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IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: Brian M. Shepard
UNOS Director of Policy

RE: Summary of actions taken at the OPTN/UNOS Board of Directors Meeting
— November 8-9, 2010

Date: December 9, 2010

The attached report summarizes bylaw changes, policy changes and other actions the OPTN/UNOS Board of Directors approved at its November 2010 meeting.

This format allows you to scan the Board’s actions and quickly determine what is required of you. The notice also includes the specific changes to OPTN/UNOS bylaws and policies. If you are interested in reviewing policy changes from previous board meetings, go to <http://optn.transplant.hrsa.gov>, click on “News,” and then select “View all Policy Notices.”

Thank you for your careful review. If you have any questions about a particular Board action, please contact your regional administrator at (804) 782-4800.

Overview of Policy Modifications/Board Actions and Affected Professionals

Who should be aware of these actions? Please review the 8 notices included on the grid below and share with other colleagues as appropriate.

Policy/Bylaw Change or Board Action (Sponsoring Committee)	Directors of Organ Procurement	Lab Directors	Lab Supervisors	OPO Data Coordinators	OPO Executive Directors	OPO Medical Directors	OPO PR/Public Education Staff	OPO Procurement Coordinators	Transplant Administrators	Transplant Coordinators	Transplant Data Coordinators	Transplant Physicians	Transplant PR/Public Education Staff	Transplant Program Directors	Transplant Social Workers	Transplant Surgeons	Compliance Officers	Page #
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2 Modifications to Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels, and Tissue Typing Materials) (<i>OPO Committee</i>)	X	X	X		X	X		X	X	X				X		X	X	4
3 Placement of Non-Directed Living Donor Kidneys (<i>Living Donor Committee</i>)	X			X	X	X	X	X	X	X	X	X	X	X	X	X	X	5
4 Reporting of Non-utilized and Redirected Living Donor Organs (<i>Living Donor Committee</i>)	X			X	X	X	X	X	X	X	X	X	X	X	X	X	X	6
5 Modification of OPO and Transplant Center Requirements for Screening, Communicating and Reporting All Potential or Confirmed Donor-Related Disease and Malignancy Transmissions (<i>Ad Hoc Disease Transmission Advisory Committee</i>)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	7
6 Modifications Requiring Deceased Donor HLA Typing by DNA Methods and Identifying Additional Antigens for Kidney, Kidney-Pancreas, Pancreas, and Pancreas Islet Offers (<i>Histocompatibility Committee</i>)	X	X	X	X	X	X		X										8
7 Modifications to Update UNOS Policy Appendix 3A (<i>Histocompatibility Committee</i>)		X	X	X		X		X	X	X				X				9
8 Modifications to Develop an Efficient, Uniform National Pancreas Allocation System (<i>Pancreas Transplantation Committee</i>)	X			X	X	X	X	X	X	X	X	X	X	X	X	X	X	10

Title of Policy Change: Allowing Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts (TAH) Thirty Days of Status 1A Time

Sponsoring Committee: Thoracic Organ Transplantation Committee

Policy Affected: Policy 3.7.3 (Adult Candidate Status)

Planned Distribution Date for Public Comment: March 2011

Planned Amendment after Public Comment: Likely

Action Required: Review Urgently; List Outpatient Candidates Implanted with TAHs as Instructed

Effective Date: November 10, 2010

Professional Groups Affected by the Change: Transplant Administrators, Thoracic Transplant Coordinators, Thoracic Transplant Physicians, Thoracic Transplant Surgeons, and Transplant Program Directors

Problem Statement	Changes	What You Need to Do
<p>Policy 3.7.3 classifies inpatient candidates implanted with a TAH as Status 1A, and previously classified outpatient candidates implanted with a TAH as Status 1B.</p> <p>Outpatient candidates with TAHs are a new patient population and their medical urgency status was not adequately addressed in policy.</p>	<p>For adult heart transplant candidates implanted with a TAH and discharged from the hospital, these candidates may now be listed as Status 1A for 30 days. When this 30-day time period ends, if these candidates are not eligible to be listed as Status 1A by other existing criteria, they must be listed as Status 1B. <u>This interim policy is now in effect.</u></p> <p>The OPTN/UNOS Board of Directors approved this as an interim policy, concurrent with public comment. The Committee and the Board of Directors will review this policy after receiving public comment.</p>	<p>Following the link below, review instructions to list candidates who meet the interim policy criteria as Status 1A and 1B.</p> <p>http://communication.unos.org/wp-content/uploads/2010/12/instructions_tah-candidates.pdf</p> <p>Additionally, provide comments on the interim policy when the Thoracic Organ Transplantation Committee distributes it for public comment in March, 2011.</p>

Title of Policy Change: Modifications to Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels, and Tissue Typing Materials)

Sponsoring Committee: OPO Committee

Policy Affected: Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels, and Tissue Typing Materials)

Effective Date: January 10, 2011

Distributed for Public Comment: March 2010 **Amended After Public Comment:** Yes

Professional Groups Affected by the change:

OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Lab Directors, and Lab Supervisors

Problem Statement	Changes	What You Need to Do
<p>Currently, each individual OPO develops their own internal labels, and these labels vary across OPOs. As a result, internal labeling is not consistent throughout the United States.</p> <p>Additionally, in situations where reallocating an organ is necessary, there are no requirements for a transplant center to inform the OPO if the packaged organ has been opened or if any procedures have been performed, including examination of the organ. To avoid contamination, an organ is packaged in a sterile environment and handled with particular care and opening an organ package poses significant risk for contamination.</p>	<p>All OPO and transplant professionals who package and label organs for transport must use the new internal label and vessel label distributed by the OPTN contractor. New policy language also clarifies policy requirements for packaging and labeling organs, tissue typing materials, and vessels. Policies addressing vessel storage have also been clarified.</p> <p>Additionally, if transplant centers repackage an organ, they must immediately notify the recovering OPO.</p> <p>These changes, which are being implemented as the new labels are introduced, should reduce or eliminate the number of labeling errors and promote packaging consistency.</p>	<p>Review the policy changes and ensure that all staff responsible for packaging and labeling organs are aware of them. OPOs and transplant centers should also train staff on how to correctly use the new internal organ and vessel labels.</p> <p>Training on how to use the new labeling system will be available through Live Meeting on December 14, 2010 at 2p.m. eastern. Visit http://communication.unos.org and click on "Resources and Training Materials" to register.</p>

Title of New Policy: Placement of Non-Directed Living Donor Kidneys

Sponsoring Committee: Living Donor Committee

Policy Affected: Policy 12.5.6 (Placement of Non-Directed Living Donor Kidneys)

Distributed for Public Comment: March 2010 **Amended After Public Comment:** Yes

Effective Date: January 10, 2011

Professional Groups Affected by the Change:

OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, OPO Public Relations or Public Education staff, Transplant Public Relations or Public Education Staff, Compliance Officers

Problem Statement	Changes	What You Need to Do
<p>The match system is programmed to identify candidates who are not suitable for the donor in many aspects, and prevents these candidates from appearing on the match run. By doing this, the match system acts as both an allocation tool and a safety mechanism, ensuring <i>basic compatibility</i> between the donor and recipient.</p> <p>Currently, these safety mechanisms are not in place for the allocation of non-directed living donor kidneys as no existing OPTN/UNOS policy addresses the placement of these organs.</p>	<p>This new policy establishes procedures for allocating non-directed living donor kidneys. The policy requires that transplant centers select the recipient of a non-directed living donor kidney using a UNetSM generated match run that identifies potential recipients for transplant.</p> <p>This policy does not apply to non-directed living kidney donors who consent to participate in a Kidney Paired Donation system.</p>	<p>Please refer to the instructions included with this notice that detail the steps for allocating a non-directed living donor kidney.</p>

Title of Policy Change: Reporting of Non-utilized and Redirected Living Donor Organs

Sponsoring Committee: Living Donor Committee

Policies Affected: Policy 12.8.5 (Reporting of Non-utilized Living Donor Organs), Policy 12.8.6 (Reporting of Redirected Living Donor Organs)

Distributed for Public Comment: March 2010 **Amended After Public Comment:** Yes

Effective Date: January 10, 2011

Professional Groups Affected by the Change:

OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, OPO Public Relations or Public Education staff, Transplant Public Relations or Public Education Staff, Compliance Officers

Problem Statement	Changes	What You Need to Do
<p>Living donor organs that are redirected or not used can have an adverse impact on the psychological and psychosocial health (both short and long-term) of the living donor and his or her intended recipient.</p>	<p>The organ recovery center will report all instances of:</p> <ul style="list-style-type: none"> • Living donor organs recovered but not used for transplant. • Living donor organs recovered but then redirected and transplanted into a recipient other than the original intended recipient. 	<p>The organ recovery center will report through the Patient Safety System all instances of living donor organs recovered but not used for transplant, and living donor organs recovered but then redirected or transplanted into a recipient other than the original intended recipient.</p> <p>When reporting the event, you will have the option to select from a list of possible reasons why the event occurred, or you can provide a written description of the event.</p>

Title of Policy Change: Modification of OPO and Transplant Center Requirements for Screening, Communicating and Reporting All Potential or Confirmed Donor-Related Disease and Malignancy Transmissions

Sponsoring Committee: Ad Hoc Disease Transmission Advisory Committee (DTAC)

Policies Affected: Policy 2.0 (Minimum Procurement Standards for an Organ Procurement Organization (OPO)), Policy 4.0 (Identification of Transmissible Diseases in Organ Recipients), Policy 5.5.1 (Documentation accompanying the organ)

Distributed for Public Comment: March 2010 **Amended After Public Comment:** Yes

Action Required: Review; Respond with patient safety contact plan by January 7, 2011

Effective Date: January 10, 2011

Professional Groups Affected by the Change: OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors, OPO Public Relations or Public Education staff, Transplant Public Relations or Public Education Staff, Compliance Officers

Problem Statement	Changes	What You Need to Do
<p>Current policies related to screening, communicating and reporting potential donor –derived disease transmission are spread out between two policy sections and are not always consistent with current clinical testing practices in the organ recovery and transplant community.</p>	<p>Substantive changes to the policy include:</p> <ul style="list-style-type: none"> • A requirement to assess donor blood for hemodilution before donor screening • A requirement to report all new and/or changed donor test results to the transplant center within 24 hours of receipt • A requirement that all member institutions establish a patient safety contact process • Modifications of OPO and transplant center responsibilities related to reporting potential donor-derived disease transmission events to the OPTN. <p>Most of the policy changes were designed to reorganize the content and clarify the language; the intent of the language affected by these modifications has not changed.</p>	<p>OPOs and transplant centers should review the policies and:</p> <ul style="list-style-type: none"> • Assess internal processes and protocols, and modify as necessary to meet new requirements for establishing a patient safety contact (Policy 4.4) • Submit your patient safety contact plan by email, including a contact telephone number, to UNOS at PatientSafetyContact@unos.org on or before January 7, 2011. • Determine if staff needs additional training on calculating and understanding hemodilution and reporting potential donor-derived disease transmissions.

Title of Policy & Bylaw Change: Modifications Requiring Deceased Donor HLA Typing by DNA Methods and Identifying Additional Antigens for Kidney, Kidney-Pancreas, Pancreas, and Pancreas Islet Offers

Sponsoring Committee: Histocompatibility Committee

Policies and Bylaw Affected: Policy 3.5.9.1 (Essential Information for Kidney Offers), Policy 3.8.2.2 (Essential Information for Pancreas Offers), and UNOS Bylaws Appendix B Attachment IIA - Standards for Histocompatibility Testing, D HLA Typing D1.000

Distributed for Public Comment: March 2010 **Amended After Public Comment:** Yes

Effective Date: June 1, 2011

Professional Groups Affected by the Change Lab Directors, Lab Supervisors, OPO Executive Directors, OPO Medical Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators

Problem Statement	Changes	What You Need to Do
<p>A high error rate has been associated with serological HLA typing. Additionally, HLA loci that identify crossmatch incompatible donors are not currently required as essential information for organ offers.</p> <p>Accurate and thorough donor HLA typing is necessary before executing a match run because of its impact on deceased donor organ allocation.</p>	<p>All required deceased donor HLA typing must be performed by DNA methods. Serologic methods may still be used <i>in addition to</i> molecular typing, if necessary.</p> <p>Also, before an OPO makes deceased donor kidney, kidney-pancreas, pancreas, or pancreas islet offers, it will be required to identify the -Cw and -DQ HLA antigens, in addition to what is currently required.</p>	<p>As of June 1, 2011:</p> <ul style="list-style-type: none"> • You must evaluate deceased donor HLA typing using molecular typing. • OPOs must identify the donors' -Cw and -DQ antigens, along with their -A, -B, and -DR antigens before making kidney, kidney-pancreas, pancreas, or pancreas islet offers.

Title of Policy Change: Modifications to Update UNOS Policy Appendix 3A

Sponsoring Committee: Histocompatibility Committee

Policy Affected: 3A-Appendix A to Policy 3

Distributed for Public Comment: March 2010 **Amended After Public Comment:** Yes

Effective Date: Pending implementation

Professional Groups Affected by the Change:

Lab Directors, Lab Supervisors, Lab Coordinators, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors

Problem Statement	Changes	What You Need to Do
<p>Appendix 3A includes two tables that are not current. Policy 3.5.14 (Broad and Split Antigen Specificities) requires that the Histocompatibility Committee review and update these tables to reflect changes in HLA typing practice and improve the utility of the unacceptable antigens.</p>	<p>The Board of Directors approved updates to Appendix 3A to reflect changes in HLA typing practice and improve the utility of the unacceptable antigens. These changes will be implemented upon computer programming.</p>	<p>You should review and familiarize yourselves with the updates to Appendix 3A. When computer programming is complete, UNOS will send a UNetSM System Notice to alert the transplant community.</p>

Title of Policy Change: Modifications to Develop an Efficient, Uniform National Pancreas Allocation System

Sponsoring Committee: Pancreas Transplantation Committee

Policies Affected: Policy 3.8 (Pancreas Allocation Policy), Policy 3.5 (Kidney Allocation Policy), Policy 3.2 (Waiting List), Policy 3.3 (Acceptance Criteria), Policy 3.4 (Organ Procurement, Distribution And Alternative Systems For Organ Distribution Or Allocation), Policy 3.9 (Allocation Systems for Organs not Specifically Addressed)

Distributed for Public Comment: March 2010 **Amended After Public Comment:** Yes

Effective Date: Pending Implementation

Professional Groups Affected by the Change:

OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, OPO Public Relations or Public Education staff, Transplant Public Relations or Public Education Staff, Compliance Officers

Problem Statement	Changes	What You Need to Do
<p>There is no nationally established allocation practice for patients with diabetes and renal failure. Consequently, waiting time for simultaneous pancreas-kidney (SPK) transplant varies widely across the country because of local or regional allocation decisions.</p> <p>Furthermore, current practice does not seek to maximize the utilization of the pancreas. SPKs commonly receive offers after other renal/extra-renal multi-organ transplants, kidney paybacks, and zero mismatch kidney-alone candidates. This allocation order leads to the discard of grafts declined for pancreas-alone (PA) transplants that would likely be transplanted</p>	<p>The Board of Directors approved the following changes to address these concerns:</p> <ol style="list-style-type: none"> 1. Combine PA and SPK candidates onto a single match run list 2. Require OPOs to offer organs to potential transplant recipients on the combined SPK/PA match run through the local classification before offering organs to candidates on the kidney-alone match run 3. Allow local candidates who are allocated a pancreas from the combined list to receive a kidney if they meet specific qualifying criteria 4. Establish specific qualifying 	<p>Once the policies are implemented, OPOs must allocate organs from the combined SPK/PA match run before allocating organs from the kidney match run. OPOs will need to understand how SPK qualifying criteria work and only allow the kidney to follow the pancreas when a candidate is receiving an offer for an SPK. The kidney cannot be allocated to a candidate based on his or her pancreas-alone listing.</p> <p>Pancreas transplant programs will need to evaluate all new SPK candidates to determine if they meet the SPK qualifying criteria. Programs will need to enter in UNetSM any data necessary to determine SPK</p>

<p>if offered in the context of SPK transplantation.</p> <p>Under the current system, 66% of pancreata are used for SPK transplant candidates; however, there are no specific listing criteria for SPK transplants with respect to the degree of pancreas dysfunction necessary to qualify to receive waiting time for an SPK transplant.</p>	<p>criteria for a diabetic uremic patient to accrue SPK waiting time:</p> <ol style="list-style-type: none"> a. The candidate must qualify for a kidney transplant based on the current qualifying criteria as defined by Policy 3.5.11.1(Time of Waiting): <ol style="list-style-type: none"> i. on dialysis; OR ii. GFR \leq 20 mL/min; OR CrCl \leq 20mL/min b. Eligibility for SPK waiting time will be restricted to patients with diabetes mellitus who meet one of the following criteria: <ol style="list-style-type: none"> i. On insulin AND c-peptide \leq 2 ng/mL; OR ii. On insulin AND c-peptide $>$ 2 ng/mL AND BMI \leq the maximum allowable BMI (initially 28 kg/m²) 	<p>qualifying criteria. Programs should also examine whether their candidates are listed for SPK, pancreas-alone, or both and whether these listings still meet the needs of their candidates, particularly in light of the improved access expected for candidates receiving a living donor kidney followed by a pancreas-alone transplant.</p>
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Affected Policy Language: [Language highlighted in yellow is the interim policy and is in effect.]

