

## ***At-a-Glance***

### **Expanding Candidate and Deceased Donor HLA Typing Requirements to Provide Greater Consistency Across Organ Types**

- **Affected/Proposed Policy:** 2.8.A (Required Information for Deceased Kidney Donors); 2.8.B (Required Information for Deceased Liver Donors); 2.8.C (Required Information for Deceased Heart Donors); 2.8.D (Required Information for Deceased Lung Donors); 2.8.E (Required Information for Deceased Pancreas Donors); 3.4.D (Candidate Human Leukocyte Antigen (HLA Information)); 4.2 (HLA Typing); and 4.6.B (HLA Typing)

#### **Histocompatibility Committee**

The proposed changes make the HLA typing methods and list of HLA loci to be reported consistent for deceased donors across all organ types. The required methods and list of HLA loci to be reported will apply both when OPTN policy requires HLA typing be performed and reported on the deceased donor prior to allocation (i.e. for kidney, kidney-pancreas, and pancreas allocation) and in instances where HLA typing is required only if requested by the candidate's transplant program (i.e. for heart, heart-lung, and lung allocation). The proposal includes new requirements for reporting HLA-DQA and HLA-DPB for deceased donors. The time period for reporting deceased donor HLA typing remains different by organ type to meet varying clinical requirements for timing of transplants. The proposal newly requires HLA typing to be performed and reported for deceased liver donors if requested by a transplant program and makes HLA typing requirements for deceased pancreas islet donors and candidates consistent with those for deceased pancreas donors and candidates.

- **Affected Groups**  
OPO Executive Directors, Medical Directors, and Coordinators  
Histocompatibility Laboratory Directors and Staff  
Transplant Administrators  
Transplant Data Coordinators  
Transplant Physicians/Surgeons  
Organ Candidates
- **Number of Potential Candidates Affected**  
All organ candidates awaiting a deceased donor are potentially affected by this policy.
- **Expected Impact on Strategic Plan and to Final Rule**  
This proposal is intended to further objectives in the Final Rule pertaining to efficient management of organ placement by improving virtual crossmatching and, therefore, preventing some unexpected positive crossmatches that result in discards or increased cold ischemia time. It is also intended to further the OPTN strategic goal of promoting transplant safety by requiring additional information on deceased donors to be used in determining donor and recipient compatibility and post-transplant monitoring.

- **Specific Requests for Comment**

This proposal includes a requirement for HLA-DQA and HLA-DPB to be reported on deceased donors (the timeframe for reporting varies based on organ type). The Histocompatibility Committee is requesting feedback on the following questions.

Does your transplant program screen candidates for antibodies to HLA-DQA and HLA-DPB?

If so, is it sufficient to have this donor HLA information recorded in DonorNet to use when making donor acceptance decisions? Or, is it imperative to add unacceptable antigen fields for these loci and program the UNOS system to automatically avoid those donors when unacceptable antigens are listed?

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### **Histocompatibility Committee**

**Public comment response period:** March 14, 2014 – June 13, 2014

### **Summary and Goals of the Proposal**

This proposal includes the following changes:

- Makes consistent the list of HLA loci required to be reported for deceased donors across organ type both when policy requires HLA typing be performed and reported on the deceased donor prior to allocation (i.e. for kidney, kidney-pancreas, and pancreas allocation) and in instances where HLA typing is required only if requested by the candidate's transplant program (i.e. for heart, heart-lung, or lung allocation). The proposal newly requires HLA typing for deceased liver donors if requested by the candidate's transplant program.
- Requires molecular typing to be performed on all deceased donors, both when policy requires HLA typing be performed and reported on the deceased donor prior to allocation (i.e. for kidney, kidney-pancreas, and pancreas allocation) and in instances where HLA typing is required only if requested by the candidate's transplant program (i.e. for deceased heart, heart-lung, lung, or liver donors)
- Adds HLA-DQA and HLA-DPB to the list of HLA loci required to be reported for deceased donors. As proposed, these fields will only be programmed into DonorNet® for physicians to use in making donor acceptance decisions.
- Aligns requirements for deceased pancreas islet donors and candidates with those of pancreas donors and candidates.

