

**OPTN/UNOS Histocompatibility Committee  
Report to the Board of Directors  
December 1-2, 2015  
Richmond, Virginia**

**Dolly Tyan, Ph.D., Chair  
Robert Bray, Ph.D., Vice Chair**

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*This report reflects the work of the OPTN/UNOS Histocompatibility Committee between the May 2015 and November 2015 period.*

**Action Items**

1. Annual Update to Equivalency Tables (2015)

*Public Comment:*        [August 14 – October 14, 2015](#)

*Board Consideration:*    *December 1-2, 2015*

OPTN/UNOS policy requires the Histocompatibility Committee (the Committee) to review and recommend any changes needed to the equivalency tables on an annual basis. In February, the Committee directed the HLA Equivalency Table Update Subcommittee to review the tables and provide recommendations. The Committee met in June and voted to send the proposal out for public comment during the fall 2015 cycle.

Public comments on the proposal revealed that several common alleles and their accompanying antigens were missing from the tables. Commenters were concerned that exclusion of these equivalencies could lead to undesired outcomes in transplant procedures. The Committee then reviewed the tables and the accompanying language change, taking into account the public comments, during the in-person meeting in Chicago on October 29, 2015. The Committee now proposes the following changes:

- Changing references of HLA – DQA, DQB, and DPB to DQA1, DQB1, and DPB1
- Striking *Policy 4.1: HLA Typing* in favor of *Policy 4.4: Requirements for Performing and Reporting HLA Typing*
- Adding missing references to pancreas and pancreas islet HLA requirements in *Policy 4.4: Requirements for Performing and Reporting HLA Typing*
- Updating the equivalency tables in *Policy 4.11: Reference Tables of HLA Antigen Values and Split Equivalencies*
- Adding unacceptable antigen equivalences for HLA DR51, DR52, and DR53
- Adding unacceptable antigen equivalences used in the Calculated Panel Reactive Antibody (CPRA) calculation for HLA DR51, DR52, and DR53

The Committee voted by a count of 15 in favor, 0 against, and 0 abstentions to send this proposal with the post-public comment amendments to the Board of Directors of Consideration.

**RESOLVED, that changes to Policy 2.11.A (Required Information for Deceased Kidney Donors), Policy 2.11.B (Required Information for Deceased Liver Donors), 2.11.C (Required Information for Deceased Heart Donors), 2.11.D (Required Information for Deceased Lung Donors), 2.11.E (Required Information for**

**Deceased Pancreas Donors), Policy 4.1 (HLA Typing), 4.2. (Requirements for Laboratory Review of Reports), 4.3 (Requirements for Waiting list Data Verification), 4.4 (Requirements for Performing and Reporting HLA Typing), 4.5 (Resolving Discrepant Donor and Recipient HLA Results) 4.6 (Antibody Screening and Reporting), 4.7 (Crossmatching), 4.8 Blood Type Determination), 4.9 (Preservation of Excess Specimens) 4.10 (HLA Antigen Values and Split Equivalences), Policy 4.11 (Reference Tables of HLA Antigen Values and Split Equivalences), 13.5.A (HLA Typing Requirements for OPTN KPD Candidates), and 13.5.C (HLA Typing Requirements for OPTN KPD Donors), as set forth in Exhibit A of the Histocompatibility Committee's report to the Board, are hereby approved, pending programming and notice to membership.**

## **Committee Projects**

### **2. Histocompatibility Testing Guidance Document**

*Public Comment:* N/A

*Board Consideration:* June 2016 (Estimated)

As part of the Comprehensive Histocompatibility Rewrite Phase II, the Histocompatibility Committee identified 28 sections of policy that should be removed from policy requirements and addressed in an accompanying guidance document. Specifically, the Committee is developing a guidance document to address *Bylaws Appendix C: Membership Requirements for Histocompatibility Laboratories* and *Policy 4: Histocompatibility*. The document seeks to address portions of the policies and bylaws members may find confusing or require additional clarification. Laboratories may also use this document to assist in ensuring they are compliant with all OPTN/UNOS bylaws and policies.

### **3. KAS CPRA and Priority Points for Candidates Undergoing Desensitization**

*Public Comment:* August 2016 (Estimated)

*Board Consideration:* December 2016 (Estimated)

The Committee continues to discuss CPRA prioritization points for kidney candidates undergoing desensitization. Under the kidney allocation system, highly sensitized kidney candidates who undergo desensitization lose allocation points associated with their CPRA score, reducing their opportunity for kidney offers. Previously, a workgroup comprised of members of the Histocompatibility, Kidney Transplantation, and Minority Affairs Committees held an introductory call on this project and discussed barriers to getting data on how many patients would benefit from a policy change.

The workgroup decided that the most effective step for moving forward was to conduct a survey of kidney transplant programs to learn whether more programs would utilize desensitization for highly sensitized candidates if these candidates could keep the prioritization associated with their CPRA score for a period of time.

The survey was distributed on June 4, 2015, and was open for response until September 4, 2015. During the Committee's October 29, 2015 in-person meeting, preliminary results of the survey were presented and discussed by the Committee. The survey was sent to 368 kidney medical directors and lab directors with a 45% response rate, for a total of 168 usable responses. Notably, 78% of respondents said that candidates should be allowed to

keep their pre-desensitization allocation points after being sensitized. The Committee also noted that 55% of respondents were currently not performing desensitization for their kidney candidates. The Committee recommended that the KAS Desensitization subcommittee review the data for a more robust analysis, which will include analysis of free response answers, and present their findings to the full committee.

4. Annual Update to the HLA Equivalency Tables (2016)

*Public Comment:* August 2016 (Estimated)

*Board Consideration:* December 2016 (Estimated)

During the in-person meeting in Chicago on October 29, 2015, the Committee discussed the need for an accurate DP equivalency table in the OPTN HLA policy. The Committee charged a subcommittee with investigating the possibility of adding DP equivalency table to policy as part of the annual update.

5. CPRA Manuscript

*Public Comment:* N/A

*Board Consideration:* N/A

The goal of this manuscript is to describe the changes in CPRA distribution that have occurred since the CPRA replaced PRA for kidney allocation based on analysis performed for the Committee. This manuscript is the final step in CPRA monitoring done by the Histocompatibility Committee. The manuscript was approved by HRSA on October 1, 2015 and submitted to a relevant journal for consideration shortly thereafter. The Committee is still awaiting the decision on whether the article will be published.

**Committee Projects Pending Implementation**

6. Require HLA-C and HLA DQB for Deceased Kidney, Kidney Pancreas, and Pancreas Donors

*Public Comment:* [March 19, 2010 – July 16, 2010](#)

*Board Approval:* [November 2010](#)

*Project Implementation:* January 21, 2016

This proposal was approved by the Board in November, 2010. This proposal requires that OPOs and their associated laboratories perform HLA typing of all deceased donors by DNA methods and identify the HLA-A, -B, Cw, DR, and DQ antigens before making any kidney, kidney-pancreas, pancreas, or pancreas islet offers. The requirement for typing deceased donors using DNA was previously implemented. Current programming focuses on programming the required antigens for making kidney, kidney-pancreas, pancreas, and pancreas islet offers.

7. Expanding Candidate and Deceased Donor HLA Typing Requirements to Provide Great Consistency Across Organ Types (DQA and DPB)

*Public Comment:* [March 14 – June 13, 2014](#)

*Board Approval:* [November 2014](#)

*Project Implementation: January 21, 2016*

In November 2014, the OPTN/UNOS Board of Directors approved new policies for histocompatibility testing required for solid organ transplantation. The changes that will be effective on January 21, 2016 include the following:

- Typing for HLA-DQA and –DPB will be mandatory for deceased kidney, kidney-pancreas, and pancreas donors. OPOs will be required to report this information in DonorNet® in order to make kidney, kidney-pancreas, or pancreas offers.
- Upon implementation, DonorNet® will contain fields to report these types. Waitlist<sup>SM</sup> will also contain unacceptable antigens for these types. The system will be programmed to automatically avoid donors with the unacceptable –DQA or –DPB antigens listed for the candidate. When performing HLA typing on deceased donors (whether the typing is required by OPTN policy or requested by the transplant program), all of the following types will be required to be reported: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA, DQB, and DPB
- OPTN policy will require HLA typing for deceased kidney, kidney-pancreas, and pancreas donors. It will only be required on deceased heart, lung, and liver donors if it is requested by a candidate's transplant program.
- HLA typing will be required for deceased pancreas islet donors and candidates.
- HLA typing for all deceased donors, whether required or requested, must be performed by molecular methods.

UNOS Instructional Innovations department will publish instructional videos that accompany these policy changes. The videos will address the policy changes and changes to the UNet<sup>SM</sup> system that will affect members.