3.7.3 Adult Candidate Status. Each candidate awaiting heart transplantation is assigned a status code which corresponds to how medically urgent it is that the candidate receive a transplant. Medical urgency is assigned to a heart transplant candidate who is greater than or equal to 18 years of age at the time of listing as follows:

Status Definition

1A A candidate listed as Status 1A is admitted to the listing transplant center hospital (with the exception for 1A(b) candidates) and has at least one of the following devices or therapies in place:

- (a) Mechanical circulatory support for acute hemodynamic decompensation that includes at least one of the following:
 - (i) left and/or right ventricular assist device implanted Candidates listed under this criterion, may be listed for 30 days at any point after being implanted as Status 1A once the treating physician determines that they are clinically stable. Admittance to the listing transplant center hospital is not required.
 - (ii) total artificial heart;
 - (iii) intra-aortic balloon pump; or
 - (iv) extracorporeal membrane oxygenator (ECMO).

Qualification for Status 1A under criterion 1A(a)(ii), (iii) or (iv) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1A for 30 days at any point in time after the discharge.

[...]

1B A candidate listed as Status 1B has at least one of the following devices or therapies in place:

- (aa) left and/or right ventricular assist device implanted; or
- (bb) continuous infusion of intravenous inotropes.

A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1B at any point in time after the discharge.

[There are no further changes to Policy 3.7.3.]

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Policy Language:**5.0 STANDARDIZED PACKAGING, LABELING AND TRANSPORTING OF ORGANS, VESSELS, AND TISSUE TYPING MATERIALS**

The purpose of Policy 5.0 and its subsections is to:

- state requirements for packaging and labeling organs, tissue typing specimens, and vessels to prevent wastage (and/or to promote safe and efficient use);
- define terms and responsibilities related to packaging, labeling, and transporting organs, tissue typing specimens, and vessels; and
- state requirements for recovering, storing, and using vessels in solid organ recipients.

The responsibility for packaging and labeling deceased donor organs is assigned to the Host OPO. Transplant Center staff may not leave the operating room without allowing the OPO to package and label the organ in accordance with OPTN Policy. The OPO must submit a report through the Patient Safety System when a Transplant Center fails to comply with this policy. The OPO will make all reasonable efforts to package and label the organ in a timely fashion. If an organ is repackaged by a transplant center for transport, the Transplant Center will package, label and ship the organ in accordance with this policy and immediately notify the recovering OPO of the repackaging.

5.1 EXTERNAL PACKAGING SPECIFICATIONS

An external transport container is defined as a: disposable shipping box, cooler or mechanical preservation machine. The transplant center or OPO must use both internal and external transport containers to package a deceased donor organ that travels outside the recovery facility.

5.1.1 Disposable Shipping Box [5.1.1 No Changes]**5.1.2 Cooler**

- Coolers are permitted for non-commercial transporting of organs when the organ recovery team is transporting the donor organ with them from the donor hospital to the candidate transplant center.
- Coolers must be labeled with the standardized label distributed ~~provided~~ by the OPTN contractor.
- Coolers may be reused if properly cleaned and sanitized.
- Before re-using a cooler, all labels from the previous donor organ must be removed.

5.1.3 Mechanical preservation machine

- Mechanical preservation machines are permitted for transporting an organ.
- The cassette containing the organ must be labeled with the organ type (i.e. left kidney, right kidney), ABO, and UNOS ID.
- The external surface of a mechanical preservation machine must be labeled with:

- the standardized external label distributed ~~provided~~ by the OPTN contractor, or
- an alternate label that contains all information included on the OPTN contractor standardized label.
- Before re-using a mechanical preservation machine that was used to transport an organ, all labels from the previous donor organ must be removed.

5.2 INTERNAL PACKAGING SPECIFICATIONS [No Changes]

5.3 EXTERNAL LABELING REQUIREMENTS

When a disposable shipping box or cooler is used to transport a deceased donor organ, the Host OPO must use the standardized external label distributed by the OPTN contractor. When a mechanical preservation machine is used, the OPO or Transplant Center, as applicable, may use an alternative label if the label contains all of the required information.

The external transport container must be labeled with the: UNOS Donor I.D. Donor ABO type, a description of the specific contents of the box, the sender's name and telephone number, and the Organ Center telephone number. The label must be securely affixed to the external transport container. The OPTN contractor distributes a standardized external label that includes this information and must be utilized.

5.4 INTERNAL LABELING REQUIREMENTS

5.4.1 Solid organ

The Host OPO is responsible for ensuring that ~~the~~ a secure label identifying the specific contents (e.g., liver, right kidney, heart) is attached to the outer bag or rigid container housing the donor organ. The OPTN contractor distributes a standardized internal label that must be utilized for this purpose. In addition to the contents of the package, the label information must include the UNOS Donor I.D and donor ABO type; ~~and a secure label identifying the specific contents (e.g., liver, right kidney, heart) are attached to the outer bag or rigid container housing the donor organ.~~

5.4.2 Tissue typing materials

Each separate specimen container of tissue typing material must have a secure label with two unique identifiers, one being UNOS Donor I.D., and one of the following three: donor date of birth, donor initials or locally assigned unique ID, (donor ABO is not considered a unique identifier). Additionally each specimen should be labeled with Donor ABO, date and time the sample was procured and the type of tissue. In the preliminary evaluation of a donor, if the UNOS ID or ABO is not available, it is permissible to use a locally assigned unique ID and one other identifier for the transportation of initial screening specimens.

5.4.3 Vessels

~~If packaged separately from the organ, the vessels must be protected by a triple sterile barrier, one of which must be a rigid container; The vessels must be labeled with the standardized vessel label distributed by the OPTN contractor. The labeled with information must contain the: recovery date, ABO, all serology results, container contents, and the UNOS Donor ID. If the donor is in a “high risk”¹ group as defined by the Centers for Disease Control and Prevention (CDC), the label must indicate that the vessels are from a donor who meets the CDC criteria for high risk. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state “for use in organ transplantation only.”~~ If packaged separately from the organ, the vessels must be protected by a triple sterile barrier, one of which must be a rigid container and the standardized vessel label must be affixed to the outermost barrier.

5.5 DOCUMENTATION ACCOMPANYING THE ORGAN OR VESSEL

5.5.1 Documentation accompanying the organ

- Complete donor documentation, ~~as described in Policy 2.5.6.1,~~ must be sent in the container with ~~all~~ each transported organs. This documentation must include:
 - ABO typing source documentation;
 - Serology/Infectious disease testing results;
 - Medical/Behavioral History form;
 - Donor Evaluation;
 - Complete record of the donor;
 - Consent form; and
 - Organ quality information as noted in Policy 2.5.
- Donor documentation must be placed in a watertight container.
- Donor documentation may be placed in either:
 - a location specifically designed for documentation, or
 - between the outer and inner containers.
- Whenever a deceased donor organ is transported, the Host OPO or the Transplant Center, as applicable, must include in the donor documentation the source documentation.

5.5.2 Documentation accompanying the vessel

~~If the vessels are not shipped in the same package as the organ, the same complete donor documentation, as described in Policy 2.5.6.1, must be included with the vessels, as is included with the organ.~~

¹ Rogers MF, Simonds RJ, Lawton KE, et al. Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs. CDC MMWR Recommendations and Reports. 1994;May 20/ 43(RR-8):1-17. <http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm>

5.6 – 5.9.1 [No Change]

5.10 VESSEL RECOVERY, TRANSPLANT, AND STORAGE

The intent of this policy is to permit:

- vessel recovery and immediate use in a solid organ transplant (for example either a current liver or pancreas transplant); and
- vessel recovery and storage for use in a subsequent solid organ transplant from a donor with a different UNOS Donor ID (for example, when the vessel(s) and the liver or pancreas allograft are being transplanted from different donors with different numbers).

5.10.1 [No Changes]

5.10.2 Vessel storage

The Transplant Center must designate a person to monitor and maintain records, destroy, and notify the OPTN of outcome and/or use of vessels. This designated person must maintain information on all donor vessels including monitoring and maintaining all records relating to the use and management of donor vessels (e.g. subsequent positive serology testing, monitor inventory of stored vascular conduits). This person must monitor the refrigerator, ensure records are up to date and available with the conduits, destroy the vessels when expired, and notify the OPTN of its use or disposal.

- The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial HTK).
- The vessels must be stored in a rigid, sterile sealed container labeled with the recovery date, ABO, serology, container contents, and the UNOS Donor ID for tracking. The standardized vessel label distributed by the OPTN contractor must be attached to the outer sterile barrier bag and information on the label must include all of the above information and all serology testing results. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state for use in organ transplantation only.
- The vessel(s) must be stored in a secured refrigerator with a temperature monitor and maintained within a range of 2 - 8 degrees Celsius.
- There must be daily monitoring of the vessel(s) with documented security and temperature checks by the transplant center.
- The vessel(s) can be stored up to a maximum of 14 days from the original recovery date.
- The transplant center must maintain a log of stored vessels.
- The transplant surgeon must have around the clock access to the donor information prior to using the donor vessel(s) in a recipient other than the intended recipient.

5.11 TRANSPORTATION RESPONSIBILITY [5.11 – 5.11.3 No Changes]

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Policy Language:**12.5.6 Placement of Non-directed Living Donor Organs**

Prior to determining the placement of a non-directed living donor kidney, the transplant center must acquire a match run of its waitlist candidates. The transplant center may obtain the match run from its local OPO or the Organ Center of the OPTN Contractor. The transplant center must document the rationale used to place the non-directed living donor kidney. If the transplant center deviates from the sequence defined by the match run, the transplant center must document its rationale for not following the match run in addition to documenting the criteria used to select the kidney recipient. This documentation must be maintained and made available to the OPTN contractor upon request. This policy does not apply to non-directed living kidney donors who consent to participate in a Kidney Paired Donation arrangement.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Instructions for a Transplant Center to Allocate a Non-Directed Living Donor Kidney

- 1) Prior to determining the placement of a non-directed living donor kidney, the transplant center must acquire a match run of its waitlist candidates. The transplant center may obtain the match run from its local OPO or the Organ Center of the OPTN Contractor.
- 2) If the transplant center contacts the Organ Center, it must complete and return a form to the Organ Center with the following required donor information:
 - donor ID
 - ABO testing, including two separate verifications and supporting documentation
 - HLA typing with supporting documentation
 - donor height and weight
 - serological testing (Anti-HCV, Anti-HBcAb, and optional Anti-HTLV I/II)
- 3) The Organ Center will update the donor's record in DonorNet® with the data required for the match run.
- 4) The transplant center will be asked to verify all information that will be used for the match run.
- 5) If verified, the Organ Center will complete the match run to generate the match ID.
- 6) The transplant center will use the match ID to access a list of potential recipients on its waitlist.
- 7) Following the match, the center will select a recipient to receive the non-directed living donor kidney.
- 8) If the center deviates from the match run, it must document its rationale used to direct placement of the kidney, and provide the OPTN contractor with this documentation upon request.

Affected Policy Language:

12.8.5 Reporting of Non-utilized Living Donor Organs. The organ recovery center must report all instances of living donor organs recovered but not transplanted and all instances of living donor organs recovered but redirected and not ultimately transplanted to the intended recipient. Transplant centers must report these incidents through the Patient Safety System within 72 hours of organ recovery. The Membership and Professional Standards Committee will review and report all cases of non-utilized and redirected living donor organs to the Board of Directors.

12.8.6 Reporting of Redirected Living Donor Organs. If a living donor organ is ultimately transplanted to a recipient other than the intended recipient, then all required donor and recipient information must still be reported through Tiedi[®]. The Membership and Professional Standards Committee will review and report all cases of redirected living donor organs to the Board of Directors.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Policy Language:**2.0 MINIMUM PROCUREMENT STANDARDS FOR AN ORGAN PROCUREMENT ORGANIZATION (OPO)**

In order to maximize the gift of donation and optimize recipient outcomes and safety, the Organ Procurement Organization (OPO) must comply with the following policies provide the for minimum procurement standards for an Organ Procurement Organization (OPO).

2.1 HOST OPO. ~~The Organ Procurement Organization (OPO) responding to an organ donor call from a hospital is the "Host OPO" for that particular donor. The Host OPO is responsible for identifying, evaluating and maintaining the donor, obtaining consent for the removal of organs, complying with accepted practice and OPTN policy throughout the donation process, and organ allocation.~~

Additionally, the Host OPO is responsible for ensuring that donor tissue typing information is entered into UNetSM and that the approved OPTN automated organ allocation computer ~~algorithm program~~ is executed for each donor organ.

~~Reasonable attempts shall be made~~ The Host OPO shall make reasonable attempts to obtain a medical/behavioral history from individual(s) familiar with the donor.

The Host OPO is responsible for organ procurement quality including appropriate preservation, and packaging of the organs, and assurance that adequate tissue typing material is procured, divided, and packaged.

The Host OPO is responsible for ~~ensuring that~~ written documentation of donor evaluation, donor maintenance, consent for donation, death pronouncement, and organ procurement quality accompanies the organ as described in Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials).

2.2 EVALUATION OF POTENTIAL DONORS. The Host OPO is responsible for performing the following activities and communicating this information to the importing OPO or transplant center for every donor:

2.2.1 Verifying that death has been pronounced according to applicable laws.

2.2.2 The Host OPO must perform the following evaluations and provide this information to the OPO or transplant center. The Host OPO must document in the donor record circumstances when such information is not available.

The Host OPO must determine whether there are conditions which may influence donor acceptance by:

2.2.2.1 Obtaining the donor's medical/behavioral history.

The Host OPO will attempt to obtain a history on each potential donor to screen for medical conditions that may affect the donated organ function and for the presence of transmissible diseases and/or malignancies, treated and untreated, or any other known condition that may be transmitted by the donor organ that may reasonably impact the candidate or recipient.

This history should also be used to identify whether the potential donor has factors associated with increased risk for ~~blood borne pathogens disease transmission, including blood borne pathogens HIV, (as defined by the US~~

Public Health Service (PHS)), and also Hepatitis B, and Hepatitis C or prion disease. If the donor meets the criteria set forth in the current US

Public Health Service (PHS) guidance¹, the Host OPO must communicate this information regarding donor history to all transplant programs receiving organs from the donor.

Potential donors who have received Human Pituitary Derived Growth Hormone (HPDGH) from human tissue (not recombinant) carry potential risk of prion disease. The Host OPO will attempt to obtain information regarding whether a potential donor has history of risk of prion disease (prior exposure or receipt of non recombinant HPDGH). If so, the Host OPO must communicate this information to all transplant programs receiving organs from the donor.

2.2.2.2 Reviewing the donor's medical chart record.

2.2.2.3 Performing a physical examination of the donor, including obtaining the potential donor's vital signs.

Obtaining the donor's vital signs.

2.2.3 Screening Potential Organ Donors.

2.2.3.1 All blood samples obtained and used for screening tests required by OPTN policy must be assessed for hemodilution (defined as a sample with plasma dilution sufficient to affect the results of communicable disease testing) utilizing an FDA-approved hemodilution calculation². Any specimen without evidence of hemodilution will be referred to as a qualified specimen, and should be used for donor screening tests if available.

If a qualified (non-hemodiluted) specimen is not available for testing, a hemodiluted specimen should be used for testing purposes. In such cases, the donor will be considered as having increased risk for disease transmission per US PHS guidelines. As hemodilution can result in false negative serology testing, any screening results from such a specimen must be communicated to the accepting Transplant Program(s) and additional information including:

- which tests were completed using hemodiluted specimens; and
- The hemodilution calculation used for this donor's specimen (if requested).

¹ The "Exclusionary Criteria" in Rogers MF, Simonds RJ, Lawton KE, et al. Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissues and Organs. CDC MMWR Recommendations and Reports. 1994; May 20/43 (RR-8):1-17. <http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm>

² "Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products." *U S Food and Drug Administration Home Page*. N.p., n.d. Web. 18 Oct. 2010. <<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm073964.htm>>.

A complete history of all transfusions received by the donor since admission must be documented in the donor medical record.

- 2.2.3.2** All potential donors are to be tested by use of a screening test licensed by the U.S. Food and Drug Administration (FDA) for Human Immune Deficiency Virus (HIV-1 and HIV-2).

If the sample is qualified, the screening test for HIV is negative, and blood for subsequent transfusions has been tested and found to be negative for HIV, re-testing the potential donor for HIV is not necessary.

- 2.2.3.3** NOTA and the Final Rule require standards for preventing the acquisition of organs from individuals known to be infected with human immunodeficiency virus/acquired immune deficiency virus. As a result, OPTN Members shall not knowingly participate in the procurement or transplantation ~~or sharing~~ of organs from donors who are known to be infected with ~~identified as HIV positive by an FDA licensed screening test~~ OPTN members may only recover organs ~~if unless subsequent confirmatory testing unequivocally indicates that the original test's results were falsely positive for HIV,~~ the laboratory data and medical-social history indicates that the donor is not HIV infected.

If ~~additional~~ multiple tests related to HIV are performed, the results of all tests must be communicated ~~immediately~~ directly to the Organ Center ~~and~~ all institutions receiving organs from the donor. Exceptions for cases in which the testing cannot be completed prior to transplant are provided in paragraph 2.2.3.4 below.

- 2.2.3.4** Exceptions to the guidelines set forth above may be made in cases involving non-renal organs, when, in the medical judgment of the staff of the Host OPO and recipient institution, an extreme medical emergency warrants the transplantation of an organ which has not been tested for HIV.

The Host OPO must provide all available information regarding donor medical and social history to the transplant program and treat this as a donor with increased risk for disease transmission based upon USPHS Guidelines due to the inability to obtain donor testing.

The transplant program must obtain and document informed consent from the recipient or next of kin, the legal next of kin, designated health care representative or appropriate surrogate before use in such cases (See Policy 4.2).

