

**Interim Report**  
**OPTN/UNOS HISTOCOMPATABILITY COMMITTEE**

**Teleconference**  
**January 25, 2012**  
**1:00-2:00 (EDT)**

**Discussion about the structure of Histo standards:** Brian Shepard, Assistant Executive Director of Contract Operations, spoke to the Committee about how the rewritten OPTN Bylaws and the Policies that govern HLA laboratories should be structured. He said that the OPTN must have its own standards; mainly because the OPTN requires a structured approval process which includes public comment and approval by the Board. He said if UNOS were to adopt the standards of another organization, it would put UNOS in the position where a key standard could change that has not gone through this process.

Committee members voiced the opinion that instead of “reinventing the wheel,” there should be a way to incorporate the ASHI and CAP standards into what is required of labs. They suggested a middle ground. Dr. Reinsmoen, chair of the committee, appointed a subcommittee to begin working on the project. She said the subcommittee must have something to report to the full Committee by our winter call which will be on February 29<sup>th</sup>. Drs. Monos, Baxter-Lowe, Bray, Tyan, and Eisenbrey volunteered to be part of the subcommittee.

**HLA Typing Requirement for ECD Kidneys:** Ms. Gore asked the Committee to vote on a problem that had been discovered when programming the new policy (sponsored by the Histocompatibility Committee) that requires “Deceased Donor HLA Typing be performed by DNA methods and identify additional antigens for Kidney, Kidney-pancreas, Pancreas, and Pancreas Islet Offers” which was approved by the BOD in November 2009.

The proposal (as written and approved) requires that OPOs and their associated laboratories perform HLA typing of **all deceased donors** by DNA methods and identify the HLA-A, -B, -Bw4, Bw6, -C, -DR, -DR51, -DR52, -DR53 and -DQ antigens before making any kidney, kidney-pancreas, pancreas, or pancreas islet.

Ms. Gore said she thought that the Committee meant for this policy to apply to all deceased donors, both Standard Criteria Donors (SCD) and Expanded Criteria donors (ECD). However, it did not directly address placement of ECD donors which today does not require HLA typing for placement.

She shared data with the Committee that showed that from January 1, 2010 to May 31, 2011, 1457 ECD kidneys were placed, all but 7 were placed with the required HLA.

The Committee voted and unanimously approved the following resolution:

**\*\* RESOLVED, the Histocompatibility Committee supports the requirement for HLA for all deceased donors, including ECD, including the proposed revisions to Policy 3.5.3.2.**

The Committee would like any programming to the system to enforce this new policy to treat both ECD and SCD donors the same. An OPO would not be required to enter HLA antigens to run a match for any donor (both SCD and ECD). However, if they run a match for both SCD and ECD donors) without all of the required HLA the match will close at sequence zero and no offers can be made.

Additionally, Policy 3.5.3.2 should be modified to remove the ability to make ECD kidney offers without HLA as follows:

- i. Policy 3.5.3.2 Computer Entry.
- ii. Information regarding each and every deceased kidney donor must be entered into UNet<sup>SM</sup> prior to kidney allocation, to determine whether there is a zero antigen mismatch between the donor and any candidate on the Waiting List. Pre-procurement tissue typing is ~~expected~~ required in allocating expanded criteria donor kidneys. ~~In the absence of pre-procurement tissue typing, allocation of expanded criteria donor kidneys shall proceed pursuant to Policy 3.5.12 according to candidate waiting time. If pre-procurement tissue typing is not initiated, the Host OPO shall provide a written explanation of the reasons to the OPTN contractor.~~

**Appendix 3A:** Ms. Gore asked if the Committee should start the process for updating Appendix A of Policy 3.0 since policy recommends it be done annually. She shared with the Committee an email sent by Dr. Cecka, former chair of the Committee. In that email Dr. Cecka said he thought the Committee should update the tables because the molecular typing policy is “changing the rules.” The Committee agreed and voted unanimously to start the process of updating the tables.

**Review of the Public Comment Proposals Comments:** Ms. Gore asked for volunteers to go over the comments received on our proposals. Drs. Tyan and Reinsmoen agreed to look over the comments about CPRA. Drs. Reinsmoen, Bray, Tyan and Baxter-Lowe agreed to look at the comments for the rewrite proposal.

<b>NAME</b>	<b>COMMITTEE POSITION</b>	<b>01/25/2012</b>
Nancy Reinsmoen, PhD	Chair	x
Lee Ann Baxter-Lowe, PhD	Vice chair	x
Massimo Mangiola, PhD	Region 1 Rep.	x
Dimitri Monos, PhD	Region 2 Rep.	x
Robert Bray, PhD	Region 3 Rep.	x
Cathi Murphy, PhD	Region 4 Rep.	
Dolly Tyan, PhD	Region 5 Rep.	x
Paul Warner, PhD	Region 6 Rep.	x
David Maurer, PhD	Region 7 Rep.	x
Sara Dionne, PhD	Region 8 Rep.	x
Rex Friedlander	Region 9 Rep.	
A. Bradley Eisenbrey MD, PhD	Region 10 Rep.	x
David Kiger, CHS, CHT	Region 11 Rep.	x
Laine Krisiunas, BS,MBA	At Large	x
Luis Campos, MD	At Large	
James Selby	At Large	x
Howard Gebel	SRTR Liaison	x
Bryn Thompson	SRTR Liaison	
Lori Gore	Committee Liaison	x
Anna Kucheryavaya	Support Staff	x
Jory Parker	Support Staff	x
James Bowman	Ex officio (HRSA)	x
Raelene Skerda, RPh, BPharm	Ex officio (HRSA)	x