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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: Recently Approved Policy Modifications and Board Actions
Date: October 18, 2007

The attached report summarizes bylaw changes, policy changes and other actions the OPTN/UNOS Board of Directors approved at its September 2007 meeting. Our ongoing goal is to keep you fully informed of these changes and also of any action required on your part.

You should now recognize the three-column format and grid designed to help you review this information quickly and easily. After reading the summaries, you can click on the accompanying link to access modified policy language and any additional policy information. We also included page numbers for those of you who prefer using paper copies.

Thank you in advance for your careful review. We welcome your feedback as we continue to improve the way that we communicate bylaw and policy changes as well as other Board actions. 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.

	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 #
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Notice of Bylaw Change—Modifications to Bylaws, Appendix B, Attachment I, Section XIII, C (2) and (4), Designated Transplant Program Criteria (Membership and Professional Standards Committee)

Action Required: Review

Effective Date: October 18, 2007

Professional Groups Affected by the change:

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

Current Issue/Policy	Change or Addition	What You Need to Do
<p>The Bylaws include specific requirements for programs that perform living donor kidney and liver transplantation, but these requirements are limited to surgeon qualifications.</p>	<p>The Bylaw changes describe additional minimal requirements that programs performing living donor transplants must meet.</p> <p>The additions will help ensure that transplant programs have essential elements in place for the evaluation, consent, and follow-up of living donors.</p> <p>Questions related to living donor programs in the existing OPTN/UNOS applications and surveys (e.g. applications for new programs, reactivation, key personnel changes, staffing surveys, and Outcomes and Activity Surveys) will be changed to incorporate the concepts outlined in the modified Bylaws as appropriate.</p> <p>The OMB must approve the new application forms. We expect approval in late 2007/early 2008. Once we obtain OMB Approval, we will distribute the application forms to the transplant hospitals. We will include detailed instructions regarding the schedule for completion at that time.</p> <p>According to Appendix A of the</p>	<p>1) Each kidney and liver transplant program that performs living donor transplants must:</p> <ul style="list-style-type: none"> • Develop, implement, and comply with written protocols that address all phases of living donation outlined in the Bylaws • Document that all phases of the living donation process are performed according to their protocols, and make this documentation available upon request <p>2) Transplant hospitals that perform or intend to perform living donor transplants will need to complete an application that demonstrates how the applicant center meets the living donor transplant requirements.</p> <p>3) Transplant hospitals that are currently designated to perform living donor <u>liver</u> transplants will be asked to provide additional information that demonstrates that they meet</p>

	<p>Bylaws, the Membership and Professional Standards Committee will review the applications and other responses as a part of the evaluation process.</p>	<p>the new living donation requirements.</p> <p>4) Transplant hospitals that currently perform living donor <u>kidney</u> transplants will need to submit an application documenting that they meet all of the requirements for living donor transplantation.</p> <p>5) Transplant hospitals will also be responsible for submitting an application or other appropriate notification form whenever there is a change in a living donation program's primary and/or key personnel.</p> <p>UNOS Staff Application Process Being Considered</p> <p>Once the applications are approved by OMB, we will distribute applications to member transplant centers. We are currently developing a phased schedule for application distribution and submission. <u>You will receive further instructions when the process is ready to begin. It is not necessary to submit any information until you receive notice.</u></p> <p>A survey of the existing <u>liver</u> programs that perform living donor transplants will be conducted to ensure that they meet the additional requirements.</p> <p>During site surveys of transplant centers with approved living donor programs, DEQ staff will review the program's written</p>
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		protocol and a sample of living donor/recipient records. DEQ staff will review the documentation in the record to verify that all phases of the living donation process were performed according to the program's protocol.
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To view the affected bylaw language, please turn to **Exhibit 1**.

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

Notice of Bylaws Change—Modifications to Appendix 3A – HLA A, B and DR Antigen Values and Split Equivalences Table (Histocompatibility Committee)

Action Required: Review Only

Effective Date: Pending implementation of Policy 3.5.11.3 (Sensitized Wait List Candidates - Calculated PRA (CPRA)), estimated as November 2007.

Professional Groups Affected by the change: Lab Directors, Lab Supervisors

Current Issue/Policy	Change or Addition	What You Need to Do
The unacceptable antigen equivalence table approved for use in the renal allocation system (Appendix 3A) does not include equivalences for Bw4, Bw6, DR51, DR52, and DR53.	Appendix 3A was amended to include the equivalences for Bw4, Bw6, DR51, DR52, and DR53 which would be used <u>solely</u> in the calculation of the CPRA.	The Calculated PRA (CPRA) will be <u>automatically</u> calculated in UNet SM when unacceptable antigens are listed for a candidate; therefore lab personnel should be aware of this change.

To view the affected bylaw language, please turn to **Exhibit 2**.

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

Notice of Board Action — Modifications to the Liver Regional Review Board Guidelines (Liver and Intestinal Organ Transplantation Committee)

Action Required: Review Only

Effective Date: To be determined- a System Notice will be sent to confirm the implementation date

Professional Groups Affected by the change:

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

Current Issue/Policy	Change or Addition	What You Need to Do
Currently, Status 1A/1B cases that do not meet the standard criteria as outlined in policy are referred directly to the Liver and Intestinal Committee for review.	The RRBs will review Status 1A/1B cases that do not meet the standard criteria as outlined in policy. The RRBs will conduct reviews electronically on UNet SM , similar to the way they review the MELD/PELD Exception cases.	Continue to submit Status 1A/1B justification forms in the same way you always have. You may notice slight modifications to the forms based on programming. We will communicate any changes to this process before we implement them.
Currently, MELD/PELD Exception cases can be appealed an indefinite number of times as long as appeals are submitted within 21 days of the original submission date of the initial request.	This change will modify the appeals process for MELD/PELD Exception cases. Appeals must be submitted within 3 days of being notified of a denied case and the RRB will have 10 additional days to reach a decision on the appeal. You can no longer appeal exception cases for an indefinite number of times.	Transplant centers that choose to appeal a case must submit a MELD/PELD Exception application appeal within three calendar days after receiving notice of a denied exception case. The RRB will then have 10 additional days to reach a decision on the appeal.