The goal of this proposal is to improve virtual crossmatching and prevent unexpected positive crossmatches that result in discards or increased cold ischemia time. The proposal is also intended to promote transplant safety by requiring additional information on deceased donors to be used in determining donor and recipient compatibility and post-transplant monitoring.

### **Background and Significance of the Proposal:**

In 2012, the Histocompatibility Committee began conducting a comprehensive rewrite of the OPTN policies governing histocompatibility testing. As part of this effort, the Committee organized all the HLA typing requirements into two tables, one for deceased donors and one for candidates (see below).

**Table 1 HLA Typing Requirements for Deceased Donors**

Organ	A	B	Bw4	Bw6	C	DR	DR51	DR 52	DR53	DPB	DQB
Kidney	•	•	•	•	•	•	•	•	•		•
Pancreas	•	•	•	•	•	•	•	•	•		•
Kidney-Pancreas	•	•	•	•	•	•	•	•	•		•
Heart*	•	•	•	•	•	•				•	•
Lung*	•	•	•	•	•	•				•	•

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

**Table 2: HLA Typing Requirements for Candidates**

Organ	A	B	Bw4	Bw6	DR
Kidney alone	•	•	•	•	•
Pancreas alone	•	•	•	•	•
Kidney-Pancreas	•	•	•	•	•

The Committee identified several problems with the current HLA typing requirements:

- It is critical for all transplant physicians to have complete HLA information when making decisions about donor acceptance and performing post-transplant monitoring. However, there are several inconsistencies in the list of HLA types required to be reported for deceased donors across organ types.
- Recent research suggests that antibodies to HLA-DQA and HLA-DPB are frequently observed in sensitized transplant candidates<sup>1</sup>. If donors with the relevant types are not avoided, these antibodies can contribute to adverse graft outcomes. However, these HLA types are not required to be reported on deceased donors. HLA-DPB is currently only required if requested for heart or lung offers and the OPO's laboratory performs this testing. Even if an OPO's histocompatibility laboratory types the donor for HLA-DQA or HLA-DPB prior to allocation, the only way to currently communicate

<sup>1</sup> Tambur, AR, JR Leventhal, and JR Zitzner, et al. "Improving organ allocation equity using HLA-DQ information." *Transplantation*. no. 4 (2013): 635-640.

this information is through an attachment function in DonorNet®, which can sometimes be overlooked.

- Publications implicate anti-HLA antibodies may contribute to negative outcomes in pancreas islet transplants and negatively impact the ability of islet recipients to undergo further islet, pancreas, or kidney transplantation.<sup>2</sup> HLA typing could be crucial for evaluating risk from pre-transplant and *de novo* HLA antibodies. However, there are currently no HLA typing requirements for deceased pancreas islet donors or candidates.
- It is critical for heart and lung transplant programs to have deceased donor HLA typing information prior to transplant. However, HLA typing is only required on deceased heart, heart-lung, and lung donors if requested by the candidate's transplant program.
- There is increasing evidence of antibody mediated rejection (AMR) in liver transplantation<sup>34</sup>. However, there is currently no requirement for HLA typing to be performed on a deceased liver donor if the candidate's transplant program requests it.
- Deceased donor HLA typing performed using molecular methods provides much superior accuracy and advantages for transplant candidates. However, laboratories are currently required to perform molecular typing on deceased kidney, kidney-pancreas, and pancreas donors only.

Early in the process, the Committee identified a list of solutions to address these problems:

- Make consistent the list of HLA loci required to be reported across organ type.
- Add HLA-DQA and HLA-DPB to the list of HLA loci required to be reported for deceased donors.
- Align requirements for deceased pancreas islet donors and candidates with those of deceased pancreas donors and candidates.
- Require HLA typing be performed and reported for deceased thoracic donors (not merely if requested), either pre-transplant or within a certain period of time after transplant.
- Require HLA typing to be performed for deceased liver donors if requested by the candidate's transplant program.
- Require molecular typing to be performed on all deceased donors (both when OPTN policy requires the typing to be performed and when it is required only if requested by a candidate's physician).