8. Histocompatibility Bylaws Rewrite: Phase 2

*Public Comment:* [September 29 – December 5, 2014](#)

*Board Approval:* [June 2015](#)

*Project Implementation:* *Second Quarter of 2016 (Estimated)*

In June 2015, the OPTN/UNOS Board of Directors approved new Histocompatibility bylaws. While a significant portion of the Bylaws Rewrite were already implemented, there still remains some IT programming that will add the General Supervisor to the list of laboratory key personnel. The IT programming is scheduled for the second quarter of 2016.

**Implemented Committee Projects**

9. Comprehensive Histocompatibility Bylaws Rewrite

*Public Comment:* [September – December 6, 2013](#)

*Board Approval:* [June 2014](#)

*Project Implementation:* *June 2015*

## OPTN/UNOS Histocompatibility Committee

In June, 2015 IT programmed the only remaining portion of this project: a requirement that labs resolve discrepancies within 30 days of notification of discrepant HLA typing results. With IT's programming, this project became fully implemented. Although the programming is in place, the data following its implementation is not yet available for review. The committee reviews typing discrepancies every quarter. The Committee will not have a chance to review data related to resolving discrepancies until December, 2015.

### **Review of Public Comment Proposals**

The Committee did not comment on any of the proposals recently released for public comment.

### **Other Committee Work**

#### **10. Quarterly Review of HLA Typing Discrepancies**

OPTN/UNOS policy requires the Histocompatibility Committee to review, at least every three months, any outstanding discrepant typing in Discrepant Donor and Recipient HLA Typing Reports in UNet<sup>SM</sup>. During past reviews, the Committee identified that between eight and ten percent of all possible match runs result in an HLA discrepancy of some sort. During the October 29, 2015 in-person meeting in Chicago, the Discrepant Typing Review Subcommittee presented this information to the full committee. The Committee tasked the Subcommittee with reviewing the data further in an attempt to better identify where and how the discrepancies are occurring in the allocation process.

### **Meeting Summaries**

The Committee held meetings on the following dates:

- June 17, 2015
- September 8, 2015
- October 13, 2015
- October 29, 2015

Meetings summaries for this Committee are available on the OPTN website at: <http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=7>.

*OPTN/UNOS Histocompatibility Committee*

# Update to the HLA Equivalency Tables (2015)

*Prepared by:  
Geoffrey P. Zindren, MPP  
UNOS Policy Department*

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# Update to the HLA Equivalency Tables (2015)

## Executive Summary

Policy 4.7: *HLA Antigen Values and Split Equivalences*, states: “The Histocompatibility Committee must review and recommend any changes needed to the tables on or before June 1 of each year.” The Board of Directors approved the most recent updates to the Equivalency Tables in November 2013. Since that time, additional equivalencies have been proposed which should be incorporated into the tables in policy. The update to the tables will help the OPTN achieve its goals of increasing transplants by reducing organ discard due to futile shipments.

This proposal also adds alleles to the Human Leukocyte Antigen (HLA) dropdown options in UNet<sup>SM</sup> to increase access to transplants for sensitized candidates according to strategic goal number two. The Histocompatibility Committee (the Committee) also proposes updating references to HLA loci in policy to HLA-DPB1, HLA-DQA1, and HLA-DQB1 to distinguish them from other similar HLA loci. Lastly, the Committee proposes the removal of Policy 4.1: *HLA Typing* as the approved but not yet implemented Policy 4.4: *Requirements for Performing and Reporting HLA Typing* replaces that section of policy.

# Update to the HLA Equivalency Tables (2015)

*Affected Policies: Policies 2.11.A: Required Information for Deceased Kidney Donors; 2.11.B: Required Information for Deceased Liver Donors; 2.11.C: Required Information for Deceased Heart Donors; 2.11.D: Required Information for Deceased Lung Donors; 2.11.E: Required Information for Deceased Pancreas Donors; 4.1. HLA Typing; 4.2. Requirements for Laboratory Review of Reports; 4.3 Requirements for Waiting list Data Verification; 4.4: Requirements for Performing and Reporting HLA Typing; 4.5 Resolving Discrepant Donor and Recipient HLA Results; 4.6 Antibody Screening and Reporting; 4.7 Crossmatching; 4.8 Blood Type Determination; 4.9 Preservation of Excess Specimens; 4.10 HLA Antigen Values and Split Equivalences; 4.11 Reference Tables of HLA Antigen Values and Split Equivalences; 13.5.A: HLA Typing Requirements for OPTN KPD Candidates; and 13.5.C: HLA Typing Requirements for OPTN KPD Donors*

*Sponsoring Committee: Histocompatibility Committee*

*Public Comment Period: August 14, 2015 – October, 14, 2015*

## What problem will this proposal solve?

This proposal addresses four different issues:

1. Updates the Equivalency Tables from the 2013 version
2. Adds new alleles to the HLA antigen dropdown in UNet<sup>SM</sup>
3. Updates terminology to reflect modern nomenclature
4. Removes duplicative sections of HLA policy

Policy 4.7: *HLA Antigen Values and Split Equivalences*, states: “The Histocompatibility Committee must review and recommend any changes needed to the tables on or before June 1 of each year.” The Board of Directors approved the most recent updates to the Equivalency Tables in November 2013. Since that time, additional equivalencies have been proposed which should be incorporated into the tables in policy.

This proposal also adds additional alleles (subtypes) to the HLA antigen dropdown options in UNet<sup>SM</sup> to increase access to transplant for sensitized candidates and improve identification of zero antigen mismatches.<sup>1</sup> Current dropdowns are unnecessarily disadvantaging candidates who have antibodies against some but not all alleles in a single antigen group. For these patients, members currently can only list corresponding antigens (inclusive of all alleles in the group) as unacceptable antigens, excluding candidates from a broader donor pool than necessary. In addition, candidates with an allele specific antibody that is in the same antigen group as their own allele cannot have the unacceptable allele or the antigen listed (e.g., candidate type: B\*44:02; unacceptable allele, B\*44:03).

Additionally, current policy references HLA-DPB, HLA-DQA, and HLA-DQB. This terminology is not medically accurate nomenclature as defined by accepted terminology from the World Health Organization and the genetics community at-large. Therefore, the Committee also proposes updating references to

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<sup>1</sup> See OPTN/UNOS Policy 1.2: Definitions for “Zero antigen mismatch”.  
[http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Policies.pdf#nameddest=Policy\\_01](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf#nameddest=Policy_01)

these HLA loci in policy to HLA-DPB1, HLA-DQA1, and HLA-DQB1 to distinguish them from other closely related loci, and to reflect commonly accepted practices within the histocompatibility community.

Lastly, in November of 2014, the Board passed a proposal to expand the Deceased Donor HLA Types. This proposal added Policy 4.4: *Requirements for Performing and Reporting HLA Typing*, which was meant to replace current Policy 4.1: *HLA Typing*. However, section 4.1 was never stricken from policy. This proposal removes the current contents in section 4.1, and adds references to pancreas and pancreas islet HLA requirements in Policy 4.4 so that they are aligned with Policy 3.4.D: *Candidate Human Leukocyte Antigen (HLA) Requirements*.

## Why should you support this proposal?

Updating the equivalency tables ensures that advances in HLA typing and the frequencies of antigens reported for donors as well as antigens and unacceptable antigens reported for candidates are correctly reflected in policy. This increases access for many candidates on the waiting list by creating opportunities for candidates to receive appropriate offers, because compatible donors will not be excluded based on outdated or broad HLA typing constraints of prior equivalency tables.

This proposal also significantly reduces the risk of shipping kidneys nationally and regionally to a candidate who has an allele (subtype) specific antibody, which would not be known until the donor material was received and either expanded typing of the donor or a positive crossmatch was obtained. This should result in less organ wastage and fewer transplants into patients other than the intended recipient.

The proposal also makes HLA policies consistent between Waitlist<sup>SM</sup> requirements and HLA typing requirements for candidates.