To view the affected RRB Guidelines language, please turn to **Exhibit 3**.

To read the Liver RRB Guidelines visit UNetSM at <https://www.unet.unos.org>, select Regional Review Board, then select Liver RRB Operational Guidelines under the RRB Help Documentation section.

Notice of Policy Change — Modifications to Policy 3.6.6 (Liver and Intestinal Organ Transplantation Committee)

Action Required: Review

Effective Date: October 18, 2007

Professional Groups Affected by the change:

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

Current Issue/Policy	Change or Addition	What You Need to Do
<p>Current policy language states that transplant centers should immediately transfer recipients of a living donor liver to inactive status until the candidate requires a subsequent transplant or one year following the candidate’s prior transplant, whichever comes first. The original intent of this language was to allow candidates to regain their waiting time if a deceased donor transplant became necessary; however, this was during the era when waiting time was an important factor in liver allocation.</p>	<p>The proposed change to the policy language will make it clear to transplant centers that recipients of live donor livers should be removed from the waiting list within 24 hours of the transplant. This change will make the policy language current with practice and programming.</p>	<p>Remove liver transplant candidates from the waiting list(s) using the appropriate removal code to notify the OPTN contractor within 24 hours after a transplant from a living or deceased donor.</p>

To view the affected policy language, please turn to **Exhibit 4**.

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.

Notice of Publication- Resource Documentation for Informed Consent of Living Donors (Living Donor Committee)

Action Required: Review Only

Effective Date: October 18, 2007

Professional Groups Affected:

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

Current Issue/Policy	Change or Addition	What You Need to Do
Wide variability of consent approaches for potential living donors exists throughout the country.	The Living Donor Committee created a resource document to assist transplant centers as they develop individual protocols for the consent of living donors. Living Donor programs may use this document to evaluate their own consent process at a transplant center.	Review this document, available on the OPTN, UNOS and Transplant Living websites, and consider: <ul style="list-style-type: none">• using it within your individual living donor programs to evaluate your consent process• sharing it with all potential living donors as a resource.

To review this resource document, please turn to **Exhibit 5**.

To review the resource document online, visit www.unos.org or www.optn.org. From the UNOS Web site, select Transplant Living and Living Donation and Informed Consent.

Notice of Policy Change — Modifications to Policy 3.3.3 (Renal Acceptance Criteria) (Operations Committee)

Action Required: Review

Effective Date: To Be Determined

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>With the implementation of DonorNet[®] and the ability of OPOs to make kidney offers more efficiently, some policies have been found to be out of date. Current policy does not give OPOs access to the Organ Center’s Renal Acceptance Criteria utility. Programming is currently underway to allow OPOs to utilize this screening tool which improves the efficiency of regional and national kidney allocation.</p>	<p>OPOs will now be able to apply the Renal Acceptance Criteria for regional and national kidney allocation, with the exception of zero antigen mismatched kidney allocation. Therefore, candidates will not receive organ offers for kidneys from non-local OPOs that do not meet the minimum renal acceptance criteria set by the transplant center.</p>	<p>The Board of Directors passed this policy change in September. Because other corresponding areas of allocation policy have not been aligned at this time, <u>implementation will be delayed.</u></p> <p>We will notify members with a system notice when we set the implementation date.</p> <p>Upon implementation, OPOs will be expected to:</p> <ul style="list-style-type: none"> • Accurately enter donor information into the Renal Acceptance Criteria utility for each kidney donor. • Apply the Renal Acceptance Criteria utility to regional and national kidney offers only. <p>Upon implementation, transplant centers will be expected to:</p> <ul style="list-style-type: none"> • Continue to define minimum renal acceptance criteria for kidney donors and enter this information into UNetSM annually as currently required.

To view the affected policy language, please turn to **Exhibit 6.**

Notice of Policy Change — Modifications to Policy 3.5.3.5 (Time Limit) (Operations Committee)

Action Required: Review

Effective Date: To be determined

Professional Groups Affected by the change: OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, and OPO Medical Directors

Current Issue/Policy	Change or Addition	What You Need to Do
<p>Current policy requires the UNOS Organ Center to offer zero mismatch kidneys to transplant centers within either four hours or two hours, depending on the type of donor (SCD or ECD). If the kidney is placed by the Organ Center with a zero mismatched candidate, the Organ Center records the payback credit for the offering OPO.</p> <p>Following implementation of DonorNet, the OPTN/UNOS Executive Committee resolved to suspend the requirement for OPOs to use the Organ Center for placement of zero mismatch kidney, kidney-pancreas and pancreas effective May 23, 2007.</p> <p>The process for payback debt accounting has been affected since the Organ Center is no longer required to place these organs. Payback debt levels affect the order of the waitlist for kidney and kidney-pancreas candidates, therefore timely reporting of payback debts and credits is necessary.</p>	<p>OPOs will be allowed to make zero mismatch kidney offers. If they do, they will make the appropriate number of zero mismatch kidney offers for standard and expanded criteria donors before either placing the kidney locally, or if no local interest, continuing to place the kidney in the sequence of the match run.</p> <p>In addition, the OPO must contact the Organ Center within 24 hours to report zero mismatch kidney sharing if the OPO places the kidney with a zero mismatch candidate.</p>	<p>The Board of Directors passed this policy change in September. Because other corresponding areas of allocation policy have not been aligned at this time, <u>implementation will be delayed.</u></p> <p>We will notify members with a system notice when we set the implementation date.</p> <p>Upon implementation, OPOs will be expected to:</p> <ul style="list-style-type: none"> • Make ten zero mismatch kidney offers for standard criteria donors and five for expanded criteria donors. If fewer than 10 (for SCD) and 5 (for ECD) zero mismatch potential recipients on the match run, then the OPO is expected to make an offer to every potential recipient identified as a zero mismatch on the match run before offering the kidney(s) to local potential recipients. • The Host OPO must contact the Organ Center within 24 hours of placing the organ to report zero mismatch kidney sharing

To view the affected policy language, please turn to **Exhibit 7**.

