

**Modifications to OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII, C (2) and
(4), Designated Transplant Program Criteria**

The proposed modifications to the Bylaws that were 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 D) 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.