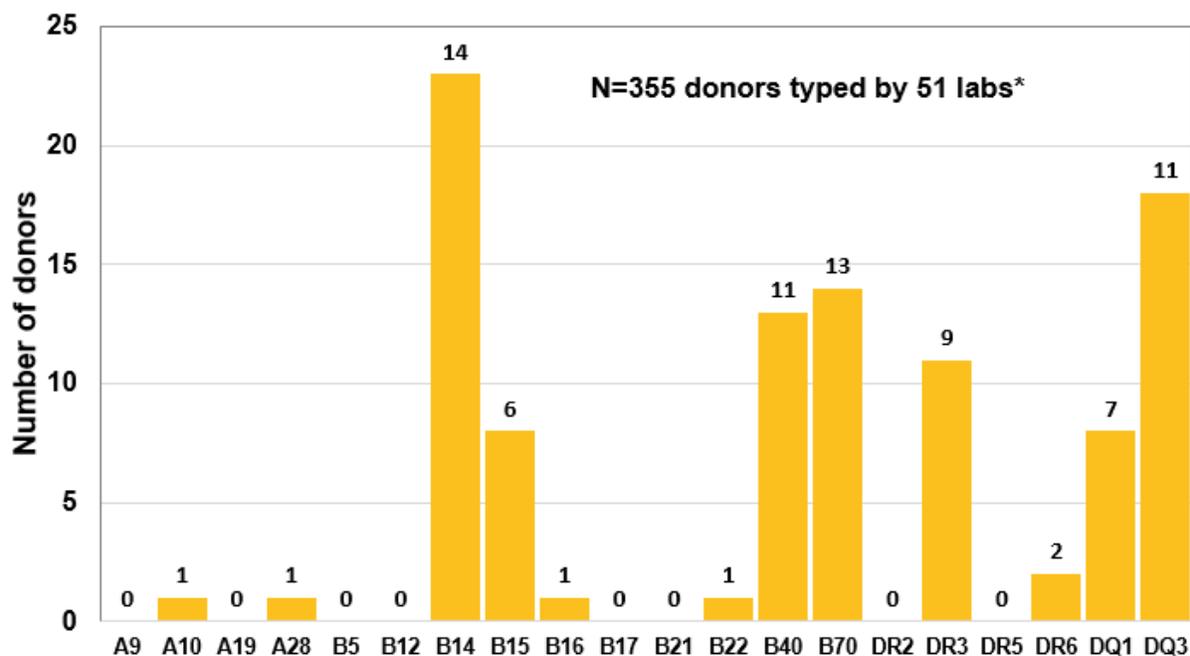
## How was this proposal developed?

The Committee members reviewed the current version of the HLA Equivalency Tables and made independent suggestions for updates based upon what current testing methods can clearly distinguish and what Committee members are commonly seeing in practice in their labs. The Committee members then compared their suggestions and agreed to the priorities for updating the tables. A unanimous vote from the Committee was obtained for the approval of the updated tables. The Committee then sent the proposal out for public comment. Following public comment, the Committee redrafted the proposal to address feedback it received. At the in-person full committee meeting in Chicago on October 29, 2015, members reviewed the proposal and voted to approve the final draft and send it to the Board of Directors for consideration by a vote of 15 in favor, 0 against, and 0 abstentions.

## How well does this proposal address the problem statement?

The Committee first focused on Tables 4-3, 4-4, and 4-5 in Policy 4.9: *Reference Tables of HLA Antigen Values and Split Equivalences*, which are used to determine 0-ABDR and DR mismatches between candidates and donors for kidney and pancreas/kidney-pancreas allocation. The Committee reviewed data regarding the frequencies of antigens reported for deceased donors and kidney, pancreas, and kidney-pancreas candidates to determine how often broad antigens are reported (Figure 1).

Figure 1. Broad antigens reported for deceased donors (2013-2014)



\* C3 was reported by 33 labs for 264 donors.

Note: Labels show the number of labs for each broad antigen.

The Committee found that broad antigens were reported for only 355 donors out of more than 16,000 donors (about 2.2%). In general, listing a broad antigen means that the actual antigen present has not been defined. For example, B70 has been subdivided into either B71 or B72. There is no longer an antigen known as B70. Therefore, certain broad antigen equivalencies will be changed in the tables (e.g., in the matching table, B70 will no longer be equivalent to B71 or B72 but only to itself whereas in the unacceptable table, B70 will be equivalent to itself and to B71 and B72 to prevent accidental offers to a candidate because centers are unaware of the equivalences). The changes to the matching and unacceptable antigen equivalency tables for certain broad antigens will have a beneficial impact on candidates with the subtypes (e.g. B71 and B72) reported as their HLA due to more compatible donor offers. Candidates that are reported with the broad antigens (e.g. B70) will simply need to be retyped. For example, for a 0-ABDR mismatch offer, a candidate's B70 will remain equivalent to a donor's B70 (i.e., undefined), but will no longer be equivalent to a donor's B71 or B72. There were only 14 deceased donors in 2013-2014 with B70 reported, compared to 283 and 407 deceased donors with B71 and B72, respectively. Both donors and candidates with broad antigens listed are expected to decrease now that molecular typing is required for all donors and the subtypes can be well defined.

The Committee decided to leave some existing broad antigens in the tables, effectively allowing them to remain in the HLA dropdowns in UNet<sup>SM</sup>, so members will be able to report values in cases of rare alleles that may not have any closer serological equivalents.

The Committee also proposed deleting A210, B1304, B3901, B3902, B5103, B7801 and B8201 because either solid phase antibody testing cannot identify an antibody to the allele or the allele designation is not necessary. Only 35 deceased donors recovered in 2013-2014, and only 172 registrations on the waiting list on June 19, 2015, had any of these antigens reported. Prior to implementation, centers will be contacted by UNOS to warn them about the upcoming changes and ask them to update candidate information on the waiting list.

The Committee also determined it is important to clarify the tables by removing asterisks that are currently in policy and adding more common alleles to the tables.

Lastly, the Committee proposes changes in labels to reflect standard nomenclature set forth by the WHO and commonly used within the genetics community. For example, there are two DQA loci: DQA1 and DQA2. The Committee is only concerned with DQA1. The same is true for DQB1 and DPB1. Therefore, the Committee proposes updating the nomenclature of HLA-DPB, HLA-DQA, and HLA-DQB to HLA-DPB1, HLA-DQA1, and HLA-DQB1. The Committee proposes changes to these loci first to coincide with current programming efforts in UNet<sup>SM</sup>.

### Was this proposal changed in response to public comment?

Comments made during the public comment period were unanimously in support of this proposal. The comments received for this proposal are on the Organ Procurement and Transplantation Network (OPTN) website at <http://optn.transplant.hrsa.gov/governance/public-comment>. In general, individuals and groups praised the Committee for making updates to the tables that reflect today's knowledge of HLA equivalences. In addition, the item was on the non-discussion agenda during regional meetings and was passed unanimously in 10 of 11 regional meetings. In Region 11 the item was pulled from the non-discussion agenda. A member of this region voiced concern over missing alleles and antigens. The region ultimately passed the proposal by a vote of 18 in favor, 2 opposed, and zero abstentions.

The singular theme that arose from the public comment period was that the tables were incomplete, missing some loci and antigen equivalencies. Several commenters described the need for accuracy in the tables. Additionally, commenters noted that there could be serious adverse outcomes to candidates if the missing antigens are not included.

Based on these comments, the committee reviewed the tables in order to identify the appropriate matching antigen equivalencies and unacceptable antigen equivalencies for each locus. Additionally, the Committee considered whether any loci were missing from the tables and added them and the relevant antigens as needed.

### Which populations are impacted by this proposal?

All candidates are positively impacted by this proposal. There will be more opportunity for zero mismatch offers. It will also improve allocation due to improved antigen definition, more accurate virtual crossmatching, and fewer unexpected positive crossmatches. It will also better ensure that regional or national sharing for very high CPRA kidney candidates will result in transplant. Additionally, it will greatly facilitate the virtual crossmatching for the OPTN/UNOS KPD Pilot Program.

### How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* This proposal increases the number of transplants by improving the efficiency of allocation and decreasing futile shipments of organs for sensitized candidates, particularly kidney candidates. The Committee hypothesizes that decreasing futile shipments of organs will decrease the number of discarded organs.
2. *Improve equity in access to transplants:* This proposal improves equity in access to transplant by allowing members to enter more specific data. Current dropdowns are unnecessarily disadvantaging candidates who have antibodies against some but not all alleles in a single antigen group. For these patients, members currently can only list corresponding antigens (inclusive of all alleles in the group) as unacceptable antigens, excluding candidates from a broader donor pool than necessary. For highly sensitized candidates, allocation will more likely

result in a transplant. Once more specific options are available, hospitals can list the appropriate unacceptable antigens or alleles and increase access to transplant for those patients.

3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* This proposal helps improve transplant recipient outcomes because a higher degree of specificity in the equivalency tables will result in better compatibility and should decrease the probability of post-transplant rejection. By more efficiently allocating the organ to the candidate most likely to have a negative crossmatch, it reduces the cold ischemia time on the organ, which increases the likelihood of a better outcome.
4. *Promote living donor and transplant recipient safety:* This proposal helps improve transplant recipient safety by reducing or eliminating loss of organs due to futile shipments that result in unexpected positive crossmatches and subsequent unacceptable cold ischemia times.
5. *Promote the efficient management of the OPTN:* This proposal promotes efficient management of the OPTN by clarifying and consolidating similar HLA policies. The removal of one HLA section will avoid any confusion among members about potentially overlapping requirements.