Notice of Bylaw Change- Modifications to OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII, C (2) and (4), Designated Transplant Program Criteria (Membership and Professional Standards Committee)

The modifications to the Bylaws that were approved by the Board of Directors are shown below as single underlines and single ~~strikeouts~~.

**BYLAWS APPENDIX B
ATTACHMENT I**

Designated Transplant Program Criteria

[...]

XIII. Transplant Programs.

- A. In order to qualify for membership, a transplant program must utilize, for its histocompatibility testing, a laboratory that meets the UNOS Standards for Histocompatibility testing, as described in UNOS Bylaws Appendix B, Attachment II, and is approved by the UNOS Membership and Professional Standards Committee.
- B. In order to qualify for membership, a transplant program must have letters of agreement or contracts with either an IOPO or hospital-based organ procurement organization which complies with the criteria as outlined in Attachment III to the extent applicable to hospital-based organ procurement organizations. These membership criteria are based substantially upon the Center for Medicare/Medicaid Services (CMS). Conditions for coverage for Organ Procurement Organizations, September 29, 1996.
- C. ~~In addition to the foregoing requirements, to qualify for membership in UNOS, a transplant program must have a clinical service which meets the following criteria. Each~~ transplant program must identify a UNOS qualified primary surgeon and physician, the requirements for whom are described below as well as the program director.

The program director, in conjunction with the primary transplant surgeon and transplant physician, must submit to UNOS in writing a Program Coverage Plan, which documents how 100% medical and surgical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable, during the year. The Program coverage Plan must address the following requirements:

- (1) All transplant programs must have transplant surgeon(s) and physician(s) available 365 days a year, 24 hours a day, 7 days a week, to provide program coverage unless a written explanation is provided that justifies the current level of coverage to the satisfaction of the MPSC. All transplant programs shall provide patients with a written summary of the Program Coverage Plan, at the

time of listing and when there are any substantial changes in program or personnel.

- (2) A surgeon/physician must be available and able to be on the hospital premises within one-hour ground transportation time to address urgent patient issues.
- (3) A transplant surgeon must be readily available in a timely manner to facilitate organ acceptance, procurement, and implantation.
- (4) Unless exempted by the MPSC for specific causal reasons, the primary transplant surgeon/primary transplant physician cannot be designated as the primary surgeon/primary transplant physician at more than one transplant center unless there are additional transplant surgeons/transplant physicians at each of those facilities.
 - (i) Additional Transplant Surgeons must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients including performing the transplant operation and procurement procedures.
 - (ii) Additional Transplant Physicians must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients.

A transplant center applying as a new member or for a key personnel change must include for the proposed primary transplant surgeon and/or physician a report from their hospital credentialing committee that the committee has reviewed the said individual's state licensing, board certification status, and training and affirm that they are "currently" a member in good standing.

D. In addition to the foregoing requirements, to qualify for membership in UNOS, a transplant program must have a clinical service which meets the following criteria.

1) Kidney Transplantation [no changes]

2)- ~~A live Donor~~ Kidney Transplant Programs that Perform Living Donor Kidney Transplants: Kidney transplant programs that perform living donor kidney transplants must demonstrate the following:

~~A. Live Donor Kidney Transplant Programs~~

a. Personnel and Resources: Kidney transplant programs that perform living kidney transplants must demonstrate the following regarding personnel and resources:

- (i) That the center meets the qualifications of a kidney renal transplant program as set forth in ~~(Section 1)~~ above; and

(ii) In order to perform open donor nephrectomies, a qualifying kidney renal donor surgeon must be on site and must meet either of the criteria of (i) and/or (ii) set forth below:

- (1) Completed an accredited ASTS fellowship with a certificate in kidney; or
- (2) Performed no fewer than 10 open donor nephrectomies (to include deceased donor nephrectomy, removal of polycystic or diseased kidneys, etc.) as primary surgeon or first assistant within the prior 5-year period.

(iii) If the center wishes to perform laparoscopic donor nephrectomies, a qualifying kidney renal donor surgeon must be on site and must have:

- (1) Acted as primary surgeon or first assistant in performing no fewer than 15 laparoscopic nephrectomies within the prior 5-year period.

If the laparoscopic and open nephrectomy expertise resides within different individuals then the program must demonstrate how both individuals will be available to the surgical team. It is recognized that in the case of pediatric living donor transplantation, the living organ donation may occur at a center that is distinct from the approved transplant center.

All surgical procedures identified for the purpose of surgeon qualification must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, and the role of the surgeon in the operative procedure.

(iv) The center must have the resources available to assess the medical condition of and specific risks to the potential living donor;

(v) The psychosocial assessment should include an assessment of the potential donor's capacity to make an informed decision and confirmation of the voluntary nature of proceeding with the evaluation and donation; and

(vi) That the center has an independent donor advocate (IDA) who is not involved with the potential recipient evaluation, is independent of the decision to transplant the potential recipient and, consistent with the IDA protocol referred to below, is a knowledgeable advocate for the potential living donor. The goals of the IDA are:

- (1) to promote the best interests of the potential living donor;
- (2) to advocate the rights of the potential living donor; and

- (3) to assist the potential living donor in obtaining and understanding information regarding the:
 - (a) consent process;
 - (b) evaluation process;
 - (c) surgical procedure; and
 - (d) benefit and need for follow-up.

b. Protocols: Kidney transplant programs that perform living donor kidney transplants must demonstrate that they have the following protocols:

- (i) Living Donation Process: Kidney transplant programs that perform living donor kidney transplants must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative, post-operative care, and submission of required follow-up forms at 6 months, one-year, and two-years post donation.

Transplant centers must document that all phases of the living donation process were performed in adherence to the center's protocol. This documentation must be maintained and made available upon request.

