Summary
Histocompatibility Committee Meeting
January 8, 2013
12:00-1:00pm ET
Conference Call

Participants:

- Committee: Lee Ann Baxter-Lowe PhD,D (ABHI), Dolly Tyan PhD, D(ABHI), Nancy Reinsmoen PhD, D(ABHI), Julie Houp, Neng Yu MD, Robert Bray PhD, D (ABHI), Cathi Murphey PhD, Ellen Klohe PhD, A. Bradley Eisenbrey MD PhD, David Kiger CHS CHT, Luis Campos MD, Laine Krisiunas MBA, Manish Gandhi MD, Rex Friedlander, Sara Dionne, PhD, Manish Gandhi, MD, Raelene Skerda RPh BPharm, and Karen Near, MD
- OPTN: Gena Boyle, Anna Kucheryavaya, Elizabeth Miller, Sally Aungier
- SRTR: Susan Leppke

Summary:

The OPTN/UNOS Histocompatibility Committee ('the committee') met via Live Meeting on January 8, 2013 to review and vote on two remaining recommendations from the committee's Bylaws Rewrite Subcommittee ('the subcommittee) to be released for public comment in Spring 2013.

The committee voted 0-Support, 9-Support as Amended, 0-Oppose, 0-Abstain to send the following changes to Appendix C: Membership Requirements for Histocompatibility Laboratories out for public comment in Spring 2013:

- C.5 *Changes in Key Laboratory Personnel*
  The committee adopted new requirements for the notification deadline and documentation required when there is a change in key laboratory personnel and to include the general supervisor in the list of key personnel changes that must be reported. This new language defines a change in key personnel as any of the following:

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

  The current bylaws require histocompatibility laboratories to notify the OPTN Contractor within 30 days of the departure date of a change in laboratory director, technical supervisor, or clinical consultant. Members of the subcommittee explained that this change is due to the fact that a substantial number of laboratories have failed to notify the OPTN Contractor, and this has delayed the MPSC's decisions regarding approvals of changes in key personnel (e.g. a lack of information about coverage at the laboratory

and qualifications of new or acting key personnel). Accordingly, the committee is adopted the following new requirements for changes in key personnel:

- If the departure of a laboratory director, technical supervisor, clinical consultant, or general supervisor is planned, then the laboratory must notify the OPTN Contractor within seven business days of becoming aware of the change and submit a Completed Personnel Change Application and an updated Laboratory Coverage Plan no less than 30 days before the end of the individual's active employment.

- If there is an emergency or unplanned departure (the laboratory receives less than 60 days notice of the change), then the laboratory must notify the OPTN Contractor within seven business days of becoming aware of the change and submit a Completed Personnel Change Application and updated Laboratory Coverage Plan within 30 days of the date of departure.

The committee also adopted language to specify that the MPSC and/or OPTN Board of Directors will take disciplinary action if a histocompatibility laboratory fails to notify the OPTN Contractor of a change in key personnel. Members of the subcommittee explained that they used Appendix D.6.E. *Failure to Notify the OPTN Contractor of Key Personnel Changes* in the OPTN bylaws as a model for the change.

- C.6 *Histocompatibility Laboratory Policies and Procedures*
  The committee adopted an additional, elevated performance standard for HLA typing on graded proficiency testing results. Members of the subcommittee explained that this new requirement will mandate that histocompatibility laboratories achieve 90% accuracy on every antigen (not analyte) reported for HLA typing on graded proficiency testing within a calendar year. Histocompatibility laboratories will still be required to achieve 80% successful proficiency testing on all other graded results, except for ABO testing which requires a 100%. Members of the subcommittee explained this requirement is intended to address the committee's increasing concern over inaccuracies in HLA typing. The subcommittee chair explained that the members considered the alternative of requiring a mandatory performance review for a defined number of discrepancies listed on the Histocompatibility Forms submitted in UNet. However, there was concern about how discrepancies are currently defined on these forms. Ultimately, the committee decided that proficiency testing is currently the best way to currently measure laboratory performance for HLA typing and is suggesting that laboratories be held to a higher standard on the HLA typing portion of the proficiency test.

The Committee adjourned at 1:00pm ET.