

## ***At-a-Glance***

### **Proposal to Modify Existing or Establish New Requirements for the Informed Consent of all Living Donors**

- **Proposed New or Modified Policies:** 14.2 (Independent Living Donor Advocate (ILDA) Requirements), and 14.3 (Informed Consent Requirements)

- **Living Donor Committee**

This proposal would modify existing policy and establish new policy requirements for the informed consent of all living donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA) to develop such policy, and is based on recommendations from a Joint Societies Steering Committee composed of representatives of the American Society of Transplantation (AST); the American Society of Transplant Surgeons (ASTS) and the North American Transplant Coordinators Organization (NATCO) to the Living Donor Committee. Policy to standardize the informed consent of living kidney donors has already been established. This proposal would modify some elements of existing policy for the informed consent of living kidney donors and establish new requirements for all other categories of living organ donors.

- **Affected Groups**

Directors of Organ Procurement  
Transplant Data Coordinators  
Transplant Physicians/Surgeons  
PR/Public Education Staff  
Transplant Program Directors  
Transplant Social Workers  
Organ Recipients  
Organ Candidates  
Living Donors  
Donor Family Members  
General Public

- **Number of Potential Candidates Affected**

In 2012, there were 5867 living organ donors including 5619 living kidney donors, 246 living liver donors, and two living lung donors.

Between 2007 and 2012 there were seven living lung donors, five living intestinal donors, and one living pancreas donor.

The proposed policy would affect all living donors and living donor transplant recipients.

- **Compliance with OPTN Strategic Plan and Final Rule**

The proposed changes are consistent with the strategic plan goals to:

- Optimize a safe environment for living donor transplantation through improved living donor informed consent
- Improve living donor consent through development and enactment of policies to protect patient safety and preserve the public trust

- Identify process and system improvements that best support critical network functions, and work to disseminate them to all members who could benefit

- **Specific Requests for Comment**

The Committee is requesting specific feedback on elements of the proposal determined to be problematic for members to implement, and especially feedback from living lung, living intestinal and living pancreas donors programs because of low volume of these types of transplants. For any identified problem please consider providing potential solutions for the Committee to consider.

The Committee is interested to receive feedback regarding if living liver donor recovery programs should be required to report the number of living liver donor organ recovery procedures it performed during the previous calendar year to potential living liver donors.

## **Proposal to Modify Existing or Establish New Requirements for the Informed Consent of all Living Donors**

**Proposed New or Modified Policies:** 14.2 (Independent Living Donor Advocate (ILDA) Requirements) and 14.3 (Informed Consent Requirements)

### **Living Donor Committee**

**Public comment response period:** March 14, 2014 – June 13, 2014

### **Summary and Goals of the Proposal**

This proposal would modify existing or establish new policy requirements for the informed consent of all living donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA) to develop such policy, and is based on recommendations from a Joint Societies Steering Committee composed of representatives of the American Society of Transplantation (AST); the American Society of Transplant Surgeons (ASTS) and the North American Transplant Coordinators Organization (NATCO) to the Living Donor Committee. Policy to standardize the informed consent of living kidney donors has already been established. This proposal would modify some elements of existing policy for the informed consent of living kidney donors and establish new requirements for all other categories of living organ donors.

### **Background and Significance of the Proposal**

On June 16, 2006, the Health Resources and Services Administration (HRSA) published a notice in the Federal Register in which the Secretary of Health and Human Services directed the Organ Procurement and Transplant Network (OPTN) to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, (in accordance with section 121.8 of the final rule). The notice directed the OPTN to develop such policies in the same manner, and with the same public comment process, that is done for policies on deceased organ donors and deceased donor organ recipients. The notice stipulated that noncompliance with such policies will subject OPTN members to the same consequences as noncompliance with OPTN policies regarding deceased donor transplantation.

Guidelines for the Consent of Living Donors were released for public comment between July 13, 2007 and August 11, 2007. The guidelines included recommendations for donor candidate selection, independent donor advocacy, donor evaluation, management, and follow-up.

In December 2009, HRSA informed the OPTN that although helpful, the voluntary guidance for the consent of living donors developed to date was not sufficient and policies were still required.

