

OPTN/UNOS Histocompatibility Committee
Meeting Summary
June 3, 2014
Conference Call

Lee Ann Baxter-Lowe, Ph.D., Chair
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Discussions of the full committee on June 3, 2014 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov>.

Committee Projects

1. Histocompatibility Bylaws Rewrite Phase II

The Histocompatibility Committee (the "Committee") met to review Bylaws Rewrite Phase II recommendations from the Bylaws Rewrite Subcommittee. The Committee expects to finalize a draft by mid-June for presentation to the ASHI Board of Directors and intends to hold a meeting in late June to vote on a final proposal to release for public comment. UNOS staff reviewed the entire Bylaws Rewrite Phase II draft with the Committee, accentuating substantive changes recommended by the Bylaws Rewrite Subcommittee, which were drafted during the subcommittee's April 29, May 16, and May 29 conference calls:

- *C.3. Histocompatibility Laboratory Key Personnel*

The Committee accepted a recommendation from the subcommittee to add general supervisor to the list of key personnel. All other necessary sections of the Bylaws were changed to reflect the addition of general supervisor.

The Committee proposes simplifying requirements for the technical supervisor, general supervisor, and clinical consultant by only requiring compliance with 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. Laboratory Director Qualifications*

The Committee agreed with modifications that clarify two education pathways for approval of laboratory directors- M.D./D.O. or Ph.D. For each pathway, the Committee accepted language that would specify education, experience, and licensing requirements.

Currently, no pathway exists for foreign equivalent education and experience in the Bylaws for laboratory directors. The Committee accepted the subcommittee's recommendation to permit a foreign equivalent education and experience pathway. Individuals with foreign education are subject to having their credentials reviewed by the MPSC in consultation with the histocompatibility accrediting agencies.

The Committee also proposes additional requirements for laboratory directors who have not served as a laboratory director five years prior to the date of application.

- C.6. Histocompatibility Laboratory Policies and Procedures
The Committee developed additional performance indicators for laboratories. The new performance indicators require review of laboratories that make HLA typing errors which result in an incompatible transplant or causes a re-allocation of the organ to an individual other than the intended recipient. In addition, this section was reorganized for clarity and to accurately reflect accrediting agency requirements.
- C.7. Histocompatibility Laboratory Testing Requirements, A-J
The Committee is in agreement with the subcommittee to delete a number of sections because they are either out of date or more appropriately monitored by the accrediting agencies. However, the Committee intends to move Waitlist Data Verification and language on reviewing reports from Bylaws to OPTN Policy, reasoning the content is more appropriate for policy.
- C.7.J. Submission Requirements for Laboratories Using New Techniques
Committee members discussed the ASHI standards for submission requirements for laboratories using new techniques. The Committee restructured this section and drafted language based on the ASHI requirements. A majority of members were concerned with only requiring a director review of five cases; therefore, the Committee decided to increase this number to twenty.

2. Expanding Candidate and Deceased Donor HLA Typing Requirements to Provide Greater Consistency Across Organ Types

The Committee reviewed an updated dropdown list for DQA and DPB based on the Committee's discussion in December 2013. The list includes all of the currently named alleles for each of the loci. The Committee agreed to accept the dropdown list as proposed.

Review of Public Comment Proposals

3. OPTN Kidney Paired Donation (KPD) Histocompatibility Testing Policies

The Committee considered this proposal during its meeting, and after brief discussion there was no opposition.

Upcoming Meeting(s)

- The Committee will meet in-person on August 11-12, 2014, in Chicago, Illinois.