## How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The Histocompatibility Committee will evaluate changes in unacceptable antigen reporting and resulting CPRA values due to revisions of unacceptable antigen equivalences immediately after the implementation compared to values immediately prior to the implementation. The policy will continue to be evaluated 1 and 2 years post-implementation.

The Committee's hypothesis is that more accurate typing will result in improved allocation due to better virtual crossmatching and increase transplants to the intended recipients. The following questions, and any others subsequently requested by the Committee, will guide the evaluation of the proposal after implementation:

1. Are members reporting donor HLA and unacceptable antigens for newly added values?
2. Has the proposal decreased reporting of broad antigens for kidney, kidney-pancreas and pancreas registrations on the waiting list?
3. Has the proposal affected the number of zero-mismatch deceased donor kidney, kidney-pancreas and pancreas transplants?
4. Has the proposal affected the number of zero and one HLA-DR mismatch deceased donor kidney transplants?
5. Has the reporting of unacceptable antigens on the waiting list increased after implementation?
6. Have the number of organ offers refused due to a positive crossmatch changed after implementation?
7. Have the number of organs not transplanted into the intended recipient changed after implementation?
8. Was there a change in CPRA values amongst kidney, kidney-pancreas, and pancreas registrations on the waiting list?

The following metrics, and any other subsequently requested by the Committee, will be compared before and after the implementation to evaluate the proposal:

1. Deceased donor HLA frequencies reported prior to allocation.
2. HLA and unacceptable antigen frequencies of kidney, kidney-pancreas and pancreas registrations on the waiting list.

3. The number and percentage of zero-HLA mismatch deceased donor kidney, kidney-pancreas, and pancreas transplants and graft survival for recipients of those transplants.
4. The number and percentage of zero and one HLA-DR mismatch deceased donor kidney transplants and graft survival for recipients of those transplants.
5. The number and percentage of offers refused due to a positive crossmatch.
6. The number of organs not transplanted the intended recipient.
7. Change in CPRA values for kidney, kidney-pancreas and pancreas registrations on the day of implementation (will be done immediately after the implementation).

## How will the OPTN implement this proposal?

IT will update UNet<sup>SM</sup> with the proposed HLA-A, B, Bw4, Bw6, C, DR, and DQB1 equivalences that are used for matching purposes, screening based on unacceptable antigens, and for calculating CPRA. UNOS IT provides cost estimates for each proposal that will require programming to implement. The estimates can be small (108-419 hrs.), medium (420-749 hrs.), large (750-1,649 hrs.), very large (1,650-3,999), or enterprise (4,000-8,000). The IT estimate for this proposal is very large at 2,500 hours for this proposal. This estimate reflects that IT will have to change HLA settings across multiple organs and within different systems of UNet<sup>SM</sup> including Waitlist<sup>SM</sup>, DonorNet<sup>SM</sup>, and the match run. The IT department will have to program new antigens as equivalencies and unacceptable. In addition, IT is changing the HLA DR fields in the UNet<sup>SM</sup> system to accept values for antigens. Currently, the DR entry method is a selection indicating that someone is either positive or negative for DR. The switch to named antigens will require many hours of testing and quality assurance, and is one of the main drivers in cost. The IT department will also update references in UNet<sup>SM</sup> of HLA DQA, DPB, and DQB to DQA1, DPB1, and DQB1, respectively.

The OPTN will educate the public on any policy or system changes through Policy Notices and System Notices. Additionally, third-party users of the UNet<sup>SM</sup> system will be updated through Vendor Notices. This proposal will also be monitored for potential instructional opportunities, in order to give members, professionals and the transplant community an avenue to gain information, ask questions, and modify processes, if necessary.

## How will members implement this proposal?

All OPTN members and vendors will need to familiarize themselves with these changes. Transplant programs may need to request updated HLA typing using molecular methods for existing candidates who may be disadvantaged by the changes to the HLA Matching Equivalences tables, especially for any candidate who has a 'broad' antigen listed in their reported HLA type. Labs in particular will be required to assign antigens less broadly to candidates than has been the practice in the past. Members may also need to review and modify unacceptable antigens reported for candidates with antibodies against alleles that are being added.

## Will this proposal require members to submit additional data?

This proposal does not require collection of any additional data fields. However, this proposal may change how a candidate's HLA antigens and unacceptable antigens (currently collected) are entered on the waiting list:

- This proposal may decrease the number of kidney, kidney-pancreas, pancreas, and pancreas islet candidates with broad HLA antigens reported on the waiting list. Proposed changes give centers an incentive to type candidates using molecular methods and to define their types more specifically to improve their opportunity for transplant.
- This proposal may result in increased reporting of some unacceptable antigens on the waiting list and will give members an opportunity to report more specific data.

## How will members be evaluated for compliance with this proposal?

The proposed language will not change the current monitoring of OPTN members. HLA typing information submitted to the OPTN Contractor may be subject to OPTN review, and members are required to provide documentation as requested.

## Policy or Bylaw Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

1 **RESOLVED**, that changes to Policy 2.11.A (Required Information for Deceased Kidney  
 2 Donors), Policy 2.11.B (Required Information for Deceased Liver Donors), 2.11.C  
 3 (Required Information for Deceased Heart Donors), 2.11.D (Required Information for  
 4 Deceased Lung Donors), 2.11.E (Required Information for Deceased Pancreas Donors),  
 5 Policy 4.1 (HLA Typing), 4.2. (Requirements for Laboratory Review of Reports), 4.3  
 6 (Requirements for Waiting list Data Verification), 4.4 (Requirements for Performing and  
 7 Reporting HLA Typing), 4.5 (Resolving Discrepant Donor and Recipient HLA Results) 4.6  
 8 (Antibody Screening and Reporting), 4.7 (Crossmatching), 4.8 Blood Type  
 9 Determination), 4.9 (Preservation of Excess Specimens) 4.10 (HLA Antigen Values and  
 10 Split Equivalneces), Policy 4.11 (Reference Tables of HLA Antigen Values and Split  
 11 Equivalences), 13.5.A (HLA Typing Requirements for OPTN KPD Candidates), and 13.5.C  
 12 (HLA Typing Requirements for OPTN KPD Donors), as set below, are hereby approved,  
 13 pending programming and notice to membership.

14

## 15 **2.11 Required Deceased Donor Information**

### 16 **2.11.A Required Information for Deceased Kidney Donors**

17 The host OPO must provide *all* the following additional information for all deceased donor kidney  
 18 offers:

19

- 20 1. Date of admission for the current hospitalization
- 21 2. Donor name
- 22 3. Donor ID
- 23 4. Ethnicity
- 24 5. Relevant past medical or social history
- 25 6. Current history of abdominal injuries and operations
- 26 7. Current history of average blood pressure, hypotensive episodes, average urine output, and  
 27 oliguria
- 28 8. Current medication and transfusion history
- 29 9. Anatomical description, including number of blood vessels, ureters, and approximate length  
 30 of each
- 31 10. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52,  
 32 DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers.
- 33 11. Indications of sepsis
- 34 12. Injuries to or abnormalities of the blood
- 35 13. Assurance that final blood and urine cultures are pending
- 36 14. Final urinalysis
- 37 15. Final blood urea nitrogen (BUN) and creatinine
- 38 16. Recovery blood pressure and urine output information
- 39 17. Recovery medications
- 40 18. Type of recovery procedure, flush solution and method, and flush storage solution
- 41 19. Warm ischemia time and organ flush characteristics

42

### 43 **2.11.B Required Information for Deceased Liver Donors**

44 The host OPO must provide *all* the following additional information for all deceased donor liver  
45 offers:

- 46
- 47 1. Donor name
  - 48 2. Donor ID
  - 49 3. Ethnicity
  - 50 4. Height
  - 51 5. Weight
  - 52 6. Vital signs, including blood pressure, heart rate and temperature
  - 53 7. Social history, including drug use
  - 54 8. History of treatment in hospital including current medications, vasopressors, and hydration
  - 55 9. Current history of hypotensive episodes, urine output, and oliguria
  - 56 10. Indications of sepsis
  - 57 11. Aspartate aminotransferase (AST)
  - 58 12. Bilirubin (direct)
  - 59 13. Other laboratory tests within the past 12 hours including:
    - 60 a. Alanine aminotransferase (ALT)
    - 61 b. Alkaline phosphatase
    - 62 c. Total bilirubin
    - 63 d. Creatinine
    - 64 e. Hemoglobin (hgb) and hemocrit (hct)
    - 65 f. International normalized ration (INR) or Prothrombin (PT) if INR is not available, and  
66 partial thromboplastin time (PTT)
    - 67 g. White blood cell count (WBC)
  - 68 14. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B,  
69 Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA<sub>1</sub>, DQB<sub>1</sub>, and DPB<sub>1</sub> antigens in the timeframe  
70 specified by the transplant program

71  
72 If a transplant program requests HLA typing for a deceased liver donor, it must communicate this  
73 request to the OPO and the OPO must provide the HLA information listed above. The transplant  
74 program must document requests for donor HLA typing, including the turnaround time specified  
75 for reporting the donor HLA typing results. The OPO must document HLA typing provided to the  
76 requesting transplant program.