In 2010, a Joint Societies Policy Steering Committee (comprised of members from the AST, ASTS, NATCO, OPTN/UNOS, and HRSA) formed to make recommendations on any OPTN policy under development that has the potential to prescribe medical care. This Steering Committee preferred developing policy recommendations for living kidney and living liver donor informed consent as separate projects and favored addressing living kidney donor informed consent first and living liver donor informed consent as a future project.

The Living Donor Committee used these recommendations to help develop proposed new policy requirements for the consent of living kidney donors. The proposed consent requirements were distributed for public comment between September 16, 2011 and January 12, 2012, and approved

by the OPTN/UNOS Board of Directors on November 12, 2012, and became effective on February 1, 2013.

Similarly, for this proposal a Joint Societies Policy Steering Committee (comprised of members from the AST, ASTS, NATCO, OPTN/UNOS, and HRSA) formed a JSWG to develop recommendations for the informed consent of living liver donors. This work group held its first meeting on August 7, 2012, and after several months of work, sent preliminary proposed policy recommendations to the leadership of the transplant professional societies on December 1, 2012, for an initial review.

After receiving feedback from the parent societies, the JSWG met to revise their initial proposed policy recommendations for the informed consent of living liver donors. The JSWG modified their policy recommendations and sent the revised recommendations back to the parent societies for approval on April 1, 2013.

On April 8, 2013, the Chairperson of the JSWG attended the Living Donor Committee meeting and gave a presentation on the work of the JSWG and its preliminary recommendations for living liver donor consent policy development.

After these preliminary recommendations were approved by each of the parent societies, the Committee considered the policy recommendations in the development of proposed policy requirements for the informed consent of living liver donors.

The Committee met by teleconference on June 10, 2013, to consider if a policy proposal for the informed consent of living liver donors should be distributed for public comment. The Committee determined that they needed additional time to review the final recommendations from the JSWG and consequently the Committee agreed to delay the proposal until some future public comment cycle.

During subsequent review of the proposal a subcommittee of the full Committee considered if common elements in existing policy for the informed consent of living kidney donor and proposed policy for the informed consent of living liver donors could be extended to apply to other types (pancreas, intestine, and lung) of living organ donors. The subcommittee determined that as currently proposed the informed consent of living pancreas, intestine and lung donors would not be addressed in any policy, and likely would not be addressed in a separate policy development process because the volumes for these types of transplants are so small.

The subcommittee understood that proposed new general policies for the informed consent of other types of living donors was a new concept that had not been previously considered by a JSWG or any organ specific committee. In response, this committee sent letters to fourteen OPTN Committees asking those committees to comment or respond with concerns regarding the plan to modify or propose informed consent requirements for all types of living donors.

The full Committee met on September 16, 2013 and reviewed responses from five (Operations and Safety, Membership and Professional Standards, Pancreas, Ethics, and Disease Transmission Advisory Committee) committees which had responded before the deadline. Each of these committees supported the plan to propose informed consent requirements to include all types of living donors. Based on this feedback, the Committee agreed to prepare a policy proposal for public comment that would include informed consent requirements for all types of living donors.

In November 2013, the OPTN/UNOS Board approved a “plain language” rewrite of OPTN policies. Under this project, the policy requirements for the informed consent of living kidney donors were rewritten into plain language (without changing the substance of the requirements) and moved from Policy 12 to Policy 14.

One of the new features of the revised policy is the increased use of tables to communicate policy requirements. Under this proposal the existing policy requirements for living kidney donor informed consent, and new proposed informed consent requirements for all other categories of living donors are integrated and presented in a table format. Under this integration, many existing policy requirements for the informed consent of living kidney donors are proposed as new policy requirements for all categories of living donors. Some existing policy for the informed consent of living kidney donors is specific to kidney donation and cannot be extended to address other categories of living donors. Consequently, the proposed policy contains informed consent requirements for all categories of living donors, followed by existing requirements specific to living kidney donors and new proposed requirements specific to living liver donors.

On December 12, 2013, the Committee met by web conference review final draft policy language for this proposal and to consider if the proposal should be distributed for public comment. The Committee chair lead a review of the proposed policy language and the committee discussed and came to consensus on a few remaining issues with the proposed policy language. The Committee voted to approve sending the proposal for public comment.

