

**Selected Recommendations of the
OPTN/UNOS Living Donor Committee to the
Board of Directors
June 22-23, 2009
Richmond, VA**

Summary

I. Action Items for Board Consideration

- The Board of Directors is asked to approve the relocation of existing living donation policies into a new separate policy section (12.0) specific to living donation. (Item 1, Page 3)
- The Board of Directors is asked to approve modifications to Policy 4.4.1 (Communication of Donor History). The proposed change would provide potential living donors with the ability to discontinue the donation process rather than have their high risk status disclosed to a potential recipient or transplant center. (Item 2, Page 10)
- The Board of Directors is asked to approve updates to a resource titled “Guidance for the Informed Consent of Living Donors.” (Item 3, Page 12)
- The Board of Directors is asked to approve a patient resource titled “Guidance for Potential Living Kidney Donors.” (Item 4, Page 18)

II. Other Significant Items

- None

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**Matthew Cooper, MD., Chair
Connie Davis, MD., Vice-Chair**

The following report represents the selected recommendation of the Living Donor Committee to the Board of Directors.

1. Proposal to Relocate Existing Living Donation Policies into a New Separate Policy Section (12.0) Specific to Living Donation.

On June 16, 2006, HRSA published a notice in the Federal Register in which the Secretary of HHS directed the OPTN to develop policies regarding living organ donors and organ donor recipients. The notice said that the consequence of centers not complying with living donor policy matches that of centers not complying with deceased donation policy, and 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.”

After publication of that notice, the Living Donor (LD) Committee began to consider potential new living donor policies. The LD Committee quickly learned that developing living donor policies to fit within the existing framework of OPTN/UNOS policies, which primarily address deceased organ donation, was problematic.

For example, the LD Committee was made aware of a living donor transplant in which a living donor kidney was transplanted into an ABO incompatible recipient in June 2008. After considering this case, and reviewing existing OPTN/UNOS policies, the LD Committee realized that existing policies for ABO verification are more stringent for deceased donors than for living donors. Current policies require deceased donors and candidates of deceased organs to be ABO tested twice (Policy 3.1.4.2 and 3.2.4); however, no similar policy for living donors exists. In response, the LD Committee began work on a policy proposal to improve the ABO verification process in living donation. Once again, the Committee was faced with the problem trying to modify an existing deceased donor policy to make it applicable for living donors. This case and other similar living donor policy issues previously considered by the Committee, demonstrated the need for a separate category of policies specific to living donation. During its October 6, 2008, the LD Committee voted to support the establishment of a separate policy section specific to living donation. Committee vote: 24-0-0.

Currently, policies addressing living donation are interspersed throughout existing OPTN/UNOS policies. The majority of those existing policies are intended to address the procurement, allocation, and distribution of organs from deceased donors. To better serve all stakeholders involved in living

donor transplantation, there is need for a dedicated section of policy that addresses the unique circumstances of living donation. Providing a separate policy section specific to living donor transplantation should reduce confusion over which policies apply to living donors.

Over the past months, steps have taken steps to build consensus regarding the need for a separate living donor policy section with stakeholders involved in living donor transplantation. As a first step, the LD Committee asked two other Committees to provide early comment on the plan for a separate policy section addressing living donation. The Operations and Transplant Administrators Committees both supported establishing a separate category for living donor policies.

To garner consensus among professional organizations, the LD Committee contacted the leadership of the American Society of Transplant Surgeons (ASTS), the American Society of Transplantation (AST), the Association of Organ Procurement Organization (AOPO), the American Society for Histocompatibility and Immunogenetics (ASHI), the North American Transplant Coordinators Organization (NATCO) and the National Kidney Foundation (NKF) to advise each group of the plan for a new and separate section of living donor policies. Additionally each organization was asked to review drafts of the proposed new living donation policy section and to comment on the need and benefit of a separate section for living donor policies, and to confirm that the intent of existing living donor policies were not changed during the relocation to the proposed new policy section.

Before the Board meeting, the LD Committee plans to contact all Regional Councilors and public members of the Board to advise them that the Board will be asked to approve a new separate section of living donor policies at the upcoming meeting. Each of these Board members will receive drafts of the proposed new policy section and with the name of a representative of the Living Donor Committee they can contact for more information or to raise questions or concerns.

All organizations and individuals notified about this plan have received or will receive two different drafts of the proposed new policy section. The first draft will contain underlining and strikeouts to indicate where language was added or deleted while relocating the existing policies to the proposed new policy section. New language added to the policy section included an introduction to explain the living donation process and the policy's purpose. Language removed or changed in the proposed new policy section included removing all references to deceased donors, updating the policies to use the term "living donor" instead of "live donor" and removing all references to the "Host OPO" since those organization are seldom involved in living donation. The second draft reflecting the anticipated final language of the proposed section, without strikeouts and underling, will be provided for readability. **(Exhibit A)** Both drafts include references to the location of the each policy in the current policy framework, however, these references will be removed before these policies are permanently relocated to Section 12.0.

Through these consensus building activities, the LD Committee hopes to gain wide-spread support for a separate living donation policy section before this plan is presented to the Board of Directors in June, 2009.

The proposed relocation of these policies is not intended to change the intent of any policy. To clarify, the Board will be asked to approve the relocation of existing living donor policies into a

separate policy section. This will not be an opportunity for the Board to comment on the content of existing living donor policies.

The LD Committee believes that this change will lead to a number of benefits including more efficient policy development going forward. With a logical framework in place, living donor policy development can focus on improving living donor safety and will not be forced to tailor living donor policies to fit within existing deceased donor policies.

In addition, this change may result in a better understanding of the requirements for living donation by the transplant community. Greater understanding may translate into improved donor safety, more equitable distribution of non-directed organs, and improved follow-up of living donors.

If ultimately approved, this change will make living donor policies more transparent for potential and actual living donors, as well as transplant candidates, and may lead to more informed decision making before, during, and after donation.

At its May 18, 2009, meeting, the Committee reviewed responses from the ASTS, AST and AOPO which supported the development of a separate living donation policy section and which confirmed that the intent of existing living donor policies were not changed during their relocation to the proposed new policy section. During this meeting, a Health Resources and Services Administration (HRSA) representative raised concerns over referencing Bylaws within the proposed new policy section. In response the Committee requested that UNOS staff revise the proposed policy section to address these concerns, and that the Committee Chair approve the revised final version to be considered by the Board. Committee vote: 22-0-0

The following proposal is recommended for consideration by the Board.

**** RESOLVED, that a new Policy 12.0 (Living Donation), set forth below, is hereby approved, effective pending distribution of notice.**

12.0 Living Donation

The following policies apply to the entire continuum of organ donation from living donors. The process of living donation begins at the time that an individual considers donating an organ, continues through the evaluation of the donor, placement of the organ (whether directed or nondirected), recovery of the organ, and post-donation care and follow-up of the donor.

The following policies, along with related Bylaws, apply to member institutions involved in living donation. These policies do not supplant medical judgment or decision-making by transplant professionals or potential or realized living donors.