### 77 **2.11.C Required Information for Deceased Heart Donors**

78  
79 The host OPO must provide *all* the following additional information for all deceased donor heart  
80 offers:

- 81
- 82 1. Height
  - 83 2. Weight
  - 84 3. Vital signs, including blood pressure, heart rate, and temperature
  - 85 4. History of treatment in hospital including vasopressors and hydration
  - 86 5. Cardiopulmonary, social, and drug activity histories
  - 87 6. Details of any documented cardiac arrest or hypotensive episodes
  - 88 7. 12-lead interpreted electrocardiogram
  - 89 8. Arterial blood gas results and ventilator settings
  - 90 9. Cardiology consult or echocardiogram, if the hospital has the facilities
  - 91 10. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B,  
92 Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA<sub>1</sub>, DQB<sub>1</sub>, and DPB<sub>1</sub> antigens prior to the final  
93 organ acceptance
  - 94 11. Toxoplasma antibody (Ab) test result or an appropriate donor sample sent with the heart for  
95 testing at the transplant hospital
- 96

97 For heart deceased donors, if a transplant program requires donor HLA typing prior to submitting  
 98 a final organ acceptance, it must communicate this request to the OPO and document the  
 99 request. The OPO must provide the HLA information required in the list above and document that  
 100 the information was provided to the transplant program.

101  
 102 The heart recovery team must have the opportunity to speak directly with the responsible ICU  
 103 personnel or the onsite donor coordinator in order to obtain current information about the  
 104 deceased donor's physiology.  
 105

### 106 **2.11.D Required Information for Deceased Lung Donors**

107 The host OPO must provide *all* the following additional information for all deceased lung donor  
 108 offers:

- 109 1. Height
- 110 2. Weight
- 111 3. Vital signs, including blood pressure, heart rate, and temperature
- 112 4. History of medical treatment in hospital including vasopressors and hydration
- 113 5. Smoking history
- 114 6. Cardiopulmonary, social, and drug activity histories
- 115 7. Arterial blood gases and ventilator settings on 5 cm/H<sub>2</sub>O/PEEP including PO<sub>2</sub>/FiO<sub>2</sub> ratio and
- 116 preferably 100% FiO<sub>2</sub>, within 2 hours prior to the offer
- 117 8. Bronchoscopy results
- 118 9. Chest x-ray interpreted by a radiologist or qualified physician within 3 hours prior to the offer
- 119 10. Details of any documented cardiac arrest or hypotensive episodes
- 120 11. Sputum gram stain, with description of sputum
- 121 12. Electrocardiogram
- 122 13. Echocardiogram, if the OPO has the facilities
- 123 14. HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51,  
 124 DR52, DR53, DQA<sub>1</sub>, DQB<sub>1</sub>, and DPB<sub>1</sub> antigens prior to final organ acceptance  
 125

126  
 127 If the host OPO cannot perform a bronchoscopy, it must document that it is unable to provide  
 128 bronchoscopy results and the receiving transplant hospital may perform it. The lung recovery  
 129 team may perform a confirmatory bronchoscopy provided unreasonable delays are avoided and  
 130 deceased donor stability and the time limitations in *Policy 5.6.B: Time Limit for Acceptance* are  
 131 maintained.  
 132

133 For lung deceased donors, if a transplant hospital requires donor HLA typing prior to submitting a  
 134 final organ acceptance, it must communicate this request to the OPO and document the request.  
 135 The OPO must provide the HLA information required in the list above and document that the  
 136 information was provided to the transplant program.  
 137

138 The lung recovery team must have the opportunity to speak directly with the responsible ICU  
 139 personnel or the onsite OPO donor coordinator in order to obtain current information about the  
 140 deceased donor's physiology.  
 141

### 142 **2.11.E Required Information for Deceased Pancreas Donors**

143 The host OPO must provide *all* the following additional information for all deceased donor  
 144 pancreas offers:

- 145 1. Donor name
- 146 2. Donor ID
- 147 3. Ethnicity
- 148 4. Weight
- 149 5. Date of admission for the current hospitalization
- 150 6. Alcohol use (if known)
- 151

- 152 7. Current history of abdominal injuries and operations including pancreatic trauma
- 153 8. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average
- 154 urine output, and oliguria
- 155 9. Current medication and transfusion history
- 156 10. Pertinent past medical or social history including pancreatitis
- 157 11. Familial history of diabetes
- 158 12. Insulin protocol
- 159 13. Indications of sepsis
- 160 14. Serum amylase
- 161 15. Serum lipase
- 162 16. HLA information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA<sub>1</sub>, DQB<sub>1</sub>, and
- 163 DPB<sub>1</sub> antigens prior to organ offers.
- 164

## 4.1 HLA Typing

### 4.1.A Requirements for Performing and Reporting HLA Typing

Laboratories must do ~~all~~ of the following:

- 1. ~~Perform HLA typing on all potential transplant recipients and donors when requested by a physician or other authorized individuals.~~
- 2. ~~Ensure that all HLA typing is accurately determined and report HLA typing results to the OPO or Transplant Program according to the turnaround time specified in the written agreement between the laboratory and any affiliated OPO or transplant program.~~
- 3. ~~Report serological split level and molecular typing results to the OPO for all required HLA types according to Table 4.1 HLA Typing Requirements for Deceased Donors Policy 2.11: Required Deceased Donor Information, whenever the lab performs HLA typing on deceased kidney, kidney pancreas, and pancreas donors.~~
- 4. ~~Report HLA typing results to the Transplant Program for all required HLA types, according to Table 4.21 HLA Typing Requirements for Candidates, whenever the laboratory performs HLA typing on candidates.~~

Table 4.1 shows HLA types required to be reported for deceased donors.

**Table 4.1: HLA Typing Requirements for Deceased Donors**

Organ	A	B	Bw4	Bw6	C	DR	DR51	DR52	DR53	DPB	DQB
Kidney	●	●	●	●	●	●	●	●	●	●	●
Pancreas	●	●	●	●	●	●	●	●	●	●	●
Kidney-Pancreas	●	●	●	●	●	●	●	●	●	●	●
Heart*	●	●	●	●	●	●	●	●	●	●	●
Lung*	●	●	●	●	●	●	●	●	●	●	●

183 \*For deceased heart and lung donors, if a transplant hospital requires donor HLA typing prior to  
 184 submitting a final organ acceptance, it must communicate this request to the OPO and document  
 185 this request. The OPO must provide the HLA information required in the table above and  
 186 document that the information was provided to the transplant program. The transplant hospital  
 187 may request HLA-DPB typing, but the OPO need only provide it if its affiliated laboratory performs  
 188 related testing.  
 189

190 Table 4.21 shows HLA types required to be reported for candidates.

191 **Table 4.21: HLA Typing Requirements for Candidates**

Organ	A	B	Bw4	Bw6	DR
Kidney alone	●	●	●	●	●
Pancreas alone	●	●	●	●	●
Kidney Pancreas	●	●	●	●	●

192 **4.21 Requirements for Laboratory Review of Reports**

193 [Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]  
 194

195 **4.4.3.A Deceased Donor HLA Typing**

196 If the laboratory performs HLA typing on a deceased donor, the laboratory must perform  
 197 molecular typing and report results at the level of serological splits to the OPO for all required  
 198 HLA types on deceased donors according to Table 4-31 Deceased Donor HLA Typing  
 199 Requirements.  
 200

201 Table 4-31 below provides the requirements of HLA typing of HLA A, B, Bw4, Bw6, C, DR, DR51,  
 202 DR52, DR53, DQA1, DQB1, and DPB1 antigens.  
 203

204 **Table 4-31: Deceased Donor HLA Typing Requirements**

If a Laboratory Performs HLA Typing on a:	Then the Laboratory Must Report Results to the OPO at the Following Times:
Deceased Kidney, Kidney-Pancreas, <u>Pancreas</u> , or Pancreas <u>Islet</u> Donor	Prior to organ offers
Deceased Heart, Heart-Lung, or Lung Donors	Prior to final acceptance, if required by the transplant program
Deceased Liver Donors	Within the period specified by the transplant program

205 **4.4.3.B HLA Typing for Candidates**

206 Laboratories must perform HLA typing on a kidney, kidney-pancreas, pancreas, or pancreas islet  
 207 candidate and report results for HLA A, B, Bw4, Bw6, and DR to the transplant program prior to  
 208 registration on the waiting list.  
 209

213 **4.5.4 Resolving Discrepant Donor and Recipient HLA Typing Results**  
 214 [Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