- 2.2.3.5** Informing Personnel. Health care personnel caring for potential donors or donors who test positive for HIV should be so informed only when necessary for medical decision making purposes.

- 2.2.3.4** **DONOR EVALUATION.** The Host OPO Donor evaluation must be performed or coordinated by the Host OPO. All donor laboratory testing must be performed in an appropriately accredited laboratory utilizing ~~following pertinent~~ FDA licensed, approved, or cleared serological screening tests ~~and provide this information to the OPO or transplant center.~~ In the event that ~~such a required screening tests are~~ is not commercially available prior to transplant, then ~~a FDA-licensed, approved or cleared diagnostic test is permissible, and a FDA approved diagnostic test is permissible to assess the donor.~~ a FDA-licensed, approved or cleared diagnostic test is permissible, and a FDA approved diagnostic test is permissible to assess the donor. ~~The~~ Host OPO must document in the donor

~~record that a FDA-approved diagnostic test which assay was utilized to assess the potential donor and must also provide this information to the transplant program(s). circumstances when such information is not available. In all cases, the transplant center will make the clinical decision whether to accept or reject the organ based on the available data or identify the need for additional information. The Host OPO may be requested to provide additional information if possible in addition to the information required on all donors. Required tests should include:~~

Exceptions: Diagnostic testing is NOT acceptable for Anti-HIV.
FDA-approved diagnostic testing IS acceptable for VDRL/RPR.

2.2.34.1 For all potential deceased donors:

- ABO typing (and confirmation as outlined in Policy 3.2.4) with sub-typing for ABO-A donors;
- FDA licensed Anti-HIV I, II (diagnostic testing not acceptable);
- CBC;
- Electrolytes;
- Hepatitis screen serological testing; including HBsAg, HBcAb, and Anti-HCV;
- VDRL or RPR (FDA-approved diagnostic tests are acceptable);
- Anti-CMV;
- EBV serological testing;
- Blood and urine cultures;
- Urinalysis within 24 hours prior to cross clamp;
- Arterial blood gases;
- Chest x-ray; and
- Serum Glucose.

If a Host OPO completes additional testing in addition to what is required in policy for a potential donor, the results of these tests must be communicated immediately to all recipient institutions.

Additional Organ Specific information is required as follows:

2.2.34.2 For potential renal donors:

- Creatinine; and
- B.U.N.

2.2.34.3 For potential liver donors:

- AST;
- ALT;
- Alkaline phosphatase;
- Direct and total bilirubin
- INR (PT if INR not available); and
- PTT.

2.2.34.4 For potential heart donors:

- 12 Lead ECG; and
- Cardiology consult and/or echocardiogram;
- ~~Toxoplasma serology;~~

2.2.34.5 For potential pancreas donors:

- Serum amylase.

2.2.34.6 For potential lung donors:

- Sputum gram stain.

2.2.5 Follow-up on Donor Testing. ~~The Host OPO is responsible for timely follow-up and reporting of any new or changed clinically relevant information regarding the donor test results to the transplant program(s).~~

~~The Host OPO must establish a procedure that defines its process for obtaining post-recovery donor testing results, from the hospital where donor recovery took place.~~

~~The Host OPO must establish and implement a process to report all positive screening or diagnostic tests received to the transplant center's Patient Safety Contact (as defined in Policy 4.4) within 24 hours of receipt by the OPO. The OPO must report updates such as identification of organism and sensitivity to the transplant program(s) as the OPO receives the information.~~

~~If during this follow-up a new disease or malignancy is discovered in the donor that may potentially be transmitted to organ recipients, the Host OPO must report the event to the OPTN Patient Safety System, as outlined in Policy 4.5.~~

2.2.6 Reporting Disease. ~~The Host OPO is responsible for making collecting historical (i.e. medical-social history), testing and laboratory assessments to identify malignant and infectious conditions that may adversely affect a potential organ recipient and sharing this information with the transplant program(s).~~

~~The Host OPO must communicate to the transplant program(s) any known or suspected infectious or neoplastic conditions that may be transmitted by the donor organ(s).~~

~~**2.2.7 Human Pituitary Derived Growth Hormone.** Individuals who have received Human Pituitary Derived Growth Hormone (HPDGH) from human tissue (not recombinant) may be evaluated as potential organ donors with organs used at the discretion of the accepting transplant center and with informed consent from the potential recipient related to potential risk of prion disease. The transplant program must obtain and document informed consent from the recipient or next of kin, the legal next of kin, designated health care representative or appropriate surrogate in the recipient medical record before use in such cases (See Policy 4.2).~~

2.3 DONOR MAINTENANCE. The Host OPO must make reasonable efforts to maintain the deceased donor, document these efforts, and communicate this information to the OPO or Transplant Center as follows:

- 2.3.1** Blood pressure is adequate to maintain perfusion of vital organs;
- 2.3.2** Vital signs are monitored;
- 2.3.3** I.V. therapy or drugs are administered as required (i.e. vasopressors, vasodilators; etc.);
- 2.3.4** Antibiotic therapy is administered as required; and
- 2.3.5** Intake and output.

2.4 OBTAINING CONSENT. The Host OPO must provide evidence of consent for donation according to applicable legal authority.

2.5 ORGAN PROCUREMENT QUALITY. Minimum standards of quality shall include documentation of the following:

2.5.1 All items in section 2.2.

2.5.2 Use of standard surgical techniques in a sterile operating environment.

2.5.3 Maintenance of flush solutions and preservation media at appropriate temperatures and recording of flush solutions and additives with their respective lot numbers; organ anatomy, organ flush characteristics, flush solution amount and type, and organ abnormalities or surgical damage if any.

The Host OPO is responsible for ensuring that the donor medications are given at appropriate times and that medication administration, including flush solutions and additives, is recorded during the retrieval process.

2.5.4 Each OPO, and their respective histocompatibility laboratory(s), will define and document the minimum tissue typing material required to generate match runs for local or regional placement of all organs. In view of the frequent need for regional shipment of pancreas and kidney allografts, however, sufficient specimens for several crossmatches are required. Minimal typing material to be obtained for EACH kidney and pancreas will include the following:

- One 7 to 10ml. clot (red top) tube for ABO verification, plus
- 2 ACD (yellow top) tubes
- 3 to 5 lymph nodes
- One 2 X 4 cm. wedge of spleen in culture medium, if available

For all other organs, the OPO will provide lymph nodes if requested and available.

2.5.5 Proper packaging of organs for transport (see Policy 5.0).

~~**2.5.6** Properly packaged documentation containing complete donor information shall accompany each organ to the recipient transplant center.~~

~~**2.5.6.1** Documentation accompanying each organ must include:~~

- ~~• ABO typing source documents;~~
- ~~• Serology results;~~
- ~~• Medical/Behavioral History form;~~
- ~~• Donor evaluation;~~
- ~~• Complete record of donor;~~
- ~~• Consent form; and~~
- ~~• Organ quality as described in section 2.5.~~

~~**2.5.7** Complete information must be maintained by the Host OPO for seven years per the Final Rule on any and all organs recovered. ~~The Host OPO is responsible for ensuring that non-local procurement teams have transportation to and from the local airport.~~~~

2.5.7 The Host OPO must maintain a serum sample for each donor from which organs were transplanted for a period of at least 10 years after the date of recovery. This serum must be available for use for retrospective testing if needed. The OPO must document the type of specimen that has been archived in the donor chart. The specimen should be a qualified (not hemodiluted) specimen if possible.

2.5.8 The Host OPO is responsible for ensuring determining that non-local procurement teams have transportation to and from the local airport.

- 2.6 INITIATING ORGAN PROCUREMENT AND PLACEMENT.** In order to maximize the number of transplantable donor organs, tissue typing and crossmatching of an organ donor shall commence as soon as possible, ideally pre-procurement.
- 2.7 REMOVAL OF NON-RENAL ORGANS.** When a non-renal organ is offered for transplantation, the recipient center procurement team must be given the option of removing the non-renal organ unless extenuating circumstances dictate otherwise. This policy also applies to non-renal organs from controlled donation after cardiac death (DCD) donors.
- 2.7.1 Multiple Abdominal Organ Procurement.** It is expected that all authorized organs should be procured from a donor if each organ is transplantable and/or recipients are identified for each organ. The OPO will document the specific reason for non-recovery of an authorized organ. Cooperation between all organ recovery teams is required.
- 2.8 RECOVERY OF DCD DONOR ORGANS** In order to recover organs from a DCD donor, an OPO must follow an established protocol that contains the standards of the DCD Model Elements as adopted in the OPTN Bylaws, Appendix B, Attachment III.
- 2.9 MULTI-CULTURAL AND DIVERSITY ISSUES.** Each OPO must develop and implement a plan to address a diverse population related to organ donation.

4.0 ~~ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS), HUMAN PITUITARY DERIVED GROWTH HORMONE (HPDGH), AND SCREENING FOR HUMAN IMMUNODEFICIENCY VIRUS (HIV), IDENTIFICATION OF TRANSMISSIBLE DISEASE RISK FACTORS AND REPORTING OF POTENTIAL DONOR DERIVED RECIPIENT DISEASES OR MEDICAL CONDITIONS, INCLUDING INFECTIONS AND MALIGNANCIES, OF DONOR ORIGIN IDENTIFICATION OF TRANSMISSIBLE DISEASES IN ORGAN RECIPIENTS~~

- 4.1 ~~SCREENING POTENTIAL ORGAN DONORS FOR HIV.~~** All potential donors are to be tested by use of a screening test licensed by the U.S. Food and Drug Administration (FDA) for Human Immune Deficiency Virus (HIV). If the potential donor's pre-transfusion test for HIV is negative and blood for subsequent transfusions has been tested and found to be negative for HIV, retesting the potential donor for HIV is not necessary. If no pre-transfusion sample of the potential donor's blood is available, the Host OPO (as defined in Policy 2.1) must provide, to the recipient transplant center the screening test results and a complete history of all transfusions received by the donor during the ten (10) day period immediately prior to removal of the organ. Organs from donors with a positive screening test are not suitable for transplantation unless subsequent confirmation testing indicates that the original tests' results were falsely positive for HIV. If additional tests related to HIV are performed, the results of all tests must be communicated immediately to the Organ Center and all institutions receiving organs from the donor. Exceptions for cases in which the testing cannot be completed prior to transplant are provided in paragraph 4.1.3 below.

~~4.1.1 **Communication of Donor History.** The Host OPO will obtain a history on each potential donor in an attempt to determine whether the potential donor is in a "high risk" group, as defined by the Centers for Disease Control and Prevention (CDC). If the donor meets the criteria set forth in CDC Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs (CDC Guidelines),^[1] the Host OPO must communicate this information regarding donor history to all institutions receiving organs from the donor.~~

~~If the transplant center receives information from the Host OPO that the donor meets any of the criteria, the transplant center must inform the potential recipient prior to implantation. The transplant center shall maintain documentation of the potential recipient's informed consent to receive an organ from the donor who meets any of the criteria. In the event that the potential recipient is not able to provide informed consent, the legal next of kin, designated healthcare representative, or appropriate surrogate may provide consent on this matter.~~

~~4.1.2 **Organ Sharing.** Members shall not knowingly participate in the transplantation or sharing of organs from donors who are confirmed HIV positive by an FDA-licensed screening test unless subsequent confirmation testing unequivocally indicates that the original test's results were falsely positive for HIV.~~

~~4.1.3 **Exceptions.** Exceptions to the guidelines set forth above may be made in cases involving non-renal organs, when, in the medical judgment of the staff of the Host OPO and recipient institution, an extreme medical emergency warrants the transplantation of an organ, the donor of which has not been tested for HIV. The transplant surgeon is obligated to obtain informed consent from the recipient or next of kin in such cases.~~

~~4.1.4 **Donor Consent Forms.** Member institutions are encouraged to include in each donor consent form a notice that all potential donors will be screened for medical acceptability for organ donation and that results of such tests may be the basis for not using the organ in transplantation.~~

4.21 SCREENING POTENTIAL TRANSPLANT RECIPIENTS FOR BLOOD-BORNE PATHOGENS HIV. Testing for HIV, Hepatitis B, and Hepatitis C, shall be a condition of candidacy for organ transplantation except in cases where such testing would violate applicable state or federal laws or regulations. Candidates whose test results are confirmed positive should undergo appropriate counseling.

~~4.2.14.1.1 **HIV Positive Transplant Candidates.** A potential candidate for organ transplantation whose test for HIV is positive but who is in an asymptomatic state should not necessarily be excluded from candidacy for organ transplantation, but should be advised that he or she may be at increased risk of morbidity and mortality because of immunosuppressive therapy, unless there is a documented contraindication to transplantation based on local policy.~~

~~4.2.24.1.2 **Informing Personnel.** Health care personnel caring for donors, potential donors, candidates, potential candidates and recipients who test~~

^[1] Rogers MF, Simonds RJ, Lawton KE, et al. Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs. CDC MMWR Recommendations and Reports. 1994;May 20/ 43(RR-8):1-17. <http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm>

positive for HIV should be so informed only when necessary for medical decision-making purposes.

~~4.2.3 **Candidate and Recipient Treatment.** Administering treatment to candidates and recipients who test positive for the HIV should not be optional or discretionary for health care personnel.~~

~~4.3 **Disclosure of Information About HIV Status.** Member institutions are urged to comply with state and federal statutes and regulations applicable to the disclosure of personalized data on actual or potential organ donors, candidates or recipients.~~

~~4.4 **GENERAL RECOMMENDATIONS.** All member institutions are requested to adopt an overall health care policy addressing special HIV related problems with regard to transplant candidates and recipients. It is recommended that each institution's HIV related health care policies incorporate the specific Policies 4.1, 4.2, and 4.3 set forth above. It is also recommended that member institutions make their policies available upon request to the press and the public.~~

~~4.5 **HUMAN PITUITARY DERIVED GROWTH HORMONE.** People who have received Human Pituitary Derived Growth Hormone (HPDGH) from human tissue (not recombinant) shall be evaluated as organ donors with potential organs used at the discretion of the accepting transplant center and with informed consent from the potential recipient. The transplant surgeon is obligated to obtain informed consent from the recipient or next of kin in such cases. The use of recombinant HPDGH carries no additional risk of transmissible disease.~~

~~4.6 **SCREENING POTENTIAL ORGAN DONORS FOR TRANSMISSION OF DISEASES OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES.** All potential donors are to be screened for transmissible diseases or medical conditions, including malignancies, through the collection of medical/social history information. Donor testing for the purpose of organ allocation **must** use a FDA licensed, approved or cleared test if commercially available.~~

~~Medical conditions that should be screened for by history include the presence of malignancies, treated and untreated, or any other known condition that may be transmitted by the donor organ that may reasonably impact the candidate or recipient. In addition, donors shall be tested for recognized transmissible diseases, as defined in policy 2.2.8.1, using FDA licensed, approved, or cleared serological screening tests capable of determining whether the donor is or has been infected with these specific diseases. In the event that such screening tests are not commercially available prior to transplant, then a FDA approved diagnostic test is permissible to assess the donor.~~

~~If additional testing is performed, the results of these tests must be communicated immediately to all recipient institutions. The OPO is responsible for timely follow up of donor screening tests.~~

~~Documentation of any suspected or confirmed transmissible disease or medical condition identified prior to or following procurement must be communicated by the Host OPO to all potential recipient centers and the OPTN according to Policy 4.7.~~

~~4.6.1 **Donor History.** The Host OPO will obtain a history on each potential donor in an attempt to determine whether the potential donor is in a "high risk" group, as defined by the Centers for Disease Control. The Host OPO must communicate the donor history to all recipient institutions.~~

~~4.6.2 **Reporting.** Known conditions that may be transmitted by the donor organ must be communicated to the transplant centers: These may include, but are not limited to, the following:~~

- ~~• Unknown infection of central nervous system (encephalitis, meningitis)~~
- ~~• Suspected Encephalitis~~
- ~~• Hepatitis C~~
- ~~• Herpes simplex encephalitis or other encephalitis~~
- ~~• History of JC virus infection (causes progressive multifocal leukoencephalopathy)~~
- ~~• West Nile virus infection~~
- ~~• Cryptococcal infection of any site~~
- ~~• Rabies~~
- ~~• Creutzfeldt-Jacob disease~~
- ~~• Other fungal or viral encephalitis~~
- ~~• Bacterial meningitis~~
- ~~• Infection with HIV (serologic or molecular)~~
- ~~• Active viremia: herpes, acute EBV (mononucleosis)~~
- ~~• Serologic (with molecular confirmation) evidence of HTLV I/II~~
- ~~• Active hepatitis A or B~~
- ~~• Infection by: Trypanosoma cruzi, Leishmania, Strongyloides, Toxoplasmosis~~
- ~~• Active Tuberculosis~~
- ~~• SARS~~
- ~~• Pneumonia~~
- ~~• Bacterial or fungal sepsis (e.g. candidemia)~~
- ~~• Syphilis~~
- ~~• Multi-system organ failure due to overwhelming sepsis, such as gangrenous bowel~~
- ~~• Malignancies other active malignant neoplasms,~~
- ~~• Melanoma, Merkel cell, including Kaposi's~~
- ~~• Hodgkins' disease and non-Hodgkin's lymphoma~~
- ~~• Multiple myeloma~~
- ~~• Leukemia~~
- ~~• Aplastic anemia agranulocytosis~~
- ~~• Miscellaneous carcinomas~~
- ~~• Any new conditions identified by the CDC as being a potentially communicable disease~~

~~4.6.3 **Exceptions.** Organs from donors with a positive screening test or confirmed medical conditions that may be transmittable, with the exception of HIV, may be transplanted at the discretion of the transplanting program with the informed consent of the recipient.~~

~~4.6.4 **Donor Consent Forms.** Member institutions are encouraged to include in each donor consent form a notice that all potential donors will be screened for medical acceptability for organ donation and that results of such tests may be the basis for not using the organ in transplantation.~~

4.2 **REQUIREMENTS FOR INFORMED CONSENT REGARDING RISK OF TRANSMISSIBLE DISEASE.** Transplant programs must obtain informed consent prior to transplant of an organ when, in the transplant program's medical judgment:

- The donor has a known medical condition that may be transmittable to the recipient, with the exception of HIV (see Policy 2.2.3.3); and/or
- The donor has recognized increased risk for ~~blood-borne viruses disease~~ transmission (including but not limited to consideration of U.S. PHS Guidelines

or when a hemodiluted specimen is used for donor HIV, HBV, and/or HCV screening (see Policy 2.2.3.1)).