- (ii) Independent Donor Advocate: Kidney transplant programs that perform living donor kidney transplants must develop, and once developed, must comply with written protocols for the duties and responsibilities of Independent Donor Advocate (IDA) that include, but are not limited to, the following elements:

- (1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure the IDA:

- (a) promotes the best interests of the potential living donor;
- (b) advocates the rights of the potential living donor; and
- (c) assists the potential donor in obtaining and understanding information regarding the:
 - (i) consent process;
 - (ii) evaluation process;
 - (iii) surgical procedure; and
 - (iv) benefit and need for follow-up.

- (iii) Medical Evaluation: Kidney transplant programs that perform living donor kidney transplants must develop, and once developed, must comply with written protocols for the medical evaluation of the potential living donors that must include, but are not limited to, the following elements:

- (1) a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to the

potential donor post-donation, which shall include a screen for any evidence of occult renal and infectious disease and medical co-morbidities, which may cause renal disease;

(2) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist, or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I) to determine decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion;

(3) screening for evidence of transmissible diseases such as cancers and infections; and

(4) anatomic assessment of the suitability of the organ for transplant purposes.

(iv) Informed Consent: Kidney transplant programs that perform living donor kidney transplants must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Nephrectomy, which include, at a minimum, the following elements:

(1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;

(2) assurance that all communication between the potential donor and the transplant center will remain confidential;

(3) discussion of the potential donor's right to opt out at any time during the donation process;

(4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance; and

(5) disclosure by the transplant center that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor.

(3) Liver Transplantation [No changes]

(4) ~~Live Donor~~ Liver Transplant Programs that Perform Living Donor Liver Transplants.

a. Personnel and Resources: Liver transplant programs that perform living donor liver transplants must demonstrate the following:

(i) That the center meets the qualifications of a liver transplant ~~program center~~ as set forth in ~~UNOS Bylaws, Appendix B, Attachment I, Section XIII~~ above; and.

(ii) That the center has on site no fewer than two surgeons who qualify as liver transplant surgeons under UNOS Bylaws Appendix B, Attachment I, and who have demonstrated experience as the primary surgeon or first assistant in 20 major hepatic resectional surgeries (to include living donor operations, splits, reductions, resections, etc.), 7 of which must have been live donor procedures within the prior 5-year period. These cases must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, and the role of the surgeon in the operative procedure. It is recognized that in the case of pediatric living donor transplantation, the live organ donation may occur at a center that is distinct from the approved transplant center;

(iii) The center must have the resources available to assess the medical condition of and specific risks to the potential living donor;

(iv) The psychosocial assessment should include an assessment of the potential living donor's capacity to make an informed decision and confirmation of the voluntary nature of proceeding with the evaluation and donation; and

(v) That the center has an independent donor advocate (IDA) who is not involved with the potential recipient evaluation, is independent of the decision to transplant the potential recipient and, consistent with the protocol referred to below, is a knowledgeable advocate for the potential living donor. The goals of the IDA are:

(1) to promote the best interests of the potential living donor;

(2) to advocate the rights of the potential living donor; and

(3) to assist the potential living donor in obtaining and understanding information regarding the:

(a) consent process;

(b) evaluation process;

(c) surgical procedure; and

(d) benefit and need for follow-up.

b. Protocols: Liver transplant programs that perform living donor liver transplants must demonstrate that they have the following protocols:

(i) Living Donation Process: Liver transplant programs that perform living donor liver transplants must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative,

post-operative care, and submission of required follow-up forms at 6 months, one-year, and two-years post donation.

Transplant centers must document that all phases of the living donation process were performed in adherence to the center's protocol. This documentation must be maintained and made available upon request.

(ii) Independent Donor Advocate: Liver transplant programs that perform living donor liver transplants must develop, and once developed, must comply with written protocols for the duties and responsibilities of the Independent Donor Advocate that include, but are not limited, to the following elements:

(1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure that the IDA:

(a) promotes the best interests of the potential living donor;

(b) advocates the rights of the living donor; and

(c) assists the potential donor in obtaining and understanding information regarding the:

(i) consent process;

(ii) evaluation process;

(iii) surgical procedure; and

(iv) benefit and need for follow-up.

(iii) Medical Evaluation: Liver transplant programs that perform living donor liver transplants must develop, and once developed, must comply with written protocols for the medical evaluation of the potential living donors must include, but are not limited to the following elements:

(1) a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which shall include a screen for any evidence of occult liver disease;

(2) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I) must also be provided to assess decision making capacity, screen for any pre-existing psychiatric illness, and evaluate potential coercion;

(3) screening for evidence of transmissible diseases such as cancers and infections; and

(4) a radiographic assessment to ensure adequate anatomy and volume of the donor and of the remnant liver.

(iv) Informed Consent: Liver transplant programs that perform living donor liver transplants must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Hepatectomy, which include, at a minimum, the following elements:

- (1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;
- (2) assurance that all communication between the potential donor and the transplant center will remain confidential;
- (3) discussion of the potential donor's right to opt out at any time during the donation process;
- (4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance; and
- (5) disclosure by the transplant center that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor.

c.2. Conditional Approval Status: If the transplant center does not have on site a second surgeon who can meet the requirement for having performed 7 live donor liver procedures within the prior 5-year period, but who has completed the requirement for obtaining experience in 20 major hepatic resection surgeries (as described above), as well as all of the other requirements to be designated as a primary liver transplant surgeon, the program may be eligible for Conditional Approval Status. The transplant program can be granted one year to fully comply with applicable membership criteria with a possible one year extension. This option shall be available to new programs as well as previously approved programs that experience a change in key personnel. During this period of conditional approval, both of the designated surgeons must be present at the donor's operative procedure.

The program shall comply with such interim operating policies and procedures as shall be required by the Membership and Professional Standards Committee (MPSC).