### **Specific Feedback and Collaboration**

The proposal is based on recommendations from a Joint Societies Steering Committee composed of representatives of the AST, ASTS and NATCO to the LD Committee. Committee representatives participated in the development of the recommendations. The Committee sent a memorandum to fourteen other committees requesting feedback on the plan to propose extending informed consent requirements for all categories of living donors. The memorandum included information on what informed consent requirements would be proposed for all living donors and what informed consent requirements would be specific to living kidney and living liver donors. Seven committees (DTAC, Ops and Safety, Pancreas, Thoracic, MPSC, Pediatric, and Ethics) responded in support of extending informed consent requirements to all categories of living donors by the deadline identified in the memorandum. None of these Committees responded with specific concerns over any of the proposed requirements not being appropriate for a particular category of donor.

### ***Combined Consent Process and Existing Policy Clarifications***

Approved and implemented living kidney donor consent policy requires two separate consent processes: (1) a consent to be evaluated for living donation and (2) an informed consent for living donation. Based on feedback from the living donor program site surveyors, the Committee understood that the policy requirement for two separate consent processes created confusion for living donor programs. In response the Committee favored combining all approved informed consent policy requirements into a single required consent process.

The Committee received several questions regarding the definition of the phrase “written assurance” in current living kidney donor policy. In response the Committee is proposing to change policy to require the donor’s signature on a document that confirms that the donor is willing to donate, is free from coercion, and has been informed that they can decline to donate at any time.

The Committee received questions regarding the current requirement to disclose any infectious disease or malignancy pertinent to acute recipient care to the donor. The Committee understands that any medical condition identified in a donor would be disclosed to the donor as part of standard medical practice, and therefore supported removing this disclosure from the requirements to reduce confusion regarding this requirement.

The Committee considered requiring programs to disclose their living liver donor transplant volumes as a component of informed consent. Ultimately, the Committee did not support including this requirement because volume may not be a reliable indicator of program experience or expertise because a program's volumes may vary with personnel changes. The Committee supported asking the transplant community for feedback regarding if living liver donor programs should be required to disclose their program volume to potential living liver donors.

### ***“Potential Living Donors” Terminology***

Under this proposal all references to “potential living donors” would change to read “living donors” in current and future policy. The Committee is proposing this change because the term “potential living donor” is not defined in policy and programs define “potential living donors” differently. Committee members questioned which elements of current living donor informed consent and medical and psychosocial evaluation policy are required at various stages of the donor evaluation process. A Committee member questioned if a program could be cited for an incomplete informed consent or medical evaluation of a potential donor who discontinues the evaluation process prior to donation. The Committee understands that programs must fulfill all current policy requirements for informed consent only for actual living donors and consequently favors removing all references to potential donors. The Committee will reconsider removing all references to “potential” living donor based on public comment responses.

Living donor program site surveyors were consulted and supported removing all references to potential living donors from policy. The site surveyors commented that they review the medical records of living donors, and would only review a potential donor medical record on rare occasions and for small volume programs with an insufficient number of actual living donor medical records available for review.

### ***Domino Donors***

The Committee considered but did not support requiring these proposed new informed consent requirements for domino liver donation. The Liver and Living Donor Committees may propose new policy requirements for domino liver donation as a separate and future project.

### ***Requirements for all Living Donors***

At this time, living kidney donor recovery programs must follow OPTN policies for the informed consent of potential living kidney donors. However under current policy, living liver donor recovery programs are required to develop and follow their own center specific protocols for the informed consent of potential living liver donors. Programs which perform living lung, intestine or pancreas donor recovery are not required to follow any OPTN policy or develop and follow their own center specific protocols for the informed consent of potential living organ donors.

This proposal was originally intended to expand the same level of detail concerning the informed consent of living kidney donor to living liver donors. It is now expanded to include all living donors.

The proposal would lead to the standardization of the informed consent process for all living donors. Under this proposal, all existing policy requirements for the informed consent of living kidney donors were compared to the (JSWG) recommended requirements for living liver donors. The common elements in existing living kidney donor policy and recommended requirements for living liver donors are proposed as new requirements for all categories of living donors. The proposal would lead to some standardization of the informed consent process for all potential living donors.