4.2.1 If additional donor risk (infectious or neoplastic) is identified pre-transplant, the transplant program must:

- explain the risks and obtain informed consent from the recipient or next of kin, the legal next of kin, designated health care representative or appropriate surrogate before transplant;
- document this consent in the recipient medical record and make it available to the OPTN contractor if requested; and
- follow the recipient of such an organ for the development of potential donor-derived disease after transplantation.

4.2.2 Transplant programs must offer the recipients of organs from donors at increased risk for blood borne pathogens:

- additional post-transplant testing for HIV, HCV, and/or HBV (as appropriate based upon the recipient's pre-transplant status); and
- monitoring and/or therapy to treat or provide prophylaxis as appropriate to minimize the risk of infection in addition to routine post-transplant follow-up care.

4.2.3 Transplant programs must also inform potential recipients of the **general** risks of potential infection and/or tumor acquisition outside of the standard donor screening requirements (as defined in Policy 2.2.4.1), to include information that:

- there is no comprehensive way to screen potential donors for all transmissible diseases; and
- on occasion, infectious agents, donor-associated tumors or genetic diseases may be identified after transplantation.

~~In all instances, the transplant program must:~~

- explain these risks and obtain informed consent from the recipient or next of kin, the legal next of kin, designated health care representative or appropriate surrogate before transplant; and
- document this consent in the recipient medical record and make it available to the OPTN contractor if requested; and
- ~~offer the recipient additional post transplant testing for HIV, HCV and/or HBV (as appropriate), monitoring and/or therapy to treat or provide prophylaxis as appropriate to minimize the risk of infection in addition to routine post-transplant follow-up care. Related documentation should be maintained in the recipient medical record and made available to the OPTN contractor if requested.~~

4.3 **Disclosure of Post-Transplant Discovery of Donor Disease or Malignancy and Notification of Recipients.** Because results from donor testing samples may be completed or change after organ transplantation and/or new clinically relevant findings are sometimes recognized post-transplant, the transplant program must:

- Notify recipient, or next of kin, the legal next of kin, designated health care representative or appropriate surrogate of a risk of transmissible disease that was not previously identified and is noted as clinically relevant by the recipient's care team.
- Document new donor information and potential risk for disease/malignancy in the transplant center's recipient medical record and make this information available to the OPTN contractor if requested; and
- ~~Offer the recipient additional testing, monitoring and/or therapy as appropriate in addition to their routine follow-up care. Related documentation should be maintained in the recipient medical record and made available to the OPTN contractor if requested.~~
- Follow a recipient at increased risk for disease and/or malignancy for the development of this potential condition after transplantation, offering the recipient additional testing, monitoring and/or therapy as appropriate in addition to their routine follow-up care.

4.3.1 Transplant programs must offer the recipient of an organ from a donor found after transplant to pose increased risk for blood borne pathogens:

- Additional post-transplant testing for HIV, HCV and/or HBV (as appropriate based upon the recipient's pre-transplant status); and
- Monitoring and/or therapy to treat or provide prophylaxis as appropriate to minimize the risk of infection in addition to routine post-transplant follow-up care.

4.4 **PATIENT SAFETY CONTACT.** Each Host OPO and Transplant Program must develop a process for identifying a Patient Safety Contact and follow this process for receiving potential disease transmission notifications and any related communication with the OPTN. The Patient Safety Contact must be available 24 hours a day, and is responsible for:

- Receiving pertinent medical information that may affect or change recipient care;
- Communicating information to the appropriate medical professional responsible for clinical care of the recipient(s) at the transplant program **as soon as possible**, and not to exceed 24 hours; and
- Facilitating communication about the current clinical status of any recipient for whom the center is informed of a concern for a possible or proven disease transmission related to the donor.

~~Transplant programs and OPOs must exchange this information to facilitate effective communication should a potential disease transmission or patient safety situation arise and~~ make this information available to the OPTN contractor if requested.

4.75 **POST-TRANSPLANT REPORTING OF POTENTIAL TRANSMISSION OF DISEASE OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES.** In order to promote prompt notification of potential risk of disease transmission through organ transplantation, all events involving unexpected potential or proven transmission of a medical condition, including infections and malignancies, discovered after procurement of a donor organ must be reported to the OPTN Patient Safety SystemSM.

- When a transplant program is informed that an organ recipient at that program is suspected to have, is confirmed positive for, or has died from a potential transmissible disease or medical condition for which there is substantial concern that it could be from donor origin, then the transplant program must notify the Host OPO by phone and provide available documentation, to the Host OPO as soon as possible, and not to exceed 24 hours of this knowledge/concern one complete working day, to the procuring OPO. The overall intent is to transfer the knowledge/concern from one transplant center to all other transplant centers who have accepted organs from the same donor as quickly as possible. The transplant center that suspects/originating the concern of potential transmission should not wait for all medical documentation that will may eventually be available, but must inform the communicate that center's concerns through Host OPO and/or the OPTN Patient Safety System to transfer knowledge/concern as soon as possible to all other centers involved with that that received organs from the same donor, as soon as possible so the other centers could use their medical judgment as to which, if any, investigations or actions need to be performed on their recipients.
- When a Host OPO learns of new information regarding a donor (i.e. final culture results, information from autopsy report, etc.) as part of its donor follow-up (See Policy 2.2.5) that indicates risk of potential transmission of disease or malignancy, the Host OPO must report the donor through the OPTN Patient Safety System.

4.5.1 Host OPO Responsibilities. The ~~procuring~~ Host OPO shall be responsible for:

- Communication of the test results and diagnosis from a suspected donor and/or affected recipient(s) that may be pertinent to acute patient care as soon as practicable, not to exceed 24 hours, to any transplant program(s) Patient Safety Contact and tissue bank(s) that received an organ(s) or tissue from the donor who is the subject of the investigation; This includes results of all tests that were not available at the time of procurement (i.e. cultures, final pathology, etc) or subsequently performed after recovery and documenting that this information is shared with all recipient centers and tissue banks.
- ~~ii.~~ Notification of the event to the OPTN Patient Safety SystemSM in UNetSM as soon as possible, and not to exceed 24 hours.
- iii. Follow-up Communication of Potential Disease Transmission
 - Completion and submission of the Potential Disease Transmission Report Form (a form that will be sent to the Host OPO after OPTN staff receives the electronic notification from the OPTN Patient Safety System UNetSM) to OPTN Patient Safety Staff within 24 hours of reporting the event through the Patient Safety SystemSM to identify:
 - The specific Patient Safety Contact at the recipient transplant program(s) and tissue bank(s) personnel that were notified of the potential transmission;
 - Disposition of all organs, tissues and vessels; and
 - Any preliminary information available regarding any remaining donor samples for additional testing, notification to state or local health department as appropriate for nationally notifiable infectious diseases, and whether an autopsy was performed on the donor.
 - If requested by the Ad Hoc Disease Transmission Advisory Committee, Submission of a Potential Disease Transmission DONOR Follow-Up

Report (a form that will be sent to the Host OPO by OPTN staff) 45 days after the initial reporting date; OPTN Patient Safety Staff may request additional information related to the donor beyond 45 days, including pending test results. ~~Potential Disease Transmission long term follow up depending on the potentially transmitted disease or condition potentially transmitted.~~

- ~~iv. submission of a final written report to the OPTN within 45 days, which specifies the organizations and individuals who were notified, when the notifications occurred, and results of the investigation including test results of the organ recipients who are the subjects of the investigation.~~
- ii.iv. Management of the review, in partnership with OPTN Patient Safety Staff, to determine whether the organ donor was diagnosed with a potentially transmissible disease or condition;

~~The OPTN shall assist the procuring OPO in identifying all organ transplant programs and recipients who received an organ from the donor who is the subject of the investigation. The OPTN will monitor the notification process to verify that the procuring OPO and all recipient organ transplant programs have been notified of the disease or medical condition and will request that any additional diagnostic test results be submitted to the procuring OPO with a copy to the OPTN. The OPTN contractor will forward a copy of the OPO's final report to the recipient transplant centers and the Division of Organ Transplantation of the Health Resources and Services Administration. Note: The identities of the donor and any organ recipient who are the subjects of the investigation shall remain confidential and all correspondence will refer to the donor and recipients by their donor identification number and recipient social security numbers. Under no circumstances should a transplant program or OPO disclose this information in a manner that is contrary to applicable law.~~

4.5.2 Transplant Program Responsibilities. Any transplant program treating recipient(s) that receiveds organ(s) from a donor who is the subject of a potential disease transmission report is responsible for:

- i. Responding to Host OPO and OPTN Patient Safety Staff requests for information regarding recipient(s) in a timely fashion and communicating updated information regarding recipient condition, test results, diagnosis, and plans for treatment and follow-up.
- ii. Submitting copies of any pertinent test results (including cultures, serologies, imaging studies, autopsy results, etc.) to both the Host OPO and the OPTN Patient Safety Staff.
- iii. Notifying recipient(s) involved in cases of ~~potential~~ or confirmed transmissions and documenting this notification in the recipient medical record as required in Policy 4.3.
- ~~iv. Providing the Host OPO with all documentation needed for the Host OPO to complete **Potential Disease Transmission Follow-Up Report** to the OPTN Patient Safety Staff within 45 days after the initial reporting date.~~
- ~~v. Providing any requested available data to the OPTN Patient Safety Staff for completion of the **Potential Disease Transmission Long Term Follow-Up Reports** depending on the disease or condition potentially transmitted. (In cases of potential malignancy transmission, the OPTN~~

~~Patient Safety Staff may also contact the recipient center within six months of the report to request updated follow-up on a recipient in an effort to determine probability of donor-derived transmission.)~~

- iv. If requested by the Ad Hoc Disease Transmission Advisory Committee, submission of a Potential Disease Transmission RECIPIENT Follow-Up Report (a form that will be sent to the transplant program by OPTN staff) within 45 days of the initial reporting date.

OPTN Patient Safety Staff may request additional information related to the recipient beyond 45 days, (including pending test results, long term follow-up testing, and/or screening results, etc.) depending on the potentially transmitted disease or condition in an effort to determine the probability of donor-derived disease transmission.

Language struck from Policies 2.5.6 and 2.5.6.1 was relocated to Policy 5.0 to keep all requirements related to organ packaging in one policy section.

5.5.1 Documentation accompanying the organ

- Complete donor documentation, ~~as described in Policy 2.5.6.1,~~ must be sent in the container with ~~all~~ each transported organs. This documentation must include:
 - ABO typing source documentation;
 - Infectious disease testing results;
 - Medical/Behavioral History form;
 - Donor Evaluation;
 - Complete record of the donor;
 - Deceased donor consent form; and
 - Organ quality information as noted in Policy 2.5.
- Donor documentation must be placed in a watertight container.
- Donor documentation may be placed in either:
 - a location specifically designed for documentation, or
 - between the outer and inner containers.
- Whenever a deceased donor organ is transported, the Host OPO or the Transplant Center, as applicable, must include in the donor documentation the source documentation.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Policy and Bylaw Language:

3.5.9.1 Essential Information for Kidney Offers. The Host OPO must provide the following information to the potential recipient center with each kidney offer:

- (i) Donor name and Donor I.D. number, age, sex, and race;
- (ii) Date of admission for the current hospitalization;
- (iii) Diagnosis;
- (iv) Blood type;
- (v) HLA A, B, Bw4, Bw6, and DR antigens HLA A, B, Bw4, Bw6, C (including Identified splits of HLA A, B, , C) DR, (including DRB1, DRB3/4/5), and DQB antigens HLA A, B, Bw4, Bw6, C, DR and DQB antigens. When reporting DR antigens, DRB1 and DRB3/4/5 must be reported. The lab is encouraged to report splits for all loci as shown in Appendix 3A;

[...]

3.8.2.2 Essential Information for Pancreas Offers. The Host OPO or donor center must provide the following donor information, with the exception of pending serologies, to the recipient center with each pancreas offer:

[...]

- 15. Familial history of diabetes; and
- 16. HLA A, B, Bw4, Bw6, and DR antigens. HLA A, B, Bw4, Bw6, C (including Identified splits of HLA A, B, , C) DR, (including DRB1, DRB3/4/5), and DQB antigens HLA A, B, Bw4, Bw6, C, DR and DQB antigens. When reporting DR antigens, DRB1 and DRB3/4/5 must be reported. The lab is encouraged to report splits for all loci as shown in Appendix 3A.

**UNOS Bylaws Appendix B Attachment IIA - Standards for Histocompatibility Testing,
D HLA Typing**

D1.000 ~~The laboratory must be able to define HLA A, B, Bw4, Bw6, C, DR and DQ antigens at a level that is appropriate for solid organ transplantation~~ The laboratory must be able to define HLA A, B, Bw4, Bw6, C (including Identified splits of HLA A, B, , C) DR, (including DRB1, DRB3/4/5), and DQB antigens at a level that is appropriate for solid organ transplantation. HLA A, B, Bw4, Bw6, C, DR and DQB antigens. When reporting DR antigens, DRB1 and DRB3/4/5 must be reported. The lab is encouraged to report splits for all loci as shown in Appendix 3A. Laboratories that perform deceased donor typing to be used in kidney, kidney-pancreas, pancreas, or pancreas islet allocation must report molecular typing results (at the level of serological splits) for all required antigens prior to organ offers.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Policy Language:

Appendix 3A

HLA Antigen Values and Split Equivalences (revisions 2010)

HLA A, B, and DR Matching Antigen Equivalences					
PATIENT A LOCUS ANTIGEN	EQUIVALENT DONOR ANTIGEN(S)	PATIENT B LOCUS ANTIGEN	EQUIVALENT DONOR ANTIGEN(S)	PATIENT DR LOCUS ANTIGEN	EQUIVALENT DONOR ANTIGEN(S)
1	1	5	5,52,53,78	1	1,103
2	2,203,240	7	7,703,2708	2	2,15,16
3	3	8	8	3	3,17,18
9	9	12	12	4	4
10	10,26,34,66,*6601,*6602	13	13	5	5,11,12
11	11	14	14,64,65	6	6,13,14,1403,1404
19	19,74	15	15,75,76,77,*1304	7	7
23	23	16	16,*3905	8	8
24	24,2403	17	17,58	9	9
25	25	18	18	10	10
26	26,*6604	21	21,4005,*1304	11	11,5
28	28,68,69	22	22,54,*8204	12	12,5
29	29	27	27	13	13,6
30	30	35	35	14	14,6,1403,1404
31	31	37	37	15	15,2
32	32	38	38	16	16,2,15
33	33	39	39,3901,3902,*3905	17	17,3,18
34	34,*6602	40	40,61,84	18	18,3,17
36	36	41	41	103	103,1
43	43	42	42	1403	1403,14,6
66	66,*6601,*6602,40	44	44	1404	1404,14,6
68	68,28	45	45	** 99	(No equivalent)
69	69,28	46	46		
74	74,19	47	47		
80	80	48	48		
203	203,2	49	49		
210	210,2	50	50,4005		
2403	2403,24	51	51,5102,5103		
*6601	*6601,66,40,26	52	52,5		
*6602	*6602,66,40,34	53	53,5,5102		
** 99	(No equivalent)	54	54,22		
		55	55		
		56	56		
		57	57		
		58	58		
		59	59		
		60	60		
		61	61,40		
		62	62		
		63	63		
		64	64,14		
		65	65,14		
		67	67		
		70	70,71,72		
		71	71,70		
		72	72,70		
		73	73		
		75	75,15		

		76	76,15		
		77	77,15		
		78	78,5		
		81	81,7,40,60,61,48		
		82	82, <u>8201</u>		
		703	703,7		
		*0804	*0804,8		
		*1304	*1304,15,21,49,50		
		2708	2708,27,7		
		3901	3901,39		
		3902	3902,39		
		*3905	*3905,46,39		
		4005	4005,21,50		
		5102	5102,51,53		
		5103	5103,51		
		7801	7801		
		*8201	*8201, <u>82,45,22,54,55,56</u>		
		** 99	(No equivalent)		

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

** Code 99 means not tested

Examples of how “Antigen Equivalences” works:

If patient has B60: Donors with B60 are considered not mismatched.

If patient has B61: Donors with B61 or B40 are considered not mismatched. Donors with B60 are considered mismatched.