This may include the submission of reports describing the surgeon's progress towards meeting the requirements and such other operating conditions as may be required by the MPSC to demonstrate ongoing quality and efficient patient care. The center must provide a report prior to the conclusion of the first year of conditional approval, which must document that that the surgeon has met or is

making sufficient progress to meet the objective of performing 7 live donor liver procedures or that the program is making sufficient progress in recruiting and bringing to the program a transplant surgeon who meets this criterion as well as all other criteria for a qualified live donor liver surgeon. Should the surgeon meet the requirements prior to the end of the period of conditional approval, the program may submit a progress report and request review by the MPSC.

The transplant program must comply with all applicable policies and procedures and must demonstrate continuing progress toward full compliance with Criteria for Institutional Membership.

The program's approval status shall be made available to the public.

Notice of Bylaws Change—Modifications to Appendix 3A – HLA A, B and DR Antigen Values and Split Equivalences Table (Histocompatibility Committee)

Affected Bylaws Appendix Language: (*Appears underlined at bottom of page 3A-4*)

HLA Antigen Values and Split Equivalences

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	2,203,210	7	7,703	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,*6601	21	21,4005,*1304	11	11,5
28	28,68,69	22	22,54,*8201	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	40,61,81	18	18,3,17
36	36	41	41	103	103,1
43	43	42	42	1403	1403,14,6
66	66,*6601,*6602,10	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	*6601,66,10,26	52	52,5		
*6602	*6602,66,10,34	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		
		703	703,7		
		*0804	*0804,8		
		*1304	*1304,15,21,49,50		
		2708	2708,27,7		
		3901	3901,39		
		3902	3902,39		
		*3905	*3905,16,39		
		4005	4005,21,50		
		5102	5102,51,53		

Exhibit 2

		5103 7801 *8201 ** 99	5103,51 7801 *8201,45,22,54,55,56 (No equivalent)		
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* 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 UNACCEPTABLE A LOCUS ANTIGEN	DONOR EQUIVALENT ANTIGEN(S)	PATIENT'S UNACCEPTABLE B LOCUS ANTIGEN	DONOR EQUIVALENT ANTIGEN(S)	PATIENT'S UNACCEPTABLE C LOCUS ANTIGEN	DONOR EQUIVALENT ANTIGEN(S)
1	1	5	5,51,5102,5103,52,78	1	1
2	2,203,210	7	7,703	2	2
3	3	8	8,*0804	3	3,9,10
9	9,23,24,2403	12	12,44,45	4	4
10	10,25,26,34,66,*6601,*6602	13	13	5	5
11	11	14	14,64,65	6	6
19	19,29,30,31,32,33,74	15	15,75,76,77	7	7
23	23	16	16,38,39	8	8
24	24,2403	17	17,57,58	9	9
25	25	18	18	10	10
26	26	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	*17	*17
33	33	39	39,3901,3902,*3905	*18	*18
34	34	40	40,60,61		
36	36	41	41		
43	43	42	42		
66	66	44	44		
68	68	45	45		
69	69	46	46		
74	74	47	47		
80	80	48	48		
203	203	49	49		
210	210	50	50,4005		
2403	2403	51	51,5102,5103		
*6601	*6601	52	52		
*6602	*6602	53	53,5102		
		54	54		
		55	55		
		56	56		
		57	57		
		58	58		
		59	59,*0804		
		60	60		
		61	61		
		62	62		
		63	63		
		64	64		
		65	65		
		67	67		
		70	70,71,72		
		71	71		
		72	72		
		73	73		
		75	75		
		76	76		
		77	77		
		78	78		
		81	81		
		82	82		
		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		
		Bw6	Bw6		

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	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
6	6,13,14,1403,1404	6	6
7	7	7	7
8	8	8	8
9	9	9	9
10	10		
11	11		
12	12		
13	13		
14	14,1403,1404		
15	15		
16	16		
17	17		
18	18		
103	103		
1403	1403		
1404	1404		
51	51		
52	52		
53	53		

* 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 and B61 listed as "unacceptable antigens": Donors typed as B60 or B61 are considered unacceptable. Donors typed as B40 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
<u>Bw4: B5, B13, B17, B27, B37, B38, B44, B47, B49, B51, B52, B53, B57, B58, B59, B63, B77</u>
<u>Bw6: B7, B8, B14, B18, B22, B35, B39, B40, B41, B42, B45, B46, B48, B50 (B*4005), B54, B55, B56, B60, B61, B62, B64, B65, B67, B70, B71, B72, B73, B75, B76, B78, B81</u>
<u>DR51: DR2, DR15, DR16</u>
<u>Dr52: DR3, DR5, DR6, DR11, DR12, DR13, DR14, DR17, DR18</u>
<u>Dr53: DR 4, DR7, DR9</u>

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

Notice of Board Action — Modifications to the Liver Regional Review Board Guidelines (Liver and Intestinal Organ Transplantation Committee)

Affected Policy Language:

LIVER REGIONAL REVIEW BOARD OPERATIONAL GUIDELINES

Revised: 08/2007

1. Purpose

The purpose of regional review is to provide prompt peer review of exceptional cases not addressed by the MELD/PELD score and Status 1A and 1B cases that do not meet the standard criteria.

2. Representation

A. There shall be a minimum of three physicians on the board representing adult and pediatric, active liver transplant programs. Each active liver transplant program shall have the opportunity to be represented on the regional review board. On a national basis, the representatives on the Regional Review Boards (RRBs) vary in number. Since larger boards may pose operational/administrative problems, some of the RRBs rotate the membership to ensure that each program is represented on the Board for one term. Each region shall determine the length of “one term”. The frequency of rotation will be determined by each region. There should be representation from both hepatology and surgery on the board. An individual involved in pediatric transplantation should also be included on pediatric cases; although the logistics of such representation may be challenging. The region may choose to include the regional representative to the Liver and Intestinal Organ Transplantation Committee on the review board as an organizational/continuity measure. In most cases, the regional representative to the Liver and Intestinal Organ Transplantation Committee will serve as the Regional Review Board Chair.

