OPTN/UNOS Policy Notice Modifications to Informed Consent Requirements for Potential Living Donors

Sponsoring Committee:	**Living Donor**
Policy/Bylaws Affected:	**Policies 13.4 (Informed Consent for KPD Donors), 14.1 (Psychosocial Evaluation Requirements), 14.2 ((Independent Living Donor Advocate (ILDA)), 14.2.B (ILDA Protocols for Living Donor Recovery Hospitals), 14.3 (Informed Consent Requirements), and Bylaws E.6 (Kidney Transplant Programs that Perform Living Donor Recovery, F.8 (Liver Transplant Programs that Perform Living Donor Recovery**
Public Comment:	**August 15, 2016 – October 15, 2016**
Effective Date:	**Pending implementation and notice to members**

Problem Statement

Since requirements for the informed consent of living kidney, liver, intestine, lung and pancreas donors were initially implemented, several new developments indicate the need to update and clarify the current informed consent policy requirements. These new developments include:

- Publication of new evidence on living kidney donor health outcomes
- Consensus-based recommendations from professional societies that there is new information regarding the health outcomes for living kidney donors that should be disclosed as part of the informed consent process
- Reports from living donor program site surveys identifying areas of existing policy language that have been frequently misunderstood by living donor recovery programs

Summary of Changes

Living donor recovery hospitals will need to disclose the following new or modified information to potential donors as components of the informed consent process:

- The risk of preeclampsia or gestational hypertension is increased in pregnancies after donation
- Living kidney donors may have a higher risk of developing ESRD than healthy non-donors with similar medical characteristics
- Transplant hospitals will determine who is a candidate for transplant based on their hospital-specific protocols and clinical judgment

What Members Need to Do

Living donor recovery hospitals will need to update their informed consent policies or protocols to address the new and modified informed consent requirements.

Affected Policy Language

New language is underlined (example) and language that is removed is struck through (~~example~~).

13.6.B Requirements for Match Run Eligibility for Potential KPD Donors

The OPTN KPD program will only match potential KPD donors that comply with *all* of the following requirements:

1. The transplant hospital registering the potential KPD donor must perform blood typing and subtyping as required by *Policy 14.5: Living Donor Blood Type Determination and Reporting* with the following modifications:

    a. The transplant hospital registering the potential KPD donor must report the potential KPD donor's blood type to the OPTN Contractor
    b. A qualified health care professional, other than the qualified health care professional who initially reported the potential KPD donor's blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential KPD donor's blood type to the OPTN Contractor
    c. The potential KPD donor is not eligible for a KPD match run until the transplant hospital verifies and reports two identical blood types

2. The transplant hospital registering the potential KPD donor must complete the informed consent process according to *Policy 13.4: Informed Consent for KPD Donors*
3. The transplant hospital registering the potential KPD donor must complete the ~~medical~~ evaluation process according to *Policy 14: Living Donation*
4. The transplant hospital registering the potential KPD donor must submit the information for the required fields below to the OPTN Contractor:

    a. Donor details, including *all* of the following:
        - Last name
        - First name
        - SSN
        - Date of birth
        - Gender
        - Ethnicity
        - ABO
        - Height and weight
        - Whether the potential KPD donor is a non-directed donor or a paired donor
        - If the potential KPD donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential KPD donor's relationship to the candidate
        - Whether the potential KPD donor has signed an agreement to participate in the OPTN KPD program
        - Whether the potential KPD donor has signed a release of protected health information

- Whether the potential KPD donor has signed an informed consent as required in policy
- Whether the potential KPD donor has undergone all ~~medical~~ evaluations as required in *Policy 14: Living Donation*
- Whether the potential KPD donor has had all ~~age appropriate~~ cancer screenings as ~~defined by the American Cancer Society~~ required in *Policy 14: Living Donation*
- KPD status: active, inactive or removed. A donor must have current active status in the OPTN KPD program to be eligible for a match run.

b. Clinical information, including *all* of the following:

- The number of anti-hypertensive medications the potential KPD donor is currently taking
- Systolic and diastolic blood pressure with date (either 24-hour monitoring or two measurements)
- Creatinine clearance or glomerular filtration rate (GFR), date, and method
- Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results

c. Donor choices, including *all* of the following:

- Whether the potential KPD donor would be willing to travel, and, if so, the transplant hospitals to which the potential KPD donor would be willing to travel or the distance the donor is willing to travel
- Whether the potential KPD donor is willing to ship a kidney
- Whether the potential KPD donor is willing to donate a left kidney, right kidney, or either kidney
- Whether the KPD candidate-donor pair and the transplant hospital are willing to participate in a three-way exchange or a donor chain
- Whether the potential KPD donor and the transplant hospital are willing for the potential KPD donor to be a bridge donor

d. Donor HLA as defined in *Policy 13.5.C: HLA Typing Requirements for OPTN KPD Donors*

5. The potential KPD donor must be paired to an active and eligible candidate registered in the OPTN KPD program or be a non-directed donor
6. The transplant hospital registering the potential KPD donor must submit a response for all previous match offers for the potential KPD donor in the OPTN KPD program, including reason for refusing offers
7. The potential KPD donor must not be in a pending exchange in the OPTN KPD program

14.1.A Living Donor Psychosocial Evaluation Requirements

Living donor psychosocial evaluation requirements apply to living kidney, liver, pancreas, lung~~, or~~ and intestine donors.

The living donor psychosocial evaluation must be performed by a psychiatrist, psychologist, ~~or~~ masters prepared social worker, or licensed clinical social worker prior to organ recovery. Documentation of the psychosocial evaluation must be maintained in the living donor medical record and include *all* of the following components:

1. An evaluation for any psychosocial issues, including mental health issues that might complicate the living donor's recovery and could be identified as risks for poor psychosocial outcome.
2. An evaluation for the presence of behaviors that may increase risk for disease transmission as defined by the *U.S. Public Health Service (PHS) Guideline*.
3. A review of the living donor's history of smoking, alcohol, and drug use, ~~abuse, and dependency~~ including past or present substance use disorder.
4. The identification of factors that warrant educational or therapeutic intervention prior to the final donation decision.
5. The determination that the living donor understands the short and long-term medical and psychosocial risks for both the living donor and recipient associated with living donation.
6. An assessment of whether the decision to donate is free of inducement, coercion, and other undue pressure by exploring the reasons for donating and the nature of the relationship, if any, to the transplant candidate.
7. An assessment of the living donor's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes evaluating whether the donor has a realistic plan for donation and recovery, with social, emotional and financial support available as recommended.
8. A review of the living donor's occupation, employment status, health insurance status, living arrangements, and social support.
9. The determination that the living donor understands the potential financial implications of living donation.

14.2.A ILDA Requirements for Living Donor Recovery Hospitals

Living donor ILDA requirements apply to living kidney, liver, pancreas, intestine, and ~~or~~ lung donors.

For any living ~~kidney~~ donor who is undergoing evaluation for donation, the living donor recovery hospital must designate and provide each 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 ILDA ~~independent living donor advocate~~ team with multiple members. An ILDA team must designate one person from the team as the key contact for each living donor. All ILDA requirements must be completed prior to organ recovery.

The ILDA must:

1. Function independently from the transplant candidate's team.
2. Advocate for the rights of 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 living donor's decision about whether to donate. ~~Document that each requirement has been met~~.
4. Review and document whether the living donor has received information on each of the following areas and assist the donor in obtaining additional information from other professionals as needed about the:
    a. Informed consent process as described in *Policy 14.3: Informed Consent Requirements*
    b. Evaluation process according to *Policies 14.1.A: Living Donor Psychosocial Evaluation Requirements* and *14.4.A: Living Donor Medical Evaluation Requirements*
    c. Surgical procedure
    ~~d. Medical risks according to *Tables 14-1* through *14-5*~~
    ~~e. Psychosocial risks according to *Tables 14-1* through *14-5*~~
    ~~f~~d. Follow-up requirements, and the benefit and need for participating in recovery hospital's requirements ~~follow-up~~ according to *Policies 18.1: Data Submission Requirements, 18.5.A: Reporting Requirements after Living Kidney Donation, 18.5:*

