

OPTN/UNOS Histocompatibility Committee
Meeting Summary
January 21, 2015
Conference Call

Dolly Tyan, Ph.D., Chair
Robert Bray, Ph.D., Vice Chair

Discussions of the full committee on January 21, 2015 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. Bylaws Rewrite Phase II

The Histocompatibility Committee (the "Committee") held a conference call to review and discuss public comment feedback on the Bylaws Rewrite Phase II proposal. A brief overview of the proposal was presented to the Committee, and UNOS staff explained limitations for post-public comment changes. Next, the Committee discussed the public comments provided from the regions, professional societies, committees, and individuals.

In response to questions surrounding the addition of the general supervisor, the Committee explained that the intent of adding the general supervisor was to extend the requirement for the laboratory accrediting agencies (currently, ASHI and CAP) to notify UNOS when changes in the general supervisor occur. CLIA requires the general supervisor to be a key personnel position; this addition in the bylaws merely places the general supervisor position under the purview of UNOS. The general supervisor plays a key role in the onsite monitoring of testing, especially when the laboratory director is not onsite day to day. Data indicates there are 154 laboratories (most with their own director) but of those, 27 of the directors are directing more than one laboratory. Also, the Committee agreed the addition of the general supervisor is not burdensome. This will only require approximately six additional questions to the general supervisor application.

The Committee agrees there should be a pathway for laboratory directors who were approved and served as directors prior to the 2003 requirement for their board certification to have that requirement waived. This is a CLIA based clause and requires waiving board certification for individuals already operating as a laboratory director prior to 2003. The Committee will draft language to include this group of individuals.

Some commenters were concerned that the requirement that laboratory directors have publications in (greater than one) peer-reviewed journals is too stringent. The majority of the Committee agreed with this recommendation and will remove the corresponding language.

In addition, there was concern that the proficiency testing performance review criteria is too excessive since the words "satisfactory" and "unsatisfactory" apply to individual send-outs. The Committee was divided on this issue and will revisit this section in March for a final Committee vote.

Upcoming Meetings

- The full Histocompatibility Committee will meet by teleconference on February 18, 2015, from 2:00PM-3:00PM EST
- The full Histocompatibility Committee will meet in-person on March 30, 2015, in Chicago, IL.