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IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: Karl J. McCleary, Ph.D., M.P.H.
UNOS Director of Policy, Membership and Regional Administration

RE: Summary of actions taken at the OPTN/UNOS Board of Directors
Meeting—March 2-3, 2009

Date: April 3, 2009

The attached report summarizes bylaw changes, policy changes and other actions the OPTN/UNOS Board of Directors approved at its March 2009 meeting.

This format allows you to scan the outcome of committee actions and quickly determine what, if anything, is required by you. You can also access the modified policy language by clicking on the link below the summary table. If you are interested in reviewing policy changes from previous board meetings, go to www.unos.org and click on Newsroom and then select “view all Policy Notices.” We have archived all policy notices from the March 2007 board meeting and forward.

Thank you for your careful review. If you have any questions about a particular notice within this document, 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 7 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	Page #
1 Modifications to allow candidates who need a pancreas for technical reasons as part of a multiple organ transplant to be listed on the pancreas waiting list (Pancreas Transplantation Committee)									X	X	X	X		X	X	X	3
2 Modifications to clarify islet allocation protocol (Pancreas Transplantation Committee)		X	X						X	X	X	X	X	X	X	X	4
3 Proposal to increase the safety of allocations to candidates who do not appear on the match run (Membership and Professional Standards Committee)	X			X	X	X		X	X	X	X	X		X		X	6
4 Modifications to clarify policy requirements, eliminate redundancy, and align policy with current OPO practices (OPO Committee)	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	8
5 Modification to align required laboratory tests with Policy 2.0 (Minimum Standards for Organ Procurement Organizations) (OPO Committee)	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	9
6 Clarification of multiple listing (Patient Affairs Committee)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	10
7 Patient notification of UNOS Patient Services number (Patient Affairs Committee)									X	X				X	X		11

Notice of Policy Change: Modifications to allow candidates who need a pancreas for technical reasons as part of a multiple organ transplant to be listed on the pancreas waiting list (Pancreas Transplantation Committee)

Policies Affected: Policy 3.2.7 (Pancreas Waiting List Criteria) and Policy 3.2.9 (Combined Kidney-Pancreas Waiting List Criteria)

Action Required: Review Only

Effective Date: May 4, 2009

Professional Groups Affected by the Change:

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
A patient must be diagnosed with diabetes or have “pancreatic deficiency” to be added to the pancreas waiting list. There are some circumstances where a candidate may need a pancreas as part of a multiple organ transplant, but has not been diagnosed with diabetes or a “pancreatic deficiency.” Policy does not have a mechanism to add candidates like this to the pancreas waiting list.	The modifications create a third pancreas waiting list criterion. This new listing criterion is for candidates who need the pancreas for technical reasons as part of a multiple organ transplant.	Transplant centers may list candidates who need the pancreas for technical reasons as part of a multiple organ transplant on the pancreas waiting list in addition to candidates who have diabetes or pancreatic exocrine insufficiency.

Notice of Policy Change: Modifications to clarify islet allocation protocol (Pancreas Transplantation Committee)

Policy Affected: Policy 3.8.1.6 (Islet Allocation Protocol)

Action Required: Review Only

Effective Date: May 4, 2009

Professional Groups Affected by the Change:

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors, Transplant PR/Public Education Staff

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
<p>Islet allocation policy does not define medical suitability and it does not provide a process for re-allocating islets if they are not medically suitable for the candidate. Additionally, the current policy allows a transplant center to accept a potentially unlimited number of pancreata for islets for a single candidate, which limits access for other candidates.</p>	<p>The revised policy language:</p> <ul style="list-style-type: none"> • defines medical suitability • defines when an islet candidate is active on the waiting list and can accrue waiting time • defines when an islet candidate must be listed as inactive • specifies the type of documentation that the center must maintain to verify that the candidate is eligible for active status • includes a process for re-allocating islets • specifies the documentation that the center must maintain to demonstrate that an islet preparation was not medically suitable for the candidate the pancreas was initially accepted for • restates the specific OPTN/UNOS policies that apply to organ allocation. 	<p>Islet Waiting List Status Transplant centers must determine if their islet candidates qualify for active status according to the new policy language. If the candidate is not eligible for active status, the center must set the candidate to inactive in UNetSM. If the candidate is eligible for active status, the transplant center must document in the candidate’s record every six months:</p> <ul style="list-style-type: none"> • that the candidate is currently insulin dependent OR • that the candidate has had an HbA1c test in the past 6 months, <u>and</u> • that the most recent HbA1c test had a value of greater than 6.5%, <u>and</u> • that the candidate is insulin independent. <p>The transplant center must document the same information to move a candidate from inactive to active status.</p> <p>Islet Allocation Transplant centers must determine if an islet preparation</p>