12.1 Definitions

--Under Development--

12.2 Informed Consent of Living Donors

--Under Development--

12.3 Medical Evaluation of Living Donors

--Under Development--

12.4 Independent Donor Advocates

--Under Development--

12.5 Placement of Living Donor Organs

12.5.1 Kidney Placement.

~~3.5.17~~ **12.5.1.1 Prospective Crossmatching.** A prospective crossmatch is mandatory for all ~~candidates~~ potential living donor recipients, ~~except where clinical circumstances support its omission. The transplant program and its histocompatibility laboratory must have a joint written policy that states when the prospective crossmatch may be omitted.~~ Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D to Policy 3. (Corresponds with OPTN/UNOS Policy 3.5.17—“Prospective Crossmatching”)

12.5.2 Liver Placement.

--Under Development--

12.5.3 Thoracic Placement.

--Under Development--

12.5.4 Pancreas Placement.

--Under Development--

12.5.5 Intestinal Placement.

--Under Development--

~~3.3.7~~ **12.6 Center Acceptance and Transplant of Organs from Living Donors. Acceptance of Living Donor Organs.** Transplant Centers that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member transplant hospitals. (Corresponds with OPTN/UNOS Policy 3.3.7- Center Acceptance and Transplant of Organs from Living Donors)

~~5.0~~ **12.7 STANDARDIZED PACKAGING AND TRANSPORTING OF ORGANS AND TISSUE TYPING MATERIALS Responsibility for Transport of Living Donor Organs.** The following policies address standardized packaging of ~~live and deceased~~ living donor organs and tissue typing materials to be transported for the purposes of organ transplantation. When an ~~deceased donor~~ organ from a living donor is procured, the ~~Host OPO~~ Transplant Center shall be responsible for ensuring the accuracy of the donor's ABO on the container label and within the donor's documentation. ~~Each OPO~~ The Transplant Center shall establish and implement a procedure for obtaining verification of donor ABO data by an

individual other than the person initially performing the labeling and documentation requirements put forth in Policy 5.2 and 5.3. The ~~OPO~~ Transplant Center shall maintain documentation that such separate verification has taken place and make such documentation available for audit. (Corresponds with OPTN/UNOS Policy 5.0—“Standardized Packaging and Transporting of Organs and Tissue Typing Materials”)

Upon receipt of an ~~live or deceased donor~~ organ from a living donor and prior to implantation, the Transplant Center shall be responsible for determining the accuracy and compatibility of the donor and recipient ABO and document this verification in compliance with Policy 3.1.2.

5.2 12.7.1 Standard Labeling Specifications. The ~~Host OPO or the~~ Transplant Center shall be responsible for ensuring that the outermost surface of the transport box containing organs and/or tissue typing specimen containers must have a completed standardized external organ container label (provided by the OPTN contractor). Any previous labels on the transport container must be removed prior to labeling the box so that only one label exists. The ~~OPO~~ transplant center shall label each specimen within the package in accordance with policy. The ~~Host OPO~~ transplant center is responsible for ensuring that each tissue or donor organ container that travels outside the recovery facility is labeled appropriately. (Corresponds with OPTN/UNOS Policy 5.2—“Standard Labeling Specifications”)

In the case of ~~deceased or live donor~~ organs from living donors that ~~who~~ remain in the same operating room suite as the intended candidate(s), the ~~Host OPO (if applicable)~~ and Transplant Center must develop, implement, and comply with a procedure to ensure identification of the correct donor organ for the correct recipient. The Transplant Center must document that the correct organ was identified for the correct candidate prior to transplant. Some type of donor organ labeling and documentation must be present in the candidate chart. A “time out” prior to leaving the donor operating room and an additional “time out” upon arrival in the candidate operating room is recommended. Exception: In the case of a single donor organ/organ segment remaining in the same operating room suite as a single intended candidate for a simultaneous transplant, donor organ labeling and “time outs” are not necessary.

In the case of ~~live donor~~ organs from living donors that travel outside the recovery facility, the Transplant Center(s) involved shall be responsible for ensuring that packaging is consistent with the requirements of OPTN Policies 5.2.1 and 5.2.3, and that the outermost surface of the transport box containing the organ must have a completed OPTN/UNOS standardized external organ container label (provided by OPTN Contractor). The recovering Transplant Center shall label each specimen within the package in accordance with OPTN/UNOS policy. The recovering Transplant Center is responsible for ensuring that each container that travels outside the recovery facility is labeled appropriately.

5.2.1 12.7.2 The ~~Host OPO or the~~ Transplant Center, ~~as applicable~~ is responsible for ensuring that the Donor I.D., Donor ABO type, and a secure label identifying the specific contents (e.g., liver segment, right kidney, ~~heart~~) are attached to the outer bag or rigid container housing the donor organ prior to transport. (Corresponds with OPTN/UNOS Policy 5.2.1)

~~5.2.2~~ **12.7.3** Each separate specimen container of tissue typing material must have a secure label with the Donor I.D., Donor ABO type, date and time the sample was procured and the type of tissue. The ~~Host OPO or the~~ Transplant Center, ~~as applicable~~ is responsible for labeling the materials appropriately. (Corresponds with OPTN/UNOS Policy 5.2.2)

~~5.2.3~~ **12.7.4** The ~~Host OPO or the~~ Transplant Center, ~~as applicable~~ is responsible for fixing to the transport container the standardized label completed with the Donor I.D., Donor ABO type, a description of the specific contents of the box, the sender's name and telephone number, and the Organ Center telephone number. A transport container is defined as a corrugated, wax coated disposable box, cooler, or mechanical preservation cassette or machine. (Corresponds with OPTN/UNOS Policy 5.2.3)

~~5.3~~ **12.7.5 Packaging.** ABO results must be provided by the ~~Host OPO or the~~ Transplant Center, ~~as applicable~~ in all circumstances during which a donor organ is transported. Properly packaged paperwork containing complete donor information, as described in Policy 2.5.7.1, will be included with the organ transport container in all instances in which the organ is transported. (Corresponds with OPTN/UNOS Policy 5.3—"Documentation")

~~5.4~~ **12.7.6 Packaging.** In all circumstances during which a donor organ is transported outside the recovery facility, the ~~Host OPO or the~~ Transplant Center, ~~as applicable~~ is responsible for packaging, labeling, and handling the organ in a manner which ensures arrival without compromise to the organ(s). Proper insulation and temperature controlled packaging including adequate ice or refrigeration shall be used to protect the organs during transport. All packaged organs, using disposable transport boxes, must have a red plastic bio-hazard bag that is water tight secured to allow for safe handling by medical and non-medical personnel during transport. This red bag may be placed between the waxed cardboard box and the insulated material holding the wet ice and the organ. All organs that have been packaged on the donor's back table must be handled using universal precautions. The packaged organs from the donor's surgical back table are to be placed directly into the wet iced shipping container. (Corresponds with OPTN/UNOS Policy 5.4—"Packaging")

12.8 Reporting Requirements.

~~7.5.1~~ **12.8.1** ~~Information pertaining to deceased donor feedback must be submitted to the OPTN within five working days of the procurement date.~~ All living donors must be registered with the OPTN Contractor via the living donor feedback form prior to surgery. (Corresponds with OPTN/UNOS Policy 7.5.1)

~~7.1.5~~ **12.8.2** The follow-up period for living donors will be a minimum of two years. (Corresponds with OPTN/UNOS Policy 7.1.5)

~~7.3.2~~ **12.8.3** Living Donor Registration Forms (LDR) must be submitted to the OPTN within 60 days of the form generation date. Recipient transplant centers must complete the LDR form when the donor is discharged from the hospital or by six weeks following the transplant date, whichever is first. The recipient transplant center must submit LDF forms for each living donor at six months, one year and two years from the date of donation. (Corresponds with OPTN/UNOS Policy 7.3.2)

12.8.4 Submission of Living Donor Death and Organ Failure Data. Transplant programs must report all instances of living donor deaths and failure of the living donor's native organ function within 72 hours after the program becomes aware of the living donor death or failure of the living donors' native organ function. Live donors' native organ failure is defined as listing for transplant for liver donors, and as transplant, listing for transplant or the need for dialysis in renal donors. Transplant centers must report these incidents through the UNetSM Patient Safety System for a period of two years from the date of the donation. The MPSC will review and report all adverse events to the Board. (Corresponds with OPTN/UNOS Policy 7.3.3—“Submission of Living Donor Death and Organ Failure Data”)

