testing that assists transplant programs and OPOs in the allocation process and carries important implications for patient safety, post-transplant care, and survival. Accordingly, the OPTN has an interest in ensuring that laboratories have adequate facilities, equipment, and resources to perform high quality histocompatibility testing.

Many of the OPTN Bylaws governing laboratories are ambiguous, fail to reflect advances in technology and current clinical practice, or are more appropriately monitored by the histocompatibility accrediting agencies (ASHI and CAP). As a result, the OPTN/UNOS Histocompatibility Committee conducted a comprehensive review of the OPTN Bylaws governing histocompatibility laboratories. The Committee determined that rewriting the Bylaws was a large project and decided to split the rewrite into two phases. In November 2013, the Committee completed and the Board of Directors approved the first phase of changes in the Bylaws. This phase included changes that required all laboratories to comply with the requirements in the documents issued by ASHI and CAP (as of a date certain), expanded the definition of changes in key personnel, and required laboratories to submit a coverage plan to the OPTN. Those changes became effective February 1, 2014. The Committee is now proposing the following additional changes:

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

Background and Significance of the Proposal:

The OPTN Bylaws specify requirements for approval of membership in the OPTN. Histocompatibility laboratories must be approved by the Membership and Professional Standards Committee (MPSC) in order to perform testing for a transplant program or Organ Procurement Organization (OPO). A joint subcommittee comprised of members of the MPSC and the Histocompatibility Committee meet on a regular basis to review histocompatibility laboratory membership applications and requests for approval in laboratory key personnel. This joint subcommittee acts in an advisory role to the MPSC in the decision making process. In addition, the MPSC may request review of laboratories that have poor outcomes or are determined to be responsible for adverse patient safety events.

Over the past several years, it has become apparent to the Histocompatibility and Membership and Professional Standards Committees that the OPTN Bylaws governing histocompatibility laboratory membership are outdated and several key problems have been identified. Over the last two years, the Histocompatibility Committee has been conducting a comprehensive review of Appendix C and making recommended changes to the OPTN Board of Directors ('the Board'). In November 2013, the Board approved several new changes to the OPTN Bylaws governing histocompatibility laboratories pertaining to laboratory coverage. Those changes became effective February 1, 2014. The Committee has now turned its attention to the sections pertaining to the education and experience required for individuals in key laboratory personnel roles, along with performance indicators for testing performed and results reported to the OPTN. The Committee is collaborating with the American Society for Histocompatibility and Immunogenetics (ASHI) and the College for American Pathologists (CAP) on this project.

This proposal contains the following substantive changes:

- *C.1. Histocompatibility Laboratory Compliance*
As part of the approved Bylaws rewrite phase I proposal, laboratories are required to comply with the 2012 ASHI standards or 2012 CAP checklists. The Committee proposes to update the ASHI and CAP reference date to accurately reflect the most recent versions (2013 ASHI Standards and 2014 CAP checklists). The Committee decided on this update since the revisions contain no substantive changes and are not in conflict with the OPTN Bylaws.
- *C.3. Histocompatibility Laboratory Key Personnel*
The Committee proposes the addition of general supervisor to the list of key personnel and to modify all other relevant sections of the Bylaws (C.4 Laboratory Coverage Plan; C.5 Changes in Key Laboratory Personnel) to reflect the addition of general supervisor. The Committee reasoned it is important to consider the general supervisor position in cases where a laboratory director serves multiple laboratories and is not frequently on site to monitor testing.

The Committee proposes simplifying requirements for the technical supervisor, general supervisor, and clinical consultant by only requiring compliance with Clinical Laboratory Improvement Amendments (CLIA) requirements. The Committee decided to remove the list of responsibilities for those positions since the list is duplicative of CLIA requirements. Additionally, the Committee proposes eliminating references to the histocompatibility technician since the Bylaws do not have requirements for this group and current Bylaw language is only definitional.

- *C.3.A. Histocompatibility Laboratory Director*

The current OPTN Bylaws mirror the federal CLIA definition for a laboratory director even though this definition contains no requirement to have specific histocompatibility and immunogenetics experience. The OPTN only recognizes one primary laboratory director and that person directs the histocompatibility laboratory serving a transplant program or OPO. As a result, the Committee proposes a recognition of “Histocompatibility Laboratory Director” in the Bylaws. The education and experience required for the OPTN/UNOS histocompatibility laboratory director more closely mirrors what is required for the CLIA technical supervisor. This proposal would make the labels different between CLIA and the OPTN Bylaws, but there are no practical implications for individuals in these positions due to this change.