The Committee then presented these solutions to the following groups for feedback:

- Organ Procurement Organization (OPO) Committee

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<sup>2</sup> Campbell, PM, PA Senior, and A Salam, et al. "High Risk of Sensitization After Failed Islet Transplantation." *American Journal of Transplantation* . no. 7 (2007): 2311-2317.

<sup>3</sup> Kozlowski, T, T Rubinas, V Nickeleit, et al. "Liver Allograft Antibody-Mediated Rejection With Demonstration of Sinusoidal C4d Staining and Circulating Donor-Specific Antibodies." *Liver Transplantation*. no.17 (2011): 357-368.

<sup>4</sup> Musat, AI, RM Agni, PY Wai, et al. "The Significance of Donor-Specific HLA Antibodies in Rejection and Ductopenia Development in ABO Compatible Liver Transplantation." *American Journal of Transplantation*. no. 11 (2011): 500-510.

- Thoracic Transplantation Committee
- Kidney Transplantation Committee
- Pancreas Transplantation Committee
- Liver and Intestine Transplantation Committee
- American Society of Histocompatibility and Immunogenetics (ASHI) Board of Directors
- College of American Pathologists (CAP) Histocompatibility Committee and Staff

In addition to the list of solutions, the Committee presented data showing that an increasing number of laboratories are reporting HLA-DPB typing results on the Donor Histocompatibility Form (DHF) completed post-transplant. For more information, please see the Supporting Evidence and/or Modeling section.

The OPO Committee expressed general support for the proposal and members indicated that there are more benefits than negatives, especially if the changes decrease unexpected positive crossmatches for kidney allocation. Some members questioned whether requiring new methods and additional loci will add to the overall allocation expense for some OPOs. The Histocompatibility Committee leadership acknowledged that there may be additional cost associated with some of the solutions, but pointed out that the changes may also offset costs OPOs are currently incurring due to unexpected positive crossmatches, cold ischemia time, and discards. Several members requested that the Committee consider delayed implementation of any future policy proposal if there is a determination that some laboratories do not have the resources to perform typing for HLA-DQA and HLA-DPB. The Committee leadership responded that Committee will discuss whether or not a delayed implementation will be necessary. The OPO Committee members also cautioned the Committee against any new HLA typing requirements for allocation of thoracic organs that would delay the OPO in making offers.

The Thoracic Transplantation Committee had similar comments with regard to thoracic allocation and any new requirements for HLA typing to be reported prior to match runs (not merely if requested). The Histocompatibility Committee leadership presented OPTN data showing that deceased donor HLA information is now being reported prior to match runs for thoracic organs about 80% of the time (for more information, see the Supporting Evidence and/or Modeling section). Members of the Thoracic Committee expressed the view that it is important to allow the heart and lung allocation process to continue without delay if the potential recipient's physician does not request HLA information on the donor. The Committee did, however, support the notion that molecular typing and the list of types required to be reported should be consistent when HLA information is requested by the candidate's transplant program. After receiving this feedback, the Committee decided not to propose requiring HLA typing for all deceased thoracic donors, but to require molecular typing be performed and the full list of HLA loci to be reported if requested by the candidate's transplant program prior to final acceptance.

The Kidney Transplantation Committee indicated strong support for these proposed solutions, especially with regard to adding HLA-DQA and HLA-DPB to the list of types required to be reported prior to kidney allocation. Several members of the Committee expressed concern that a number of unexpected positive crossmatches are due to these types not being reported on the match run, and that this problem will only be more complex with implementation of the new kidney allocation system. The Pancreas Transplantation Committee also supported the solutions outlined for additional information to be reported for pancreas donors and candidates and pancreas islet donors and candidates.

Members of the Liver and Intestine Transplantation Committee agreed with the notion that HLA typing should be required if requested by the liver transplant program and that laboratories should be required to report molecular typing results for the complete list of types for the liver transplant physician to consider. In addition, several members commented that the timing specifications for reporting HLA typing for liver allocation or transplantation will vary greatly from that for other organ types. Members requested that the Committee require only that the information be reported in the time period specified by the transplant program.

Both ASHI and CAP indicated support for the proposed solutions.

