OPTN/UNOS Histocompatibility Committee Meeting Minutes May 9, 2017 Conference Call

Robert Bray, PhD, D(ABHI), Chair Cathi Murphey, PhD, HCLD/CC(ABB), Vice Chair

Introduction

The Histocompatibility Committee (the Committee) met via Citrix GoToTraining teleconference on 05/09/2017 to discuss the following agenda items:

- 1. Membership and Professional Standards Committee (MPSC) Key Personnel Memo
- 2. Review of HLA Tables (2016)
- 3. Expedited Action Pathway

The following is a summary of the Committee's discussions.

1. Membership and Professional Standards Committee (MPSC) Key Personnel Memo

The MPSC sent a memo to Histocompatibility Committee leadership about the current key personnel requirements for histocompatibility lab directors.

Summary of discussion:

Committee leadership recapped an earlier discussion with the MPSC about the contents of the memo. During this discussion, the MPSC suggested that the Committee consider making changes to the current Bylaws language surrounding requirements for lab directors. Since some lab directors serve as director at more than one lab, the MPSC is looking for the Committee to provide more specific parameters for certain lab director responsibilities, such as how much time is considered satisfactory for a director to be on-site at a laboratory. While Committee leadership expressed that this would be a difficult and complicated task, they agreed with the MPSC that it was important. A Committee member asked if there was a specific reason the MPSC was requesting the Committee take up this issue now. UNOS staff clarified that there were recent discussions between the MPSC and an MPSC workgroup over whether or not to accept certain lab director applications if the lab director was the director of more than one lab and consequently may not have enough time to serve as director of an additional lab as outlined in their application.

The Committee began to brainstorm some ideas for how to quantify the amount of time a lab director needs to be on site. One suggestion was providing documentation about how a lab director stays involved with the work at the lab. Since the American Society for Histocompatibility and Immunogenetics (ASHI) has a checklist they use during lab inspections that includes questions about lab director engagement, the Committee considered using that as a reference or template for this effort. Several Committee members expressed that it will be difficult to come up with a list that would apply to all types of labs. For instance, the volume of transplants a lab is involved in varies greatly across labs. Some labs may also only be affiliated with one transplant center while others may serve several centers in different capacities. The Committee concluded that while ASHI may not collect specific data on what would qualify as enough time for a lab director to spend at a lab, they do ask for documentation on certain areas that may be informative as the Committee considers this MPSC request, such as documentation of how often a lab director is on-site, how often the lab director stays in contact with clinicians,

and how often the lab director reviews and signs cases. As several Committee members mentioned, lab inspectors make value judgments based on lots of information.

Next steps:

Committee leadership would like to discuss this matter more at future meetings and create a subcommittee that can dedicate more time to potential project specifics. Committee members interested in participating in this subcommittee can contact the Committee liaison.

2. Review of HLA Tables (2016)

The DPB1/Annual Equivalency Table Review Subcommittees continue to work on the next set of equivalency table updates, with the goal to send them out for public comment in July 2017.

Summary of discussion:

The Committee heard a status update on the next equivalency table updates from Committee leadership. The Committee liaison expressed that these tables would be voted on by the full Committee at the June meeting instead of on this call as projected in order to give the Subcommittee and UNOS staff more time to review the tables.

Next steps:

The Committee will vote on the equivalency updates at the June 13, 2017, meeting.

3. Expedited Action Pathway

The Committee liaison gave a presentation to the Committee on OPTN Bylaw 8.11: Expedited Actions. At previous meetings, Committee members expressed frustrations with length of time between providing updates to the equivalency tables and when these updates are implemented. Since the equivalency tables are part of OPTN policy (Policy 4.10: Reference Tables of HLA Antigen Values and Split Equivalences), any updates to the tables follow the traditional policy development process. The Committee liaison outlined a potential pathway for getting some of these updates into policy with the expedited action pathway. Some options for utilizing this pathway would be for the more "standard" updates to the equivalency tables – for example, the updates to the testing kits that may include different antigens. A Committee member commented that updates to the equivalency tables are based on the Committee's scientific understanding of HLA alleles and newly discovered alleles.

Upcoming Meeting

• June 13, 2017

Attendance

• Committee Members

- o Robert Bray
- Laurine Bow
- Cathy Gebhart
- o Steve Geier
- o Sam Ho
- o Peter Lalli
- o John Lunz
- o Allen Norin
- o Rajalingam Raja
- o Carley Shaut
- Kurt Shutterly
- o Dolly Tyan
- o Gabriella Wheeler

• HRSA Representatives

- o James Bowman
- o Raelene Skerda

SRTR Staff

Katie Audette

• OPTN/UNOS Staff

- Alison Wilhelm
- o Jason Chicirda
- o Emily Kneipp
- Anna Kucheryavaya