The proposal contains additional elements as components of informed consent specific to living kidney and liver donors. In general the additional elements address education about expected post donation native organ function and potential medical and surgical risk associated with these specific types of living donation. The Committee considered but did not propose any additional element of informed consent specific to living lung, pancreas, or intestine donation because the volume of living lung, pancreas, and intestine donation is so low that that the risks associated with these surgeries may not be fully known. Given the low volumes, there is limited published data on complications or long term outcomes and there is unlikely to be a consensus conference for the development of an expert opinion.

### Supporting Evidence

**Table 1. Living Donors in the US by Volume and Type of Donor  
January 1, 2007 – December 31, 2012**

<b>Year of Donation</b>	<b>Kidney</b>	<b>Liver</b>	<b>Lung</b>	<b>Intestine</b>	<b>Pancreas</b>
<b>2005</b>	6573	323	2	7	2
<b>2006</b>	6436	288	5	4	1
<b>2007</b>	6043	266	6	1	0
<b>2008</b>	5968	249	0	0	1
<b>2009</b>	6387	219	1	2	0
<b>2010</b>	6277	282	0	1	0
<b>2011</b>	5771	247	2	1	0
<b>2012</b>	5619	246	2	0	0

### Data subject to change based on future data submission or correction

Several consensus statements have been published affirming basic principles governing the informed consent of prospective living kidney donors (Adams et al., 2002; Ethics Committee of the Transplantation Society, 2004; Abecassis et al., 2000). These principles include ensuring that prospective donors are capable of making the decision to donate, willing to donate, free of coercion or undue pressure to donate, medically and psychosocial suitable to donate, and fully informed of the risks and benefits of donation. These principles provide the framework for the current proposal.

### Expected Impact on Living Donors or Living Donation

A standardized informed consent process should improve the transparency of the living donation process and could improve the confidence of living donors with regard to the safety of living donation. Over time, analysis of the living donor informed consent process could contribute to better outcomes.

## Expected Impact on Specific Patient Populations

There should be no impact on the candidate pool. However, the proposal has the potential to affect all living donors.

In 2012, there were 5867 living organ donors including 5619 living kidney donors, 246 living liver donors, and two living lung donors.

Between 2007 and 2012 there were seven living lung donors, five living intestinal donors, and one living pancreas donor.

## Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule

<i>HHS Program Goals</i>	<i>Strategic Plan Goals</i>
<b>Patient Safety</b>	The OPTN will promote safe, high-quality care for transplant candidates, transplant recipients, and living donors
<b>Best Use</b>	To achieve the best use of donated organs the OPTN will refine policies by incorporating objective, measurable criteria related to concepts of donor risk/quality and recipient benefit
<b>Operational Effectiveness</b>	The OPTN will identify process and system improvements that best support critical network functions, and work to disseminate them to all members who could benefit

## Plan for Evaluating the Proposal

The Committee will request biannual blinded reports on the number of centers found out of compliance during UNOS living donor program audits, and will evaluate if the policy requirements for the informed consent of living donors need clarification or revision to aid centers with compliance.

## Additional Data Collection

The proposal does not require changes to the OPTN data collection system.

## Expected Implementation Plan

If this policy proposal is approved by the Board of Directors, living donor recovery centers would be required to follow new policies for the informed consent of living kidney donors. The UNOS Living Donor Site Surveyors will evaluate center compliance. The proposal will not require programming in Unet<sup>SM</sup>.

## Communication and Education Plan

The proposal addresses both modifications to existing policy and new requirements. Its applicability to all potential living donors requires an above-average effort to ensure that living donor transplant programs are aware of the requirements. Communication and education efforts

will address the details of the new and revised requirements and support members who may need to revise their individual protocols.

Information about the new requirements would be included in an ongoing effort to provide educational webinars to members regarding patient and living donor safety, with particular emphasis on practices at living donor transplant programs. It also would be incorporated into the OPTN Evaluation Plan and addressed in the context of ongoing member notification as the plan is periodically updated.