In December 2013, the Committee held a conference call to review feedback from the OPO and organ specific committees. After discussing the feedback, the Committee unanimously agreed to distribute this proposal for public comment.

### **Supporting Evidence and/or Modeling:**

In the deliberation process, the committee considered or presented the following data:

#### Molecular typing

Since molecular typing is only currently required for deceased kidney, kidney-pancreas, and pancreas donors, the Committee requested data to determine whether it is common for laboratories to perform HLA typing using other methods for deceased liver or thoracic alone donors. The Committee reviewed data on the typing methods for kidney and/or pancreas donors and donors who donated neither kidney nor pancreas by organ for deceased donors recovered from June 1, 2013 through May 31, 2013 (Exhibit A). The results showed:

- Most deceased donors (91.1%) were kidney and/or pancreas donors. The majority (82%) of donors who donated neither kidney nor pancreas were liver alone donors.
- 98.2% of all deceased donors were HLA typed.
- Of the deceased donors that were HLA typed, 99.9% were typed using molecular methods and 17.5% were also typed by serology
- Serological only typing was reported by 3 donor laboratories for 4 donors (0.1% of HLA typed donors). Two of those laboratories reported using molecular methods or both serology and molecular typing for other deceased donors. One laboratory had only one deceased donor and reported typing by serology only. That laboratory reported molecular typing for most kidney, kidney-pancreas and pancreas recipients.

#### HLA typing for thoracic donors

UNOS staff provided the following data to the OPTN/UNOS Thoracic and OPO Committees on the frequency of HLA typing for deceased thoracic donors and how often HLA was reported for deceased thoracic donors prior to a match run:

While almost all thoracic donors were HLA typed, HLA typing was available prior to 79% of thoracic offers (Table 3).

**Table 3. HLA available\* prior to match run: thoracic matches run for deceased donors recovered June 1, 2011 – May 31, 2013**

Offer type	HLA prior to match run				All	
	No		Yes		N	%
	N	%	N	%		
Heart-lung	980	20.9	3,707	<b>79.1</b>	4,687	100.0
Heart	601	19.3	2,519	<b>80.7</b>	3,120	100.0
Lung	1,672	22.7	5,708	<b>77.3</b>	7,380	100.0
All	3,253	21.4	11,934	<b>78.6</b>	15,187	100.0

\*at least one antigen reported at the HLA-A, B, and DR loci.

#### Requiring HLA-DQA and HLA-DPB to be reported for all deceased donors

In order to determine whether to require HLA-DQA and HLA-DPB to be reported for deceased donors, the Committee requested data that would determine the frequency with which solid organ candidates have antibodies to these types. Although the absence of current OPTN data fields and varied clinical practice make it difficult to assess the total number of transplant candidates who would currently have unacceptable antigens listed to these types, the Committee conducted an initial survey among several of the committee members whose laboratories serve transplant programs that screen for antibodies to these HLA types. The Committee requested information on the number of candidates at the program who have unacceptable antigens to HLA-DQA or HLA-DPB according to their center's practice in assigning unacceptable antigens. The results were as follows:

For Lab 1: Out of 2,783 candidates, 21.6% (602 patients) have antibodies to HLA-DQA and 33.7% (939 patients) have antibodies to HLA-DPB.

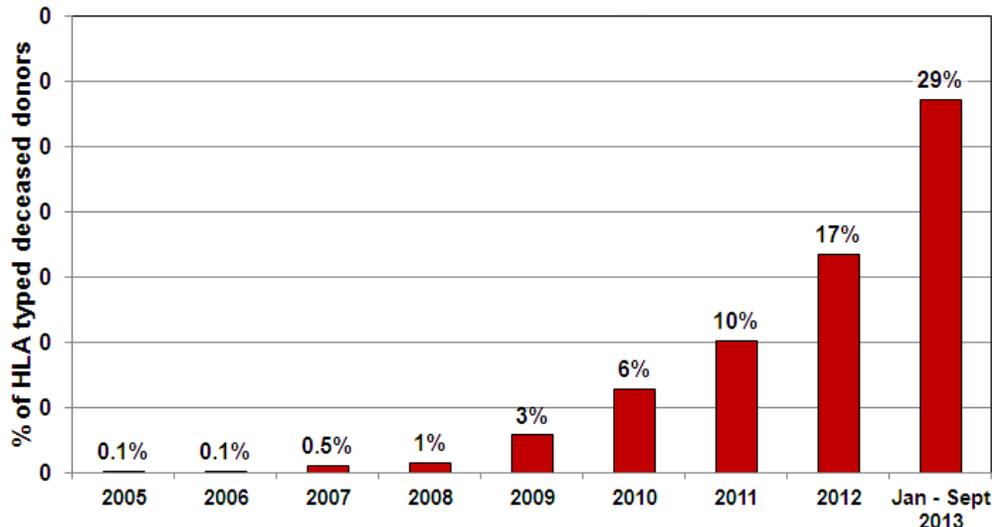
For Lab 2: Out of 846 candidates, 4.0% (34 patients) have antibodies to HLA-DQA and 4.6% (39 patients) have antibodies to HLA-DPB.