The Committee agreed on modifications that clarify two pathways for approval of laboratory directors- M.D./D.O. or through an earned doctoral degree. The changes in this section are meant to address several different problems identified by the Committee.

Within each pathway (which specifies the education, experience, and certification requirements that OPTN/UNOS histocompatibility laboratory directors must meet) the Committee has added language recognizing foreign equivalent education and experience. The current Bylaws are silent on the issue and this has led to qualified individuals not being approved as OPTN/UNOS histocompatibility laboratory directors. The Membership and Professional Standards Committee (MPSC), in consultation with the OPTN histocompatibility accrediting agencies (the American Society for Histocompatibility and Immunogenetics or ASHI and the College of American Pathologists or CAP), will make a final determination about whether the experience is considered equivalent to individuals in the United States. This process will mirror the process followed for determining foreign equivalent education and experience for primary transplant physicians and surgeons.

The Committee was concerned that the current requirement that individuals with an M.D. or D.O. have a license to practice medicine in the state where the laboratory is located prevents qualified individuals from becoming histocompatibility laboratory directors, even if they have the appropriate experience and credentials in histocompatibility and immunogenetics. The Committee recognized that this is a requirement in the federal CLIA regulations, but those regulations also allow for an earned doctoral degree pathway that the current OPTN/UNOS Bylaws do not. Therefore, the Committee is proposing that individuals with an M.D. or D.O. that do not have a license to practice medicine in the state where the laboratory is located have the opportunity to qualify through the earned doctoral degree pathway.

The Committee presented these recommendations to the American Society for Histocompatibility and Immunogenetics (ASHI) Board of Directors prior to releasing them for public comment. Several members of the ASHI Board requested that the Committee consider amending the proposal to allow for certain pre-doctoral experience to qualify for laboratory directors. This request was intended to capture individuals who have extensive pre-doctoral experience in the laboratory (for example, a general supervisor) and should have the opportunity to have that experience recognized if being considered for the laboratory director position. The Committee agreed and is proposing that appropriate pre-doctoral experience qualify. In addition, members of the ASHI Board were concerned that the laboratory director qualification requiring certification in pathology under the M.D./D.O. pathway was too limiting and suggested the inclusion of additional medical specialties. ASHI Board members were concerned because many of the other medical specialties do

not have expertise in laboratory medicine or clinical pathology, and anatomical pathology by itself is not adequate preparation. The Committee agreed and proposes certification in “anatomic and clinical or clinical pathology.” The Committee further indicates medical specialty concerns are adequately addressed pursuant to the second, earned doctoral degree, pathway.

The Committee also proposes that individuals who have not served as a laboratory director or clinical consultant at an OPTN laboratory in the five years prior to the date of application submit additional documentation for the MPSC to consider in the approval process. This is to address the concern that these individuals may not have appropriate experience in the latest histocompatibility technologies and techniques.

- *C.6. Histocompatibility Laboratory Policies and Procedures*

The Committee is proposing additional performance criteria for mandatory reviews of histocompatibility laboratories, most significantly review of laboratories that make HLA typing errors that result in an incompatible transplant or re-allocation of an organ to an individual other than the intended recipient. The Committee reviews quarterly HLA typing discrepancies flagged on match runs and donor and recipient histocompatibility forms. The data suggests that these allocation errors do occur, although they are rare. If such an error is discovered during the quarterly review, the Committee will refer the error to the MPSC for further investigation. The MPSC will make the final determination of what action is most appropriate.

In addition to this change, the section specifying requirements for proficiency testing was reorganized for clarity and to accurately reflect histocompatibility accrediting agency requirements. No substantive changes are being proposed to proficiency testing requirements.

- *C.7. Histocompatibility Laboratory Testing Requirements*

The Committee recommends deleting a number of sections because they are either out of date or more appropriately monitored by the histocompatibility accrediting agencies. However, the Committee intends to move Waitlist Data Verification and language on reviewing reports from Bylaws to OPTN Policy 4.2 (Requirements for Laboratory Review of Reports) and 4.3 (Requirements for Waiting List Data Verification). These requirements have not changed.