In addition, notification of the amended policy requirements would be included in the following routine communication vehicles:

- Policy notice
- System notice
- UNOS Update article
- Member e-newsletter/blog article
- Notification to a listserv group for transplant administrators

## **Monitoring and Evaluation**

At living donor recovery hospitals, UNOS site surveyors may:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that:

- There is documentation of the donor's signature on a statement that the donor:
  - Is willing to donate
  - Is free from inducement or coercion
  - Has been informed that he/she may decline to donate at any time
- The potential donor was offered an opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential
- An ILDA was available to assist the potential donor during the process
- The recovery hospital provided information or disclosure to the donor including all of the required elements

Interview relevant staff, and substantiate the information obtained in the interview through review of internal policies, procedures and/or protocols; a sample of living donor medical records; or any material incorporated into the medical record by reference to obtain evidence that the hospital's standard practice is to provide information to donors in a language in which the donor is able to engage in a meaningful dialogue with the recovery program staff.

## **Policy or Bylaw Proposal**

In this proposal the existing policy requirements for living kidney donor informed consent, and new proposed informed consent requirements for all other categories of living donors are integrated and presented in a table format. Under this integration, many existing policy requirements for the informed consent of living kidney donors are proposed as new policy requirements for all categories of living donors. Some existing policy for the informed consent of living kidney donors is specific to kidney donation and cannot be extended to other types of living donors. Consequently, the proposed policy contains informed consent requirements for all

categories of living donors, followed by existing requirements specific to living kidney donors and next new proposed requirements specific to living liver donors.

Modification of existing policy is typically indicated with strikeouts and underlining. The proposal contains both new and extensive reorganization of existing policy which would typically be presented with strikeouts of the policy in its original location and underlining of the same policy language in the new location. Since the proposed changes would be difficult to read with numerous strikethroughs and underlining, the proposed changes are being presented differently. For your convenience, only proposed new, modified or deleted policy is presented with strikethroughs and underlining. Existing policy language that is unchanged but reorganized or repositioned is not presented with strikethroughs and underlining.

## 14.2 Independent Living Donor Advocate (ILDA) Requirements

### 14.2.A ILDA Requirements for Kidney Living Donor Recovery Hospitals

For any ~~potential~~ living kidney donor who is undergoing evaluation for donation, the living kidney donor recovery hospital must designate and provide each ~~potential~~ living donor with an ILDA who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient. The ILDA may be one person or an independent living donor advocate team with multiple members. An ILDA team must designate one person from the team as the key contact for each ~~potential~~ living donor.

The ILDA must:

1. Function independently from the transplant candidate's team.
2. Advocate for the ~~potential~~ living donor ~~and the living donor~~.
3. Fulfill the qualification and training requirements specified in the recovery hospital's protocols regarding knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressure on the ~~potential~~ living donor's decision about whether to donate. Document that each requirement has been met.
4. Review whether the ~~potential~~ living donor has received information on each of the following areas and assist the ~~potential~~ donor in obtaining additional information from other professionals as needed about the:
  - Informed-consent process as described in *Policy 14.3: Informed Consent Requirements and its subsections*
  - Evaluation process according to *Policies ~~14.3.A.ii~~, ~~14.51-A~~: Living Kidney Donor Psychosocial Evaluation Requirements and ~~14.4.B~~: Living Kidney Donor Medical Evaluation Requirements and its subsections*
  - Surgical procedure
  - Medical risks according to *Policy ~~14.3.A.ii~~-Tables 14-1 through 14-5*

- Psychosocial risks according to ~~Policy 14.3.A.ii~~ Tables 14-1 through 14-5
- Follow-up requirements, and the benefit and need for participating in follow-up according to *Policies 18.1: Data Submission Requirements, 18.5.A: Reporting Requirements after Donation and 18.5.B: Submission of Living Donor Death and Organ Failure*

5. Document that each topic was reviewed.

## **14.2.B ILDA Protocols for Kidney Living Donor Recovery Hospitals**

The living kidney donor recovery hospital must develop, and once developed must comply with written protocols for:

1. The composition of the ILDA team, if the hospital uses a team
2. The qualifications and training (both initial and ongoing) required for the ILDA. Minimum qualifications must include knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressures on the potential living donor's donation decision.
3. The duties and responsibilities of the ILDA, which must include at least the functions and duties listed throughout *Policy 14.2.A: ILDA Requirements for Kidney Living Donor Recovery Hospitals*.
4. The process the living donor recovery hospital will provide for the ILDA to file a grievance when necessary to protect the rights or best interests of the living donor.
5. The process the living donor recovery hospital will use to address any grievance raised by the ILDA concerning the rights or best interests of the living donor.

