

**OPTN/UNOS Histocompatibility Committee
Meeting Minutes
April 11, 2017
Conference Call**

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Introduction

The Histocompatibility Committee (the Committee) met via Citrix GoToTraining teleconference on 04/11/2017 to discuss the following agenda items:

1. Guidance Document Public Comments

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

1. Guidance Document Public Comments

The Histocompatibility Bylaws and Policies Guidance Document went out for public comment from January 23, 2017-March 24, 2017. The Committee made minor changes based on comments received before their last meeting on March 21, 2017, and considered the remaining comments at this meeting.

Summary of discussion:

- The Committee choose to make several minor changes to the guidance document after public comment. Most changes were one word clarifications. Throughout the development of this guidance document, the Committee carefully considered the language as to not be too prescriptive or imply that recommendations should be considered for policy changes in the future. The Committee continued to consider word choice as they incorporated post public comment changes.

The proposal received overwhelming support from each region. The American Society of Transplantation (AST) supported the information included in the guidance document, but wanted to be sure that the guidance document is used as guidelines and not regulations. The Committee created the guidance document to provide the community with suggested practices, and supports AST's comments that the guidance document should only serve as guidelines and is not intended to be a regulatory document. The American Society of Transplant Surgeons (ASTS) supported the proposal as written.

Comments received from ASHI were considered in detail by the Committee. Some of ASHI's suggested changes were mentioned in other public comments as well; the Committee made changes to several sections that were addressed in multiple public comments. The Committee chose to exclude some suggested revisions that were too content specific or would require frequent updates in the future. Other clarifications were made in response to ASHI's comments, which are documented in more detail below.

- The Committee considered all comments and chose to make the following clarifications:

- **Table 1: Sensitization History for Bylaw C.2.C Compliance:**
 - The Committee softened one of the column titles from "Consideration" to "Consideration, if available." Concern that the considerations listed would imply that the information would be available for every patient caused the Committee to clarify that this information should be considered only if available for the individual patient.

- In response to one public comment, the Committee decided to add “composite tissue allografts” to the list of possible previous grafts. This addition will make the list of possible previous grafts more comprehensive.
- **C.2.C #11: The criteria for crossmatching**
 - The Committee considered the recommendation from one public comment and reworded the language under the first point of this section, removing “should” and putting “it is recommended that” before the statement about when to perform a physical crossmatch if it cannot be completed before the transplant:
 1. In kidney transplantation, there may be cases when it is better to proceed with the transplant before a physical crossmatch can be completed. If, after careful consideration, a pre-transplant physical crossmatch cannot be completed, then it is recommended that the laboratory should perform the physical crossmatch concurrently with the transplant or retrospectively to guide post-transplant care.
- **Table 3: Assays to Identify Antibody to HLA: Screening, Specificity, or Crossmatching**
 - The Committee clarified that Enzyme-Linked Immuno Sorbent Assay (ELISA) is a solid phase assay. After consideration about the sensitivity of listed tests, the Committee removed “more sensitive” from one of the sections.
- **C.2.C #12: The assay format that will be used for antibody screening and for crossmatching**
 - The Committee changed the wording in this section from “several sera” to “multiple sera” to clarify that the number of sera could be two or more instead of three or more.
- **Virtual Crossmatching**
 - The Committee softened the language under the second point in this section by replacing “should” with “it is recommended.”
- **4.7 Blood Type Determination**
 - The Committee added to this section in order to clarify that it referred to laboratories that perform ABO subtyping.
- **4.8 Preservation of Excess Specimens**
 - In order to emphasize that this document is meant for guidance, the Committee softened language in this section to replace “it would be appropriate” with “it would be beneficial.” The Committee also changed “donor tissue” to “donor material” to broaden the recommendation.

- The Committee voted to approve the changes made to the guidance document post-public comment and send it to the Board for consideration at the June 5-6, 2017 Board Meeting (14 yes; 0 no; 0 abstained)

Next steps:

-The Guidance Document briefing paper will be prepared for the June Board Meeting by the Committee Liaison.

Upcoming Meeting

- May 9, 2017