For Lab 3: Out of 2,625 candidates, 1.6% (42 patients) have antibodies to HLA-DQA and 6.6% (173 patients) have antibodies to HLA-DPB.

Please note that the three labs above serve centers with different MFI cutoffs for assigning unacceptable antigens.

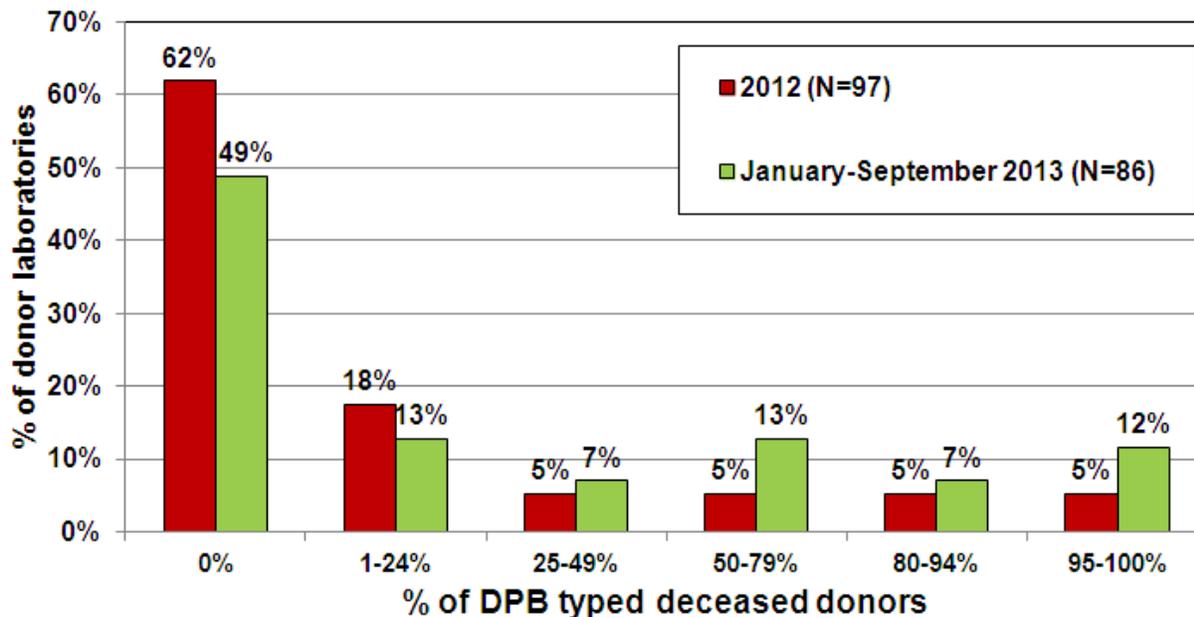
While neither DQA or DPB are collected for deceased donors prior to transplant, HLA-DPB is collected on the OPTN donor and recipient histocompatibility forms submitted after transplant. Trends in HLA-DPB typing of deceased donors can be used as a surrogate marker for donation service areas with centers that are considering candidate antibodies to HLA-DPB. As Figure 1 below shows, data suggest that typing for HLA-DPB on deceased donors continues to increase since 2005.