HLA A, B, C, DR, and DQ Unacceptable Antigen Equivalences					
PATIENT'S UNACCEPT-ABLE A LOCUS ANTIGEN	DONOR EQUIVALENT ANTIGEN(S)	PATIENT'S UNACCEPT-ABLE B LOCUS ANTIGEN	DONOR EQUIVALENT ANTIGEN(S)	PATIENT'S UNACCEPT-ABLE C LOCUS ANTIGEN	DONOR EQUIVALENT ANTIGEN(S)
1	1	5	5,51,5102,5103,52,78	w1	w1
2	2,203,210	7	7,703,2708	w2	w2
3	3	8	8,*0804	w3	w3,w9,w10
9	9,23,24,2403	12	12,44,45	w4	w4
10	10,25,26,34,66,*6601,*6602	13	13	w5	w5
11	11	14	14,64,65	w6	w6
19	19,29,30,31,32,33,74	15	15,62,63,75,76,77	w7	w7
23	23,9	16	16,38,39	w8	w8
24	24,2403,9	17	17,57,58	w9	w9
25	25,10	18	18	w10	w10
26	26,10	21	21,49,50,4005	*12	*12
28	28,68,69	22	22,54,55,56	*13	*13
29	29	27	27,2708	*14	*14
30	30	35	35	*15	*15
31	31	37	37	*16	*16
32	32	38	38,16	*17	*17
33	33	39	39,3901,3902,*3905,16	*18	*18
34	34	40	40,60,61		
36	36	41	41		
43	43	42	42		
66	66,*6601,*6602,10	44	44,12		
68	68,28	45	45,12		
69	69,28	46	46		
74	74	47	47		
80	80	48	48		
203	203	49	49,21		
210	210	50	50,4005,21		
2403	2403	51	51,5102,5103		
*6601	*6601,66	52	52		
*6602	*6602,66	53	53,5102		
		54	54,22		
		55	55,22		
		56	56,22		
		57	57,17		
		58	58,17		
		59	59,*0804		
		60	60,40		
		61	61,40		
		62	62,15		
		63	63,15		
		64	64,14		
		65	65,14		
		67	67		
		70	70,71,72		
		71	71,70		
		72	72,70		
		73	73		
		75	75		
		76	76		
		77	77		
		78	78		
		81	81		

		82	82, *8201		
		703	703		
		*0804	*0804		
		*1304	*1304		
		2708	2708		
		3901	3901		
		3902	3902		
		*3905	*3905		
		4005	4005		
		5102	5102		
		5103	5103		
		7801	7801		
		*8201	*8201		
		Bw4	Bw4 (see below)		
		Bw6	Bw6(see below)		

HLA A, B, C, DR, and DQ Unacceptable Antigen Equivalences (continued)

PATIENT'S UNACCEPTABLE DR LOCUS ANTIGEN	DONOR EQUIVALENT ANTIGEN(S)	PATIENT'S UNACCEPTABLE DQ LOCUS ANTIGEN	DONOR EQUIVALENT ANTIGEN(S)
1	1, <u>103</u>	1	1,5,6
2	2,15,16	2	2
3	3,17,18	3	3,7,8,9
4	4	4	4
5	5,11,12	5	5, <u>1</u>
6	6,13,14,1403,1404	6	6, <u>1</u>
7	7	7	7, <u>3</u>
8	8	8	8, <u>3</u>
9	9	9	9, <u>3</u>
10	10		
11	11		
12	12		
13	13, <u>6</u>		
14	14,1403,1404, <u>6</u>		
15	15, <u>2</u>		
16	16, <u>2</u>		
17	17, <u>3</u>		
18	18, <u>3</u>		
103	103		
1403	1403, <u>6</u>		
1404	1404, <u>6</u>		
51*	51, <u>2,15,16</u>		
52*	52, <u>3,5,6,11,12,13,14,17,18</u>		
53*	53, <u>9</u>		

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

*** Please refer to the end of this section for information

Example of how "Unacceptable Antigen Equivalences" works:

If a patient has B40 listed as an "unacceptable antigen": Donors typed as B40, B60, or B61 are considered unacceptable.

If a patient has B60 listed as an "unacceptable antigen": Donors typed as B40, B60 are considered unacceptable, donors typed as B61 are considered acceptable.

Therefore, if a patient has antibodies to all splits of a broad antigen, enter the broad antigen as well as the splits as unacceptable antigens, or enter only the broad antigen as an unacceptable antigen.

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

Bw4 should exclude B5,B13, B17, B27, B37, B38, B44,B47,B49, B51,B52,B53, B57,B58, B59,B63,B77,Bw4.

Bw6 should exclude

B7,B8,B14,B18,B22,B35,B39,B40,B41,B42,B45,B48,B50,(B*4005),B54,B55,B56,B60,B61,B62,B64,B65,B67,B70,B71,B72,B75,B76 ,B78,B81,Bw6

DR51 should also exclude DR2,DR15,DR16:

DR52 should also exclude DR3,DR5,DR6,DR11,DR12,DR13,DR14,DR17,DR18:

DR53 should also exclude DR4,DR7,DR9.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Policy Language:

Because of the major substantive and formatting changes, only new content in the proposed policy language is underlined. Changes in location within Policy 3.8 are *not* denoted by underlines and strikethroughs. For policy not located in section 3.8 (Pancreas Allocation Policy), modified policy language is underlined (example) and deleted policy language is stricken through (~~example~~). Changes made after public comment are denoted with a double underline (example) or an underline with a strikethrough (~~example~~).

Policy 3.8 Pancreas Allocation Policy

Purpose: The following policies describe the process for listing pancreas, kidney-pancreas candidates, and pancreas islet candidates and for allocating organs to pancreas, kidney-pancreas, and pancreas islet candidates.

Key Terms:

Body Mass Index (BMI) - A measure of body size, calculated as weight in kilograms divided by height in meters squared.

Calculated Panel Reactive Antibody (CPRA) - The percentage of donors expected to have one or more of the unacceptable antigens indicated on the Waiting List for the candidate. The CPRA is derived from HLA antigen/allele group and haplotype frequencies for the different racial/ethnic groups in proportion to their representation in the national deceased donor population.

C-Peptide - A byproduct of insulin production, usually by the pancreas. The level of C-peptide is a gauge of how much insulin is being produced in the body.

Creatinine Clearance (CrCl) - A measure used to determine kidney function, the CrCl indicates the volume of serum or plasma that would be cleared of creatinine by one minute's excretion of urine.

Glomerular Filtration Rate (GFR) - A measure used to determine kidney function, the GFR indicates the kidney's ability to filter and remove waste products.

Pancreas-Alone Transplant – A type of pancreas transplant where the pancreas is transplanted without any other organs

Simultaneous Pancreas-Kidney (SPK) Transplant - A type of pancreas transplant where the pancreas and kidney from the same donor are transplanted at the same time (also known as a combined kidney-pancreas transplant)

3.8.1 Pancreas and Kidney-Pancreas Listing and Qualifying Criteria

3.8.1.1 Pancreas Waiting List Criteria. Each candidate registered on the Pancreas Waiting List must be diagnosed with diabetes or have pancreatic exocrine insufficiency or require the procurement or transplantation of the pancreas for technical reasons as part of a multiple organ transplant.

3.8.1.2 Previous Kidney Donor Antigens Considered “Self” Antigens in Pancreas Match Runs. Upon listing a candidate for pancreas after kidney transplantation, the transplant program has the option of entering the candidate’s prior kidney donor’s antigens, which will then be considered “self” antigens in pancreas match runs. In the event a candidate’s prior kidney donor’s antigens are entered, the match system for pancreas allocation will take into account the candidate’s antigens and all of the kidney donor’s mismatched

antigens that are entered into UNetSM. ~~Mismatches~~ Antigens that are common to a candidate's prior kidney donor and a subsequent pancreas donor are considered as matches and the candidate will appear on the match-run print out for all pancreas donors who meet these mismatch criteria. Use of these modified mismatch criteria is optional.

3.8.1.3 Combined Kidney-Pancreas Waiting List Criteria. Each candidate registered on the Kidney-Pancreas Waiting List must be diagnosed with diabetes or have pancreatic exocrine insufficiency with renal insufficiency.

3.8.1.4 Criteria to Accrue Kidney-Pancreas Waiting Time Qualifying Criteria. In order to be eligible to accrue waiting time for a kidney-pancreas transplant, a kidney-pancreas candidate must:

- Qualify for a solitary kidney transplant according to the criteria used for a kidney candidate to accrue waiting time specified in Policy 3.5.11.1 (Time of Waiting); and
- Meet one of the following criteria:
 1. On insulin and eC-peptide less than or equal to 2 ng/mL; or
 2. On insulin and eC-peptide greater than 2 ng/mL and BMI less than or equal to the maximum allowable BMI.
 - a. Upon implementation, the maximum allowable BMI shall be 28 kg/m².
 - b. The OPTN contractor will review the kidney-pancreas waiting list to determine the percentage of candidates who meet criteria 2 above every six months beginning six months after implementation.
 - c. Whenever such reviews determine that the percentage of active candidates on the kidney-pancreas waiting list who meet criteria two is greater than fifteen percent, the maximum allowable BMI shall be reduced by 2 kg/m².
 - d. Whenever such reviews determine that the percentage of active candidates on the kidney-pancreas waiting list who meet criteria two is less than ten percent, the maximum allowable BMI shall be increased by 2 kg/m². The maximum allowable BMI shall not exceed 30 kg/m².
 - e. Whenever the maximum allowable BMI is reduced or increased according to (c) or (d), the new maximum allowable BMI shall be published in the OPTN contractor's evaluation plan, and the OPTN contractor shall notify all member kidney programs and all member pancreas programs of the change.

Candidates who do not meet these criteria will not be eligible for waiting time for a kidney-pancreas offer on a match run. Once a candidate qualifies for waiting time according to the criteria above, the candidate will remain qualified for SPK waiting time, regardless of any changes to the maximum allowable BMI.

Programs must be able to verify with appropriate supporting documentation that the candidate met the criteria on the dates submitted; this documentation will be subject to audit by the OPTN contractor either through on site audits or otherwise upon request for submission to the OPTN contractor.

3.8.1.4.1 Exceptions. Candidates listed for an SPK transplant on or before their 18th birthday do not have to meet SPK qualifying criteria.

3.8.2 Required Information

3.8.2.1 Inclusion of HLA Data. ~~Recipient-Candidate~~ HLA (at least 1 A, 1 B, and 1 DR antigen) information must be included when listing a potential pancreas or combined kidney-pancreas candidate on the Waiting List.

3.8.2.2 Essential Information for Pancreas Offers. The Host OPO or donor center must provide the following donor information, with the exception of pending serologies, to the recipient center with each pancreas offer:

1. Donor name and Donor I.D. number, age, sex, race and weight;
2. Date of admission for the current hospitalization;
3. Diagnosis;
4. Blood type;
5. Current history of abdominal injuries and operations including pancreatic trauma;
6. Pertinent past medical or social history including pancreatitis;
7. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria;
8. Indications of sepsis;
9. Pre-or post-transfusion serologies as indicated in Policies 2.2.3.1 and ~~2.2.3.52-2.7.4~~ (pre-transfusion preferred);
10. Current medication and transfusion history;
11. Blood glucose;
12. Amylase;
13. Insulin protocol;
14. Alcohol use (if known);
15. Familial history of diabetes; and
16. HLAA, B, Bw4, Bw6, and DR antigens.

3.8.2.3 Prospective Crossmatching. A prospective crossmatch is mandatory for all candidates, except where clinical circumstances support its omission. The transplant program and its histocompatibility laboratory must have a joint written policy that states when the prospective crossmatch may be omitted. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D to Policy 3.

3.8.3 Allocation Sequence

3.8.3.1 Order of Allocation to Pancreas, Kidney-Pancreas, and Kidney Candidates. The Host OPO must offer organs from the combined pancreas/kidney-pancreas match run through the local pancreas and kidney-pancreas candidates as described in Policy 3.8.3.2 (Allocation Sequence) before offering organs to any isolated kidney candidates.

3.8.3.2 Blood Type O Kidney-Pancreas Allocation. For combined kidney-pancreas candidates, blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2 (ABO "O" Kidneys into ABO "O" Recipients and ABO "B" Kidneys into ABO "B" Recipients), unless there is a zero antigen mismatch between the candidate and donor and the candidate has a CPRA greater than or equal to 80% as defined in Policy 3.8.4.1 (CPRA).

3.8.3.23 Allocation Sequence. Pancreata, kidney-pancreas combinations, and pancreas islets from donors 50 years of age or less and who have a BMI less than or equal to 30 kg/m² shall be allocated according to the following sequence:

1. Local zero mismatch pancreas and kidney-pancreas candidates with a CPRA \geq 80%;
2. Local pancreas and kidney-pancreas candidates with a CPRA \geq 80%;
3. Regional zero mismatch pancreas and kidney-pancreas candidates with a CPRA \geq 80%;
4. National zero mismatch pancreas and kidney-pancreas candidates with a CPRA \geq 80%;
5. Local pancreas and kidney-pancreas candidates;

6. Regional pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas regionally) with a CPRA \geq 80%;
7. Regional pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas regionally);
8. National pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas nationally regionally) with a CPRA \geq 80%;
9. National pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas nationally);
10. Local pancreas islet candidates;
11. Regional pancreas islet candidates;
12. National pancreas islet candidates.

Pancreata, kidney-pancreas combinations, and pancreas islets from donors greater than 50 years of age or from donors who have a BMI greater than to 30 kg/m² shall be allocated according to the following sequence:

1. Local zero mismatch pancreas and kidney-pancreas candidates with a CPRA \geq 80%;
2. Local pancreas and kidney-pancreas candidates with a CPRA \geq 80%;
3. Regional zero mismatch pancreas and kidney-pancreas candidates with a CPRA \geq 80%;
4. National zero mismatch pancreas and kidney-pancreas candidates with a CPRA \geq 80%;
5. Local pancreas and kidney-pancreas candidates;
6. Local pancreas islet candidates;
7. Regional pancreas islet candidates;
8. National pancreas islet candidates;
9. Regional pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas regionally) with a CPRA \geq 80%;
10. Regional pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas regionally);
11. National pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas nationally regionally) with a CPRA \geq 80%;
12. National pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas nationally).

In the event that a kidney is not available at the time of the organ offer, the OPO may offer the pancreas to pancreas-alone candidates only.

3.8.3.34 Facilitated Pancreas Allocation. In the event that the Organ Center has attempted, but has been unable, to place the pancreas for a period of at least five (5) hours, or upon notice to the Organ Center that organ retrieval is anticipated within one (1) hour, then irrespective of whether the entire regional and/or national Waiting List of candidates has by that time been exhausted, the pancreas shall be offered through the Organ Center for pancreas-alone candidates listed with those transplant centers that have recorded in writing their desire, to participate in the system of facilitated pancreas allocation. A pancreas offered by this facilitated method shall be offered to candidates who have not previously received an offer for that pancreas. The pancreas shall be offered to pancreas-alone candidates listed at transplant centers participating in the facilitated pancreas option according to the sequence in Policy 3.8.3.2 (Allocation Sequence), ~~in the following sequence, based on the transplant candidate's length of waiting time within each of the enumerated categories below.~~

Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive.

- ~~Isolated pancreas candidates with unacceptable HLA antigens listed in UNetSM sufficient to yield CPRA \geq 80%¹; and~~

- ~~Combined kidney pancreas candidates if the kidney is voluntarily being offered. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2 and the kidney must be paid back as specified in Policy 3.5.5.~~

Any transplant center desiring to participate in this system shall be allowed to do so provided that it (a) agrees to accept offers for pancreata that have been procured by institutions located outside of its OPO and (b) ~~agrees to accept offers for pancreata on a conditional basis pending tissue typing information and redistribution of the organs pursuant to Policy 3.8.1.7 in the event there is a candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, and~~ (c) documents this agreement and its desire to participate in the system in writing.

3.8.3.4.5 Organ Offer Limits. All pancreata to be shared as zero antigen mismatches, either alone or in combination with kidneys, must be offered to the appropriate recipient transplant centers through UNetSM or through the Organ Center within eight hours after organ procurement. Offers must be made for the first 10 zero antigen mismatched potential recipients¹ according to the national lists of candidates waiting for combined kidney/pancreas or isolated pancreas transplantation, as applicable. If there are less than 10 zero antigen mismatched potential recipients on the match list, offers must be made for all zero antigen mismatched potential recipients on the match list. If these offers are turned down (either explicitly refused or the notification time or evaluation time is exceeded as defined in Policy 3.4.1), the Host OPO must either:

- allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.3.23.8.1, as applicable (first locally, then regionally, and then nationally); or
- allocate the organ(s) for the remaining zero antigen mismatched potential recipients.

If the Host OPO continues to offer kidney/pancreas combinations for zero antigen mismatched potential recipients beyond the 10th potential recipient, a kidney payback will be generated pursuant to Policy 3.5.5 (Payback Requirements). If the Host OPO chooses to share a zero antigen mismatched kidney/pancreas combination through UNetSM, the Host OPO must submit a completed Kidney Payback Accounting Sheet within 5 business days of the recovery of the organ(s), defined as cross clamp of the donor aorta, to report the share. A payback credit will not be assigned until: 1) the Organ Center receives the Kidney Payback Accounting Sheet documenting the zero antigen mismatch share; and 2) the zero antigen mismatch share can be verified (i.e. cross clamp and final acceptance has been entered) in UNetSM. No obligation to pay back the pancreas will be generated. If the Host OPO does not report the sharing within 5 business days of the organ(s) recovery, the OPO will forfeit the payback credit.

3.8.3.5.6 Regional or National Allocation to Alternate Recipients. For a pancreas that is shared regionally or nationally, the Organ Center will advise the OPO for the transplant center for the candidate who has the highest number of points at that center to seek alternate candidates on the OPO's waiting list to receive the pancreas in the event that the pancreas cannot be used by that candidate. Selection of alternate candidates must be according to the pancreas allocation policy.