12.9 Long-term Care or Support of Living Donors.

12.9.1 Follow-up

--Under Development--

12.9.2 Insurance.

--Under Development--

3.5.11.6 12.9.3 ~~Donation Status.~~ **Priority on the Waitlist.** A candidate will be assigned 4 points if he or she has donated for transplantation within the United States his or her vital organ or a segment of a vital organ (i.e., kidney, liver segment, lung segment, partial pancreas, small bowel segment). To be assigned 4 points for donation status under Policy 3.5.11.6, the candidate's physician must provide the name of the recipient of the donated organ or organ segment, the recipient's transplant facility and the date of transplant of the donated organ or organ segment, in addition to all other candidate information required to be submitted under policy. Additionally, at the local level of organ distribution only, candidates assigned 4 points for donation status shall be given first priority for kidneys that are not shared mandatorily for 0 HLA mismatching, or for renal/non-renal organ allocation irrespective of the number of points assigned to the candidate relative to other candidates. When multiple transplant candidates assigned 4 points for donation status are eligible for organ offers under this policy, organs shall be allocated for these candidates according to length of time waiting. (Corresponds with OPTN/UNOS Policy 3.5.11.6—“Donation Status”)

3.5.5.2 12.9.4 **Exception for Prior Living Donor Organs.** Kidneys procured from standard criteria deceased donors shall be allocated locally first for prior living organ donors as defined in Policy 3.5.11.6 (Donation Status) before they are offered in satisfaction of kidney payback obligations. (Corresponds with OPTN/UNOS Policy 3.5.5.2—“Exception for Prior Living Organ Donors”)

2. **Proposal to Modify the High Risk Donor Policy to Protect the Confidential Health Information of Potential Living Donors** ((Policy 4.1.1 (Communication of Donor History))

In its current form, Policy 4.1.1 (Communication of Donor History) requires that potential organ recipients be informed if their donor has a high risk status. The proposed policy changes would provide the potential living donor with the ability to discontinue the donation process rather than have their high risk status disclosed to a potential recipient or transplant center. This proposed change is designed to protect the health information of potential living donors.

In June 2007, the Operations Committee requested public comment on proposed modifications to the Communication of Donor History Policy. Public comment was being requested on Organ Procurement Organization (OPO) and transplant center requirements for screening, communicating, and reporting all potential or confirmed donor-related disease and malignancy transmission events. This proposal was intended to reflect current clinical practices and to standardize reporting of donor-related disease transmission events, thus improving patient safety and recipient outcomes through timely communication of clinically significant information. The modified policy proposal was in response to recent occurrences of donor related infection and malignancy transmission that illustrated potential gaps in both the microbiologic screening of organ donors and the mechanisms to communicate and investigate transmission events associated with transplantation.

At that time, the Living Donor (LD) Committee supported the intent of the proposed changes and agreed that information on **deceased** donors with high risk behavior, or classified as high risk based on CDC criteria, should be communicated to all institutions receiving organs from the donor and to the potential organ recipient. However, during this same public comment period, some Committees and regions submitted comments questioning if the policy would also apply to living donors.

Since public comment demonstrated confusion about the intent of the policy, the LD Committee became concerned that the policy could be applied to living donors. Specifically, that a potential living donor might not be provided the opportunity to discontinue the donation process rather than have their high risk status disclosed to a potential recipient or recipient transplant center.

In response, the LD Committee commented that the policy proposal should be modified to clarify it did not apply to potential living donors. The concerns of the Committee were not addressed because the proposal was not considered by the Board after the conclusion of the June 2007 public comment period.

In December 2007, the Executive Committee approved policy language to require that transplant centers inform potential organ recipients about any known high risk behavior (as defined by CDC Guidelines) by the donor. The intent of this policy was to clarify the criteria for high risk behavior that requires transplant professionals to notify potential organ recipients prior to implantation. This policy was approved prior to public comment to address potential patient safety issues.

The Executive Committee did not modify the existing policy language following the conclusion of public comment. Consequently, the policy does not address concerns from the LD Committee because, in its final form, the policy did not specify it would not apply to potential living donors.

In response, the LD Committee proposed modifying the policy to provide potential living donor the option to discontinue the donation process rather than have their “high risk” donor status disclosed to the institution or recipient expected to receive his or her organ. The LD Committee approved sending a proposal for public comment. The proposal was released for public comment period between February 6 and April 24, 2009, and received strong support from all stakeholders. The Committee reviewed all public comment during a May 18, 2009 meeting, and in response recommended minor changes to the policy proposal. A summary of the public comment and Committee’s responses are included in the briefing paper. **(Exhibit B)**

In its current form, the policy may be applied to potential living donors. In response, the LD Committee is again seeking a modification for policy 4.1.1 to provide potential living donors an opportunity to discontinue the evaluation or donation process rather than have their health information disclosed to any other institution or potential recipient.

The following proposal is recommended for consideration by the Board. Committee vote: 22-0-0

**** RESOLVED that Policy 4.1.1 (Communication of Donor History), shall be modified as set forth below and implemented pending distribution of appropriate notice and programming, if applicable:**

4.1.1 Communication of Donor History. The Host OPO will obtain a history on each potential deceased donor in an attempt to determine whether the potential donor is in a "high risk" group, as defined by the Centers for Disease Control and Prevention (CDC). If the donor meets the criteria set forth in CDC Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs (CDC Guidelines),^[1] the Host OPO must communicate this information regarding donor history to all institutions receiving organs from the donor. In cases of living donation, the transplant center must offer the A potential living donor ~~must have~~ the option to discontinue the donation process rather than have their “high risk” status communicated to the institution intended to receive his or her organ.

If the transplant center receives information from the Host OPO that the deceased donor meets any of the criteria, the transplant center must inform the potential recipient prior to implantation. In cases of living donation, the transplant center must give a A potential living donor ~~must have~~ the option to discontinue the donation process rather than have their “high risk” status communicated to the intended recipient of his or her organ. The transplant center shall maintain documentation of the potential recipient’s informed consent to receive an organ from the donor who meets any of the criteria. In the event that the potential recipient is not able to provide informed consent, the legal next of kin, designated healthcare representative, or appropriate surrogate may provide consent on this matter.

3. **Guidance for the Informed Consent of Living Donors**

In January 2007, the OPTN/UNOS President sent a letter to all transplant programs that perform live donor transplants requesting copies of their informed consent, medical evaluation, and living donor follow-up protocols. The Living Donor (LD) Committee planned to use these protocols to make recommendations to the Board of Directors regarding new living donor policies and guidelines.

The LD Committee's evaluation of these protocols revealed wide variation in the consent process throughout the country. Some centers had no formalized guidelines for living donor consent. In an effort to provide Members with a shared knowledge base, the Living Donor Committee used the 80/20 rule in evaluating submitted protocols. If the majority (or 80%) of programs had a particular element as part of their standardized consent processes, the Committee included that element in the final recommendations. The Committee reviewed and incorporated recommendations from a variety of sources, including the Advisory Committee on Organ Transplantation (ACOT), Centers for Medicare and Medicaid Services (CMS), and the State of North Carolina living donor statutes in the development of these recommendations. Based on the information reviewed the Committee developed a set of recommendations for the informed consent of living donors.

These recommendations titled, "Guidance for the Informed Consent of Living Donors" were distributed for public comment. In September 2007, the OPTN/UNOS Board approved the resource, and instructed to Living Donor Committee to review and update the resource as necessary and on a regular basis. Since Board approval, this resource has been available through the UNOS and Transplant Living websites.

In November 2007, the OPTN/UNOS President requested that the resource be modified to include two additional elements:

- Disclose that the medical evaluation of the potential donors could reveal conditions that must be reported to governmental authorities; examples include HIV and some venereal diseases; and
- Explain that some medical information about the potential donor may need to be revealed to the intended recipient, and that some medical information on the intended recipient may need to be revealed to the potential donor, to enable each party to evaluate if they should donate or receive the organ.