**Figure 1. Reporting of HLA-DPB for Deceased Donors on Donor Histocompatibility Forms by Year**



62% of donation service areas and 51% of donor laboratories reported DPB typed deceased donors in January – September 2013, compared to 55% and 38% in 2012, respectively. In 2013, 11 laboratories (13%) reported DPB typing for 50%-79% of their donors, 6 (7%) reported it for 80-94% and 10 (12%) laboratories reported it for 95-100% of donors, compared to 5 (5%), 5 (5%) and 5 (5%) in 2012, respectively (Figure 2).

**Figure 2. Distribution of Donor Laboratories by the Percentage of DPB Typed Deceased Donors and Year**



For deceased donors not DPB typed by donor laboratories, recipient laboratories subsequently DPB typed deceased donors for some recipients (10% in 2013 vs. 6% in 2012), likely due to candidate's antibodies.

The values on the HLA-DPB dropdown are incomplete and the Committee is currently finalizing changes to update the dropdown. Due to the incomplete values, some deceased donors typed for HLA-DPB are likely being reported as 'not typed' and the numbers above are likely an underestimate.

#### HLA typing for pancreas islet candidates

Of the 198 pancreas islet registrations waiting on January 3, 2014, 52% had HLA-A, -B, -Bw4, -Bw6 and -DR reported, 38% had some but not all of these antigens reported, and 10% had no antigens reported.

#### **Expected Impact on Living Donors or Living Donation**

Not applicable; these requirements would only apply to deceased donors and candidates.

#### **Expected Impact on Specific Patient Populations**

This proposal will increase transplant safety for sensitized patients by providing transplant programs with information vital to the donor screening and acceptance process.

#### **Expected Impact on Strategic Plan and Adherence to OPTN Final Rule**

This proposal is intended to further objectives in the Final Rule pertaining to efficient management of organ placement by improving virtual crossmatching and, therefore, preventing some unexpected positive crossmatches that result in discards or increased cold ischemia time. It is also intended to further the OPTN strategic goal of promoting transplant safety by preventing negative graft outcomes through more effective donor screening.

#### **Plan for Evaluating the Proposal**

The Histocompatibility Committee will evaluate the effect of this proposal 1 and 2 years post-implementation.

Following implementation, the Committee's hypothesis is that collection of additional data will result in improved allocation due to more accurate virtual crossmatching and that organ offer refusals due to an unacceptable positive crossmatch will decrease. Since external factors and other changes in transplant policy can have an influence on the post-implementation period, interpreting the apparent impact of the additional optional fields based on "before vs. after" analysis must be done with caution.

The following questions, and any others subsequently requested by the Committee, will guide the evaluation of the proposal after implementation:

1. Has the number and the percentage of organ offers refused due to a positive crossmatch decreased?
2. Has the number and percentage of organ offers accepted but organs not transplanted into the intended recipient decreased?

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

1. The number and percentage of offers refused due to a positive crossmatch by organ for kidney, kidney-pancreas and pancreas offers.
2. The number and percentage of offers accepted but organs not transplanted into the intended recipient by organ for kidney, kidney-pancreas and pancreas offers.

The committee will also evaluate the effect of the policy on specific patient populations (pediatric, minority and sensitized candidates).

#### **Additional Data Collection:**

This proposal does require additional data collection. If approved, fields for HLA-DQA and HLA-DPB will be required to be reported on all deceased donors prior to match runs for kidney, kidney-pancreas, and pancreas allocation. HLA-A, HLA-B, HLA-Bw4, HLA-Bw6 and HLA-DR fields will also be required for pancreas islet registrations. These data are being collected to improve the efficiency and safety of the allocation system by enhancing donor screening and to ensure that institutional members are complying with HLA typing policy.

#### **Expected Implementation Plan:**

If public comment is favorable, this proposal will likely go to the Board of Directors for approval in November 2014. If approved, the proposal will be effective pending programming in UNet<sup>SM</sup> and notice to the OPTN membership.

#### **Compliance Monitoring:**

During routine reviews of OPOs, UNOS may request and review donor-specific records to verify documentation showing compliance with the required timeframes for reporting HLA information to transplant programs and the OPTN Contractor.

