

**OPTN/UNOS Histocompatibility Committee**  
**Meeting Summary**  
**June 26, 2014**  
**Conference Call**

**Lee Ann Baxter-Lowe, Ph.D., Chair**  
**Dolly Tyan, Ph.D., Vice Chair**

*Discussions of the full committee on June 26, 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**

In early June, the Committee reviewed Bylaws Rewrite Phase II recommendations from the Bylaws Rewrite Subcommittee and endorsed a draft for the American Society for Histocompatibility and Immunogenetics (ASHI) to evaluate. A conference call was scheduled with ASHI's Board of Directors in mid-June to discuss their evaluation of the proposal. UNOS staff communicated ASHI's comments to the Committee for any necessary changes to the Bylaws and in anticipation of a final vote to release the proposal for fall public comment.

UNOS staff reminded the Committee that as part of the approved Bylaws Rewrite Phase I proposal, there is a requirement for laboratories to comply with the 2012 ASHI Standards or 2012 CAP checklists. Based on UNOS staff recommendations, the Committee proposed to update the ASHI and CAP reference dates to accurately reflect the most recent versions (2013 ASHI Standards and 2014 CAP checklists).

ASHI's Board of Directors was concerned the laboratory director qualification requiring certification in pathology under the first, M.D. or D.O., pathway was too limiting and suggested including additional medical specialties. UNOS staff relayed this concern to the Committee; however, the Committee explained that ASHI's recommendations are covered in the proposed Bylaws pursuant to the second, doctoral degree, pathway.

ASHI's Board of Directors also asked the Committee to consider adding a clause allowing pre-doctoral experience as a qualifier under the second pathway for individuals applying as a histocompatibility laboratory director (current ASHI standards allow for individuals with certain pre-doctoral experience to qualify). Members of the ASHI Board requested that the Committee consider a pre-doctoral pathway to allow for individuals with experience as general supervisors to get credit for this experience. Committee members agreed with this approach and decided to add "four years pre-doctoral experience" in immunology, histocompatibility, or immunogenetics:

- 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.

In addition to addressing the two issues identified by ASHI, the Committee made a few edits characterized as stylistic to improve the Bylaws readability.

After discussion on the Bylaws Rewrite Phase II proposal ceased, UNOS staff conducted a voice vote on the proposal. The Committee unanimously voted to recommend to the Executive Committee that the proposal be distributed for fall 2014 public comment.

## **Other Significant Items**

### **2. Update from the June 2014 Board of Directors Meeting**

UNOS staff provided an update on the June 2014 Board of Directors meeting. The Board approved the Histocompatibility Policy Rewrite Proposal (38-1-0). There was minimal discussion. The majority of the proposal becomes effective September 1, 2014, while a change requiring laboratories to resolve discrepancies within 30 days will become effective with IT programming. The Committee also presented an update to the Board on the Bylaws Rewrite Phase II proposal and Expanding Consistency in HLA Typing Requirements Across Organ Types proposal. The update presentation primarily focused on showing new DPB and DQA data. Overall, the Board commended the Committee's due diligence in presenting compelling data supporting the benefits of adding those fields; however, the Board is still concerned with the IT estimate presented last June.

UNOS staff also updated the Committee on the Executive Committee's vote to propose changes to the Bylaws which will result in creating two additional tracks for policy development process. These changes will be distributed for fall 2014 public comment. The first change, known as the "emergency track" would be utilized for emergency situations (e.g. public health issue) when the Board needs to act prior to public comment. The second track, known as the "expedited track" would be used for routine policy and bylaws changes that update allocation algorithms and other issues that are thought to be non-controversial. UNOS staff explained that this proposed new expedited track may be appropriate for the Histocompatibility Bylaws that reference ASHI and CAP documents and for updating the donor cohort used in the CPRA algorithm.

After an explanation of the proposed policy tracks, UNOS staff explained a new OPTN development calendar that will be implemented in 2015. The new calendar will schedule Board meetings in June and December and will allow the Board to be more responsive to policy changes that are needed. The Committee commented very favorably on this approach.

## **Upcoming Meeting(s)**

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