As instructed by the Board, the LD Committee has completed a first review and update of this resource. During this review and update, the Committee focused on adding provisions to address the special circumstances of altruistic living donors and considered living donors who may wish to participate in Kidney Paired Donation. A version of this resource without underlining and strikeouts is provided for improved readability. **(Exhibit C)**

These voluntary recommendations are intended to help transplant program develop living donor evaluation protocols which consistently meet the needs and interests of potential living donors, and that reflect the consensus of expertise among medical professionals involved in living donor transplantation. The Committee recommends the following for consideration by the Board.
Committee Vote: 22-0-0

**** RESOLVED, that the “Recommendations for the Informed Consent of Living Donors are hereby approved, as set forth below:**

Guidance for the Informed Consent of Living Donors

Purpose

The OPTN/UNOS Living Donor Committee developed this resource ~~document~~ to help transplant professionals ~~obtain the informed~~ develop consent of processes for 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. Most living donors give their organ to a family member or acquaintance. However, some living donors are nondirected or altruistic donors who do not direct placement of their donated organ. This resource contains some recommendations that only apply to altruistic donors. Above all else, the potential donor must understand that ~~the donor can~~ he or she may 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 ~~,the following:~~

- a. ~~An~~ 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. The disclosure that the donor will receive a thorough medical and psychosocial evaluation.

The medical evaluation will be conducted by ~~someone with mental health training~~ a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post donation, which ~~could~~ will include; a screen for example, a licensed clinical social worker, nurse specialist ~~any evidence of occult renal and infectious disease and medical co-morbidities which may cause renal disease.~~

The psychosocial evaluation will be conducted by a psychiatrist, psychologist, or ~~psychiatrist~~ social worker with experience in transplantation to determine decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion.

~~A disclosure of alternative procedures or courses of treatment social worker with experience in transplantation to determine decision making capacity, screen 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 any-existing, life threatening conditions psychiatric illness, and evaluate any potential coercion.~~

- c. A disclosure that living donor transplant programs must provide and Independent Donor Advocate whose responsibilities include but are not limited to the following:
- to promote the best interests of the potential living donor
 - advocates for the rights of the potential recipient should be disclosed to donor
 - assist the potential donor prior to in obtaining and understanding information regarding the:
 - (i) consent process
 - (ii) evaluation process
 - (iii) surgical procedure, and
 - (iv) benefit and need for follow-up
- 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. ~~Printed~~ The provision of 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. ~~Sufficient~~ The provision of education that discusses what remaining organ function will be left after the donation and what the impact on the donor might be.
- g. The provision of sufficient time for the potential donor to reflect after consenting to donate.
- h. Disclosure of alternate procedure or courses of treatment for the potential donor and recipient including deceased donation. All potential donor should be informed if the intended recipient has or has not been listed for deceased donation. An offer for any potential donor of a general, nonspecific statement of unsuitability for donation should they wish not to proceed with donation. An explanation Pre-existing life threatening

conditions of the potential recipient should be disclosed to the potential donor prior to obtaining consent.

- i. Explain that a potential donor's decision by the potential donor not to proceed with the donation can only will not be disclosed if authorized by without the prior consent of the potential donor.
- j. ~~An understanding~~ A determination that the potential donor undertakes understands that he or she will undertake risk and receives will receive no medical benefit from the operative procedure of donation.
- k. A disclosure that the potential donor's medical evaluation could reveal conditions that the transplant center must report to governmental authorities such as HIV or certain venereal diseases.
- l. An explanation that medical information on ~~both~~ the potential donor ~~and~~ may not be revealed to a potential recipient may need to be revealed unless authorized by the potential donor. If the potential donor has a condition that might harm a recipient the medical team in order for both parties to determine whether they should donate charge of his or receive the organ her evaluation will not allow the donation to occur.
- m. A specification of the medical, psychological, and financial risks associated with being a living donor, ~~to~~. These risks may be transient or permanent and include, but are not limited to the following:
 - i. Potential Medical Risks
 - potential for surgical complications including risk of donor death
 - potential for decreased kidney function in kidney donors. Every kidney donor will experience a decrease in the kidney function compared to pre-donation. The amount will depend upon the potential donor's age and history. The anticipated change in their individual kidney function is to be discussed with each donor
 - 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~~ depression, anxiety, or emotional distress
- 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
- n. ~~A disclosure~~ Disclose that transplant centers ~~must~~ are required to report living donor follow-up information for at least two years, so the donor should expect to be contacted by the transplant program regarding their current health status.
- o. ~~A statement from~~ Disclose that living donor follow-up is the best method for the collection of information on the health implications of living donation.
- p. Disclose that ~~C~~centers will specify who is responsible for the cost of follow-up care.
- q. The agreement of the potential donor to commit to post-operative follow-up testing coordinated by the recipient transplant center for a minimum of two years.

- r. ~~Disclose A-Disclosure~~ Disclose 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
- s. ~~A disclosure~~ Disclose that living donor follow-up is the only method for the collections of information on the short-term health implications of living donation.
- t. 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~~ national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center.
- u. Disclose to all potential non-directed or altruistic living donors the following:
 - (i) the transplant program will determine who will receive the donated organ;
 - (ii) the transplant center will take all reasonable precautions to provide anonymity for the donor and recipient;
 - (iii) the transplant center should obtain a separate consent to allocate your organ to a paired donation system; and
 - (iv) the transplant center should disclose there is an increased risk associated with the transport of nondirected living donor organs and obtain additional consent to transplant the organ if it will not be transplanted at the recovery center.

4. Guidance for Potential Living Kidney Donors

In January 2007, the OPTN/UNOS President sent a letter to all transplant programs that perform live donor transplants requesting copies of their informed consent, medical evaluation, and living donor follow-up protocols. The Living Donor (LD) Committee planned to use these protocols to make recommendations to the Board of Directors regarding new living donor policies and guidelines.

The LD Committee's review of these protocols revealed wide variation in the medical evaluation process for living donors throughout the country. Some centers did not have formalized guidelines for the medical evaluation of their donors. In an effort to provide Members with a shared knowledge base, the Living Donor Committee used the 80/20 rule in evaluating submitted protocols. If the majority (or 80%) of programs had a particular element as part of their standardized medical evaluation for their living donors, the Committee included that element in the final recommendations. Additionally, the Committee reviewed recommendation from the American Society of Transplantation (AST) and the Report of the Amsterdam Forum on the Care of the Living Kidney Donor; completed an extensive literature review; and completed a focused survey of 16 large transplant centers in the development of its recommendations.

The recommendations were titled, "Guidance for the Development of Program-Specific Living Donor Medical Evaluation Protocols." When first introduced, the recommendations were very controversial as the transplant community was concerned that the recommendations were too prescriptive, and although voluntary, could evolve into policy requirements. To ease concerns of the transplant community, the Board of Directors asked the LD Committee to prepare two separate sets of recommendations for the medical evaluation of potential living kidney donors. The first set would be a resource that transplant professionals could voluntarily adapt for the medical evaluation of potential living donors. The second set of recommendations, for the lay public, would be a resource that potential donors could use to better understand how transplant centers typically evaluate potential living kidney donors.

In June 2008, the OPTN/UNOS Executive Committee approved the professional resource titled Guidance for the Development of Program-Specific Living Donor Medical Evaluation Protocols, and that resource is available through the UNOS website.

Once the professional resource was approved, the LD Committee began work on a the resource for the lay public which potential living kidney donors can use as they consider living kidney donation. The resource is now complete, and is titled Guidance for Potential Living Kidney Donors, and has been approved by the Committee. The Committee is now asking the Board to approve this resource so it may be made available to anyone considering living kidney donation. The LD Committee will plan to review and update the resource as necessary and on a regular basis. The following is recommended for consideration by the Board. Committee Vote: 22-0-0 (**Exhibit D**)

**** RESOLVED, that the resource titled “Guidance for Potential Living Kidney Donors” is hereby approved, as set forth below, effective June 23, 2009:**

Guidance for Potential Living Kidney Donors

Background

Since 1984, the Organ Procurement and Transplantation Network (OPTN) has been managing and creating policy regarding organ donation from deceased individuals. In June 2006 the Department of Health and Human Services (HHS) directed the OPTN to also develop policies regarding living organ donors. OPTN members involved in living donor transplantation must now comply with the living donation policies the same way they follow policies regarding deceased donor transplantation. Non-compliance with living donation policies has the same consequences as non-compliance with other OPTN policies.