Other health care providers, including non-transplant physicians may be included, such as one non-medical (public) representative as non-voting members to serve the purpose of public oversight. The non-transplant representatives should be familiar with transplant issues. Suggested sources for these representatives include medical ethics, public servants involved in health care policy, clergy, patients and donor family members. A possible source of these individuals would be those with previous OPTN/UNOS committee experience. Review board members who are appointed as General Public Members should not be employed by a member center having an active liver program.

B. Each review board member is required to have **one or more alternate representatives** identified to UNOS and to the Review Board chair, to be contacted if the representative is not available for more than 72 hours. It is the responsibility of each member center to provide UNOS with the contact information for the review board member by providing the information for both the primary representative and the alternate representative to the UNOS Membership Department in writing through their Site Administrator. Should a representative leave their transplant center, then the center’s alternate representative will

become the permanent representative. If a regional chair should leave their center, the alternate still becomes the permanent representative and a new alternate is chosen. A member center may also appoint a new permanent representative and continue with the same alternate. An alternate member replacing a chair does not serve out the term as chair unless designated by the Regional Councilor or the RRB as described in 2A. Each Review Board should have an alternate chair to break a tie in the event that the case was submitted by the chair's center and no majority resolution is possible; it is recommended that immediate past Review Board chair serve as the alternate chair.

- C. If a member center withdraws or inactivates its liver program, it is no longer entitled to representation on the regional review board. The term of the member center's representative on the review board ends upon withdrawal or inactivation. Should a program reactivate, the member center shall again have representation on the regional review board.
- D. Each review board Chair shall be an active liver transplant practitioner but may not be required to represent his/her center as a review board member.

3. Responsibilities of the Review Board Members

- A. Vote, within 72 hours, on all MELD/PELD exception applications and Status 1A and 1B cases not meeting standard criteria. For MELD/PELD exception applications, if a majority vote has not been reached by the RRB within 21 days, the patient candidate's transplant physician may choose to withdraw the application; otherwise, the patient candidate will be assigned the most recently requested MELD/PELD score and the case will be referred to the Liver and Intestinal Organ Transplantation Committee. During this 21-day period, the center may opt to appeal a case that has been denied or found to be indeterminate (tied) by the RRB. The appeal must be submitted within 3 days of a denial and the RRB will have 10 days to make a decision on the appeal. For Status 1A and 1B cases not meeting standard criteria, if a case is not approved majority vote is not reached by the RRB within 21 days, and the case resulted in a transplant, the case will be referred to the Liver and Intestinal Organ Transplantation Committee.
- B. Vote within 72 hours on all appeal cases. Appeals of RRB decisions will be submitted to the RRB for review ~~both electronically (MELD/PELD) within 21 day timeframe.~~ Refer to Section 4.B. for more information on the Appeal Process for MELD/PELD Exceptions."
- C. Prompt appointment of alternates. If an RRB member is unavailable at any time to review the ~~exceptional~~ case applications, an alternate reviewer at their program should be designated and the appropriate arrangements within their office and with the UNOS office should be made to provide this individual with appropriate UNetSM site privileges.

UNOS staff will contact any members who have not voted on a case within 7 days of submission to the Review Board and notify the chair so that he/she may also contact the member. If the member is unavailable then UNOS staff will contact the alternate and notify the chair. If no alternate is available then the chair may be asked by UNOS staff to vote in order to close the case.

If a review board member:

- does not vote on a case in which the outcome is “failed to reach majority vote within 21 days;”
- on three separate instances within a 3 month period; and,
- has failed to give prior notification of his/her unavailability,
- the Chair has the authority to replace the non-responding member with an alternate.

If a center has a pattern of non-response as evidenced by the removal of two or more members from the review board, the chair may suspend the center’s participation for a period of three months after notifying the program director. Further non-compliance with the review board process may result in cessation of the center’s representation on the Review Board until such a time as the non-responding member center can satisfactorily assure the Chair of its willingness to participate in the system. The center may also be referred to the Liver and Intestinal Organ Transplantation Committee.

D. All Review Board members and alternates will be required to sign a UNOS Confidentiality/Conflict of Interest Statement prior to service on the RRB.

4. Voting Procedures

A. Initial Review of MELD/PELD Exceptions

As part of the MELD/PELD Exception program in UNetSM, RRB members will be notified of new cases via electronic mail. Thus, RRB members must notify UNOS staff if they will not be available by e-mail for any reason (e.g., vacation) or if their e-mail address changes. Furthermore, all RRB members must have UNetSM access in order to fulfill their role on the RRB.

In order to access cases to be reviewed, click on the link in the e-mail that is sent to the member or go to <https://www.unet.unos.org/>, log in using the member’s UNetSM username and password, and click on "Waitlist" and "RRB" in order to access the regional review board area.

Voting on an exception request is closed when no additional votes will change the outcome of the vote. Potential voting outcomes are appropriate, not appropriate, or indeterminate (tie) votes.

The chair will have the option to break a tie vote either positively - in which case the requested score is granted - or negatively - in which case the listing program may appeal. Once voting has closed on a case, the member will no longer have the ability to vote on that case (the vote "button" is no longer operational).

In cases in which neither the regular board member nor the alternate can be reached for 72 hours, the chair will also be allowed to make the final decision on the outcome of a case as long as the chair is from a different institution than the requesting center and is non-voting.

Requested MELD/PELD exception scores are not granted until the review board approves the request (except for HCC exceptional cases as specified under Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)), so a timely response is critical. If a representative does not expect to be able to access cases and conduct reviews for any period exceeding 72 hours, RRB members must arrange for an alternate for their program.