		<p>is medically suitable for the candidate the islets were accepted for. The center's IND defines suitability. The center must document whether the islets were medically suitable or unsuitable, and, if unsuitable, the reason the islets were medically unsuitable for the candidate.</p> <p>If the transplant center decides to re-allocate the islets, it must offer the islets to the next medically suitable candidate covered by its IND, based on waiting time in compliance with OPTN/UNOS policies. The center must document and file this re-allocation process.</p> <p>Note: The policy revisions are intended for candidates with Type I diabetes only.</p>
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Notice of Policy Change : Modification to increase the safety of allocations to candidates who do not appear on the match run (Membership and Professional Standards Committee)

Policies Affected: Policies 3.1 (Definitions), 3.2.4 (Match System Access), and 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates)

Action Required: Review Only

Effective Date: May 4, 2009

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 Data Coordinators

Current Issue/Policy	Change or Addition	What You Need to Do
<p>Directed organ donation is not defined in policy.</p> <p>Policy 3.2.4 requires all organ recipients to appear on an organ match run. There are other policies that prevent the member from complying with this requirement in some organ allocation scenarios.</p> <p>Policy 3.9.3 does not specify on which match run the recipient is required to appear when multiple organs are allocated to a single potential recipient.</p>	<p>This proposal adds the definition of directed donation to policy; requires the transplant center to compare specific donor and candidate characteristics before transplanting a candidate who did not appear on the match run; and clarifies what “on a match run” means for a multi-organ candidate.</p>	<p>OPO and transplant center personnel need to review the policy modifications, familiarize themselves with the changes, and assess alignment with its procedures and Policies 3.1.13, 3.2.4, and 3.9.3.</p> <p>If a transplant center transplants a candidate who does not appear on a match run, it must document the elements required by Policies 3.1.13 and 3.2.4. The written justification must include:</p> <ul style="list-style-type: none"> • the rationale for transplanting the candidate who did not appear on the match run • the reason the candidate did not appear on the match run • if the center is willing to accept an expanded criteria donor organ or a donation after cardiac death donor organ as applicable • documentation that the transplant center verified suitability between the

		<p>donor organ and recipient prior to transplant in at least, but not limited to, the following areas as applicable to each organ type:</p> <ul style="list-style-type: none">○ <input type="checkbox"/> ABO○ <input type="checkbox"/> Serologies○ <input type="checkbox"/> Donor HLA and candidate's unacceptable antigens○ <input type="checkbox"/> Height○ <input type="checkbox"/> Weight <p>If a transplant center transplants a candidate who does not appear on a match run, it must maintain the appropriate documentation and submit to UNOS, if requested, the written justification described in policy.</p>
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Policy Notice

Notice of Policy Change: Modifications to clarify policy requirements, eliminate redundancy, and align policy with current OPO practices (OPO Committee)

Policy Affected: Policy 2.0 (Minimum Procurement Standards for an Organ Procurement Organization)

Action Required: Review Urgently; No Response Needed

Effective Date: May 4, 2009

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 Data Coordinators, Lab Directors, Lab Supervisors, OPO PR/Public Education staff, Transplant PR/Public Education Staff

Current Issue/Policy	Change or Addition	What You Need to Do
In Policy 2.0, some of the laboratory standards and terms used are inconsistent with current practice. Additionally, some of the policy language is duplicative. As a result, the language and organization of Policy 2.0 may place OPOs at risk for non-compliance.	<p>The changes reorganize the content, eliminate repetition of laboratory tests, and update terms.</p> <p>We have eliminated the requirement to obtain GGT levels for potential liver donors; however, a transplant center can request any test if it is available at the donor hospital.</p>	<p>OPO and transplant center personnel need to review the policy modifications, familiarize themselves with the changes, and determine if their internal procedures align with Policy 2.0.</p> <p>OPOs will work with their histocompatibility labs to define and document the minimum tissue typing material required.</p>

Notice of Policy Change: Modification to align required laboratory tests with Policy 2.0 (Minimum Standards for Organ Procurement Organizations) (OPO Committee)

Policy Affected: Policy 3.6.9.1 (Essential Information Category)

Action Required: Review Only

Effective Date: May 4, 2009

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 Data Coordinators, Lab Directors, Lab Supervisors, OPO PR/Public Education staff, and Transplant PR/Public Education Staff

Current Issue/Policy	Change or Addition	What You Need to Do
The requirement in Policy 3.6.9.1 to perform the gamma-glutamyl transferase (GGT) laboratory test contradicts the recently updated Policy 2.0.	The policy modification eliminates the requirement to perform the GGT test, consistent with Policy 2.0.	OPO and transplant center personnel need to review the modification to Policy 3.6.9.1, and assess alignment with its procedures and Policy 3.6.9.1.