215

216 **4.10.9 HLA Antigen Values and Split Equivalences**

217 HLA matching of A, B, and DR locus antigens is based on the antigens which are listed in *Policy 4.140:*  
 218 *Reference Tables of HLA Antigen Values and Split Equivalences*. The Histocompatibility Committee must  
 219 review and recommend any changes needed to the tables on or before June 1 of each year. For  
 220 matching purposes, split antigens not on this list will be indicated on the waiting list as the parent antigens  
 221 and will match only with the corresponding parent antigens.  
 222

223 **4.11.10 Reference Tables of HLA Antigen Values and Split**  
 224 **Equivalences**

225 *Tables 4-32, 4-43, and 4-54, show patient-candidate-donor antigen combinations and whether they are*  
 226 *mismatches. For each candidate antigen, the donor antigens that are not mismatched are listed below. All*  
 227 *other combinations are considered mismatches. Antigens with an \* indicate an allele that may not have a*  
 228 *World Health Organization (WHO)-approved serologic specificity. Antigens given \*\*99 means the patient*  
 229 *locus was not tested.*

230 **Table 4-32 HLA A Matching Antigen Equivalences**

Patient A Locus Antigen	Equivalent Donor Antigens	Patient A Locus Antigen	Equivalent Donor Antigens	Patient A Locus Antigen	Equivalent Donor Antigens
1	1	<u>2403</u>	<u>2403, 24</u>	36	36
2	2, <u>0201</u> , <u>0202</u> , <u>0203</u> , <u>0205</u> , <u>0206</u>	25	25	43	43
<u>0201</u>	<u>0201, 2</u>	26	26	66	66, *6601, *6602
<u>0202</u>	<u>0202, 2</u>	28	28	<u>6601</u>	<u>6601, 66</u>
<u>0203</u>	<u>0203, 2</u>	29	29, <u>2901</u> , <u>2902</u>	<u>6602</u>	<u>6602, 66</u>
<u>0205</u>	<u>0205, 2</u>	<u>2901</u>	<u>2901, 29</u>	68	68, <u>6801</u> , <u>6802</u>
<u>0206</u>	<u>0206, 2</u>	<u>2902</u>	<u>2902, 29</u>	<u>6801</u>	<u>6801, 68</u>
3	3	30	30, <u>3001</u> , <u>3002</u>	<u>6802</u>	<u>6802, 68</u>
9	9	<u>3001</u>	<u>3001, 30</u>	69	69
10	10	<u>3002</u>	<u>3002, 30</u>	74	74
11	11, <u>1101</u> , <u>1102</u>	31	31	80	80
<u>1101</u>	<u>1101, 11</u>	32	32	203	203, 2
<u>1102</u>	<u>1102, 11</u>	33	33, <u>3301</u> , <u>3303</u>	240	240, 2
19	19	<u>3301</u>	<u>3301, 33</u>	2403	2403, 24
23	23	<u>3303</u>	<u>3303, 33</u>	*6604	*6601, 66
24	24, <u>2402</u> , 2403	34	34	*6602	*6602, 66
<u>2402</u>	<u>2402, 24</u>	<u>3401</u>	<u>3401, 34</u>	** 99	(No equivalent)
		<u>3402</u>	<u>3402, 34</u>		

231

232

233

Table 4-43: HLA B Matching Antigen Equivalences

Patient B Locus Antigen	Equivalent Donor Antigens
5	5
7	<del>7, 703, 0702</del>
<u>0702</u>	<u>0702, 7</u>
8	8
<u>0802</u>	<u>0802</u>
<u>0803</u>	<u>0803</u>
<u>0804</u>	<u>0804</u>
12	12
13	13, <u>1301, 1302</u>
<u>1301</u>	<u>1301, 13</u>
<u>1302</u>	<u>1302, 13</u>
14	14, <del>64, 65</del>
<u>1401</u>	<u>1401, 64</u>
<u>1402</u>	<u>1402, 65</u>
15	15
<u>1501</u>	<u>1501, 62</u>
<u>1502</u>	<u>1502, 75</u>
<u>1503</u>	<u>1503, 72</u>
<u>1510</u>	<u>1510, 71</u>
<u>1511</u>	<u>1511, 75</u>
<u>1512</u>	<u>1512, 76</u>
<u>1513</u>	<u>1513, 77</u>
<u>1516</u>	<u>1516, 63</u>
<u>1517</u>	<u>1517, 63</u>
16	16
17	17
18	18
21	21
22	22
27	27, <u>2705</u>
<u>2705</u>	<u>2705, 27</u>
<u>2708</u>	<u>2708</u>
35	35
37	37
38	38

Patient B Locus Antigen	Equivalent Donor Antigens
39	39, 3901, 3902, *3905, <u>3913</u>
<u>3901</u>	<u>3901, 39</u>
<u>3902</u>	<u>3902, 39</u>
<u>3905</u>	<u>3905, 39</u>
<u>3913</u>	<u>3913, 39</u>
40	40, <del>64</del>
<u>4001</u>	<u>4001, 60</u>
<u>4002</u>	<u>4002, 61</u>
<u>4005</u>	<u>4005, 50</u>
<u>4006</u>	<u>4006, 61</u>
41	41
42	42
44	44, <u>4402, 4403</u>
<u>4402</u>	<u>4402, 44</u>
<u>4403</u>	<u>4403, 44</u>
<u>4415</u>	<u>4415, 45</u>
45	45, <u>4415</u>
46	46
47	47
48	48
49	49
50	50, 4005
51	51, <u>5101, 5102, 5103</u>
<u>5101</u>	<u>5101, 51</u>
<u>5102</u>	<u>5102, 51</u>
52	52
53	53
54	54
55	55
56	56
57	57, <u>5701, 5703</u>
<u>5701</u>	<u>5701, 57</u>
<u>5703</u>	<u>5703, 57</u>

Patient B Locus Antigen	Equivalent Donor Antigens
58	58
59	59
60	60, <u>4001</u>
61	61, <u>4002, 4006</u>
62	62, <u>1501</u>
63	63, <u>1516, 1517</u>
64	64, <u>1401</u>
65	65, <u>1402</u>
67	67
70	70, <del>71, 72</del>
71	71, <del>70, 1510</del>
72	72, <del>70, 1503</del>
73	73
75	75, <u>1502, 1511, 45</u>
76	76, <del>45, 1512</del>
77	77, <del>45, 1513</del>
78	78
81	81
82	82, *8204
<del>703</del>	<del>703, 7</del>
*0804	*0804, 8
*1304	*1304, 15, 21, 40, 50
<del>2708</del>	<del>2708, 27</del>
<del>3901</del>	<del>3901, 39</del>
<del>3902</del>	<del>3902, 39</del>
*3905	*3905, 39
4005	4005, 50
5101	5101, 51
5102	5102, 51, 53
5103	5103, 51
7801	7801
*8201	*8201, 82
** 99	(No equivalent)

234

235

236

237

Table 4-54: HLA DR Matching Antigen Equivalence

238

Patient DR Locus Antigen	Equivalent Donor Antigens
1	1, <del>103</del> 0101, 0102
0101	0101, 1
0102	0102, 1
103	103
2	2
3	3
0301	0301, 17
0302	0302, 18
4	4
0401	0401, 4
0402	0402, 4
0403	0403, 4
0404	0404, 4
0405	0405, 4
0407	0407, 4
5	5
6	6
7	7

Patient DR Locus Antigen	Equivalent Donor Antigens
8	8
9	9
0901	0901, 9
0902	0902, 9
10	10
11	11
1101	1101, 11
1104	1104, 11
12	12
1201	1201, 12
1202	1202, 12
13	13, 1301, 1303
1301	1301, 13
1303	1303, 13
14	14, 1401, 1402, 1403, 1404, 1454
1401	1401, 14, 1454

Patient DR Locus Antigen	Equivalent Donor Antigens
1402	1402, 14
1403	1403, 14
1404	1404, 14
1454	1454, 14, 1401
15	15
1501	1501, 15
1502	1502, 15
1503	1503, 15
16	16
1601	1601, 16
1602	1602, 16
17	17, 0301
18	18, 0302
403	403, 1
1403	1403, 14, 6
1404	1404, 14, 6
** 99	(No equivalent)

239

240

241 \* Indicates an allele; may not have a WHO approved serologic specificity

242 \*\* Code 99 means not tested

243 Examples of how “Matching Antigen Equivalences” works:

244

- 245 • If the patient candidate types as has B70: only donors that type as with B70, B71, and B72 are  
246 considered not mismatched.
- 247 • If the patient candidate types as has B71: only donors that type as with B71 or B1510 and B720 are  
248 considered not mismatched. Donors with B72 are considered mismatched.

249

250 Tables 4-5, 4-6, 4-7, 4-8, 4-9, 4-10, 4-11 and 4-12, show candidate-donor unacceptable antigen  
251 combinations. For each candidate antigen, the donor antigens that are unacceptable are listed below.