During routine reviews of member histocompatibility labs, UNOS may request and review donor-specific records to verify:

- Documentation showing compliance with the required timeframes for reporting HLA information to OPOs as noted in Table 4-4 Requirements for HLA Typing.
- That the lab performed molecular typing and that results were reported at the level of serological splits as noted in Table 4-4 Requirements for HLA Typing.
- That the lab performed HLA typing on all kidney, kidney-pancreas, pancreas, or pancreas islet candidates and results were reported as noted in Policy 4.2.B. HLA Typing for Candidates to the transplant program prior to registration of the candidate on the waiting list.

## Policy or Bylaw Proposal:

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

### **2.8.A Required Information for Deceased Kidney Donors**

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

1. Date of admission for the current hospitalization
2. Donor name
3. Donor ID
4. Ethnicity
5. Relevant past medical or social history
6. Current history of abdominal injuries and operations
7. Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria
8. Current medication and transfusion history
9. Anatomical description, including number of blood vessels, ureters, and approximate length of each
10. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR51, DR52, DR53, DQA, and DQB, and DPB antigens prior to organ offers. ~~The lab is encouraged to report splits for all loci as outlined in *Policy 4: Histocompatibility*.~~
11. Indications of sepsis
12. Injuries to or abnormalities of the blood
13. Assurance that final blood and urine cultures are pending
14. Final urinalysis
15. Final blood urea nitrogen (BUN) and creatinine
16. Recovery blood pressure and urine output information
17. Recovery medications
18. Type of recovery procedure, flush solution and method, and flush storage solution
19. Warm ischemia time and organ flush characteristics

### **2.8.B Required Information for Deceased Liver Donors**

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

1. Donor name
2. Donor ID
3. Ethnicity
4. Height
5. Weight
6. Vital signs, including blood pressure, heart rate and temperature
7. Social history, including drug use
8. History of treatment in hospital including current medications, vasopressors, and hydration
9. Current history of hypotensive episodes, urine output, and oliguria
10. Indications of sepsis
11. Aspartate aminotransferase (AST)
12. Bilirubin (direct)
13. Other laboratory tests within the past 12 hours including:
  - a. Alanine aminotransferase (ALT)
  - b. Alkaline phosphatase
  - c. Total bilirubin
  - d. Creatinine
  - e. Hemoglobin (hgb) and hemocrit (hct)

- f. International normalized ration (INR) or Prothrombin (PT) if INR is not available, and partial thromboplastin time (PTT)
  - g. White blood cell count (WBC)
14. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA, DQB, and DPB antigens in the timeframe specified by the transplant program

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

### **2.8.C Required Information for Deceased Heart Donors**

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

1. Height
2. Weight
3. Vital signs, including blood pressure, heart rate, and temperature
4. History of treatment in hospital including vasopressors and hydration
5. Cardiopulmonary, social, and drug activity histories
6. Details of any documented cardiac arrest or hypotensive episodes
7. 12-lead interpreted electrocardiogram
8. Arterial blood gas results and ventilator settings
9. Cardiology consult or echocardiogram, if the hospital has the facilities
10. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA, and DQB, and DPB antigens prior to final organ acceptance

For heart deceased donors, if a transplant ~~hospital~~ program requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and the ~~transplant hospital~~ OPO must provide the HLA information ~~required in the table~~ listed above and document this request. ~~The transplant hospital may request HLA-DPB typing, but the OPO need only provide it if its affiliated laboratory performs related testing.~~ The OPO must document HLA typing provided to the requesting transplant hospital program.