3.8.4 Determinants for Scoring

¹ For the purposes of Policy 3.8.3.3, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

- 3.8.4.1 CPRA.** To receive priority in the allocation of isolated pancreata or kidney-pancreas combinations based upon CPRA, candidate unacceptable HLA antigens sufficient to yield an 80% or greater probability of incompatibility with deceased donors (i.e., Calculated Panel Reactive Antibody (CPRA) \geq 80%)² sufficient to yield CPRA \geq 80%) must be entered into UNetSM ~~as described in Policies 3.8.1.1—3.8.1.4.~~ Pancreata from donors with antigens included among the unacceptable antigens for a candidate will not be offered for that candidate.
- 3.8.4.2 Zero antigen mismatches.** To receive priority in the allocation of pancreata or kidney-pancreas combinations based on a zero mismatch between the candidate and the donor, the candidate must meet the following definition:

A zero antigen mismatch is defined as occurring when a candidate on the Waiting List has an ABO blood type that is compatible with that of the donor and the candidate and donor both have all six of the same HLA-A, B, and DR antigens. A zero antigen mismatch is also defined as a match occurring when there is phenotypic identity between the donor and recipient with regard to HLA, A, B, and DR antigens when at least one antigen is identified at each locus.

Phenotypic identity means that the donor and candidate each has the same antigens identified at each pair of A, B, and DR HLA loci. Candidates with only one antigen identified at an HLA locus (A, B, or DR) are presumed "homozygous" at that locus (i.e. homologous chromosomes are presumed to code for identical antigens at that locus). For example, a donor or candidate typed as A2, A- (blank) would be considered A2, A2.

A zero antigen mismatch would also include cases where both antigens are identified at a locus in the candidate but the donor is typed as being homozygous for one of the candidate's antigens at that locus. For example, there would be a zero antigen mismatch if the recipient were typed as A1, A31, B8, B14, DR3, DR4 and the donor were typed as A1.A- (blank), B8, B14, DR3, DR-(blank). If the donor is homozygous at any A, B, or DR locus, the match can be said to be a zero antigen mismatch, as long as none of the identified A, B, or DR donor antigens are different from those of the recipient.

- 3.8.4.3 Waiting Time.** Within each classification in Policy 3.8.3.2 (Allocation Sequence), candidates will be ranked based on waiting time.

Waiting time for pancreas and pancreas islet candidates begins on the date the candidate was is listed for the organ.

Once an adult kidney-pancreas candidate is eligible for kidney-pancreas waiting time according to Policy 3.8.1.4 (Criteria to Accrue Kidney-Pancreas Waiting Time), waiting time for adult kidney-pancreas candidates begins on the date the candidate is eligible to receive waiting time for a kidney transplant according to Policy 3.5.11.1 (Time of Waiting) ~~met the criteria specified in Policy 3.5.11.1 (Time of Waiting) regardless of listing date (i.e., the date the candidate began dialysis or the date the candidate had a GFR or CrCl less than or equal to 20 mL/min).~~

~~If~~ For a candidate who is listed for an SPK transplant ~~on or~~ before his or her 18th birthday ~~qualifies for an SPK, then~~ the candidate's waiting time begins on the date the candidate is eligible to receive waiting time for a kidney transplant according to Policy 3.5.11.1 (Time

² For purposes of Policy 3.8, requirements for identifying and listing unacceptable antigens, as well as the definition of and parameters for calculating CPRA, are the same as those listed in Policy 3.5.11.3 (Sensitized Wait List Candidates) for assigning priority in the allocation of deceased donor kidneys.

~~of Waiting), regardless of whether the candidate meets the criteria stated in Policy 3.8.1.4 (Criteria to Accrue Kidney-Pancreas Waiting Time) on the earlier date of:~~

- ~~• the date the candidate met the criteria specified in Policy 3.5.11.1 (Time of Waiting) regardless of listing date (i.e., the date the candidate began dialysis or the date the candidate had a GFR or CrCl less than or equal to 20 mL/min); or~~
- ~~• the date of listing.~~

~~If a candidate is listed for an SPK transplant on or before his or her 18th birthday does not qualify for an SPK, then waiting time begins at the date of listing.~~

~~Candidates shall continue to accrue waiting time while registered on the waiting list as inactive.~~

3.8.5 Waiting Time Adjustments

3.8.5.1 Waiting Time Adjustments. ~~Waiting time accrued by an isolated pancreas transplant candidate while registered on the waiting list shall not be assigned to the listing for a combined kidney-pancreas transplant or an isolated kidney transplant except as outlined in Policy 3.2.1.8 (Waiting Time Modification).~~

~~Waiting time accrued by a combined kidney pancreas transplant candidate while registered on the waiting list shall not be assigned to the listing for an isolated pancreas transplant or an isolated kidney transplant except as outlined in Policy 3.2.1.8 (Waiting Time Modification).~~

~~Waiting time accrued by a combined kidney-pancreas transplant candidate while registered on the waiting list will be assigned to the listing for an isolated kidney transplant or an isolated pancreas transplant.~~

~~Waiting time accrued by an isolated kidney transplant candidate while registered on the waiting list shall not be assigned to the listing for a combined kidney-pancreas transplant or an isolated pancreas transplant except as outlined in Policy 3.2.1.8 (Waiting Time Modification).~~

~~Waiting time accrued by an isolated kidney transplant candidate while registered on the waiting list will be assigned to the listing for an isolated pancreas transplant. Waiting time accrued by an isolated kidney transplant candidate while registered on the waiting list will be assigned to the listing for a combined kidney-pancreas transplant, provided that the candidate meets the criteria outlined in Policy 3.8.1.4 (Criteria to Accrue Kidney-Pancreas Waiting Time).~~

~~Waiting time accrued by a combined kidney pancreas candidate who has received a kidney alone transplant may be assigned to a pancreas alone and/or islet alone listing for that candidate.~~

~~A combined kidney-pancreas candidate who has received a kidney-alone transplant and is added to the pancreas-alone or pancreas islet waiting list will be assigned waiting time beginning on the earlier date of:~~

- ~~• The date the candidate was listed for a pancreas-alone transplant, or~~
- ~~• The date the candidate was listed for a combined kidney-pancreas transplant, or~~
- ~~• The date the candidate began accruing waiting time for a combined kidney-pancreas transplant.~~

3.8.5.2 Waiting Time Transfer for Whole Pancreas and Pancreatic Islet Cell Candidates

1. Waiting time accrued by a pancreas islet transplant candidate while registered on the waiting list shall not be assigned to the listing for a combined kidney-pancreas

transplant or an isolated kidney transplant except as outlined in Policy 3.2.1.8 (Waiting Time Modification).

2. Waiting time accrued by an isolated whole pancreas transplant candidate while registered on the waiting list shall be transferred to the listing for pancreatic islet cell transplant after consideration and approval of a request for such transfer by the OPTN/UNOS Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that such transfer is reasonable and is in the candidate's best interest, and comply with other application requirements as may be developed by the Committee from time to time. Requests for waiting time transfer between the whole pancreas and pancreatic islet waiting lists, along with decisions of the Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.
3. Waiting time accrued by a pancreatic islet cell transplant candidate while registered on the waiting list shall be transferred to the listing for whole pancreas transplant after consideration and approval of a request for such transfer by the OPTN/UNOS Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that such transfer is reasonable and is in the candidate's best interest, and comply with other application requirements as may be developed by the Committee from time to time. Requests for waiting time transfer between the pancreatic islet and whole pancreas waiting lists, along with decisions of the Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.

3.8.5.3 Waiting Time Reinstatement for Pancreas Recipients. In those instances where there is immediate and permanent non-function of a transplanted deceased or living donor pancreas, the candidate may be reinstated to the waiting list and retain the previously accumulated waiting time without interruption for that transplant only. For purposes of this policy, immediate and permanent non-function shall be defined as pancreas graft failure requiring the removal of the organ within the first two weeks of transplant. Waiting time will be reinstated upon receipt by the Organ Center of:

- A completed Pancreas Waiting Time Reinstatement Form, and
- A pancreatectomy operative report

OR

- A completed Pancreas Waiting Time Reinstatement Form, and
- A statement of intent from the transplant center to perform a pancreatectomy, and
- A statement that there is documented, radiographic evidence indicating that the transplanted pancreas has failed. This documentation must be maintained and submitted upon request.

The Organ Center will send a notice of waiting time reinstatement to the transplant center involved.

3.8.6 Removal of Pancreas Transplant Candidates from Pancreas Waiting Lists When Transplanted or Deceased. If a pancreas transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all pancreas waiting lists and shall notify within 24 hours of the event. If the pancreas recipient is again added to a pancreas waiting list, waiting time shall begin as of the date and time the candidate is relisted. If the recipient is waiting for a combined kidney-pancreas transplant and receives only an isolated pancreas transplant, the recipient's accrued waiting time while listed for the combined organ transplant shall automatically be transferred to the isolated Kidney Waiting List.

3.8.7 Islet Allocation Protocol

3.8.7.1 Criteria for Active Status. A candidate is not eligible for active status if the candidate:

- Is insulin independent and
- Has an HbA1c value of less than or equal to 6.5%.

The transplant center is responsible for keeping the candidate's listing status current in UNetSM.

If the candidate is listed as active and is insulin dependent, the transplant center must maintain documentation in the candidate's record of his/her current insulin status. To retain active status for an insulin dependent candidate, the transplant center must document in the candidate's record every six months that the candidate is currently insulin dependent.

If the candidate is listed as active and is insulin independent, the transplant center must maintain documentation in the candidate's record of his/her insulin status and HbA1c level with the date of the HbA1c test. To retain active status for an insulin independent candidate, the transplant center must document in the candidate's record every six months:

- That the candidate has had an HbA1c test within the past six months with a result of greater than 6.5%, and
- That the candidate is insulin independent.

The transplant center must use the most recent HbA1c value when determining whether the candidate is eligible for active status.

If a candidate's clinical condition changes, and the candidate is no longer eligible for active status, the transplant center must change the candidate's status in UNetSM within 72 hours of the transplant center's knowledge of this candidate's clinical change. The transplant center must maintain documentation in the candidate's record of when the center learned of this clinical change.

If a transplant center wishes to list an inactive candidate as active, the transplant center must have documentation that the candidate had the appropriate HbA1c level and insulin status in the past six months.

The transplant center must present any documentation required by this policy to the OPTN upon request.

3.8.7.2 Accrual of Waiting Time. A candidate is eligible to accrue waiting time:

- while listed in an active or inactive status; and
- until the candidate has received a maximum of three islet infusions.

Waiting time will begin when a candidate is placed on Waiting List. Waiting time will end when the candidate is removed from the waiting list. Waiting time will accrue for a candidate until he/she has received a maximum of three islet infusions or the transplant center removes the candidate from the waiting list, whichever is the first to occur. If the candidate is still listed at this time or subsequently added back to the Waiting List, waiting time will start anew.

One point will be assigned to the candidate waiting for the longest period with fractions of points assigned proportionately to all other candidates, according to their relative waiting time. For example, if there are 75 candidates waiting for islets, the candidate waiting the longest would receive 1 point ($75/75 \times 1 = 1$). A person with the 60th longest time of waiting would be assigned 0.2 points ($(75-60)/75 \times 1 = 0.2$). The calculation of points is conducted separately for each geographic (local, regional and national) level of islet allocation. The local points calculation includes only candidates on the local Waiting List. The regional points calculation includes only candidates on the regional

list, without the local candidates. The national points calculation includes all candidates on the national list excluding all candidates listed on the Host OPO's local or regional waiting list.

3.8.7.3 Medical Suitability. Allocation of pancreata for islet transplantation shall be to the most medically suitable candidate based upon need and transplant candidate length of waiting time. After islet processing is completed, the transplant center will determine if the islet preparation is medically suitable for the candidate. Medical suitability is defined as meeting the islet transplant center's islet product release criteria contained in the center's Investigational New Drug (IND) application, as approved by the FDA. The center must document whether the islets are medically suitable or medically unsuitable for the candidate for whom the center accepted the islets. If the islets are medically unsuitable for the candidate, the center must also document the reason the islets were medically unsuitable for the candidate. This documentation must be maintained and submitted upon request.

3.8.7.4 Process for Re-Allocating Islets. If the transplant center determines that the islets are medically unsuitable for the candidate for whom the center accepted the islets, the islets from that pancreas will be reallocated to a medically suitable candidate at a transplant center covered by the same IND, based upon waiting time. The transplant center that accepted the islets on behalf of the original candidate is responsible for documenting:

- to which candidate the center re-allocated the islets, and
- that the center re-allocated the islets to the medically suitable candidate covered by the same IND who had the most waiting time.

The transplant center must maintain this documentation and submit it upon request.

Islet allocation must abide by all applicable OPTN/UNOS policies, including but not limited to:

- Policy 3.2.1 (Mandatory Listing of Potential Recipients), which states that all candidates who are potential recipients of deceased donor organs must be on the Waiting List,
- Policy 3.2.1.4 (Prohibition for Organ Offers to Non-Members), which stipulates that organ offers cannot be made to non-member centers,
- Policy 3.2.4 (Match System Access), which requires that organs only be allocated to candidates who appear on a match run,
- Policy 6.4.1 (Exportation), which states that the exportation of organs from the United States or its territories is prohibited unless a well documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List.

3.8.7.5 Removal from the Pancreas Islet Waiting List. The transplant center must remove the candidate from the waiting list within 24 hours of the candidate receiving his/her third islet infusion.

Current Policy Language for Policy 3.8 (Pancreas Allocation Policy)

~~3.8 — PANCREAS ALLOCATION. The following policies shall apply to the allocation of pancreata.~~

~~3.8.1 — **Pancreas Organ Allocation.** For local pancreas allocation, recipients may be selected from candidates awaiting an isolated pancreas, kidney pancreas combination, or a combined solid organ islet transplant from the same donor, unless there is a candidate on the Waiting List who meets the requirements of Policy 3.5.4 or Policy 3.8.1.7 and for whom there is a zero antigen mismatch with the donor. Within the Waiting List for isolated pancreas, candidates shall be prioritized as set forth in Policy 3.8.1.1 below. Within the Waiting Lists for kidney pancreas combination and combined solid organ islet transplant, length of time waiting shall be considered for the selection of organ recipients. Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive. For combined kidney pancreas candidates, blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.1, unless there is a zero antigen mismatch between the candidate and donor and the candidate is highly sensitized as defined in Policy 3.5.4. If the pancreas is not placed locally for an isolated or combined whole organ transplant, a combined solid organ islet transplant, a zero antigen mismatch candidate or pursuant to Policy 3.5.4 the pancreas, if procured from a donor less than or equal to 50 years old and with body mass index (BMI) less than or equal to 30 kg/m², shall be allocated regionally and then nationally, or for candidates listed for facilitated pancreas placement as described in Policy 3.8.1.3, in the following sequence. Pancreata procured from donors greater than 50 years old or with body mass index (BMI) greater than 30 kg/m² that are not placed locally for an isolated or combined whole organ transplant, a combined solid organ islet transplant, a zero antigen mismatch candidate or pursuant to Policy 3.5.4, shall be allocated according to Policy 3.8.1.5 below:~~

~~3.8.1.1 — **Local Whole Pancreas Allocation.** Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive.~~

- ~~• Isolated pancreas candidates with unacceptable HLA antigens listed in UNetSM sufficient to yield an 80% or greater probability of incompatibility with deceased donors (i.e., Calculated Panel Reactive Antibody (CPRA) \geq 80%)³; and~~
- ~~• All other isolated pancreas candidates.~~

~~3.8.1.2 — **Regional Whole Pancreas Allocation.** Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive.~~

- ~~• Isolated pancreas candidates with unacceptable HLA antigens listed in UNetSM sufficient to yield CPRA \geq 80%)³;~~
- ~~• All other isolated pancreas candidates; and~~
- ~~• Combined kidney pancreas candidates if the kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2 and the kidney must be paid back as specified in Policy 3.5.5.~~

³ For purposes of Policy 3.8, requirements for identifying and listing unacceptable antigens, as well as the definition of and parameters for calculating CPRA, are the same as those listed in Policy 3.5.11.3 (Sensitized Wait List Candidates) for assigning priority in the allocation of deceased donor kidneys.

~~3.8.1.3 National Whole Pancreas Allocation.~~ Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive.

- ~~Isolated pancreas candidates with unacceptable HLA antigens listed in UNetSM sufficient to yield CPRA \geq 80%)[†];~~
- ~~All other isolated pancreas candidates; and~~
- ~~Combined kidney pancreas candidates if the kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2 and the kidney must be paid back as specified in Policy 3.5.5.~~

~~3.8.1.4 Facilitated Pancreas Allocation.~~ In the event that the Organ Center has attempted, but has been unable, to place the pancreas for a period of at least five (5) hours, or upon notice to the Organ Center that organ retrieval is anticipated within one (1) hour, then irrespective of whether the entire regional and/or national Waiting List of candidates has by that time been exhausted, the pancreas shall be offered through the Organ Center for candidates listed with those transplant centers that have recorded in writing their desire, to participate in the system of facilitated pancreas allocation. A pancreas offered by this facilitated method shall be offered to candidates who have not previously received an offer for that pancreas. The pancreas shall be offered, in the following sequence, based on the transplant candidate's length of waiting time within each of the enumerated categories below. Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive.