All living donor transplant centers must develop and follow written protocols to address all phases of the living donation process. Those protocols must include their process for the medical and psychosocial evaluation of a potential living kidney donor and descriptions of what you can expect before, during and after the operation. These protocols also cover how center will collect and submit donor two years of follow-up information to the OPTN.

Currently there is no standard process for the evaluation of living donors. Each transplant program determines its own testing and acceptance criteria for potential living kidney donors. Transplant centers may use different tests to obtain the same information. If you are considering living kidney donation, you may want to compare the protocol(s) at your center with the following elements developed by the OPTN/UNOS (United Network for Organ Sharing) Living Donor Committee.

Considering Living Donation

If you are considering donating a kidney, you need to know as much as possible about the process before you make a final decision. This document is a good start. **Although every donor is unique, and each transplant center evaluates donors differently, this guide will give you a general idea of what to expect as you consider becoming a living kidney donor.**

Talk with your personal physician and other living donors. Learn as much as you can about living donation. Visit these Web sites for information: [Living Donors Online](#); [The Kidney Foundation](#) and the [American Association of Kidney Patients \(AAKP\)](#).

It is very important that you talk to your family and/or close friends to see how they feel about you being a living donor. If you choose to donate your decision will affect your family and friends. You must weigh your options carefully to make the right personal decision.

If you do decide to become a living donor, the benefits of living donor transplantation for patient with kidney disease are tremendous, and can improve survival 2 to 3 fold for some recipients. Living donor kidney transplantation allows patient to schedule surgery at a time when they are in

the best physical condition and best able tolerate the procedure. It also gives them the best survival of all treatments for end stage kidney disease. Those patients who receive a kidney transplant prior to starting dialysis have the best overall survival; and have fewer rejections episode and other complications.

In addition to a survival benefit, living donor kidney transplantation allows the donor and potential recipient to schedule surgery at a time that is convenient for both and both are healthy and best able to undergo the procedure.

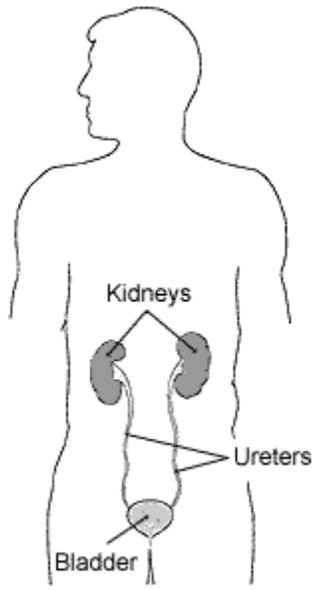
Other positive aspects of donation may include the satisfaction that their recipient has the best chance of recovery and rehabilitation of all possible end stage kidney treatments. Living donors who donate to someone close to them may also experience an improvement in their own quality of life because of the improvement in the recipient. Specifically, the recipient may have more freedom, they can travel, the recipient can participate in activities that require more physical strength and the recipient should have an improved overall quality of life.

It's Your Decision

- Know that alternatives to living donation exist. Generally, if someone is a candidate for living donation, they are already on the waiting list to receive a kidney from a deceased donor. Candidates on the wait list are able to continue to receive dialysis while waiting for an organ to become available..
- Remember, each center relies on the experience and knowledge of their health care team. Physician expertise and training can vary from center to center.
- Ask the center for data on donor and recipient outcomes of living donor transplantation, both nationally and at the center where you will receive care.
- Educate yourself and be ready to ask questions. You need to make a decision that you can support for the rest of your life.
- It is always a good idea to have a trusted friend or family member to go with you to all appointments at the center to give you support and to ask questions you may not have thought to ask.
- It is important to understand that a donated kidney may not work or may be rejected by the recipient.
- You can stop the process at any time for any reason; the transplant center can tell the intended recipient that you are not an acceptable candidate.
- Remember, once the surgery is complete, it is final, it cannot be reversed; up until that time however, you may stop the process.

What Kidneys Do

Before even considering living donation, you should understand what your kidneys do and the role they play within your body.



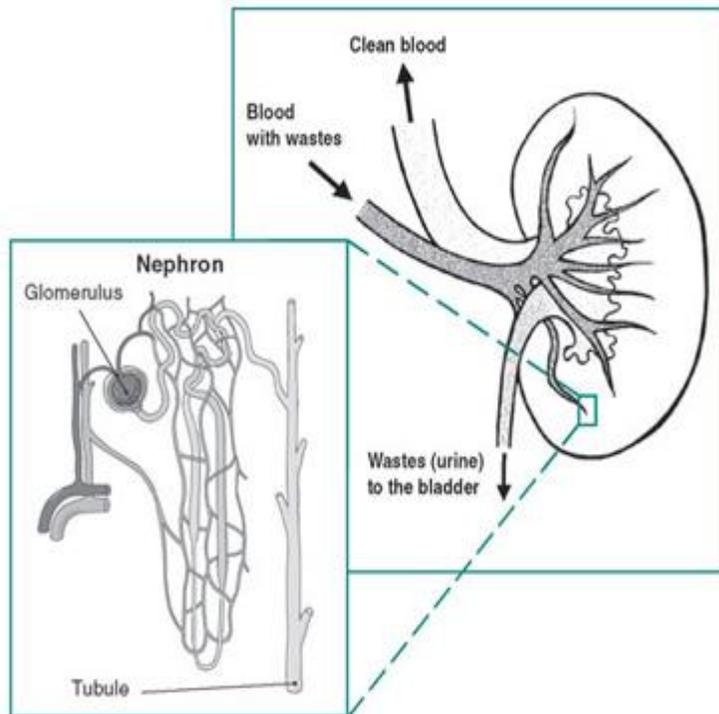
Your kidneys are bean-shaped organs, each about the size of your fist. They are located near the middle of your back, just below the rib cage. Every day, your kidneys process about 200 quarts of blood to remove waste products and excess water. The kidneys are designed to know which chemicals to keep in the body and which ones to get rid of into the urine. Some of these chemicals are poisons; some are salts, phosphorus, and excess water. The waste and extra water become urine, which flows to your bladder through tubes called ureters. Your bladder stores urine until you urinate.

The wastes in your blood come from the normal breakdown of tissues, energy generating processes and from the food you eat. After your body has taken what it needs from the food, some wastes are sent to the blood. If your kidneys did not remove these wastes, the wastes would build up in the blood and damage your body. This may lead to the feelings of fatigue, being cold, nausea, achiness, muscle cramps, shortness of breath, mental fuzziness and body swelling, starting usually in the feet and legs.

The actual filtering occurs in tiny units inside your kidneys called nephrons. Every kidney has about a million nephrons. In the nephron, a glomerulus—which is a tiny blood vessel, or capillary—intertwines with a tiny urine-collecting tube called a tubule. A complicated chemical exchange takes place, as waste materials and water leave your blood and enter your urinary system.

At first, the tubules receive a combination of waste materials and chemicals that your body can still use. Your kidneys measure out chemicals like sodium, phosphorus, and potassium and release them back to the blood to return to the body. In this way, your kidneys regulate the body's level of these substances. The right balance is necessary for life, but excess levels can be harmful. Kidney function is usually monitored by a blood test that measures serum creatinine. This blood test can be taken together with your age, gender and race and used to calculate the estimated Glomerular Filtration Rate (eGFR). On average a normal serum creatinine level is 0.7 to 1.4mg/dl depending upon the laboratory where the blood is tested and your gender and race. A normal eGFR is usually over 80 cc/minute/1.73m² with most people at/or over

100cc/minute/1.73m². People with an eGFR ≤ 20 may be listed on the kidney transplant list. People with an eGFR <15 will often have a dialysis access placed. People with an eGFR < 15 may need to start dialysis especially if they have diabetes. However, most of the time this happens with an eGFR between 5-10cc/minute. Starting dialysis is a decision made between a patient and their physician based upon laboratory tests, how they are handling their body fluids and how they feel.



[d] In the nephron (left), tiny blood vessels intertwine with urine-collecting tubes. Each kidney contains about 1 million nephrons.