## **14.3 Informed Consent Requirements**

~~Education is important so that the potential living donor understands all aspects of the donation process, especially the risks and benefits.~~

### **~~14.3.A Informed Consent of Living Kidney Donors~~**

~~Informed consent is required to ensure that a potential living donor understands:~~

- ~~1. That the living donor will undertake risk and will receive no medical benefit from donating a kidney.~~
- ~~2. That there are both the general risks of the surgery as well as hospital-specific risks.~~

#### **~~14.3.A.i Living Donor Informed Consent for Evaluation of Potential Living Donors~~**

~~The kidney recovery hospital must maintain documentation in the living donor's medical record that the recovery hospital informed the potential living donor of all of the following:~~

**14.3.A.ii Living Donor Informed Consent Requirements**

The recovery hospital must obtain informed consent from any potential living kidney donor that must include written assurance by the potential living donor of *all* of the following:

The kidney recovery hospital must document in the potential donor's medical record that the hospital provided the potential donor with *all* of the following:

The recovery hospital is responsible for informed consent which must include *all* of the components in Tables 14-1 – 14-5.

Documentation of informed consent must be maintained in the donor medical record.

**Table 14-1: Requirements for Living Donor Informed Consent**

The recovery hospital must:	These elements of informed consent
Obtain from all living donors	<p>Written assurance by the potential donor <u>The donor's signature on a document that confirms that the donor:</u></p> <ul style="list-style-type: none"><li>• That the potential donor is willing to donate</li><li>• That the potential donor is free from inducement and coercion and</li><li>• That the potential donor has been informed that he or she may decline to donate at any time.</li></ul>

The recovery hospital must:	These elements of informed consent
Provide to all living donors	<p>The potential living donors must be offered aAn opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential.</p> <p>The ILDA must be available to assist the potential donor during this the consent process, according to <i>Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements</i>.</p> <p>Instruction about all phases of the living donation process, which include:</p> <ul style="list-style-type: none"> <li>• eConsent</li> <li>• mMedical and psychosocial evaluations</li> <li>• pPre and post operative care, and</li> <li>• rRequired post-operative follow up according to <i>Policy 18.5: Living Donor</i>.</li> </ul> <p>Teaching or instructional material can include any media, one-on-one or small group interaction.</p> <p>Teaching or instruction must be provided in a language in which the donor is able to engage in meaningful dialogue with transplant program recovery hospital's staff.</p>

The recovery hospital must:	These elements of informed consent
Disclose to all living donors	<p><del>The disclosure that t</del>The recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient.</p> <p><del>The disclosure that i</del>It is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for anything of value including, but not limited, to cash, property, and vacations.</p> <p><del>Disclosure t</del>That <u>the</u> recovery hospital must provide an ILDA.</p> <p><del>The disclosure of a</del>Alternate procedures or courses of treatment for the recipient, including deceased donor transplantation, and that:</p> <ul style="list-style-type: none"> <li>a) A deceased donor <u>kidney organ</u> may become available for the recipient <u>candidate</u> before the recovery hospital completes the <u>potential</u> living donor's evaluation or the living donor transplant occurs.</li> <li>b) Any transplant candidate may have risk factors for increased morbidity or mortality that are not disclosed to the <u>potential</u> donor.</li> </ul> <p><del>The disclosure that h</del>Health information obtained during the evaluation is subject to the same regulations as all records and could reveal conditions that must be reported to local, state, or federal public health authorities.</p> <p><del>The disclosure that t</del>The recovery hospital is required to:</p> <ul style="list-style-type: none"> <li>a) Report living donor follow up information, at the time intervals specified in <i>Policy 18.5: Living Donor</i>.</li> <li>b) Have the <u>potential</u> donor commit to post operative follow up testing coordinated by the recovery hospital.</li> </ul> <p><del>The disclosure that a</del>Any infectious disease or malignancy pertinent to acute recipient care discovered during the <u>potential</u> donor's first two years of follow up care:</p> <p style="padding-left: 40px;"><del>Will be disclosed to the donor</del></p> <ul style="list-style-type: none"> <li>a) May need to be reported to local, state or federal public health authorities</li> <li>b) Will be disclosed to their recipient's transplant center</li> <li>c) Will be reported through the OPTN Improving Patient Safety Portal.</li> </ul>