- ~~Isolated pancreas candidates with unacceptable HLA antigens listed in UNetSM sufficient to yield CPRA \geq 80%)[†]; and~~
- ~~Combined kidney pancreas candidates if the kidney is voluntarily being offered. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2 and the kidney must be paid back as specified in Policy 3.5.5.~~

~~Any transplant center desiring to participate in this system shall be allowed to do so provided that it (a) agrees to accept offers for pancreata that have been procured by institutions located outside of its OPO (b) agrees to accept offers for pancreata on a conditional basis pending tissue typing information and redistribution of the organs pursuant to Policy 3.8.1.7 in the event there is a candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, and (c) documents this agreement and its desire to participate in the system in writing.~~

~~3.8.1.5 Islet Transplantation.~~ If the donor is less than or equal to 50 years old and has body mass index (BMI) less than or equal to 30 kg/m² and suitable recipient is not identified by the allocation criteria specified in Policies 3.8.1, 3.8.1.1, 3.8.1.2, 3.8.1.3, or 3.8.1.4, then the Host OPO shall offer the pancreas locally for clinical islet transplantation. If the organ is not used locally, the Host OPO shall offer the pancreas regionally and then nationally for clinical islet transplantation. If the organ is not used for transplantation, then the Host OPO should offer the pancreas for research.

~~If the donor is greater than 50 years old or has BMI greater than 30 kg/m², and a suitable recipient is not identified at the local level of organ allocation by the criteria specified in Policy 3.8.1, then the Host OPO shall offer the pancreas locally for clinical islet transplantation. If the organ is not used locally, the Host OPO shall offer the pancreas regionally and then nationally for clinical islet~~

~~transplantation, and then regionally followed by nationally for whole organ transplantation. If the organ is not used for transplantation, then the Host OPO should offer the pancreas for research.~~

~~**3.8.1.6 Islet Allocation Protocol.** Allocation of pancreata for islet transplantation shall be to the most medically suitable candidate based upon need and transplant candidate length of waiting time. After islet processing is completed, the transplant center will determine if the islet preparation is medically suitable for the candidate. Medical suitability is defined as meeting the islet transplant center's islet product release criteria contained in the center's Investigational New Drug (IND) application, as approved by the FDA. The center must document whether the islets are medically suitable or medically unsuitable for the candidate for whom the center accepted the islets. If the islets are medically unsuitable for the candidate, the center must also document the reason the islets were medically unsuitable for the candidate. This documentation must be maintained and submitted upon request.~~

~~If the transplant center determines that the islets are medically unsuitable for the candidate for whom the center accepted the islets, the islets from that pancreas will be reallocated to a medically suitable candidate at a transplant center covered by the same IND, based upon waiting time. The transplant center that accepted the islets on behalf of the original candidate is responsible for documenting:~~

- ~~• to which candidate the center re-allocated the islets, and~~
- ~~• that the center re-allocated the islets to the medically suitable candidate covered by the same IND who had the most waiting time.~~

~~The transplant center must maintain this documentation and submit it upon request.~~

~~Islet allocation must abide by all applicable OPTN/UNOS policies, including but not limited to:~~

- ~~• Policy 3.2.1 (Mandatory Listing of Potential Recipients), which states that all candidates who are potential recipients of deceased donor organs must be on the Waiting List,~~
- ~~• Policy 3.2.1.4 (Prohibition for Organ Offers to Non Members), which stipulates that organ offers cannot be made to non member centers,~~
- ~~• Policy 3.2.4 (Match System Access), which requires that organs only be allocated to candidates who appear on a match run,~~
- ~~• Policy 6.4.1 (Exportation), which states that the exportation of organs from the United States or its territories is prohibited unless a well documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List.~~

Waiting Time

~~A candidate is eligible to accrue waiting time:~~

- ~~• while listed in an active or inactive status; and~~
- ~~• until the candidate has received a maximum of three islet infusions.~~

~~Waiting time will begin when a candidate is placed on Waiting List. Waiting time will end when the candidate is removed from the waiting list. Waiting time will accrue for a candidate until he/she has received a maximum of three islet infusions or the transplant center removes the candidate from the waiting list, whichever is the first to occur. If the candidate is still listed at this time or~~

subsequently added back to the Waiting List, waiting time will start anew.

One point will be assigned to the candidate waiting for the longest period with fractions of points assigned proportionately to all other candidates, according to their relative waiting time. For example, if there are 75 candidates waiting for islets, the candidate waiting the longest would receive 1 point ($75/75 \times 1 = 1$). A person with the 60th longest time of waiting would be assigned 0.2 points ($(75 - 60)/75 \times 1 = 0.2$). The calculation of points is conducted separately for each geographic (local, regional and national) level of islet allocation. The local points calculation includes only candidates on the local Waiting List. The regional points calculation includes only candidates on the regional list, without the local candidates. The national points calculation includes all candidates on the national list excluding all candidates listed on the Host OPO's local or regional waiting list.

Active and Inactive Status

A candidate is **not** eligible for active status if the candidate:

- Is insulin independent **and**
- Has an HbA1c value of less than or equal to 6.5%.

The transplant center is responsible for keeping the candidate's listing status current in UNetSM.

If the candidate is listed as active and is insulin dependent, the transplant center must maintain documentation in the candidate's record of his/her current insulin status. To retain active status for an insulin dependent candidate, the transplant center must document in the candidate's record every six months that the candidate is currently insulin dependent.

If the candidate is listed as active and is insulin independent, the transplant center must maintain documentation in the candidate's record of his/her insulin status and HbA1c level with the date of the HbA1c test. To retain active status for an insulin independent candidate, the transplant center must document in the candidate's record every six months:

- That the candidate has had an HbA1c test within the past six months with a result of greater than 6.5%, **and**
- That the candidate is insulin independent.

The transplant center must use the most recent HbA1c value when determining whether the candidate is eligible for active status.

If a candidate's clinical condition changes, and the candidate is no longer eligible for active status, the transplant center must change the candidate's status in UNetSM within 72 hours of the transplant center's knowledge of this candidate's clinical change. The transplant center must maintain documentation in the candidate's record of when the center learned of this clinical change. If a transplant center wishes to list an inactive candidate as active, the transplant center must have documentation that the candidate had the appropriate HbA1c level and insulin status in the past six months. The transplant center must present any documentation required by this policy to the OPTN upon request.

Removal from the Waiting List

The transplant center must remove the candidate from the waiting list within 24

hours of the candidate receiving his/her third islet infusion.

3.8.1.7 ~~Mandatory Sharing of Zero Antigen Mismatch Pancreata.~~ In the event there is a candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, the pancreas from that donor shall be offered, first, to the appropriate Member for any highly sensitized candidate waiting for a combined kidney/pancreas transplant with a zero antigen mismatch, pursuant to Policy 3.5.4 (first locally, then regionally, and then nationally, based upon length of time waiting). The pancreas shall then be offered to the appropriate Member for any highly sensitized candidate (i.e. candidate with unacceptable HLA antigens listed in UNetSM sufficient to yield CPRA \geq 80%)⁴ waiting for an isolated pancreas transplant with a zero antigen mismatch, first locally, then regionally, and then nationally, based upon length of time waiting, unless there is a candidate listed on the Host OPO's local candidate waiting list for combined kidney/pancreas or isolated pancreas transplantation who is mismatched with the donor and also has unacceptable HLA antigens listed in UNetSM sufficient to yield CPRA \geq 80%. In this event, for local allocation, the pancreas shall be offered for the mismatched candidate(s) with unacceptable HLA antigens listed in UNetSM sufficient to yield CPRA \geq 80% (based upon length of time waiting if more than one candidate meets these criteria) before being offered for highly sensitized zero antigen mismatched isolated pancreas transplant candidates regionally and nationally.

3.8.1.7.1 ~~Organ Offer Limit.~~ All pancreata to be shared as zero antigen mismatches, either alone or in combination with kidneys, must be offered to the appropriate recipient transplant centers through UNetSM or through the Organ Center within eight hours after organ procurement. Offers must be made for the first 10 zero antigen mismatched potential recipients⁴ according to the national lists of candidates waiting for combined kidney/pancreas or isolated pancreas transplantation, as applicable. If there are less than 10 zero antigen mismatched potential recipients on the match list, offers must be made for all zero antigen mismatched potential recipients on the match list. If these offers are turned down (either explicitly refused or the notification time or evaluation time is exceeded as defined in Policy 3.4.1), the Host OPO must either:

- ~~allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.1, as applicable (first locally, then regionally, and then nationally); or~~
- ~~allocate the organ(s) for the remaining zero antigen mismatched potential recipients.~~

If the Host OPO continues to offer kidney/pancreas combinations for zero antigen mismatched potential recipients beyond the 10th potential recipient, a kidney payback will be generated pursuant to Policy 3.5.5 (Payback Requirements). If the Host OPO chooses to share a zero antigen mismatched kidney/pancreas combination through UNetSM, the Host OPO must submit a completed Kidney Payback Accounting Sheet within 5 business days of the recovery of the organ(s), defined as cross clamp of the donor aorta, to report the share. A payback credit will not be assigned until: 1) the Organ Center receives the Kidney Payback Accounting Sheet documenting the zero antigen mismatch share; and 2) the zero antigen mismatch share

⁴ For the purposes of Policy 3.8.1.7.1, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

can be verified (i.e. cross clamp and final acceptance has been entered) in UNetSM. No obligation to payback the pancreas will be generated. If the Host OPO does not report the sharing within 5 business days of the organ(s) recovery, the OPO will forfeit the payback credit.

3.8.2 ~~Waiting Time Adjustment.~~ ~~Waiting time accrued by a transplant candidate for one or more organs shall be transferred as follows if it is determined that the candidate requires another organ or organ combination:~~

- ~~(i) — Waiting time accrued by a kidney transplant candidate while registered on the Waiting List shall be assigned also to the listing for a combined kidney pancreas transplant if it is determined that the candidate requires a combined kidney pancreas transplant.~~
- ~~(ii) — Waiting time accrued by a kidney transplant candidate while registered on the Waiting List shall be assigned also to the listing for an isolated pancreas transplant if it is determined that the candidate requires a pancreas transplant.~~
- ~~(iii) — Waiting time accrued by a kidney pancreas transplant candidate while registered on the Waiting List shall be assigned also to the listing for an isolated pancreas transplant if it is determined that the candidate is suitable for a pancreas alone transplant.~~
- ~~(iv) — Waiting time accrued by a kidney pancreas transplant candidate while registered on the Waiting List shall be assigned also to the listing for an isolated kidney transplant if it is determined that the candidate is suitable for a kidney alone transplant.~~
- ~~(v) — Waiting time accrued by an isolated pancreas transplant candidate while registered on the Waiting List shall not be assigned to the listing for a combined kidney pancreas transplant.~~
- ~~(vi) — Waiting time accrued by an isolated pancreas transplant candidate while registered on the Waiting List shall not be assigned to the listing for an isolated kidney transplant.~~

3.8.2.1 ~~Waiting Time Transfer for Whole Pancreas and Pancreatic Islet Cell Candidates~~

- ~~(i) — Waiting time accrued by an isolated whole pancreas transplant candidate while registered on the waiting list shall be transferred to the listing for pancreatic islet cell transplant after consideration and approval of a request for such transfer by the OPTN/UNOS Pancreas Transplantation Committee. — Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that such transfer is reasonable and is in the candidate's best interest, and comply with other application requirements as may be developed by the Committee from time to time. — Requests for waiting time transfer between the whole pancreas and pancreatic islet waiting lists, along with decisions of the Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.~~
- ~~(ii) — Waiting time accrued by a pancreatic islet cell transplant candidate while registered on the waiting list shall be transferred to the listing for whole pancreas transplant after consideration and approval of a request for such transfer by the OPTN/UNOS Pancreas Transplantation Committee. — Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that such transfer is reasonable and is in the candidate's best interest, and comply with other application requirements as may be developed by the Committee from time to time. — Requests for waiting time transfer between the pancreatic islet and whole pancreas waiting lists, along~~

~~with decisions of the Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.~~

~~**3.8.3 Inclusion of HLA Data.** Recipient HLA information must be included when listing a potential pancreas or combined kidney pancreas candidate on the Waiting List.~~

~~**3.8.4 Reporting Candidates' Unacceptable Antigens.** To receive priority in the allocation of isolated pancreata based upon CPRA, candidate unacceptable antigens sufficient to yield CPRA \geq 80%) must be entered into UNetSM as described in Policies 3.8.1.1—3.8.1.4. Pancreata from donors with antigens included among the unacceptable antigens for a candidate will not be offered for that candidate.~~

~~**3.8.5 Regional or National Allocation to Alternate Recipients.** For a pancreas that is shared regionally or nationally, the Organ Center will advise the OPO for the transplant center for the candidate who has the highest number of points at that center to seek alternate candidates on the OPO's waiting list to receive the pancreas in the event that the pancreas cannot be used by that candidate. Selection of alternate candidates must be according to the pancreas allocation policy.~~

~~**3.8.6 Minimum Information for Pancreas Offers.**~~

~~**3.8.6.1 Essential Information Category.** The Host OPO or donor center must provide the following donor information, with the exception of pending serologies, to the recipient center with each pancreas offer:~~

- ~~(i) Donor name and Donor I.D. number, age, sex, race and weight;~~
- ~~(ii) Date of admission for the current hospitalization;~~
- ~~(iii) Diagnosis;~~
- ~~(iv) Blood type;~~
- ~~(v) Current history of abdominal injuries and operations including pancreatic trauma;~~
- ~~(vi) Pertinent past medical or social history including pancreatitis;~~
- ~~(vii) Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria;~~
- ~~(viii) Indications of sepsis;~~
- ~~(ix) Pre or post transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred);~~
- ~~(x) Current medication and transfusion history;~~
- ~~(xi) Blood glucose;~~
- ~~(xii) Amylase;~~
- ~~(xiii) Insulin protocol;~~
- ~~(xiv) Alcohol use (if known);~~
- ~~(xv) Familial history of diabetes; and~~
- ~~(xvi) HLA A, B, Bw4, Bw6, and DR antigens.~~

~~**3.8.7 Removal of Pancreas Transplant Candidates from Pancreas Waiting Lists When Transplanted or Deceased.** If a pancreas transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all pancreas waiting lists and shall notify within 24 hours of the event. If the pancreas recipient is again added to a pancreas waiting list, waiting time shall begin as of the date and time the candidate is relisted. If the recipient is waiting for a combined kidney pancreas transplant and receives only an isolated pancreas transplant, the recipient's accrued waiting time while listed for the combined organ transplant shall automatically be transferred to the isolated Kidney Waiting List.~~

~~3.8.8 **Waiting Time Reinstatement for Pancreas Recipients.** In those instances where there is immediate and permanent non function of a transplanted deceased or living donor pancreas, the candidate may be reinstated to the waiting list and retain the previously accumulated waiting time without interruption for that transplant only. For purposes of this policy, immediate and permanent non function shall be defined as pancreas graft failure requiring the removal of the organ within the first two weeks of transplant. Waiting time will be reinstated upon receipt by the Organ Center~~

- ~~• A completed Pancreas Waiting Time Reinstatement Form, and~~
- ~~• A pancreatectomy operative report~~
- ~~OR~~
- ~~• A completed Pancreas Waiting Time Reinstatement Form, and~~
- ~~• A statement of intent from the transplant center to perform a pancreatectomy, and~~
- ~~• A statement that there is documented, radiographic evidence indicating that the transplanted pancreas has failed. This documentation must be maintained and submitted upon request.~~

~~The Organ Center will send a notice of waiting time reinstatement to the transplant center involved.~~

~~3.8.9 **Prospective Crossmatching.** A prospective crossmatch is mandatory for all candidates, except where clinical circumstances support its omission. The transplant program and its histocompatibility laboratory must have a joint written policy that states when the prospective crossmatch may be omitted. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D to Policy 3.~~

Other Affected Policy Language: Policy 3.2 (Waiting List)

3.2.1 Renal and Renal-Pancreas Combination Candidate Listing. In order to list a potential recipient of a kidney ~~or a kidney-pancreas combination~~ transplant on the Waiting List, the potential recipient's complete HLA antigen information (at least 1 A, 1 B, and 1 DR antigen) must be included at the time of listing the potential recipient. This requirement shall not apply to potential recipients listed for combined kidney-nonrenal transplantation, with the exception of kidney-pancreas transplantation as specified in Policy 3.8.2. (Inclusion of HLA Data). The entry of the complete HLA antigen information for candidates on the Waiting List shall require the use of current World Health Organization (WHO) Nomenclature. (This requirement that WHO nomenclature be used shall be implemented with the implementation of the New Data Collection Forms.)

3.2.1.8 Waiting Time Modification. Transplant candidates on the Waiting List may have waiting time accrued under a previous Waiting List registration reinstated under the following circumstances:

- i. The candidate was incorrectly removed from the Waiting List, as a result of errors and/or miscommunication between clinical/clerical personnel. The reinstated waiting time shall include time accrued under the previous registration, in addition to the time interval during which the candidate was removed from the Waiting List.
- ii. The candidate was removed from the Waiting List for medical reasons other than having received a transplant and subsequently was relisted for the same organ with the same diagnosis. The reinstated waiting time only shall include time accrued under the previous registration and not the time interval during which the candidate was removed from the Waiting List.

Upon receipt by the Organ Center of a completed Waiting Time Modification Form (with all required information) and verification of the information through review of the candidate's history, Organ Center staff may reinstate the candidate's waiting time.