To learn more about kidney function you can visit a comprehensive Web site produced by the [National Institute of Diabetes and Digestive and Kidney Diseases](#).

Transplant Center Obligation to Living Donors

- Transplant Centers are required to have written protocols in place for all phases of living donation to include the evaluation, the surgery, discharge, aftercare, and data collection on living donors for two years following donation.
- Transplant centers are required to have key staff assigned to care for living donors, including an Independent Donor Advocate or Independent Donor Advocate Team.
- Transplant centers are required to submit follow-up forms to the Organ Procurement and Transplant Network (OPTN) for 24 months following the donation.

The Importance of Independent Advocacy for Donors

The transplant center must assign an IDA (Independent Donor Advocate) to anyone considering living donation. If an entire team is dedicated to advocacy, it is called an Independent Donor Advocate Team (IDAT). This requirement is part of the OPTN bylaws that pertain to living donor transplant programs. You may read this bylaw on the OPTN Web site ([Appendix B, XI](#)).

This advocate or advocate team should be knowledgeable about all phases of living organ donation and may be a physician, nurse, social worker or other medical professional. Your advocate will represent you and will help you gather and process information about the consent process, the evaluation process, the surgical procedure, and follow-up care. You should be open with your advocate about your desires to donate or not to donate. You should ask your advocate questions about the process so you understand as much as possible about donating a kidney. If you ultimately decide against donation, your IDA can tell the transplant team or your potential recipient that you are not a candidate for donation.

Getting Evaluated

Each transplant center determines its own protocols for the evaluation of potential living kidney donors. Some centers prefer certain tests over others for providing information on the potential donors' health status, and different test may provide the similar information about the health of a potential kidney donor.

Medical professionals at a transplant center will ask you many questions to determine whether you are a good candidate for living donation. These questions are not simply about your physical health. They help medical professionals determine whether you are emotionally able to participate in the process and whether you would have adequate social support and financial resources during your recovery from surgery.

Your medical evaluation will help determine whether you have any obvious illness or medical condition that would put you at risk if you donated one of your kidneys. It might also identify a disease that you could unknowingly pass on to the recipient. This is especially important since recipients must take medication after their transplant, which can weaken their immune system and makes them more susceptible to certain diseases. Additionally, the medical evaluation should define the anatomy of your organ so the surgical team can determine ahead of time if the organ is the right size and shape. Finally, your medical evaluation may reveal problems that otherwise might have not been identified.

Because there are so many questions and so much information given to you during the evaluation process, it is often wise to consider bringing a friend or family member with you to the appointments. They can help you to ask questions at the appointments and help you discuss the risks and develop new questions to take to future appointments.

Donor Risk

Removing a kidney from a healthy person involves risk. Based on current available information, the short-term risks are relatively low, and can include:

- Risks associated with anesthesia

- Surgical complications such as pain, infection, blood loss, blood clots and the need for a blood transfusion
- Death – the risk of dying from living donor surgery is .04% (1 death for every 2500 living donors)

The risk of being a living kidney donor comes from studies of previous donors at individual transplant programs and from follow-up reports that centers send to UNOS. Programs are required to report information on the health status of each living donor for two years. Transplant centers must immediately report adverse outcomes and the deaths of any living donors to UNOS.

Currently, information long-term health and psychological outcomes of living donors is limited, however, based on information that is available:

- The risk of end stage kidney disease, and the need for dialysis or to receive a kidney transplant is between 1 per 1000-2000 (0.10 to 0.52%)
- The risk may be higher if the potential donor is African American.
- Between January, 1996, and February, 2008, there were 172 kidney transplant candidates identified to be previous living kidney donors. The median time from donation to listing was 19 years.
- The risk for the development of medical conditions that may affect kidney function is not absolutely known for each individual. It is possible that a living kidney donor may later develop the following: diabetes, kidney cancer, other cancers needing treatment with medications that decrease kidney function, a new kidney disease, or multiple kidney stones.
- The rate of kidney cancer in living donors is relatively low (18.3 per 100,000 men and 9.2 per 100,000 women) but it is increasing especially in individuals who are overweight. Thus if one kidney has been removed and the remaining kidney develops a cancer, part of the remaining kidney will need to be removed. This might put the donor at risk to lose their kidney function and require dialysis in time. Consideration of kidney donation means considering the development of these events and being willing to accept this risk to future health.
- One recent Canadian study did not find any increase in cardiovascular risk for kidney donor up to 10 years after donation.
- Recent studies from Canada, Norway and the University of Minnesota showed an increased risk (16% compared to 11%) of high blood pressure in kidney. Previous kidney donors who become pregnant have a increased risk (5% compared to 2%) for preeclampsia.

You must balance your concern about the long-term risk of donation to your health against the benefit the transplant recipient will receive. Patients who stay on dialysis have a higher risk of dying than those who receive a transplant. There is also strong evidence that the longer a transplant candidate remains on dialysis, the greater the risk that their transplanted organ will fail or that they will die after their transplant.

You must seriously ask yourself if helping another person worth the possible risk to your health? Your kidney function will be less than it was before the donation. On average, it is 65-80% of the pre donation value. Kidney function does decline with age. This may one day put you in a

situation where the effects of some medicines and medical procedures that are commonly used will have a harmful effect on your health. You should discuss these risks with your medical team and determine whether the risk of having a healthy kidney surgically removed is worth the benefit the transplant recipient will be expected to receive.

Risks of the Donor Evaluation Procedure

The living donor evaluation process can present certain risks.

- Drugs used to image your kidney may cause allergic reactions.
- Your medical evaluation might uncover unknown illnesses.
- If the medical team discovers certain illnesses (sexually transmitted diseases) they will be required to report them to health agencies.
- The tissue typing blood tests (Human Leucocyte Antigen) that determine whether your organ would be a good match could reveal the true identity of family relationships. You may find out that you are not a blood relative to who you think you are. This could create issues that you or your family members may not want revealed.
- Some tests may determine the need for additional testing that is not part of the routine evaluation. Often the costs of these additional tests would be your financial responsibility.

Your physician's knowledge and experience are critical to this process. Your healthcare team should use good judgment when choosing screening tests and should be careful about confidentiality when they communicate any positive results.

You should base your final decision to donate on:

- Your medical test results
- Your psychosocial evaluation
- Your relationship to the potential recipient
- The assessment of your risk based upon current medical knowledge
- Your personal faith/belief system

Once you decide to donate, the medical team needs to contact the recipient so they can make a final decision whether to move forward with the transplant.

Are you emotionally prepared to be a donor?

A psychiatrist, psychologist or social worker with experience in transplantation will ask you a series of questions. These questions will help them determine whether you are psychologically prepared to participate in this donation process. These questions will also help them determine if you have a solid social network in place to help you after the surgery. Although some of the questions may make you uncomfortable, the answers to these questions are an important part of the overall process.

You can expect the following during your psychosocial evaluation:

- A discussion of any history of depression, lack of social connectedness or any issues that might complicate your recovery or predict a worrisome outcome.
- A determination of whether you have any current or previous symptoms of psychiatric disorders, such as mood disorders, anxiety disorders, substance abuse problems, or others conditions such as bi-polar disorder, schizophrenia, or eating disorders.
- Questions about your social support and the satisfaction you receive from relationships with your family, friends, and co-workers. If you are thinking about donating an organ to a family member, the clinician will ask you about the dynamics in your family. You may be asked to bring a support person along with you. Having this person there will help you make plans for the support you will need after you leave the hospital.
- An assessment that your decision to donate is free from coercion and pressure and that you have not agreed to accept financial payment for the donation.
- A determination that you have made a fully informed decision to donate, understand the short term risks of donation, and realize there is limited data on the long-term impact on the health of living organ donors.
- An understanding that any health information obtained during your evaluation is subject to the same regulations as other medical records and this information may not be additionally protected.
- A review of your financial circumstances— Are you adequately employed? Do you have enough vacation time or sick leave? Can you afford non-medical costs such as childcare fees and travel to the center.
- A discussion of the possibility that you may experience problems obtaining disability, life and health insurance after donation.
- A discussion about how you would respond if your kidney doesn't function in the recipient or if the recipient has other complications or dies as a result of the surgery

Remember, these questions are typical of what you might be asked, but every donor is unique and every transplant center evaluates their donors differently. Use these suggestions as a guideline for the care you receive.