The Committee restructured sections that pertain to submission requirements for laboratories using new techniques by drafting language that more closely mirrors ASHI requirements and requires a laboratory director review of twenty cases.

These substantive changes are accompanied with further changes that are characterized as either stylistic, noncontroversial, or to improve the Bylaws readability.

Expected Impact on Living Donors or Living Donation:

Living donors are typed by histocompatibility laboratories and crossmatches are performed for both deceased and living donor transplants; therefore, this proposal has the potential to affect living donor organs.

Expected Impact on Specific Patient Populations:

Histocompatibility testing is important for all organ transplant candidates. To the extent that this proposal improves accuracy in HLA typing, it will particularly benefit sensitized patients.

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

This proposal will further the OPTN Goals of promoting transplant safety and efficient management of the OPTN. The proposal will promote transplant safety by requiring histocompatibility laboratories to accurately determine and report HLA typing, resolve HLA typing discrepancies in a timely manner, and provide a layer of accountability by DEQ and MPSC review. The proposal promotes the efficient management of the OPTN by clarifying Bylaws governing histocompatibility and eliminating Bylaws that are outdated or adequately addressed by the histocompatibility accrediting agencies. The proposal will increase access to transplants by providing a layer of accountability in the event HLA typing errors occur and potentially reducing these typing errors in the future.

Plan for Evaluating the Proposal:

The Bylaw requirement is intended to work in conjunction with Policy 4.2 which requires the Histocompatibility Committee to review at least every three months, any outstanding discrepant typing recorded since the last review. This review includes detailed discrepancies on HLA used for match runs.

The Histocompatibility Committee will evaluate this proposal 1 and 2 years post implementation by comparing percentage of HLA discrepancies prior and post implementation. The Committee's hypothesis is that increased quality of histocompatibility testing will result in decreased percentages of HLA discrepancies.

Additional Data Collection:

The addition of general supervisor position to the list of key personnel will result in the following additional data collection:

- The OPTN Contractor will send an initial survey to collect information on the individual who will be named the primary general supervisor.
- Data collection will occur anytime a new laboratory applies or there is a change in primary general supervisor.

These data will be collected to determine if the laboratories are complying with the requirements of Membership.

Expected Implementation Plan:

If public comment is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015 and will go into effect on September 1, 2015. The addition of general supervisor(s) as key personnel will require IT programming; therefore, the implementation of that section will be delayed until programming is complete.

Communication and Education Plan:

The following communication and education activities will help notify members of the clarified Bylaws language:

- Policy notice
- Presentation at Regional Meetings

Compliance Monitoring:

The OPTN Contractor will perform the following:

- Conduct a survey of all histocompatibility laboratories to verify which individuals in their laboratory meet the new definition of primary general supervisor
- Monitor the occurrence of HLA typing discrepancies

Policy or Bylaw Proposal:

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

Appendix C: Membership Requirements for Histocompatibility Laboratories

C.1 Histocompatibility Laboratory Compliance

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

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

C.2 Facilities and Resources

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

A. Facilities

The laboratory must have:

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

B. Records Access

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

C. Transplant Program Affiliation

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

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

Candidate Blood Type Determination and Reporting before Waiting List Registration.

17. If post-transplant monitoring is performed, then a protocol for monitoring antibody levels.

D. OPO Affiliation

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

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

C.3 Histocompatibility Laboratory Key Personnel

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

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

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

A. Histocompatibility Laboratory Director

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

Laboratory Director Qualifications

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

1. Pathway 1 :

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

2. Pathway 2:

- Have a doctoral degree in a medical, chemical, physical, biological, or clinical laboratory science from an accredited institution, or equivalent degree from another country
- Be certified as a Diplomate by the American Board of Histocompatibility and Immunogenetics, a high complexity laboratory director by the American Board of Bioanalysis, or a Diplomate by the American Board of Medical Laboratory Immunology
- Have at least two years full-time, post-doctoral experience or four years pre-doctoral experience in immunology, histocompatibility, or immunogenetics, and two years post-doctoral training in directing or supervising clinical histocompatibility testing for solid organ transplantation

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

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

Laboratory Director Candidate Requirements

Any professional being considered for the position of histocompatibility laboratory director who has not served in the role of laboratory director or clinical consultant at an approved OPTN histocompatibility laboratory within five years prior to the date of application must also provide ~~one~~ all of the following:

- ~~Proof of certification by the American Board of Histocompatibility and Immunogenetics.~~
 - A portfolio of 50 cases, covered during the five years prior to the date of application, that demonstrates the professional's analytical skills, ability to recognize and resolve testing and interpretation issues, and instances when the applicant made recommendations for additional testing or clinical care.
 - Proof of active ~~laboratory~~ interaction with transplant professionals.
 - A letter from the applicant that describes all experience in immunology and clinical histocompatibility testing, including A a summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks performed.
 - A current curriculum vitae or resume.
 - ~~Demonstrated knowledge of the fundamentals of immunology, genetics, and histocompatibility testing and this knowledge should be reflected by participation in~~ transplant or clinical laboratory professional conferences and publications in peer-reviewed journals. ~~An American Board of Histocompatibility and Immunogenetics Diplomate (ABHI-D) certification is highly recommended.~~
3. ~~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:~~

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

Laboratory Director Responsibilities

A histocompatibility laboratory director has the following responsibilities:

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

B. Technical Supervisor Qualifications and Responsibilities

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

A technical supervisor has the following responsibilities:

1. ~~Select appropriate test methodologies.~~
2. ~~Establish performance criteria, validation, and quality control for all tests.~~
3. ~~Ensure proficiency testing is performed properly and reviewed with staff.~~
4. ~~Ensure that technical problems are resolved and corrective action is taken when appropriate.~~

- ~~5. Ensure that test reports are issued only when test systems are functioning properly.~~
- ~~6. Identify training needs and provide in-service training as needed.~~
- ~~7. Evaluate staff competency and performance.~~

C. General Supervisor

A general supervisor must meet the qualifications for a general supervisor as defined by Clinical Laboratory Improvement Amendments (CLIA) 42 CFR 493 and have at least three years experience in human histocompatibility or transplant immunology testing under the supervision of a qualified histocompatibility laboratory director or technical supervisor.

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

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

D. Histocompatibility Technologist Qualifications

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

E. Histocompatibility Technician Qualifications

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

FE. Clinical Consultant Qualifications and Responsibilities

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

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

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

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

GF. Competency Testing and Continuing Education of Staff

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

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

C.4 Laboratory Coverage Plan

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

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

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

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

C.5 Changes in Key Laboratory Personnel

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

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

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

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

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

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

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

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

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

C.6 Histocompatibility Laboratory Policies and Procedures

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

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

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

- Failure to comply with the requirements and regulations according to C.1. *Histocompatibility Laboratory Compliance*.
- Any of the following performance indicators on external proficiency testing:

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

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

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

B. Information Required from Laboratories with Unsatisfactory Performance

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

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

C. Periodic Reviews

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

D. Regulatory Agency Adverse Actions

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

E. Inactive Status

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

C.7 Histocompatibility Laboratory Testing Requirements

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

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

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

~~A. Handling of Specimens~~

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

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

~~B. Handling of Reagents~~

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

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

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

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

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

C. Testing Standards

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

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

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

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

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

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

Proficiency Testing and Competency Evaluation

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

~~semi-annually for each analyte. The laboratory must test proficiency samples in the same manner as that for testing clinical samples.~~

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

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

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

~~D. Quality Assurance~~

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

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

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

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

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

~~E. Procedure Manual~~

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

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

F. ~~Records and Test Reports~~

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

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

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

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

~~All test reports must contain:~~

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

~~Reports must be reviewed by the Director, or Technical Supervisor, or a staff member who meets at least the minimum requirements of a General Supervisor~~

~~prior to release. All deceased donor HLA typing or crossmatch reports must be reviewed during the next day of regular laboratory operation.~~

Waiting List Data Verification

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

G. Service Requirements

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

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

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

HA. Subcontracting

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

- ~~1. CLIA certified or unless exempt under federal law.~~
- ~~2. OPTN-approved, ASHI accredited, or CAP accredited for that testing.~~

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

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

B. Submission Requirements for New Laboratories

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

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

C. Submission Requirements for Laboratories Using New Techniques

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

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

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

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

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

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

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

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

OPTN Policies

4.2 Requirements for Laboratory Review of Reports

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

4.3 Requirements for Waiting List Data Verification

All histocompatibility laboratories must review and verify the waiting list histocompatibility data for every patient whose test results the laboratory completed. Documentation of 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.

4.24 Resolving Discrepant Donor and Recipient HLA Typing Results

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