252

253 **Table 4-65: HLA A Unacceptable Antigen Equivalences**

Patient Unacceptable A Locus Antigen	Donor Equivalent Antigens	Patient Unacceptable A Locus Antigen	Donor Equivalent Antigens	Patient Unacceptable A Locus Antigen	Donor Equivalent Antigens
1	1	19	19, 29, 2901, 2902, 30, 3001, 3002, 31, 32, 33, 3301, 3303, 74	33	33, 3301, 3303
2	2, 0201, 0202, 0203, 0205, 0206, 240	23	23	3301	3301
0201	0201	24	24, 2402, 2403	3303	3303
0202	0202	2402	2402	34	34, 3401, 3402
0203	0203	2403	2403	3401	3401
0205	0205	25	25	3402	3402
0206	0206	26	26	36	36
3	3	28	28, 68, 69, 6801, 6802	43	43
9	9, 23, 24, 2402, 2403	29	29, 2901, 2902	66	66, *6601, *6602
10	10, 25, 26, 34, 3401, 3402, 66, *6601, *6602, 43	2901	2901	6601	6601
11	11, 1101, 1102	2902	2902	6602	6602
1101	1101	30	30, 3001, 3002	68	68, 6801, 6802
1102	1102	3001	3001	6801	6801
		3002	3002	6802	6802
		31	31	69	69
		32	32	74	74
				80	80
				203	203
				210	210
				2403	2403
				*6601	*6601
				*6602	*6602

254

255

256

Table 4-76 HLA B Unacceptable Antigen Equivalences

Patient Unacceptable B Locus Antigen	Donor Equivalent Antigens
5	5, 51, <u>5101</u> , <u>5102</u> , <del>5403</del> , <del>52</del> , <del>78</del>
7	7, <del>703</del> , <u>0702</u>
<u>0702</u>	<u>0702</u>
8	8
<u>0802</u>	<u>0802</u>
<u>0803</u>	<u>0803</u>
<u>0804</u>	<u>0804</u>
12	12, 44, <u>4402</u> , <u>4403</u> , <u>4415</u> , 45
13	13, <u>1301</u> , <u>1302</u>
<u>1301</u>	<u>1301</u>
<u>1302</u>	<u>1302</u>
14	14, 64, 65, <u>1401</u> , <u>1402</u>
<u>1401</u>	<u>1401</u>
<u>1402</u>	<u>1402</u>
15	15, 62, 63, 75, 76, 77, <u>1501</u> , <u>1502</u> , <u>1503</u> , <u>1510</u> , <u>1511</u> , <u>1512</u> , <u>1513</u> , <u>1516</u> , <u>1517</u>
<u>1501</u>	<u>1501</u>
<u>1502</u>	<u>1502</u>
<u>1503</u>	<u>1503</u>
<u>1510</u>	<u>1510</u>
<u>1511</u>	<u>1511</u>
<u>1512</u>	<u>1512</u>
<u>1513</u>	<u>1513</u>
<u>1516</u>	<u>1516</u>
<u>1517</u>	<u>1517</u>
16	16, 38, 39, <u>3901</u> , <u>3902</u> , <u>3905</u> , <u>3913</u>

Patient Unacceptable B Locus Antigen	Donor Equivalent Antigens
17	17, 57, <u>5701</u> , <u>5703</u> , 58
18	18
21	21, 49, 50, 4005
22	22, 54, 55, 56
27	27, <u>2705</u> , <u>2708</u>
<u>2705</u>	<u>2705</u>
<u>2708</u>	<u>2708</u>
35	35
37	37
38	38
39	39, 3901, 3902, *3905, <u>3913</u>
<u>3901</u>	<u>3901</u>
<u>3902</u>	<u>3902</u>
<u>3905</u>	<u>3905</u>
<u>3913</u>	<u>3913</u>
40	40, 60, 61, <u>4001</u> , <u>4002</u>
<u>4001</u>	<u>4001</u> , 60
<u>4002</u>	<u>4002</u>
<u>4005</u>	<u>4005</u> , 50
<u>4006</u>	<u>4006</u>
41	41
42	42
44	44, <u>4402</u> , <u>4403</u>
<u>4402</u>	<u>4402</u>
<u>4403</u>	<u>4403</u>
<u>4415</u>	<u>4415</u> , 45
45	45, <u>4415</u>
46	46
47	47
48	48

Patient Unacceptable B Locus Antigen	Donor Equivalent Antigens
49	49
50	50, 4005
51	51, <u>5101</u> , <u>5102</u> - <u>5103</u>
<u>5101</u>	<u>5101</u>
<u>5102</u>	<u>5102</u>
52	52
53	53
54	54
55	55
56	56
57	57, <u>5701</u> , <u>5703</u>
<u>5701</u>	<u>5701</u>
<u>5703</u>	<u>5703</u>
58	58
59	59
60	60
61	61, <u>4002</u> , <u>4006</u>
62	62, <u>1501</u>
63	63, <u>1516</u>
64	64, <u>1401</u>
65	65, <u>1402</u>
67	67
70	70, 71, 72, <u>1503</u> , <u>1510</u>
71	71, <u>1510</u>
72	72, <u>1503</u>
73	73
75	75, <u>1502</u> , <u>1511</u>
76	76, <u>1512</u>
77	77, <u>1513</u>
78	78
81	81
82	82, *8204
703	703
*0804	*0804

Patient Unacceptable B Locus Antigen	Donor Equivalent Antigen
*1304	*1304
2708	2708
3904	3904
3902	3902
*3905	*3905
4005	4005, 50
5102	5102
5103	5103
7804	7804, 78
*8204	*8204, 82

Patient Unacceptable B Locus Antigen	Donor Equivalent Antigen
Bw4	Bw4, <u>0802</u> , <u>0803</u> , <u>0804</u> , 5, 13, <u>1301</u> , <u>1302</u> , <u>1513</u> , <u>1516</u> , <u>1517</u> , 17, 27, 37, 38, 44, <u>4402</u> , <u>4403</u> , <u>4415</u> , 47, 49, 51, <u>5101</u> , <u>5102</u> , 52, 53, 57, <u>5701</u> , <u>5703</u> , 58, 59, 63, 77

Patient Unacceptable B Locus Antigen	Donor Equivalent Antigen
Bw6	Bw6, 7, <u>0702</u> , 8, <u>0801</u> , 14, <u>1401</u> , <u>1402</u> , <u>1501</u> , <u>1502</u> , <u>1503</u> , <u>1510</u> , <u>1511</u> , <u>1512</u> , 18, 22, 2708, 35, 39, <u>3901</u> , <u>3902</u> , <u>3905</u> , <u>3913</u> , 40, <u>4001</u> , <u>4002</u> , <u>4006</u> , 41, 42, 45, 48, 50, *4005, 54, 55, 56, 60, 61, 62, 64, 65, 67, 70, 71, 72, 75, 76, 78, 81, 82

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Table 4-87: HLA C Unacceptable Antigen Equivalences

Patient Unacceptable C Locus Antigen	Donor Equivalent Antigen
w <u>01</u>	w <u>01</u>
w <u>02</u>	w <u>02</u>
w <u>03</u>	w <u>03</u> , w <u>09</u> , w <u>10</u>
w <u>04</u>	w <u>04</u>
w <u>05</u>	w <u>05</u>
w <u>06</u>	w <u>06</u>

Patient Unacceptable C Locus Antigen	Donor Equivalent Antigen
w <u>07</u>	w <u>07</u> , <u>0701</u> , <u>0702</u>
<u>0701</u>	<u>0701</u>
<u>0702</u>	<u>0702</u>
w <u>08</u>	w <u>08</u>
w <u>09</u>	w <u>09</u>
w <u>10</u>	w <u>10</u>

Patient Unacceptable C Locus Antigen	Donor Equivalent Antigen
* <u>12</u>	* <u>12</u>
* <u>14</u>	* <u>14</u>
* <u>15</u>	* <u>15</u>
* <u>16</u>	* <u>16</u>
* <u>17</u>	* <u>17</u>
* <u>18</u>	* <u>18</u>

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Table 4-98: HLA DR Unacceptable Antigen Equivalences