Living Donor Data Submission Requirements, and ~~*18.5.C: Submission of Living Donor Death and Organ Failure*~~ *18.6: Reporting of Living Donor Adverse Events*

~~5. Document that each topic was reviewed.~~

14.2.B ILDA Protocols for Living Donor Recovery Hospitals

The living 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. Document that each requirement has been met.
3. The duties and responsibilities of the ILDA, which must include at least the functions and duties ~~listed throughout~~ according to *Policy 14.2.A: ILDA Requirements for 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

The living donor recovery hospital is responsible for obtaining and documenting ~~Living donor~~ informed consent ~~requirements~~ prior to organ recovery. Informed consent requirements apply to living kidney, liver, pancreas, ~~and~~ intestine, and ~~or~~ lung donors and must~~.~~
~~The recovery hospital is responsible for informed consent which must~~ include *all* of the components in *Tables 14-1* through *14-~~5~~4*. Documentation of informed consent must be maintained in the living donor medical record.

Table 14-1: Requirements for Living Donor Informed Consent

The recovery hospital must:	These elements of informed consent :
Obtain from living donors	The living donor's signature on a document that confirms that the donor: • 1. Is willing to donate • 2. Is free from inducement and coercion ~~and~~ • 3. Has been informed that he or she may decline to donate at any time
Provide to living donors	1. An opportunity to discontinue the living donor consent or evaluation process in a way that is protected and confidential. 2. The ILDA must be available to assist the living donor during the consent process, according to *Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements.* 3. Instruction about all phases of the living donation process, which includes: • Consent • Medical and psychosocial evaluations • Pre- and post-operative care • Required post-operative follow-up according to *Policy 18.5: Living Donor Data Submission Requirements*~~.~~ Teaching or instructional material can include any media, one-on-one or small group interaction. Teaching or instruction must be provided in a language in which the living donor is able to engage in meaningful dialogue with recovery hospital's staff.

The recovery hospital must:	These elements of informed consent :
Disclose to living donors	~~The recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient.~~ 1. 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. 2. The recovery hospital must provide an ILDA. 3. Alternate procedures or courses of treatment for the recipient including deceased donor transplantation.~~, and that:~~ 4. ~~a.~~ A deceased donor organ may become available for the candidate before the recovery hospital completes the living donor's evaluation or the living donor transplant occurs. ~~b. Any transplant candidate may have risk factors for increased morbidity or mortality that are not disclosed to the donor.~~ 5. Transplant hospitals determine candidacy for transplantation based on existing hospital specific guidelines or practices and clinical judgment. 6. The recovery hospital will take all reasonable precautions to provide confidentiality for the living donor and recipient. 7. Any transplant candidate may have an increased likelihood of adverse outcomes (including but not limited to graft failure, complications, and mortality) that: • Exceed local or national averages • Do not necessarily prohibit transplantation • Are not disclosed to the living donor 8. The recovery hospital can disclose to the living donor certain information about candidates only with permission of the candidate, including: • The reasons for a transplant candidate's increased likelihood of adverse outcomes • Personal health information collected during the transplant candidate's evaluation, which is confidential and protected under privacy law 9. Health information obtained during the living donor evaluation is subject to the same regulations as all medical records and could reveal conditions that must be reported to local, state, or federal public health authorities. 10. The recovery hospital is required to: a. Report living donor follow-up information, at the time intervals specified in *Policy 18.5: Living Donor Data Submission Requirements*.~~.~~ b. Have the donor commit to post-~~operative~~ donation follow-up testing coordinated by the recovery hospital~~.~~ 11. Any infectious disease or malignancy that is pertinent to acute recipient care discovered during the donor's first two years of follow-up care: a. May need to be reported to local, state or federal public health authorities b. Will be disclosed to their recipient's transplant ~~center~~ hospital c. Will be reported through the OPTN Improving Patient Safety Portal 12. A living donor must undergo a medical evaluation according to *Policy 14.4: Medical Evaluation Requirements for Living Donors* and a psychosocial evaluation as required by *Policy 14.1: Psychosocial Evaluation Requirements for Living Donors*. 13. The hospital may refuse the living donor. In such cases, the recovery hospital must inform the living donor that a different recovery hospital may evaluate the living donor using different selection criteria. 14. The following are inherent risks associated with evaluation for living donation: a. Allergic reactions to contrast