Notice of Policy Change: Clarification of multiple listing (Patient Affairs Committee)

Policy Affected: Policy 3.2.2 (Multiple Listing Permitted)

Action Required: Review Only

Effective Date: May 4, 2009

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 PR/Public Education staff, Transplant PR/Public Education Staff

Current Issue/Policy	Change or Addition	What You Need to Do
<p>Numerous professionals and patients have requested modification of policy 3.2.2 (Multiple Listing Permitted) to clarify that patients are permitted to be listed at multiple transplant centers in the same donation service area (DSA).</p> <p>Further, current educational materials distributed by UNOS and the Health Resources and Services Administration (HRSA) convey that this type of multiple listing is permitted. Currently, over 500 candidates are listed at multiple centers within a DSA.</p>	<p>This policy modification clarifies that a candidate may be listed at multiple transplant centers within a DSA.</p>	<p>Review the revised policy language.</p> <p>Note: It is <u>still</u> the transplant center's decision to list a candidate who is already listed at another transplant center.</p>

Notice of Bylaw Change: Patient notification of UNOS Patient Services number (Patient Affairs Committee)

Affected Bylaw: Appendix B, Section II. F. (Patient Notification)

Action Required: Review and act by July 1, 2009

Effective Date: July 1, 2009

Professional Groups Affected by the change:

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, and Transplant Social Workers

Current Issue/Bylaw	Change or Addition	What You Need to Do
<p>Transplant centers must include the UNOS Patient Services number in their notification letters. An unintended consequence of this requirement is that at least 25% of the callers mistakenly call the UNOS Patient Services number to contact their transplant centers.</p> <p>This mistake delays critical communication between patients and centers, thereby presenting a patient safety concern.</p>	<p>The UNOS Patient Information Letter provides the following information to patients:</p> <ul style="list-style-type: none"> • description of the OPTN and UNOS and the services provided (including the UNOS Patient Services number) • OPTN and UNOS web addresses • location of information regarding the public comment process, policies, OPTN data, and educational materials <p>Transplant centers must now send the UNOS Patient Information Letter with their notification letters (see referenced bylaw). Transplant centers must also remove the UNOS Patient Services number from their notification letters but indicate that they have included the Patient Information Letter.</p> <p>Transplant centers can download this letter from the UNOS and OPTN websites. NOTE: This letter is on the UNOS letterhead to differentiate it from transplant center material.</p>	<p>Review this bylaw change.</p> <p>Transplant centers can download the UNOS Patient Information Letter from the UNOS and OPTN websites beginning April 10, 2009. Visit www.unos.org or www.optn.org > Resources > Professional Resources.</p> <p>As of July 1, 2009, transplant centers must send the UNOS Patient Information Letter with their notification letters (see referenced bylaw below). Transplant centers must also remove the UNOS Patient Services number from their notification letter, and include a new statement that references the inclusion of the UNOS Patient Information Letter. You are encouraged to use this sample language:</p> <p>“Attached is a letter from the United Network for Organ Sharing (UNOS). It describes the services and information offered to patients by UNOS and the Organ Procurement and Transplant Network.”</p>

Affected Policy Language:

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

3.2.9 Combined Kidney-Pancreas Waiting List Criteria. Each candidate registered on the Kidney-Pancreas Waiting List must be diagnosed with diabetes ~~as a diabetic~~ or have pancreatic exocrine insufficiency ~~deficiency~~ with renal insufficiency.

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

Affected Policy Language:

3.8.1.56 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~~after islet processing is completed, the transplant center will determine if the islet preparation is medically unsuitable 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. ~~to the next most suitable candidate within the OPO that the Investigational New Drug (IND) application allows.~~

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.

~~The purpose of this policy is to allow for the application of medical judgment and to avoid islet wastage. The outcomes of this allocation policy will be reported to the Board by the Kidney & Pancreas Transplantation Committee within three years.~~

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

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.

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

Affected Policy Language:

3.1.13 Definition of Directed Donation – OPOs are permitted to allocate an organ(s) to a specific transplant candidate named by the person(s) who authorized the donation, unless prohibited by state law. All recipients of a deceased donor organ(s) from a directed donation must be added to the waiting list prior to transplantation.