All other requests for waiting time reinstatement that are not specified under Policy 3.2.3.2 (Waiting Time Reinstatement for Kidney Recipients), or other policies which describe permissible waiting time adjustments, shall be first approved by unanimous agreement among the hospitals (with transplant programs for the applicable organ) within the local area in which the candidate is listed, and then submitted to the appropriate organ-specific committees and Board of Directors for review with appropriate supporting documentation. Notwithstanding the above, however, upon demonstration to the appropriate organ-specific committee that unanimous agreement among the relevant parties cannot be obtained despite efforts to do so, such a request may be submitted with appropriate supporting documentation, including without limitation, reasons provided by the dissenting party(ies) for any disagreement, for consideration despite the lack of unanimous approval. Modification requests for isolated kidney and combined kidney/pancreas waiting time shall indicate and substantiate with supporting documentation that the candidate met waiting time criteria as defined in Policy 3.5.11.1 (Time of Waiting), ~~or Policy 3.5.12.1 (Time of Waiting), or Policy 3.8.4.3 (Waiting Time)~~ as of the ~~listing~~ date requested. Under the circumstances described in this paragraph, waiting time modifications will be made, in the case of requests for modifying kidney or pancreas waiting time, after consideration and approval by the Kidney Transplantation Committee (for kidney and kidney/pancreas candidates) or ~~&~~ Pancreas Transplantation Committee (for kidney/pancreas and pancreas candidates), or, in the case of pediatric (*i.e.*, less than 18 years old) kidney candidates, with approval from the Chair

of the ~~Kidney & Pancreas~~ Transplantation Committee to proceed to a subcommittee of the full Committee followed by consideration and unanimous approval by this subcommittee. Pediatric candidate cases addressed by a subcommittee of the ~~Kidney & Pancreas~~ Transplantation Committee will subsequently be referred to the full Committee for consideration of final action as determined appropriate by the Committee and in the case of requests for modifying waiting time for organs other than kidney, kidney-pancreas, and pancreas (except as provided in Policy 3.2.1.8.1 (Waiting Time Modification for Urgent Status Candidates)) only upon approval by the Board of Directors, or by the Executive Committee subject to ratification by the Board of Directors. Requests for modifying kidney or pancreas waiting time, along with decisions of the ~~Kidney Transplantation Committee & Pancreas Transplantation Committee~~ or subcommittee in the case of pediatric candidates and Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.

3.2.4 Match System Access. OPOs are required to use the Match System (UNetSM) for the allocation of all deceased donor organs. The Host OPO must enter required information about the donor (Policies 3.5.7, 3.6.9, 3.7.9, and ~~3.8.53.8.2.2~~) and execute the Match System to determine organ allocation priorities. Such information must be entered into the Match System for all deceased donors. The OPO shall be responsible for two separate determinations 1) two samples sent to two labs, or 2) two samples from separate draws sent to the same lab of the donor's ABO type prior to incision and for ensuring the accuracy of the donor's ABO data. The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit. Each OPO shall establish and implement a procedure utilizing the ABO source documents for on-line verification of donor ABO data by an individual other than the person initially entering the donor's ABO data in UNetSM.

Organs shall be allocated only to candidates who appear on a match run. In the event that an organ has not been placed after the organ has been offered for all potential recipients on the initial match run, the Host OPO may give transplant programs the opportunity to update their transplant candidates' data, and the Host OPO may re-run the match system. In any event, the organ shall be allocated only to a candidate who appears on a match run.

If the transplant center deems it necessary to transplant a candidate who does not appear on at least one of the deceased donor's match runs for at least one organ type, such as in the event of a directed donation or to prevent organ wastage, the transplant center must maintain all related documentation and provide written justification to the OPTN contractor upon request. The written justification must include:

- the rationale for transplanting a candidate who did not appear on the match run;
- the reason the candidate did not appear on the match run;
- the center is willing to accept an ECD or DCD organ, as applicable; and
- documentation that the transplant center verified suitability between the donor organ and recipient prior to transplant in at least, but not limited to, the following areas as applicable to each organ type:
 - ABO;
 - Serologies;
 - Donor HLA and candidate's unacceptable antigens;
 - Height; and
 - Weight.

For all deceased donor organs, the organ must be transplanted into the original designee or be released back to the Host OPO or to the Organ Center for distribution. If an organ is accepted for a candidate who ultimately is unavailable to receive the transplant at

his/her listing transplant center in the organ allocation unit to which the organ is being distributed, then the organ shall be released back to the Host OPO or to the Organ Center for allocation to other transplant candidates in accordance with the organ-specific allocation policies. The Host OPO may delegate this responsibility to the Local OPO. Further allocation at the local OPO level must be done according to the match run. The final decision whether to use the organ will remain the prerogative of the transplant surgeon and/or physician responsible for the care of that candidate. This will allow physicians and surgeons to exercise judgment about the suitability of the organ being offered for the specific candidate. If an organ is declined for a candidate, a notation of the reason for the decision refusing the organ for that candidate must be made on the appropriate form and promptly submitted.

- 3.2.4.1 Removal of Kidney Transplant Candidates from Kidney Waiting Lists When Transplanted or Deceased.** If a kidney, ~~kidney/pancreas or kidney/islet~~ transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all organ Waiting Lists for that transplanted organ and shall notify the OPTN contractor within 24 hours of the event. If the recipient is again added to a Waiting List for that transplanted organ, waiting time shall begin as of the date and time the candidate is relisted. ~~If the recipient is waiting for a combined kidney/pancreas or kidney/islet transplant and receives only an isolated kidney transplant, the recipient's accrued kidney waiting time shall automatically be transferred to the isolated pancreas or islet, as applicable, Waiting List.~~
- ~~**3.2.7 Pancreas Waiting List Criteria.** Each candidate registered on the Pancreas Waiting List must be diagnosed with diabetes or have pancreatic exocrine insufficiency or require the procurement or transplantation of the pancreas for technical reasons as part of a multiple organ transplant.~~
- ~~**3.2.8 Previous Kidney Donor Antigens Considered "Self" Antigens in Pancreas Match Runs.** Upon listing a candidate for pancreas after kidney transplantation, the transplant program has the option of entering the candidate's prior kidney donor's antigens, which will then be considered "self" antigens in pancreas match runs. In the event a candidate's prior kidney donor's antigens are entered, the match system for pancreas allocation will take into account the candidate's antigens and all of the kidney donor's mismatched antigens that are entered into UNetSM. Mismatches that are common to a candidate's prior kidney donor and a subsequent pancreas donor are considered as matches and the candidate will appear on the match run print out for all pancreas donors who meet these mismatch criteria. Use of these modified mismatch criteria is optional.~~
- ~~**3.2.9 Combined Kidney Pancreas Waiting List Criteria.** Each candidate registered on the Kidney Pancreas Waiting List must be diagnosed with diabetes or have pancreatic exocrine insufficiency with renal insufficiency.~~
- 3.2.107 Waiting Time Adjustment for Candidates Needing a Life-Saving Organ Transplant When the Need for a Second Organ Transplant Arises.** Waiting time accrued by a candidate for a transplant of a life-saving organ while waiting on the Waiting List may also be accrued for a second organ, when it is determined that the candidate requires a multiple-organ transplant. For purposes of this policy, a life-saving organ shall be defined as the heart, lung or liver. Kidney, pancreas or intestine may qualify as life-saving organs if routine alternative therapies are not possible and demonstrable and after all transplant centers and programs within those centers, the other transplant programs within the OPO and the OPO itself agree to the waiting time adjustment.

Other Affected Policy Language: Policy 3.3 (Acceptance Criteria)

- 3.3.5 Transplant Recipient Backup for Organ Offers.** OPOs are encouraged to make backup offers for all organs. A backup offer shall be considered equivalent to an actual organ offer and the backup center shall have one hour to respond after receiving the minimum data required for an organ offer pursuant to Policies 3.5.9, 3.6.9, 3.7.12 and/or ~~3.8.5~~3.8.2.2. Refusal to consider or respond to a backup offer will be considered as a refusal to accept the organ. The backup center may later refuse to accept the organ based on medical or logistical criteria. The backup center should be notified promptly of any change in donor status or organ disposition.

Other Affected Policy Language: Policy 3.4 (Organ Procurement, Distribution And Alternative Systems For Organ Distribution Or Allocation)

- 3.4.2 Time Limit For Acceptance.** A transplant center, or its designee, must access donor information within UNetSM within one hour of receiving the initial organ offer notification. If UNetSM is not accessed within one hour by the transplant center or its designee, the offer will be considered refused. Once the appropriate donor information is provided as described in Policies 3.5.9, 3.6.9, 3.7.12, and ~~3.8.5~~3.8.2.2, a transplant center shall be allowed one hour from the time of accessing the donor information, except as otherwise provided in Policies 3.5.3.5 (Time Limit) and ~~3.8.1.6.1 (Time Limit)~~ 3.8.3.4 (Organ Offer Limit), in which to communicate its acceptance or refusal of the organ. After one hour elapses, or shorter period as defined under Policies 3.3.5 and ~~3.8.1.6.1~~3.8.3.4, without a response, the offer will be considered refused and the offering entity may offer the organ to the transplant center(s) for the patient(s) listed next in priority on the match list.

Other Affected Policy Language: Policy 3.5 (Kidney Allocation Policy)

3.5.3.4 Kidney/Non-Renal Exception. ~~When kidneys are procured for the purpose of simultaneous kidney and non-renal organ transplantation, only one of the kidneys procured must be shared as a zero antigen mismatch. In the event the kidney/non-renal organ transplant is not performed, the kidney retained for that transplant must be immediately offered for zero antigen mismatched candidates. This exception does not apply to kidney islet combined transplants or kidney-pancreas combined transplants for zero antigen mismatched highly sensitized candidates as defined in Policy 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates).~~

3.5.3.5 Organ Offer Limit. Kidneys to be shared as zero antigen mismatches, either alone or with pancreata, must be offered to the appropriate recipient transplant centers through UNetSM or through the Organ Center within 8 hours after organ procurement for standard donors and within 4 hours after organ procurement for expanded criteria donors (organ procurement is defined as cross clamping of the donor aorta). For standard criteria donor (SCD) kidneys, offers must be made for at least 10 zero antigen mismatched potential recipients.⁵ If there are less than 10 zero antigen mismatched potential recipients on the match list, then offers must be made for all zero antigen mismatched potential recipients on the match list. For expanded criteria donor (ECD) kidneys, offers must be made for at least the first 5 zero antigen mismatched potential recipients. If there are less than 5 zero antigen mismatched potential recipients on the match list, then offers must be made for all zero antigen mismatched potential recipients on the match list. If these offers are turned down (either explicitly refused or the notification time or evaluation time is exceeded as defined in Policy 3.4.1), the Host OPO must either:

- allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.43.2 (first locally, then regionally, and then nationally); or
- allocate the organ(s) for the remaining zero antigen mismatched potential recipients.

If the Host OPO chooses to continue offering the kidney (s) for zero antigen mismatched potential recipients beyond the 10th potential recipient for a SCD or 5th potential recipient for an ECD, no obligation to pay back the kidney pursuant to Policy 3.5.5 (Payback Requirements) will be generated, even if the kidney is accepted for a zero antigen mismatched potential recipient. If the Host OPO chooses to share the zero antigen mismatch through UNetSM, the Host OPO must submit a completed Kidney Payback Accounting Sheet within 5 business days of the organ(s) recovery, defined as cross clamping of the donor aorta, to report the sharing. A payback credit will not be assigned until: 1) the Organ Center receives the Kidney Payback Accounting Sheet documenting the zero antigen mismatch share and 2) the zero antigen mismatch share can be verified (i.e. cross clamp and final acceptance has been entered) in UNetSM. If the Host OPO does not report the sharing within 5 business days of the organ(s) recovery, the OPO will forfeit the payback credit.

3.5.4 Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates. ~~Please refer to Policy 3.8.3 (Allocation Sequence). An offer of a donor kidney to a highly sensitized candidate for whom there is a zero antigen mismatch with the donor, who is also a candidate for a combined kidney-pancreas transplant, must be~~

⁵ For the purposes of Policy 3.5.3.5, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

~~accompanied by an offer of the pancreas from the donor. For purposes of this policy, “highly sensitized” is defined as panel reactive antibody (PRA) level of 80% or greater regardless of preliminary crossmatch results.~~

~~**3.5.4.1 Sharing.** When kidneys are procured with the option of simultaneous kidney and pancreas transplantation, if there is any highly sensitized candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, the kidney and pancreas from that donor shall be offered to the appropriate Member for the candidate with the zero antigen mismatch, first locally, then regionally, and then nationally, based upon length of time waiting.~~

3.5.5 Payback Requirements. Except as otherwise provided in Policy 3.5.3.5 (Sharing of Zero Antigen Mismatched Kidneys - Time Limit), ~~3.8.1.6.1 (Sharing of Zero Antigen Mismatch Pancreata - Time Limit), 3.8.3.4 (Organ Offer Limit),~~ 3.5.5.2 (Exception for Prior Living Organ Donors), and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged Less than 35 Years), when a kidney is shared pursuant to: (i) the zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a candidate with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the Organ Center a kidney from the next suitable standard donor that does not meet the criteria for a Donation after Cardiac Death donor¹, six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after Cardiac Death donor, or (iii) donor is less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

¹For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after Cardiac Death donors shall be defined as follows: (1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written consent for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after Cardiac Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before consent for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until consent can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a candidate who is consented for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

3.5.5.1 Kidney/Non-Renal Organ Sharing.

3.5.5.1.1 Deferment of the Kidney/Non-Renal Exception. OPOs that have accumulated six or more payback obligations within the blood type of a locally procured donor shall not be permitted to defer the obligation to offer the kidneys from this donor in satisfaction of payback debts by retaining a kidney for transplant with a non-renal organ locally, except for ~~kidneys allocated for a kidney pancreas transplant pursuant to Policy 3.5.4,~~ or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, ~~or~~ liver, or pancreas. The kidney/non-renal exception shall be deferred until the OPO has reduced its payback obligation to less than six.

3.5.5.1.2 Deferment of Voluntary Arrangements. OPOs that have accumulated six or more payback obligations within the same blood type shall not be offered, and, if offered, shall not accept kidneys shared with a non-renal organ from a donor of the same blood type as the accumulated payback obligations, except for ~~kidneys allocated for a kidney pancreas transplant pursuant to Policy 3.5.4, or~~ a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, ~~or liver, or pancreas.~~ The offer/acceptance of kidneys voluntarily shared with non-renal organs shall be deferred until the OPO has reduced its payback obligation to less than six.

3.5.11.1 Time of Waiting. Except for candidates who are less than 18 years old, the "time of waiting" begins as of the time an active candidate listed for an isolated kidney ~~or combined kidney/pancreas~~ transplant meets the minimum criteria set forth below and this information (along with the date the criteria are met) is recorded on UNetSM; provided, however, that "time of waiting" under this policy shall not precede the date of the candidate's listing. Programs must be able to verify with appropriate supporting documentation that the candidate met the criteria as of the date submitted; this documentation will be subject to audit by the OPTN contractor either through on site audits or otherwise upon request for submission to the OPTN contractor. Programs shall enter information required by the Waiting Time Qualification Form on UNetSM, including whether the candidate met the following criteria.

- measured (actual urinary collection) or calculated or creatine clearance or GFR (Cockcroft-Gault or other reliable formula) less than or equal to 20 ml/min; or
- initiation of chronic maintenance dialysis (defined as dialysis that is regularly furnished to an End-Stage Renal Disease (ESRD) candidate in a hospital based, independent (non-hospital based), or home setting).

"Time of waiting" for candidates listed for an isolated kidney ~~or combined kidney/pancreas~~ transplant who are less than 18 years old begins when the candidate is placed on the Waiting List. While not required for purposes of initiating waiting time, programs shall report whether or not pediatric candidates are on dialysis, and if on dialysis, a dialysis start date. Candidates, regardless of age, shall continue to accrue waiting time while registered on the Waiting List as inactive.

Other Affected Policy Language: Policy 3.9 (Allocation System For Organs Not Specifically Addressed)

- 3.9.3 Organ Allocation to Multiple Organ Transplant Candidates.** Candidates for a multiple organ transplant where one of the required organs is a heart, lung, or liver shall be registered on the individual Waiting list for each organ. When the candidate is eligible to receive a heart, lung or liver pursuant to Policies 3.6 (Allocation of Livers) and 3.7 (Allocation of Thoracic Organs) or an approved variance to these policies, the second required organ shall be allocated to the multiple organ candidate from the same donor if the donor is located with the same local organ distribution unit where the multiple organ candidate is registered. If the multiple organ candidate is on a waiting list outside the local organ distribution unit where the donor is located, voluntary sharing of the second organ is recommended. When the second organ is shared, the same organ of an identical blood type shall be paid back to the Host OPO from the next acceptable donor procured by the recipient OPO, unless the second organ is a kidney in which case the organ shall be paid back pursuant to Policy 3.5.4.5 (Payback Requirements). This policy shall not apply to the allocation of heart-lung combinations. Heart-lung combinations shall be allocated in accordance with Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates) and all other applicable provisions of Policy 3.7, or an approved variance to these policies. For candidates awaiting a combined liver-intestine transplant, please refer to Policy 3.11.4 or Policy 3.6.4.8. For candidates awaiting a combined kidney-pancreas transplant, please refer to Policy 3.8.3 (Allocation Sequence).

Candidates who:

- have been listed for multiple organs, and
- are eligible to receive a heart, lung or liver pursuant to Policies 3.6 (Allocation of Livers) and 3.7 (Allocation of Thoracic Organs) or an approved variance to these policies, must appear on the heart, lung, or liver match run.

Candidates who:

- have been listed for multiple organs, and
- have been named as the recipient of a directed organ(s) donation by the person(s) who authorized the donation, must appear on at least one of the deceased donor's match runs for at least one organ type.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.