The recovery hospital must:	These elements of informed consent :
Disclose to living donors	b. Discovery of reportable infections c. Discovery of serious medical conditions d. Discovery of adverse genetic findings unknown to the living donor e. Discovery of certain abnormalities that will require more testing at the living donor's expense or create the need for unexpected decisions on the part of the transplant team 15. There are surgical, medical, psychosocial, and financial risks associated with living donation, which may be temporary or permanent and include, but are not limited to, *all* of the following: a. Potential medical or surgical risks: i. Death ii. Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure iii. Abdominal symptoms such as bloating, nausea, and developing bowel obstruction iv. That the morbidity and mortality of the living donor may be impacted by age, obesity, hypertension, or other donor-specific pre-existing conditions b. Potential psychosocial risks: i. Problems with body image ii. Post-surgery depression or anxiety iii. Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies iv. Changes to the living donor's lifestyle from donation c. Potential financial impacts: 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 ii. Need for life-long follow-up at the living donor's expense iii. Loss of employment or income iv. Negative impact on the ability to obtain future employment v. Negative impact on the ability to obtain, maintain, or afford health insurance, disability insurance, and life insurance vi. Future health problems experienced by living donors following donation may not be covered by the recipient's insurance

Table 14-~~3~~2: Additional Requirements for the Informed Consent of Living Kidney Donors

The recovery ~~program~~ hospital must:	These additional elements as components of informed consent for living kidney donors:
Provide to all living kidney donors	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: a. On average, living donors will ~~may~~ have a 25-35% permanent loss of kidney function after donation. b. ~~Baseline~~ Although risk of ESRD for living kidney donors does not exceed that of the general population with the same demographic profile, risk of ESRD for living kidney donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors. 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 living donor cannot predict lifetime risk of CKD or ESRD. 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. e. Dialysis is required if the living donor develops ESRD. f. Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to *Policy 8.3: Kidney Allocation Points*.
Disclose to all living kidney donors	Surgical risks may be transient or permanent and include but are not limited to: ~~• Potential medical or surgical risks:~~ • Decreased kidney function • Acute ~~K~~kidney failure and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period
Disclose to all female living kidney donors	Risks of preeclampsia or gestational hypertension are increased in pregnancies after donation

Table 14-~~4~~3: Additional Requirements for the Informed Consent of Living Liver Donors

The recovery ~~program~~ hospital must:	These additional elements as components of informed consent for living liver donors:
Disclose to all living liver donors	Surgical risks may be transient or permanent and include but are not limited to: • Acute liver failure with need for liver transplant. • Transient liver dysfunction with recovery. The potential for transient liver dysfunction depends upon the amount of the total liver removed for donation. • Risk of red cell transfusions or other blood products. • Biliary complications, including leak or stricture that may require additional intervention. • Post-donation laboratory tests may result in abnormal or false positive results that may trigger additional tests that have associated risks.

As part of the informed consent process, recovery hospitals must also provide transplant recipient outcome and transplanted organ survival data to living donors according to *Table 14-4*.

Table 14-24: Required Recipient Outcome and Transplanted Organ Survival Data

If the recovery hospital and the recipient hospital:	Then the recovery hospital must provide the living donor with:	Including *all* the following information:
Are the same	~~The recovery hospital must provide the living donor with~~ bBoth national and that hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) program-specific reports.	• National 1-year patient and transplanted organ survival • The hospital's 1-year patient and transplanted organ survival • Notification about all Centers for Medicare and Medicaid Services (CMS) outcome requirements not being met by the transplant hospital
Will not be the same and the recipient hospital is known	~~The recovery hospital must provide the living donor with b~~Both national and the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR program-specific reports.	• National 1-year patient and transplanted organ survival • The recipient hospital's 1-year patient and transplanted organ survival • Notification about all CMS outcome requirements not being met by the recipient hospital
Will not be the same and the recipient hospital is not known	National transplant recipient outcomes from the most recent SRTR reports.	• National 1-year patient and transplanted organ survival