The recovery hospital must:	These elements of informed consent
<b>Disclose to all living donors</b>	<p><del>potential</del> A living donor must undergo a medical evaluation according to <i>Policy 14.4 ( Medical Evaluation Requirements for Living Donors)</i> and a psychosocial evaluation as required by <i>Policy 14.5.1 (Psychosocial Evaluation Requirements for Living Donors)</i></p> <p>The hospital may refuse the <del>potential</del> donor. In such cases, the recovery hospital must inform the <del>potential</del> donor that a different recovery hospital may evaluate the <del>potential</del>-donor using different selection criteria.</p> <p>The following are inherent risks associated with evaluation for living donation:</p> <ul style="list-style-type: none"> <li>a) Allergic reactions to contrast</li> <li>b) Discovery of reportable infections</li> <li>c) Discovery of serious medical conditions</li> <li>d) Discovery of adverse genetic findings unknown to the donor</li> <li>e) Discovery of certain abnormalities that will require more testing at the donor's expense or create the need for unexpected decisions on the part of the transplant team</li> </ul> <p><del>That the following</del> <u>There are</u> surgical, medical, psychosocial, and financial risks are associated with living kidney donation. <del>This disclosure must state that these risks</del> <u>which</u> may be temporary or permanent and include, but are not limited to, <i>all</i> of the following:</p>

The recovery hospital must:	These elements of informed consent
<b>Disclose to all living donors</b>	<ul style="list-style-type: none"> <li>a. Potential medical or surgical risks: <ul style="list-style-type: none"> <li>i. Death</li> <li>ii. Scars, pain, fatigue, and other consequences typical of any surgical procedure</li> <li>iii. Abdominal symptoms such as bloating, nausea, and developing bowel obstruction</li> <li>iv. That the morbidity and mortality of the <del>potential</del> donor may be impacted by obesity, hypertension, or other donor-specific pre-existing conditions</li> <li><del>v. Decreased kidney function</del></li> <li><del>vi. Kidney failure and the need for dialysis or kidney transplant for the donor</del></li> </ul> </li>   <li>b. Potential psychosocial risks: <ul style="list-style-type: none"> <li>i. Problems with body image</li> <li>ii. Post-surgery depression or anxiety</li> <li>iii. Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies</li> <li>iv. Changes to the donor's lifestyle from donation</li> </ul> </li>   <li>c. Potential financial impacts: <ul style="list-style-type: none"> <li>i. Personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation-related costs</li> <li>ii. Need for life-long follow up at the donor's expense</li> <li>iii. Loss of employment or income</li> <li>iv. Negative impact on the ability to obtain future employment</li> <li>v. Negative impact on the ability to obtain, maintain, or afford health insurance, disability insurance, and life insurance</li> <li>vi. Future health problems experienced by living donors following donation may not be covered by the recipient's insurance</li> </ul> </li> </ul>

**Table 14-42: Required Recipient Outcome and Transplanted Kidney Organ Survival Data**

If the recovery hospital and the recipient hospital:	Then:	Including <i>all</i> the following information:
Are the same	The recovery hospital must provide the <del>potential</del> living donor with both national and that hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) hospital-specific reports.	<ul style="list-style-type: none"> <li>• National 1-year patient and transplanted <del>kidney</del> <u>organ</u> survival</li> <li>• The hospital's 1-year patient and transplanted <del>kidney</del> <u>organ</u> survival</li> <li>• Notification about all Centers for Medicare and Medicaid Services (CMS) outcome requirements not being met by the transplant hospital</li> </ul>
Will not be the same and the recipient hospital is known	The recovery hospital must provide the <del>potential</del> living donor with both national and the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR hospital-specific reports.	<ul style="list-style-type: none"> <li>• National 1-year patient and transplanted <del>kidney</del> <u>organ</u> survival</li> <li>• The recipient hospital's 1-year patient and transplanted <del>kidney</del> <u>organ survival</u></li> <li>• Notification about all CMS outcome requirements not being met by the recipient hospital</li> </ul>