When the candidate does not appear on at least one of the deceased donor’s match runs for at least one organ type, the transplant center must document the reason why the candidate does not appear and ensure that the organ is safe and appropriate for the candidate. 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 the 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 expanded criteria donor organ or a donation after cardiac death donor 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.

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 3.8.5) 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 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 expanded criteria donor organ or a donation after cardiac death donor 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.

3.9.3 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.

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 www.optn.org. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

Affected Policy Language:

2.0 MINIMUM PROCUREMENT STANDARDS FOR AN ORGAN PROCUREMENT ORGANIZATION (OPO)

The following policies provide the 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, ~~verifying pronouncement of death~~ and organ allocation. Additionally, the Host OPO is responsible for ensuring that donor tissue typing information ~~about the donor~~ is entered into the OPTN computer UNetSM and that the approved OPTN organ allocation computer program is executed for each donor organ. ~~Every~~ Reasonable attempts shall be made to obtain a ~~social~~ medical/behavioral history from individual(s) familiar with the donor ~~and not restricted to the person granting permission for organ donation~~. 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 OPO or transplant center for every donor:

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

~~2.2.2~~ Perform pertinent tests including:

- ~~• ABO typing;~~
- ~~• FDA licensed Anti-HIV I, II.~~

~~In addition, the Host OPO shall perform the following evaluations and provide this information to the OPO or transplant center, documenting in the donor record circumstances when such information is not available.~~

2.2.2 ~~In addition,~~ The Host OPO must perform the following evaluations and provide this information to the OPO or transplant center. ~~and~~ The Host OPO must document in the donor record circumstances when such information is not available. ~~2.2.3~~ The Host OPO must determine ~~ing~~ whether there are conditions which may influence donor acceptance by:

- 2.2.4** Obtaining the donor's medical/behavioral history.
- 2.2.5** Reviewing the donor's medical chart.
- 2.2.6** Performing a physical examination of the donor.

- ~~2.2.7~~ Obtaining the donor's vital signs.

2.2.83 The Host OPO must perform the following Performing pertinent tests—including; 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. 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.

2.2.83.1 For all potential donors:

- ABO typing with sub-typing for ABO-A donors;
- FDA licensed Anti-HIV I, II.
- CBC;
- Electrolytes;
- Hepatitis screen serological testing; including HBsAg, HBcAb, and Anti-HCV;
- VDRL or RPR;
- Anti-HTLV I/II;
- Anti-CMV;
- EBV serological testing;
- Blood and urine cultures ~~if the donor is hospitalized 72 hours or longer;~~
- Urinalysis within 24 hours prior to cross clamp; and
- Arterial blood gases;
- Chest x-ray;
- Serum Glucose.

Additional Organ Specific information is required as follows:

2.2.83.2 For potential renal donors:

- ~~Urinalysis;~~
- Creatinine; ~~and~~
- B.U.N.

2.2.83.3 For potential liver donors:

- AST
- ALT
- Alkaline phosphatase
- ~~GGT~~
- Direct and tTotal bilirubin;

- ~~Direct bilirubin (if requested);~~
- INR (PT if INR not available);
- PTT; ~~and~~
- ~~Blood group subtyping of ABO-A donors.~~

2.2.83.4 For potential heart donors:

- 12 Lead ECG; and
- Cardiology consult and/or echocardiogram; ~~and~~
- ~~Blood gases.~~

2.2.83.5 For potential pancreas donors:

- Serum amylase; ~~and~~
- ~~Serum lipase (if requested); and~~
- ~~Glucose.~~

2.2.83.6 For potential lung donors:

- ~~Blood gases, and~~
- Sputum gram stain.

2.3 DONOR MAINTENANCE. The Host OPO must ~~ensure that~~ make reasonable efforts to maintain the deceased donor, document these efforts, and communicate this information to the OPO or Transplant Center is maintained 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 ~~Final urinalysis;~~ All items in section 2.2
- 2.5.2 ~~Monitoring and recording of blood pressure and temperature;~~

2.5.32 Use of standard surgical techniques in a sterile operating environment;

2.5.43 Maintenance of flush solutions and preservation media at appropriate temperatures and recording of flush solutions and additives; 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.

2.5.54 Each OPO, ~~with~~ and their respective histocompatibility laboratory(s)ies, will ~~establish minimum written requirements~~ define and document the minimum tissue typing material required to generate match runs for local or regional placement of all organs. ~~Organ procurement organizations will establish minimum requirements for tissue typing material required for local disposition of livers, hearts and lungs.~~ 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 topped) tube for ABO verification, plus
- 2 ACD (~~Y~~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.