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

### **2.8.D Required Information for Deceased Lung Donors**

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

1. Height
2. Weight
3. Vital signs, including blood pressure, heart rate, and temperature
4. History of medical treatment in hospital including vasopressors and hydration
5. Smoking history
6. Cardiopulmonary, social, and drug activity histories
7. Arterial blood gases and ventilator settings on 5 cm/H2O/PEEP including PO2/FiO2 ratio and preferably 100% FiO2, within 2 hours prior to the offer
8. Bronchoscopy results

9. Chest x-ray interpreted by a radiologist or qualified physician within 3 hours prior to the offer
10. Details of any documented cardiac arrest or hypotensive episodes
11. Sputum gram stain, with description of sputum
12. Electrocardiogram
13. Echocardiogram, if the OPO has the facilities
14. HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, and DQA, DQB, and DPB antigens prior to final organ acceptance

If the host OPO cannot perform a bronchoscopy, it must document that it is unable to provide bronchoscopy results and the receiving transplant hospital may perform it. The lung recovery team may perform a confirmatory bronchoscopy provided unreasonable delays are avoided and deceased donor stability and the time limitations in *Policy 5.5.B: Time Limit for Acceptance* are maintained.

For lung deceased donors, if a transplant ~~hospital~~ program requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and the ~~transplant hospital~~ OPO must provide the HLA information ~~required in the table~~ listed above and document this request. ~~The transplant hospital may request HLA-DPB typing, but the OPO need only provide it if its affiliated laboratory performs related testing.~~ The OPO must document HLA typing provided to the requesting transplant ~~hospital~~ program.

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

### **2.8.E Required Information for Deceased Pancreas Donors**

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

1. Donor name
2. Donor ID
3. Ethnicity
4. Weight
5. Date of admission for the current hospitalization
6. Alcohol use (if known)
7. Current history of abdominal injuries and operations including pancreatic trauma
8. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria
9. Current medication and transfusion history
10. Pertinent past medical or social history including pancreatitis
11. Familial history of diabetes
12. Insulin protocol
13. Indications of sepsis
14. Serum amylase
15. HLA information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, and DQA, DQB<sub>1</sub>, and DPB antigens prior to organ offers ~~The lab is encouraged to report splits for all loci as outlined in *Policy 4: Histocompatibility*.~~

### 3.4.D Candidate Human Leukocyte Antigen (HLA) Requirements

The candidate's transplant program must report to the OPTN Contractor complete human leukocyte antigen (HLA) information (at least 1A, 1B, and 1DR antigen) according to *Table 3-1* below:

**Table 3-1: HLA Requirements**

If the candidate is registered for a...	Then, HLA information is...
Kidney alone	Required
Kidney-pancreas	Required
Kidney with any other non-renal organ	Not required
Pancreas alone	Required
Pancreas islet alone	Required

Transplant programs must report this HLA information using current World Health Organization (WHO) nomenclature when the candidate is registered on the waiting list.

## Policy 4: Histocompatibility

### 4.2 Requirements for Performing and Reporting HLA Typing

Laboratories must 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.

#### 4.2.A Deceased Donor HLA Typing

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

*Table 4-4* below provides the requirements of HLA typing of HLA A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, and DQA, DQB, and DPB antigens.

**Table 4-4: 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:
<u>Deceased Kidney, Kidney-Pancreas, or Pancreas Donor</u>	<u>Prior to organ offers</u>
<u>Deceased Heart, Heart-Lung, or Lung Donors</u>	<u>Prior to final acceptance, if required by the transplant program</u>
<u>Deceased Liver Donors</u>	<u>Within the period specified by the transplant program</u>
Uses cytotoxicity techniques to perform HLA typing	Conform to all relevant standards in <i>Policy 4.8: Cytotoxicity Methods.</i>
Uses nucleic acid analysis, to perform HLA typing	Conform to all relevant standards in <i>Policy 4.10: Nucleic Acid Analysis.</i>
Uses alternative methods for HLA typing	Define the procedures, validate the procedures, and include sufficient controls to ensure accurate assignment of HLA types. The laboratory must conform to all relevant standards from the above sections.

#### 4.2.B HLA Typing for Candidates

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

#### 4.2 — HLA Typing

Laboratories should report splits for all loci shown in *Policy 4.16: Reference Tables of HLA Antigen Values and Split Equivalences.*

#### **4.6.B — HLA Typing**

Laboratories must perform prospective typing of donors and candidates for HLA-A, B, Bw4, Bw6, and DR antigens. In addition, laboratories must perform prospective typing of donors for HLA-DR51, DR52, DR53, C, and DQB antigens. Laboratories should perform prospective typing of candidates for HLA-C and DQB antigens and for DR51, DR52, DR53.