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

~~If the recovery hospital and the recipient hospital:~~	~~Then:~~	~~Including *all* the following information:~~
~~Are the same~~	~~The recovery hospital must provide the living donor with the hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) hospital-specific reports.~~	~~The hospital's 1-year living donor recipient's survival and recipient's graft survival rates~~
~~Will not be the same and the recipient hospital is known~~	~~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.~~	~~The recipient hospital's 1-year living donor recipient's survival and graft survival rates~~

[*Subsequent table captions and cross-references to tables affected by the re-numbering of tables will also be changed as necessary.*]

OPTN Bylaws

E.6 Kidney Transplant Programs that Perform Living Donor Recovery

A. ~~Potential~~ Living Donor Medical Evaluation

The kidney recovery hospital must have the clinical resources available to assess the medical condition of and specific risks to the ~~potential~~ living donor.

B. ~~Psychological~~ Living Donor Psychosocial Evaluation ~~Assessments~~

The kidney recovery hospital must have the clinical resources to perform a psychosocial ~~assessment~~ evaluation of the ~~potential~~ living donor~~'s ability to make an informed decision~~. ~~This psychosocial assessment should also confirm that the evaluation and donation are completely voluntary.~~

C. Independent Living Donor Advocate (ILDA)

The kidney recovery hospital must have an ~~i~~independent living ~~D~~donor ~~A~~advocate (IL~~D~~A) who is not involved with the evaluation or treatment decisions of the potential recipient, and is a knowledgeable advocate for the ~~potential~~ living donor. The IL~~D~~A must be independent of the decision to transplant the potential recipient and follow the ~~P~~protocols that outline the duties and responsibilities of the IL~~D~~A ~~as described in~~ according to OPTN *Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements*.

~~The goals of the IDA are:~~

- ~~To promote the best interests of the potential living donor.~~
- ~~To advocate the rights of the potential living donor.~~
- ~~To assist the potential living donor in obtaining and understanding information about the consent process, evaluation process, surgical procedure, as well as the benefit of and need for follow-up care.~~

~~G. Required Living Donor Protocols~~

~~Kidney recovery hospitals must develop protocols that address:~~

1. ~~The living donation process~~
2. ~~Duties for the Independent Donor Advocate (IDA)~~
3. ~~Medical evaluations~~
4. ~~Informed consent~~

~~The requirements for these protocols are described in detail in *OPTN Policy 14.0*.~~

[Subsequent headings and cross-references to headings affected by the re-numbering of this policy will also be changed as necessary.]

F.8 Liver Transplant Programs that Perform Living Donor Recovery

B. ~~Potential~~ Living Donor Medical Evaluations~~s~~

The liver recovery hospital must have the clinical resources available to assess the medical condition of and specific risks to the ~~potential~~ living donor.

C. ~~Potential~~ Living Donor ~~Psychological Assessments~~ Psychosocial Evaluation

~~This~~ The liver recovery hospital must have the clinical resources to perform a psychosocial ~~assessment~~ evaluation of the ~~potential~~ living donor~~'s ability to make an informed decision~~. ~~This psychosocial assessment should also reinforce and confirm that the evaluation and donation are completely voluntary.~~

D. Independent Living Donor Advocate (ILDA)

The liver recovery hospital must have an independent living donor advocate (ILDA) who is not involved with the evaluation or treatment decisions of the potential recipient, and is a knowledgeable advocate for the living donor. ~~is~~ The ILDA must be independent of the decision to transplant the potential recipient and follow the protocols that outline the duties and responsibilities of the ILDA~~, and is a knowledgeable advocate for the potential living donor~~ according to OPTN *Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements*.

~~The goals of the IDA are:~~

~~To promote the best interests of the potential living donor.~~
~~To advocate the rights of the potential living donor.~~
~~To assist the potential living donor in obtaining and understanding information about the consent process, the evaluation process, and the surgical procedure.~~
~~To explain the benefits of and need for follow-up care.~~

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