Patient Unacceptable DR Locus Antigen	Donor Equivalent Antigens
1	1, <u>0101</u> , <u>0102</u>
<u>0101</u>	<u>0101</u>
<u>0102</u>	<u>0102</u>
<u>103</u>	<u>103</u>
2	2, 15, <u>1501</u> , <u>1502</u> , <u>1503</u> , <u>16</u> , <u>1601</u> , <u>1602</u>
3	3, 17, 18, <u>0301</u> , <u>0302</u>
<u>0301</u>	<u>0301</u> , <u>17</u>
<u>0302</u>	<u>0302</u> , <u>18</u>
4	4, <u>0401</u> , <u>0402</u> , <u>0403</u> , <u>0404</u> , <u>0405</u> , <u>0407</u>
<u>0401</u>	<u>0401</u>
<u>0402</u>	<u>0402</u>
<u>0403</u>	<u>0403</u>
<u>0404</u>	<u>0404</u>
<u>0405</u>	<u>0405</u>
<u>0407</u>	<u>0407</u>
5	5, 11, <u>1101</u> , <u>1104</u> , 12, <u>1201</u> , <u>1202</u>
6	6, 13, <u>1301</u> , <u>1303</u> , 14, <u>1401</u> , <u>1402</u> , <u>1403</u> , <u>1404</u> , <u>1454</u>
7	7
8	8
9	9, <u>0901</u> , <u>0902</u>
<u>0901</u>	<u>0901</u>
<u>0902</u>	<u>0902</u>
10	10
11	11, <u>1101</u> , <u>1104</u>
<u>1101</u>	<u>1101</u>

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Patient Unacceptable DR Locus Antigen	Donor Equivalent Antigens
<u>1104</u>	<u>1104</u>
12	12, <u>1201</u> , <u>1202</u>
<u>1201</u>	<u>1201</u>
<u>1202</u>	<u>1202</u>
13	13, <u>1301</u> , <u>1303</u>
<u>1301</u>	<u>1301</u>
<u>1303</u>	<u>1303</u>
14	14, <u>1401</u> , <u>1402</u> , <u>1403</u> , <u>1404</u> , <u>1454</u>
<u>1401</u>	<u>1401</u>
<u>1402</u>	<u>1402</u>
<u>1403</u>	<u>1403</u>
<u>1404</u>	<u>1404</u>
<u>1454</u>	<u>1454</u>
15	15, <u>1501</u> , <u>1502</u> , <u>1503</u>
<u>1501</u>	<u>1501</u>
<u>1502</u>	<u>1502</u>
<u>1503</u>	<u>1503</u>
16	16, <u>1601</u> , <u>1602</u>
<u>1601</u>	<u>1601</u>
<u>1602</u>	<u>1602</u>
17	17, <u>0301</u>
18	18, <u>0302</u>
403	403
4403	4403
4404	4404
51*	51
52*	52
53*	53

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**Table 4-9: HLA DR51 Unacceptable Antigen Equivalences**

<u>Patient Unacceptable DR51 Locus Antigen</u>	<u>Donor Equivalent Antigens</u>
<u>5*01:01</u>	<u>5*01:01</u>
<u>5*02:02</u>	<u>5*02:02</u>
<u>51</u>	<u>51, 5*01:01, 5*02:02</u>

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**Table 4-10: HLA DR52 Unacceptable Antigen Equivalences**

<u>Patient Unacceptable DR52 Locus Antigen</u>	<u>Donor Equivalent Antigens</u>
<u>3*01:01</u>	<u>3*01:01</u>
<u>3*02:02</u>	<u>3*02:02</u>
<u>3*03:01</u>	<u>3*03:01</u>
<u>52</u>	<u>52, 3*01:01, 3*02:02, 3*03:01</u>

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**Table 4-11: HLA DR53 Unacceptable Antigen Equivalences**

<u>Patient Unacceptable DR 53 Locus Antigen</u>	<u>Donor Equivalent Antigens</u>
<u>4*01:01</u>	<u>4*01:01</u>
<u>4*01:03</u>	<u>4*01:03</u>
<u>53</u>	<u>53, 4*01:01, 4*01:03</u>

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**Table 4-102: HLA DQB1 Unacceptable Antigen Equivalences**

<u>Patient Unacceptable DQB1 Locus Antigen</u>	<u>Donor Equivalent Antigens</u>
<u>1</u>	<u>1, 5, 6, 0501, 0502, 0601, 0602, 0603, 0604, 0609</u>
<u>2</u>	<u>2, 0201, 0202</u>
<u>3</u>	<u>3, 7, 8, 9, 0301, 0302, 0303, 0319</u>
<u>0301</u>	<u>0301, 7</u>
<u>0302</u>	<u>0302, 8</u>
<u>0303</u>	<u>0303, 9</u>
<u>0319</u>	<u>0319, 7</u>
<u>4</u>	<u>4, 0401, 0402</u>
<u>0401</u>	<u>0401</u>
<u>0402</u>	<u>0402</u>
<u>5</u>	<u>5, 0501, 0502, 4</u>
<u>0501</u>	<u>0501</u>
<u>0502</u>	<u>0502</u>
<u>6</u>	<u>6, 4, 0601, 0602, 0603, 0604, 0609</u>
<u>0601</u>	<u>0601</u>
<u>0602</u>	<u>0602</u>
<u>0603</u>	<u>0603</u>
<u>0604</u>	<u>0604</u>

Patient Unacceptable DQB1 Locus Antigen	Donor Equivalent Antigens
<u>0609</u>	<u>0609</u>
7	7, 3, <u>0301, 0319</u>
8	8, 3, <u>0302</u>
9	9, 3, <u>0303</u>

271 \* ~~Indicates an allele; may not have a WHO approved serologic specificity~~

272 \*\*\* ~~Please refer to the end of this section for information~~

273

274 Examples of how “Unacceptable Antigen Equivalences” works:

275

276 If a ~~patient candidate~~ has B70 listed as an “unacceptable antigen”, donors typed as B70, B71, ~~and or~~  
 277 B72, 1503, or 1510 are considered unacceptable. Donors typed as B73 and B75 are considered  
 278 acceptable.

279

280

281

**Table 4-13: Additional Unacceptable Antigen Equivalences to be used in the Calculated Panel Reactive Antibody (CPRA) Only**

Locus	Patient Unacceptable Antigen	Unacceptable DR antigen equivalences used for CPRA calculation
<u>DR51</u>	<u>5*0101</u>	<u>2, 15, 16</u>
	<u>5*0202</u>	<u>2, 15, 16</u>
	<u>51</u>	<u>2, 15, 16</u>
<u>DR52</u>	<u>3*0101</u>	<u>3, 5, 6, 11, 12, 13, 14, 17, 18</u>
	<u>3*0202</u>	<u>3, 5, 6, 11, 12, 13, 14, 17, 18</u>
	<u>3*0301</u>	<u>3, 5, 6, 11, 12, 13, 14, 17, 18</u>
	<u>52</u>	<u>3, 5, 6, 11, 12, 13, 14, 17, 18</u>
<u>DR53</u>	<u>4*0101</u>	<u>4, 7, 9</u>
	<u>4*0103</u>	<u>4, 7, 9</u>
	<u>53</u>	<u>4, 7, 9</u>

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283 ~~Additional Unacceptable Antigen Equivalences to be used in the Calculated PRA Only:~~

284

285 ~~DR51 should also include DR2, DR15, DR16.~~

286 ~~DR52 should also include DR3, DR5, DR6, DR11, DR12, DR13, DR14, DR17, DR18.~~

287 ~~DR53 should also include DR4, DR7, DR9.~~

288

### 289 13.5 OPTN KPD Histocompatibility Testing

#### 290 13.5.A HLA Typing Requirements for OPTN KPD Candidates

291 Before a candidate can appear on an OPTN KPD match run, the paired candidate’s transplant hospital is  
 292 responsible for reporting to the OPTN Contractor serological split level molecular typing results for *all* of  
 293 the following:

294

- 295 • HLA-A
- 296 • HLA-B
- 297 • HLA-Bw4
- 298 • HLA-Bw6
- 299 • HLA-DR

300  
 301 If the candidate has unacceptable antigens listed for any of the following HLA types, then the paired  
 302 candidate's transplant hospital is responsible for reporting to the OPTN Contractor serological split level  
 303 molecular typing results for the corresponding HLA type before the candidate can appear on an OPTN  
 304 KPD match run:

- 305
- 306 • HLA-C
- 307 • HLA-DR51
- 308 • HLA-DR52
- 309 • HLA-DR53
- 310 • HLA-DPB1
- 311 • HLA-DQA1
- 312 • HLA-DQB1
- 313

### 314 **13.5.C HLA Typing Requirements for OPTN KPD Donors**

315 Before a donor can appear on an OPTN KPD match run, the donor's transplant hospital is responsible for  
 316 reporting to the OPTN Contractor serological split level molecular typing results for *all* of the following:

- 317
- 318 • HLA-A
- 319 • HLA-B
- 320 • HLA-Bw4
- 321 • HLA-Bw6
- 322 • HLA-C
- 323 • HLA-DR
- 324 • HLA-DR51
- 325 • HLA-DR52
- 326 • HLA-DR53
- 327 • HLA-DPB1
- 328 • HLA-DQA1
- 329 • HLA-DQB1

330 #