B. Appeal Process for MELD/PELD Exceptions

Member centers supporting the application of candidates whose listing or status upgrade is deemed inappropriate by the process described above may then appeal the decision of the review board. The appeal must be submitted within 3 days of the denial. Additional information supporting the member request on behalf of the candidate and responding to the comments of dissenting reviewers will be submitted to the Review Board members for further consideration. The RRB will then have 10 days to vote on the appeal. All reviewer comments will be made available in UNetSM. If the appeal is not approved, ~~at the request of~~ the member center may request a telephone conference ~~may~~ be arranged between the board and a practitioner at the listing center serving as the candidate's advocate as soon as possible. The chair should work with UNOS staff to ensure that any decision of the RRB rendered during a conference call is captured in UNetSM and accurately reflect the comments of the reviewers who participated on the call; the conference call will be tape-recorded and archived at UNOS.

~~MELD/PELD exception application appeals may be submitted an indefinite number of times as long as the appeal is submitted within 21 days of the original submission date of the initial request.~~

If a pediatric case is appealed, pediatric representation is required on the conference call. If no pediatric surgeon or physician is eligible to vote on the case in the Region, one may be selected from another region to assist in the RRB's deliberation in a non-voting capacity at the request of the Review Board chair.

~~Status 1 listings not meeting the criteria in Policy 3.6 will be referred to the Liver and Intestinal Organ Transplantation Committee.~~

For MELD/PELD cases, the listing center may initiate a final appeal to the Liver and Intestinal Organ Transplantation Committee or the RRB may refer a case to the Liver and Intestinal Organ Transplantation Committee if the final outcome of the regional appeal is negative or split without a way to achieve a decisive vote (indeterminate outcome). The RRB may also refer a case to the Liver and Intestinal Organ Transplantation Committee if the listing center does not respond to requests for a statement of intent to appeal, or to subsequent requests to submit additional information in support of the appeal. Referral of cases to the Liver and Intestinal Organ Transplantation Committee will include information about the number of previous case referrals from that center and the outcome of those referrals. Based on the finding of this review, the Liver and Intestinal Organ Transplantation Committee may refer the center to the Membership and Professional Standards Committee for disciplinary action. The Membership and Professional Standards Committee will have the option of determining that no action is required.

Individual ~~patients~~ candidates are not eligible to appeal board rulings. Listing centers will submit applications and appeals on behalf of their candidates.

C. Initial Review of Status 1A and 1B Cases that Do Not Meet Criteria

The RRB’s review of Status 1A /1B cases that do not meet criteria will be conducted electronically through UNetSM, similar to the manner in which the RRB currently reviews MELD/PELD cases. Additional information regarding how to access and vote on cases will be provided to RRB members when programming has been completed and implementation occurs.

- If the RRB determines a Status 1A or 1B listing is not appropriate, the candidate will not be automatically downgraded by UNetSM.
- If a case is submitted after normal business hours, the case will be submitted to the RRB on the next business day; this is congruent with the processing of MELD/PELD cases.
- The RRB will review all Status 1A/1B listings that do not meet criteria, this includes the initial listing and all extension listings submitted for each candidate.
- If an extension listing is submitted before the RRB has reached a decision on the initial listing, the RRB’s review of the initial listing will cease. Both listings will be joined together as one case and submitted to the RRB for review; the narrative information supplied by the center for each listing will be available for the RRB’s review. The RRB’s decision on this case, which will include narrative information from the initial listing and the extension listing, will apply to both listings. This process will continue for every subsequent extension listing that is submitted before the RRB has reached a decision on the preceding listing. If the RRB has reached a decision on the initial or preceding listing prior to the submission of an extension listing, then the RRB’s review of the extension listing will only pertain to the extension listing.

Other Potential Conditions not Addressed by MELD/PELD

For candidates with other conditions not addressed by the MELD/PELD scores, centers will have the opportunity to prospectively request increased MELD/PELD scores.

Each request must include the desired MELD/PELD score as well as a short narrative specifying the diagnosis and justifying the rationale for awarding additional MELD/PELD points for review by the RRB. These requests will be reviewed in UNetSM and RRB members will be notified of new cases via electronic mail *prior* to the candidate receiving the requested increased score.

To read the Liver RRB Guidelines visit UNetSM at <https://www.unet.unos.org>, select Regional Review Board, then select Liver RRB Operational Guidelines under the RRB Help Documentation section.

Notice of Policy Change — Modifications to Policy 3.6.6 (Liver and Intestinal Organ Transplantation Committee)

Affected Policy Language:

- 3.6.6 Removal of Liver Transplant Candidates from Liver Waiting Lists When Transplanted or Deceased.** If a liver 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 liver waiting lists and shall notify the contractor within 24 hours of the event. If the deceased or living donor liver recipient is again added to a liver waiting list, waiting time shall begin as of the date and time the candidate is relisted. ~~If a liver transplant candidate on the Waiting List has received a transplant from a living donor, the listing center, or centers if the candidate is multiple listed, shall immediately transfer that candidate to inactive status until the candidate requires a subsequent transplant or one year following the date of the candidate's prior transplant, whichever is the first to occur. If the candidate has not returned to active status during this one year period, then the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all liver waiting lists and shall notify the contractor within 24 hours of the event.~~ Data necessary to calculate the candidate's current MELD or PELD score is required upon removal from the waiting list.

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.

Resource Document for Informed Consent of Living Donors

Purpose

The OPTN/UNOS Living Donor Committee developed this resource document to help transplant professionals obtain the informed consent of all living donors.

Introduction

Education is important in the consent process for any potential living donor. The potential donor must understand all aspects of the donation process and understand the risk and benefit associated with being a living donor as well as center-specific risk factors. Above all else, the potential donor must understand that the donor can stop the evaluation or donation process at any time.