**Table 14-3: Additional Requirements for the Informed Consent of Living Kidney Donors**

The recovery program must	These additional elements as components of informed consent for living kidney donors
Provide to all living kidney donors	<p>Education about expected post-donation kidney function, and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the living donor in the future, to include:</p> <ol style="list-style-type: none"> <li>a. On average, living donors may have a 25-35% permanent loss of kidney function after donation.</li> <li>b. Baseline risk of ESRD for living kidney donors does not exceed that of the general population with the same demographic profile.</li> <li>c. Living donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occurs, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young <del>potential</del> living donor cannot predict lifetime risk of CKD or ESRD.</li> <li>d. Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD may be faster with only one kidney.</li> <li>e. Dialysis is required if the donor develops ESRD.</li> <li>f. Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to <i>Policy 8.3: Points</i></li> </ol>
Disclose to all living kidney donors	<p><del>Disclosure that these</del> <u>Surgical</u> risks may be transient or permanent and include but are not limited to:</p> <ul style="list-style-type: none"> <li>• Potential medical or surgical risks: <ul style="list-style-type: none"> <li>○ Decreased kidney function</li> <li>○ Kidney failure and the need for dialysis or kidney transplant for the donor</li> </ul> </li> </ul>

**Table 14-4: Additional Requirements for the Informed Consent of Living Liver Donors**

The recovery program must	These additional elements as components of informed consent for living liver donors
Disclose to all living liver donors	<p><u>Surgical risks may be transient or permanent and include but are not limited to:</u></p> <ul style="list-style-type: none"> <li>• <u>Acute liver failure with need for liver transplant.</u></li> <li>• <u>Transient liver dysfunction with recovery. The potential for transient liver dysfunction depends upon the amount of the total liver removed for donation.</u></li> <li>• <u>Risk of red cell transfusions or other blood products.</u></li> <li>• <u>Biliary complications including leak or stricture that may require additional intervention.</u></li> <li>• <u>Hernia, wound infection, scars, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure.</u></li> <li>• <u>Post-donation laboratory tests may result in abnormal or false positive results that may trigger additional tests that have associated risks.</u></li> </ul>

**Table 14-5: Additional Required Living Liver Donor Recipient Outcome and Transplanted Living Donor Liver Survival Data**

<u>If the recovery hospital and the recipient hospital:</u>	<u>Then:</u>	<u>Including all the following information:</u>
<u>Are the same</u>	<u>The recovery hospital must provide the living donor with the t hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) hospital-specific reports.</u>	<ul style="list-style-type: none"> <li data-bbox="927 506 1338 638">• <u>The hospital's 1-year living donor recipient's survival and recipient's graft survival rates</u></li> </ul>
<u>Will not be the same and the recipient hospital is known</u>	<u>The recovery hospital must provide the living donor with the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR hospital-specific reports.</u>	<ul style="list-style-type: none"> <li data-bbox="927 842 1333 974">• <u>The recipient hospital's 1-year living donor recipient's survival and graft survival rates</u></li> </ul>

**14.3.B Living Liver Donor Required Protocols for Informed Consent for Evaluation**

Liver recovery hospitals must develop and comply with written protocols for the informed consent process and for the living donor liver recovery that must include, but are not limited to, all 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. The assurance that all communication between the potential living donor and the transplant hospital will remain confidential.
3. A discussion of the potential living donor's right to opt out at any time during the donation process.
4. A discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance.
5. The disclosure by the liver recovery hospital 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.
6. A plan to collect the required follow up information about each donor.
7. Providing the toll-free Patient Services Line that is available for living donors to report concerns or grievances to the OPTN.
8. The disclosure that it is a federal crime for any person to knowingly acquire, obtain, or otherwise transfer any human organ for anything of value, including, but not limited, to cash, property, and vacations. This documentation must be maintained in the potential donor's official medical record.