

At-a-Glance

- **Proposal to improve the safety of living donation by restricting the acceptance and transplant of living donor organs to OPTN member institutions.**
- **Policy affected: add OPTN Policy 3.3.7 (Center Acceptance of Organs from Living Donors)**
- **Living Donor Committee**
- This proposal would require OPTN member transplant programs that perform living donor transplants to only transplant organs recovered at an OPTN member institution.
- **Affected groups**

OPO Executive Directors, Transplant Administrators, Transplant Coordinators, Transplant Physicians and Surgeons, Transplant Program Directors, Transplant Recipients, Transplant Candidates, Living Donors, and Donor Family Members.

Proposal to improve the safety of living donation by restricting the acceptance and transplant of living donor organs to OPTN member institutions.

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Living Donor Committee

Summary and Goals of the Proposal:

Living donation is unique in its potential for both harm and benefit to the volunteer donor. For this reason, the OPTN is committed to developing and maintaining system-wide standards that provide the best possible care and the least potential harm for living donors. Living donors recovered at non-OPTN member facilities may not be afforded the same protections provided at OPTN member institutions. Consequently, the Committee proposes that living donor organs must be recovered at OPTN member institutions.

Background and Significance of the Proposal:

In a statement published in the Federal Register on June 16, 2006, HRSA determined that OPTN policies addressing issues of donor safety and equitable allocation of living donor organs will have the same enforceability as deceased donor policies under the OPTN Final Rule. The Federal Register notice expresses that the emphasis of living donor guidelines and policies, should be “to promote the safety and efficacy of living donor transplantation for the donor and recipient.”

The bylaws establish membership criteria for deceased donor transplantation programs as well as for transplant programs that perform living donor transplants. These bylaws help standardize quality level among transplant programs. In September 2007, the OPTN/ UNOS Board approved new bylaws for member transplant centers that operate kidney and/or liver programs involving living donor transplants.

Under existing bylaws¹, transplant centers:

- must develop, and once developed must comply with written protocols to address all phases of the living donation process.
- must document that they performed all phases of the living donation process according to the center’s protocol.
- must provide an Independent Donor Advocate who is responsible to:
 - (a) promote the best interests of the potential living donor;
 - (b) advocate the rights of the potential living donor; and
 - (c) assist 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.
- 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
 - (a) 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;
 - (b) 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;
 - (c) screening for evidence of transmissible diseases such as cancers and infections; and
 - (d) anatomic assessment of the suitability of the organ for transplant purposes.
- must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process, which include, at a minimum, the following elements:
 - (a) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;
 - (b) assurance that all communication between the potential donor and the transplant center will remain confidential;
 - (c) discussion of the potential donor's right to opt out at any time during the donation process;
 - (d) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance

Committee members reviewed Living Donor Registration (LDR) forms and noted that 22 living donors donated their organ at non-OPTN member hospitals during the last five years. The Committee was very concerned that these donors would not be afforded the same protections provided at OPTN member institutions. In response, the Committee proposes that living donors' organs only be recovered within OPTN member institutions.

The Committee realizes that potential living donors might want to specify that their organ donation occur at a non-OPTN member institution. However, the Committee, with a membership of 1/3 living donors, feels strongly that living organ donation should only occur at OPTN member institutions in order to best protect living donors. The Committee questioned what would occur if a living donor experienced complications or died after donating their organ at a non-OPTN member institution. In this scenario, UNOS would not be able to investigate the circumstances contributing to this adverse donor outcome.

The Committee supported the possible development of a new OPTN/UNOS membership category for institutions for institutions wanting only to perform living donor organ recoveries, if those institutions were subject to OPTN/UNOS bylaws and policies for the care, evaluation, and follow-up of living donors.

¹Appendix B, Attachment I, Section XIII, D (2) and (4), Designated Transplant Program Criteria

Supporting Evidence and/or Modeling:

As noted above, a recent review of Living Donor Registration (LDR) forms revealed that 22 living donors donated their organ at a non-OPTN member hospital during the past five years. Non-OPTN/UNOS facilities are not subject to the membership criteria required of OPTN member transplant programs that perform living donor transplants. Consequently, any future living donor who donates an organ at a non-OPTN member hospital would not be guaranteed the same protection mandated in the OPTN/UNOS Policies and Bylaws

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

The proposal contributes to a strategic plan goal. Limiting living donor organ recovery to OPTN member institutions helps protect living donors by attempting to ensure that those donors are consented, evaluated and receive follow-up as specified in the bylaws.

Plan for Evaluating the Proposal:

The Committee will ask the UNOS Help Desk to report any complaints or problems concerning the policy. The Committee reviews the number of living donor transplants annually, and may be able to determine if the policy has had any negative impact on donation.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

Policy implementation is not dependent on programming in UNetsm. When possible the “ZZZZ-TX1” code that is used to designate a non-member recovery center will be removed from the LDR form.

Communication and Education Plan:

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
Policy Notice (summary of all policy changes approved by the board in a PDF format)	Transplant Hospitals	Electronic (email sent from the UNOS Communications mailbox)	30 days after the board approves the change.

Monitoring and Evaluation:

Transplant centers will be expected to comply with this policy. The UNOS Department of Evaluation and Quality (DEQ) staff will evaluate member compliance with this policy.

Transplant centers are expected to:

- Accept and transplant living donor organs only when the organs were recovered at OPTN Member Institutions
- Accurately indicate the recovery facility on the Living Donor Registration Form
- Maintain documentation to support information submitted to Tiedi® about the living donor
- Present documentation to UNOS staff upon request

The Department of Evaluation and Quality (DEQ) staff may detect potential violations of this proposed policy by:

- researching confidential reports of complaints received through the OPTN Member Reporting Line or Patient Services Line;
- reviewing living donor records during site surveys of transplant centers with approved living donor programs;
- reviewing OPTN data; or
- receiving referrals from OPTN/UNOS Committees, OPTN/UNOS Staff, or OPTN/UNOS Members.

DEQ staff will explore all potential policy violations and forward any results to the OPTN/UNOS Membership and Professional Standards Committee for confidential medical peer review.

Policy Proposal:

3.3 ACCEPTANCE CRITERIA. The following policies apply to donor and organ acceptance criteria:

3.3.1 No Changes

3.3.2 No Changes

3.3.3. No Changes

3.3.4 No Changes

3.3.5 No Changes

3.3.6 No Changes

3.3.7 Center Acceptance and Transplant of Organs from Living Donors. Transplant centers that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member institutions.