The Medical Evaluation

A physician or surgeon experienced in living donation must perform your medical evaluation.

This evaluation will:

- Determine if you and your intended recipient are a suitable medical match by testing your blood type and other tissues.
- Assess your general health and any future health risk associated with having only one kidney.
- Determine if you have any diseases that you could pass on to the recipient
- Assess the anatomy of your kidneys.

Your physician will conduct a series of medical tests to evaluate if you can be considered to be a living donor. It is impossible to list every test but here is a partial list of what your medical evaluation should include:

General History Exam includes testing for:

- high blood pressure
- diabetes
- lung disease (asthma, emphysema, Chronic Obstructive Pulmonary Disease (COPD) and others)
- heart disease (Coronary Artery disease, Cardiomyopathy, Aortic or Mitral Valve Stenosis)
- gastrointestinal disease
- autoimmune disease (lupus, multiple sclerosis, rheumatoid arthritis, etc.)
- neurologic disease
- genitourinary disease (kidney stones)
- history of cancer
- history of infection
- blood diseases and bleeding/clotting disorders
- smoking, alcohol and drug use/abuse, including intravenous drug use/abuse and other high risk behavior
- active and past medication use (medications that could harm your kidney or chronic use of pain medications and NSAIDS, such as Aleve or Motrin)
- allergies
- family history (coronary, artery disease, cancer, other)

Some questions are specifically about your kidney history:

- Kidney disease, proteinuria (excess protein in the urine indicates kidney damage), blood in the urine
- Kidney injury, e.g., car accidents, severe falls
- Diabetes
- Chronic infection
- Kidney stones
- Recurrent urinary tract infections (bladder or kidney infections)
- Gout or other arthritis
- Gestational diabetes

Some questions are about your family's kidney history:

- Kidney disease, kidney stones

- Diabetes
- High blood pressure
- Reflux, urine backing back into the kidney from the bladder
- Early blood vessel or heart disease

Social History

A medical professional will give you a thorough psychosocial evaluation; however, during the medical evaluation you will be asked by the physician about:

- Employment, health insurance status, living arrangements, social stability
- Psychiatric illness, depression, suicide attempts

The transplant team needs to know if your job will allow you to be away from work long enough to donate and to properly recover from surgery. Although the recipient's insurance generally covers your operation and recovery expenses, you would need your own insurance to cover any possible long-term problems that might result from kidney donation.

The team also needs to know what sort of social network you have in place and if you have friends and family you can depend on during your recovery period. It's important for them to know that you are emotionally stable and do not have any psychiatric illnesses that could negatively impact your donation experience.

Physical Exam

The remaining sections deal with the medical examinations you could undergo and the tests you could receive if you choose to become a living donor.

- Height, weight, BMI (body mass index, see below). Many programs have standard measurements for maximum BMI for potential donors.
- Your physician will be examining your heart, lungs, abdomen, palpating your pulses,, examining your lymph nodes, checking your legs for swelling and testing your overall neurological system.

Your BMI is a measure of body fat based on height and weight. It applies to both adult men and women. You can get a rough idea of your BMI using this table. A healthy BMI is ≤ 25 , overweight is a BMI between 25-30, obesity is a BMI ≥ 30 , morbid obesity is a BMI over 40 kg/m².

BMI	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
Height (inches)	Body Weight (pounds)																
58	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167
59	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173
60	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179
61	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185
62	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191
63	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197
64	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204
65	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210
66	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216
67	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223
68	125	131	138	144	151	158	164	171	177	184	190	197	203	210	216	223	230
69	128	135	142	149	155	162	169	176	182	189	196	203	209	216	223	230	236
70	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243
71	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250
72	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258
73	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265
74	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272
75	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279
76	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287

Kidney-specific Exams and Testing

- Blood pressure -- Your blood pressure will be measured on several occasions during the evaluation process to make sure it is within acceptable levels. Some programs may require 24 hour blood pressure monitoring. This involves a blood pressure cuff and a radio sized device. The cuff is placed on your arm and left there for 24 hours, the blood pressure is taken every 20 to 30 minutes.
- Vascular evaluation --Using ultrasound instruments, technicians may sometimes evaluate how your blood flows through the arteries and veins surrounding your kidney. This will let

them know if you have any blood flow blockages to the kidney that may cause you not to be a kidney donor,

- Pathology evaluation—some potential donors may need a biopsy which requires obtaining a small sample of your kidney for a microscopic study .This is not very commonly done. It is done if a prospective donor has some protein and or red cells in the urine and truly wants to consider donation. Otherwise the test might be done as part of their usual care. If performed in the later situation it would be at the expense of the prospective donor.
- Detailed urinalysis; microscopy (looking at the urine under the microscope for cells and other inclusions) as indicated. [This does not mean a kidney biopsy for all prospective donors! A kidney biopsy however might be suggested depending upon exam and if you have protein or red cells in your urine as discussed above.]
- Urine culture if clinically indicated
- Measurement of protein excretion
- Measurement of glomerular filtration rate by collecting your urine for 24 hours this test is based upon the serum creatinine discussed below as well as the amount of creatinine excreted into the urine.
- Screening for Polycystic Kidney Disease as indicated by family history. If the prospective donor is over age 30, this is usually accomplished with an ultrasound. In those under age 30, genetic blood testing remains the gold standard.
- Uric acid (the substance in the joints that causes gout, it is also a marker of kidney disease)
- Glucose Tolerance Test in relatives of diabetics as indicated to see how your body handles blood sugar.

General Laboratory Tests

- CBC (complete blood count) —this includes testing of your platelets (your ability to clot blood); Hgb or Hemoglobin (low Hgb indicates that you are anemic); white blood cells (WBC) –these are the cells that help your body fight disease; and red blood cells.
- Prothrombin Time/Partial Thromboelastin Time (measures how quickly your blood can clot)
- Comprehensive panel — measure the electrolytes (chemicals) in your blood, and includes sodium, calcium, phosphorus and others. The comprehensive panel also measures your creatinine level which shows physicians how well your kidney is functioning. A normal creatinine reading falls within the range of .7 – 1.4mg/dl. This value may vary depending upon the laboratory in which it is measured as well as the person’s age, gender, muscle mass and meat/ protein intake.
- Pregnancy test for women < 55 years old
- Chest X-Ray
- Electrocardiogram (ECG) – traces your heart’s rhythm
- Evaluation for coronary artery disease, as suggested by the American College of Physicians
- Lung function tests for smokers, as suggested by the American College of Anesthesiology and American Lung Association. A variety of tests will measure how much air your lungs can hold, how quickly you can move air in and out of your lungs, and how well your lungs put oxygen into and remove carbon dioxide from your blood.
- Age and gender appropriate cancer screening tests. The transplant program may choose to follow the screening recommendations from the American Cancer Society.

- Yearly mammograms to screen for breast cancer are recommended for women after age 40.
- Beginning at age 50, men and women at high risk for colon or rectal cancer should be screened.
- Beginning at age 21 (and earlier if they are sexually active), women should be screened yearly for cervical cancer with a Pap test.
- After menopause, women should be screened for uterine cancer.
- Beginning at age 50, men should be screened for prostate cancer.

Immunological testing

- ABO blood group. It is important to consider blood type to avoid suddenly losing the kidney; mismatching for certain blood groups will cause the kidney transplant to clot. There are 4 different blood types. The ability to donate to other blood groups or to receive blood or organs from different blood groups is shown in the table below. Blood group A may be divided into two groups A1 and A2, the A2 group may donate to O and B recipients if the antibody titer in the recipients against the A group protein by the O and B individuals is low.