2.5.65 Proper packaging of organs for transport (see Policy 5.0); ~~and~~

2.5.76 Properly packaged ~~paperwork~~ documentation containing complete donor information shall accompany each organ to the recipient ~~institution~~ transplant center.

2.5.71 ~~2.5.6.1~~ Written ~~Documentation~~ Documentation accompanying each organ must include:

- ABO typing source documents;
- Serology results;
- Medical/~~Social~~Behavioral History form;
- Donor evaluation;
- Complete record of donor ~~maintenance~~ management;
- ~~Documentation of~~ eConsent form; and
- ~~Documentation of~~ eOrgan quality as described in section 2.5.

2.5.87 ~~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 duly recorded during the retrieval process. Complete~~

information must be maintained by the Host OPO on any and all organs recovered, and must include any abnormal anatomy found during the retrieval process. The Host OPO is responsible for ensuring that non-local procurement teams have appropriate 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. ~~Tissue typing is initiated only after the consent of either the donor by previous designation or the next of kin.~~

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. ~~Cases in which this option is not given to the recipient transplant team must be reported in writing by the Host OPO and recipient transplant center to the appropriate organ-specific OPTN committee.~~ 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 ~~both liver and pancreas~~ 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. ~~If both the liver and pancreas are not procured, the OPO should document in writing on the donor form the specific reason(s) for failure to procure both organs.~~ Cooperation between ~~liver and pancreas~~ all organ recovery teams is ~~expected~~required.

2.8 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.

2.89 MULTI-CULTURAL AND DIVERSITY ISSUES. Each OPO must develop and implement a plan to address a diverse population related to organ donation.

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

Affected Policy Language:

3.0 ALLOCATION OF LIVERS [No Changes Proposed]

3.6.1 – 3.6.8 [No Changes Proposed]

3.6.9 Minimum Information for Liver Offers.

3.6.9.1 Essential Information Category. When the Host OPO or donor center provides the following donor information, with the exception of pending serologies, to a recipient center, the recipient center must respond to the offer within one hour pursuant to Policy 3.4.1 (Time Limit for Acceptance); however, this requirement does not preclude the Host OPO from notifying a recipient center prior to this information being available:

- (i) Donor name and Donor I.D. number, age, sex, race, height and weight;
- (ii) ABO type;
- (iii) Cause of brain death/diagnosis;
- (iv) History of treatment in hospital including current medications, vasopressors and hydration;
- (v) Current history of hypotensive episodes, urine output and oliguria;
- (vi) Indications of sepsis;
- (vii) Social and drug activity histories; Vital signs including blood pressure, heart rate and temperature;
- (ix) Other laboratory tests within the past 12 hours including:
 - (1) Total Bilirubin
 - (2) ALT
 - (3) INR (PT if INR not available)
 - (4) Alkaline phosphatase
 - ~~(5) GGT~~
 - ~~(6) WBC~~
 - ~~(7) HH~~
 - ~~(8) Creatinine;~~
- (x) Arterial blood gas results;

Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred).

3.6.9.2 – 3.6.13 [No Changes proposed]

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

Affected Policy Language:

Policy 3.2.2 (Multiple Listing Permitted):

3.2.2 Multiple Listing Permitted. ~~Candidates may be listed on multiple transplant center local Waiting Lists. Each such multiple local listing may be added to the Waiting List so that the same candidate may be listed on the Waiting List multiple times. However, transplant centers may not list the same candidate on more than one organ procurement organization's Waiting List.~~ Candidates may be waitlisted at multiple transplant centers. These transplant centers may be located within the same OPO service area. These transplant centers may be located within different OPO service areas.

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

Affected Bylaw Language:

Appendix B, Section II. F. (Patient Notification):

II. Transplant Hospitals

[...]

F. Patient Notification. Transplant Hospitals are expected to notify patients in writing: (i) within ten business days (a) of the patient's being placed on the Waiting List including the date the patient was listed, or (b) of completion of the patient's evaluation as a candidate for transplantation, that the evaluation has been completed and that the patient will not be placed on the Waiting List at this time, which ever is applicable; and (ii) within ten business days of removal from the Waiting List as a transplant candidate for reasons other than transplantation or death that the patient has been removed from the Waiting List. Each such written notification must reference and include the OPTN contractor's "Patient Information Letter," which provides the telephone number that is available to patients and others to report concerns or grievances through the OPTN. All candidates currently on the Waiting List should be notified by their listing center about the patient notification hotline, or other information as directed by the Executive Committee. Transplant Hospitals are further expected to maintain documentation of these notifications and make it available to UNOS upon request for purposes of monitoring compliance with this provision. If the Member fails voluntarily to comply with this provision, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws in all other cases.

[...]

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.