Living Donor Consent

The consent process for any potential living donor should include, but is not limited to:

- a. The assurance that the potential donor is willing to donate, free from inducement and coercion, and understands that he or she may decline to donate at any time.
- b. A psychosocial evaluation of the potential donor completed by someone with mental health training which could include, for example, a licensed clinical social worker, nurse specialist, psychologist, or psychiatrist.
- c. Disclosure of alternate procedures or courses of treatment for the potential donor and recipient, including deceased donation. All potential donors should be informed if the intended recipient has or has not been listed for deceased donation. Pre-existing, life threatening conditions of the potential recipient should be disclosed to the potential donor prior to obtaining consent.
- d. An evaluation of the potential donor's ability to comprehend the donation process, including procedures employed for both donor and recipient and possible outcomes.
- e. Providing printed materials that explain all phases of the living donation process. Materials should be written at an appropriate reading level and provided in the potential donor's native language. When necessary, independent interpreters should be provided to make certain the potential donor comprehends all phases of living donation and its associated risks and benefits.
- f. Ensure that the potential donor has time to reflect after consenting to donate.
- g. Offer any potential donor a general, nonspecific statement of unsuitability for donation should they wish not to proceed with donation.
- h. Explain that a decision by the potential donor not to proceed with the donation will only be disclosed after obtaining the consent of the potential donor.
- i. An understanding that the donor undertakes risk and receives no medical benefit from the operative procedure of donation.

- j. A specification of the medical, psychological, and financial risks associated with being a living donor, to include, but not be limited to the following:
- i. Potential Medical Risks
 - potential for surgical complications including risk of donor death
 - potential for organ failure and the need for a future organ transplant for the donor
 - potential for other medical complications including long- term complications currently unforeseen
 - scars
 - pain
 - fatigue
 - abdominal or bowel symptoms such as bloating and nausea
 - increased risk with the use of over the counter medications and supplements
 - ii. Potential Psychosocial Risks
 - potential for problems with body image
 - possibility of post surgery adjustment problems
 - possibility of transplant recipient rejection and need for re-transplantation
 - possibility that the transplant recipient will have a recurrence of disease
 - possibility of transplant recipient death
 - potential impact of donation on the donor's lifestyle
 - iii. Potential Financial Risks
 - personal expenses of travel, housing, and lost wages related to live donation might not be reimbursed; however, the potential donor should be informed that resources may be available to defray some donation-related costs
 - child care costs
 - possible loss of employment
 - potential impact on the ability to obtain future employment
 - potential impact on the ability to obtain or afford health, disability, and life insurance
 - health problems experienced by living donors following donation may not be covered by the recipient's insurance
- k. Disclose that transplant centers are required to report living donor follow-up information for at least two years

- l. Centers will specify who is responsible for the cost of follow-up care
- m. The agreement of the potential donor to commit to postoperative follow-up testing coordinated by the recipient transplant center for a minimum of two years
- n. Disclosure that donors may not receive valuable consideration (including without limitation monetary or material gain) for agreeing to be a donor. In certain cases, donors may be reimbursed for limited travel expenses and may receive subsistence assistance.
- o. Disclosure that living donor follow-up is the only method for the collections of information on the long-term health implications of living donation.
- p. The stipulation that transplant centers will provide potential donors with both national and their center-specific outcomes from the most recent SRTR center-specific report. This information should include, but not be limited to, 1-year patient and graft survival, National 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center.

Notice of Policy Change — Modifications to Policy 3.3.3 (Renal Acceptance Criteria) (Operations Committee)

Affected Policy Language:

3.3.3 Renal Acceptance Criteria. All renal transplant programs~~centers~~ must ~~inform the Organ Center~~ submit their minimum renal acceptance criteria annually through UNetsm defining which import deceased donor kidneys will be offered to the program from non-local OPO~~s of the criteria according to which they will accept deceased kidneys allocated through the Organ Center.~~ The renal transplant program~~Organ Center~~ will not subsequently be offered import offer to that transplant center deceased kidneys that fail to meet the program's~~center's~~ acceptance criteria. The renal acceptance criteria will not apply to import zero antigen mismatched kidney offers.

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.

Notice of Policy Change — Modifications to Policy 3.5.3.5 (Time Limit) (Operations Committee)

Affected Policy Language:

~~3.5.3.5 Organ Offer Time 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 candidates, or all candidates if fewer than 10 appear on the match list. For extended criteria donor (ECD) kidneys, offers must be made for at least 5 candidates, or all candidates if fewer than 5 appear 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 Organ Center will attempt to place standard donor organ(s) for zero antigen mismatched candidates according to the national lists of candidates waiting for combined kidney/pancreas or isolated kidney transplantation, as applicable, for a period of four hours (starting from the time the Organ Center makes the first offer) after which time the Organ Center will notify the Host OPO that it may 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 (first locally, then regionally, and then nationally). The period of time allowed for acceptance of zero antigen mismatched standard kidney offers made within the four hours permitted for placing these organs, but with less than an hour before the four hours will expire, shall equal the time remaining within the four hour period for placement of standard zero mismatched donor kidneys. In the event the Host OPO declines the opportunity to allocate standard donor organ(s) locally, then the Organ Center shall continue to attempt to place the organ(s) for zero antigen mismatched candidates according to the national lists of waiting candidates. Acceptance of organs declined by the Host OPO will not generate an obligation to pay back the kidney pursuant to Policy 3.5.5 (Payback Requirements) even if accepted for a zero antigen mismatched candidate. The Organ Center will attempt to place expanded criteria donor organ(s) for zero antigen mismatched candidates according to the national lists of candidates waiting for expanded criteria donor kidney transplantation for a period of two hours (starting from the time the Organ Center makes the first offer) after which time the Organ Center will notify the Host OPO that it may~~

~~allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 (first locally, then regionally, and then nationally) for candidates designated as eligible to receive expanded criteria donor kidneys. The period of time allowed for acceptance of zero antigen mismatched expanded criteria donor kidney offers made within the two hours permitted for placing these organs, but with less than an hour before the two hours will expire, shall equal the time remaining within the two-hour period for placement of expanded criteria zero mismatched donor kidneys. Time available for organ acceptance, if shorter than one hour, shall be communicated with the organ offer. The Organ Center will document each offer and each response. If the Host OPO chooses to share the zero antigen mismatch through UNetsm, it must contact the Organ Center within 24 hours to report the sharing. A payback credit will not be assigned until the Host OPO contacts the Organ Center and the zero antigen mismatch share can be verified in UNetsm.~~

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.