Blood Group Matching Possibilities

Blood Group	May Donate To	May Receive From
A	A	A and O
B	B	B and O
O	A, B, AB and O	O
AB	AB	A, B, AB and O

- Tissue typing (HLA): This test determines how well your tissues match those of the person you want to donate to.
- Cross match: this test determines whether the recipient would react negatively to your organ. If the test is positive then you historically would not have been able to donate. There are alternative approaches, however, rather than just not doing the transplant. There is the option to enter paired organ exchange programs where incompatible donors donate to another recipient that they are compatible with while their original recipient also receives a kidney from a compatible donor. Or there are some instances where the antibodies in the potential recipient can be decreased by special treatments. You should discuss these options with your physician.

Metabolic Focused Testing

These tests will help physicians determine if you are likely to suffer from kidney disease yourself or from any other metabolic disorders that could have a negative impact on your health or the health of the person you want to donate a kidney to.

- Fasting blood glucose (this measures the amount of sugar in your blood on an empty stomach. Abnormally low or high levels could indicate medical conditions like low blood sugar or diabetes.)
- Fasting cholesterol levels (Cholesterol, Triglycerides, HDL Cholesterol, and LDL Cholesterol) with Fasting Lipid Profile if cholesterol/triglycerides are elevated. This test measures your good and bad cholesterol levels and indicates whether you might be at risk for heart disease.
- Uric acid (High uric acid levels are associated with the metabolic syndrome and independently with reduced kidney function)

Although currently healthy, you may be at increased risk for developing diabetes or other disorders if your blood relatives have those disorders.

Anatomic Assessment

This assessment helps physicians determine which one of your kidneys is most appropriate for the recipient. They base this assessment on characteristics such as kidney size, the presence of cysts or stones, and the number of arteries.

We'll have an illustration here that shows two kidneys each with different anatomy. For example, one with stones and cysts, one without.

Your physician may assess your kidney using a CT angiogram, 3D CT, MR angiogram or angiogram

Screening for transmissible diseases

You will be screened for diseases that could be passed on to the recipient. The presence of the diseases may or may not prevent you from donating, but the recipient will be at an increased risk for developing the disease and may need to take additional medications to reduce risks associated with the disease. These disease screening tests include:

- CMV (Cytomegalovirus)
 - Commonly known as Human Herpes virus group. This virus can remain latent in the body for long periods of time and can cause mononucleosis, herpes simplex and other viruses. Since transplant recipients take drugs that suppress their immune system, the presence of CMV in their blood system could lead to serious disease.
 - EBV (Epstein Barr Virus) –This is also a virus of the herpes family and is one of the most common viruses in humans. It is often does not have any symptoms but can cause mononucleosis.
- HIV 1,2 (Human Immunodeficiency Virus)
 - This virus can lead to acquired immunodeficiency syndrome (AIDS) which causes the immune system to fail and can lead to life threatening infections.
- HTLV I (Human T-cell Lymphotropic Virus) antibody testing
 - This virus leads to leukemia and lymphoma.
- Hepatitis B Virus Tests
 - This virus infects the liver and causes inflammation called hepatitis
 - This virus causes cirrhosis of the liver
 - This virus is associated with the development of liver cancer
- Hepatitis C Virus Tests
 - This virus can also cause kidney disease

- This virus causes cirrhosis of the liver
 - This virus can cause kidney cancer
 - RPR (the Rapid Plasma Reagin Syphilis Test)
 - This test screens for a sexually transmitted disease.
 - This agent may cause severe nerve damage and brain dysfunction
 - Tuberculosis
 - This microbial agent can cause severe pneumonia and systemic disease
- Depending on where you live or activities you are involved in, doctors may also screen you for the following:

- Strongyloides for donors from endemic areas
- Trypanosoma cruzi for donors from endemic areas
- West Nile for endemic areas
- Toxoplasmosis: Transmission is low if recipients are treated with appropriate antibiotics.

Cancer screening

The screening tests follow the practices advised by the American Cancer Society. Depending on your gender, age, or family history, you will be screened for the following:

- Cervical Cancer
- Breast Cancer
- Prostate Cancer
- Colon Cancer
- Skin Cancer

The American Cancer Society does not currently recommend routine lung cancer screening. However, if you are older and have been smoking for a long time, your physician may consider it.

Criteria that might prevent you from being a donor

Again, remember that every donor is unique and every center does things differently, however some characteristics might make an individual unsuitable for living donation. These include:

- Someone under 18 years of age or someone mentally incapable of making their own decision,
- Uncontrollable high blood pressure
- History of high blood pressure with evidence of serious organ damage
- History of high blood pressure in a Caucasian younger than age 50 or older than age 50 and taking more than one anti-high blood pressure medication
- High blood pressure in a non-Caucasian (high blood pressure can lead more swiftly to kidney disease in the non-Caucasian population), or in patients taking more than one anti-blood pressure medication.
- Diabetes
- Significant history of thrombosis or embolism (a blocked blood vessel)
- Bleeding disorders
- Uncontrollable psychiatric illness
- Morbid obesity (a BMI above 35 -40)
- Heart Disease

- Circulatory problems
- Chronic lung disease that requires oxygen support
- Recent malignancy, or cancers that may take a long time to recur (e.g., breast cancer)
- History of melanoma (skin cancer)
- History of metastatic cancer (cancer that has spread to other parts of the body)
- Recurring kidney stones affecting both kidneys
- Significant problems with the anatomy of the kidney
- An abnormal creatinine score.
- Excessive protein in the urine (proteinuria)
- Human Immunodeficiency Virus infection (AIDS)
- Hepatitis C Virus infection
- Active Hepatitis B Virus infection

Living Donation Procedures

Once you have made a fully informed decision to become a living donor, your physician will discuss your surgical options with you.

You have three surgical options:

- Laparoscopic Nephrectomy
- Hand-assisted Laparoscopic Nephrectomy
- Open Nephrectomy

Laparoscopic: this minimally invasive procedure, also known as band aid surgery, is a modern surgical procedure, where operations in the abdomen are performed using very small incisions. Surgeons will make two or three small incisions near your belly button. They will remove your kidney through one of the incisions. They will insert a special camera called a laparoscope into the other incision. This will transmit a real-life picture of your internal organs to a video monitor and guide them through your procedure. Your doctor will let you know if you are a good candidate for this procedure.

Hand-assisted Laparoscopic Nephrectomy: Requires an additional 3-4 inch incision for removal of the kidney.

Open: this procedure has been the standard for the last 35 years and involves a five to seven inch incision on the side of your chest and upper abdomen. Surgeons will use an instrument called a retractor to spread your ribs in order to gain access to your kidney. This operation typically lasts three hours.

Recovering from Surgery

If you have the laparoscopic procedure, you will usually spend less time in the hospital. Many donors are discharged after two days and may return to work or their normal activities within four weeks.

If you have the open procedure, you will be in the hospital for four to five days. Donors can usually return to normal activity within four to twelve weeks.

OPTN/UNOS Living Donor Follow-up

Transplant centers must submit follow-up forms on every living donor at 6 weeks, 6 months, one-year and two-years. Information on these forms help collect information about the short term complications associated with living donation.

Medical Evaluation after Living Donation

After you donate you should see your doctor on a regular basis and continue to lead a healthy life style. Make sure you ask a doctor to routinely check the following:

- Blood pressure
- Height, weight and waist circumference
- An age appropriate physical exam

Your follow-up laboratory tests should include:

- Urinalysis
- Urine albumin:creatinine ratio
- Serum creatinine
- Fasting blood glucose
- Lipid profile

End Stage Kidney Disease in Living Donors

If you should tragically develop end-stage kidney disease after being a living kidney donor you would receive extra points when placed on the kidney waiting list and this would allow you to receive a deceased donor kidney from the kidney waiting list faster.

Regulations Governing Living Donor Transplant Programs

To learn more about the requirements for transplant centers that perform living donation read the [OPTN/UNOS bylaws](#).