

Modifications to Informed Consent Requirements for Potential Living Donors

OPTN/UNOS Living Donor Committee

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Executive Summary	1
Is the sponsoring Committee requesting specific feedback or input about the proposal?	1
What problem will this proposal solve?	2
Why should you support this proposal?	3
Which populations are impacted by this proposal?	9
How does this proposal impact the OPTN Strategic Plan?	10
How will the OPTN implement this proposal?	10
How will members implement this proposal?	10
How will members be evaluated for compliance with this proposal?	10
How will the sponsoring Committee evaluate whether this proposal was successful post implementation?	10
Policy or Bylaws Language.....	11

Modifications to Informed Consent Requirements for Potential Living Donors

Affected Policies and Bylaws: 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

Sponsoring Committee: Living Donor

Public Comment Period: August 15, 2016 – October 15, 2016

Executive Summary

In February 2013, the OPTN/UNOS implemented the current requirements for the informed consent of living kidney donors. Informed consent requirements for living liver, pancreas, intestine and lung donors followed in 2014. Since initial implementation, several developments support the need to update and clarify the current informed consent policy requirements including:

- Publication of new evidence on living kidney donor health outcomes
- Consensus-based recommendations from professional societies that the new information regarding the health outcomes for living kidney donors should be disclosed as part of the informed consent process
- Release of living donor program-specific reports (PSRs) by the Scientific Registry of Transplant Recipients (SRTR)
- Reports from living donor program site surveys identifying areas of existing policy language that have been frequently misunderstood by living donor recovery programs

The OPTN/UNOS Living Donor Committee (Committee) reviewed the informed consent requirements for living donors and proposes clarifying existing requirements and adding other new requirements. The proposal also includes related changes to the informed consent requirements for kidney paired donation, and modification and elimination of some related OPTN Bylaws requirements.

This is a goal 3 project under the OPTN Strategic Plan to improve waitlisted patient, living donor, and transplant recipient outcomes.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

- 1) The Committee is interested in feedback concerning whether there are other informed consent processes or consent elements that should be considered as requirements for living kidney, liver, lung, pancreas or intestine donors but are not addressed in current policy or in these proposed changes.
- 2) The Committee is requesting specific feedback on how elements of the proposal would be problematic for members to implement. Feedback is especially encouraged from living lung, intestine, and pancreas donor programs because of the low volume of these types of live donations.

For any identified problem, please provide potential solutions for the Committee to consider.

What problem will this proposal solve?

In February 2013, the OPTN/UNOS implemented the current requirements for the informed consent of living kidney donors. Informed consent requirements for living liver, intestine, lung and pancreas donors followed, and the OPTN implemented these in February 2014. Since initial implementation, there have been several developments that support the need to update and clarify the current informed consent policy requirements including:

- 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
- Release of living donor program-specific reports (PSRs) by the SRTR
- Reports from living donor program site surveys identifying areas of existing policy language that have been frequently misunderstood by living donor recovery programs.

As an example of content areas warranting reevaluation, while existing informed consent policy refers to informing a living kidney donor about their risk of End Stage Renal Disease (ESRD) compared to the general population with the same demographic profile, this is arguably an incomplete description of what donors should be told about ESRD risk based on recent studies. Three studies^{1,2,3} published after February 2013 support a small but statistically significant increase in the risk of kidney failure after donation compared to risk among non-donors who also have similar baseline health status – i.e., in contrast with studies controlling only for demographics, these studies indicate the potential for elevated ESRD risk attributable to donation. Existing policy also does not require living donor recovery programs to provide any information on the possible impact of kidney donation on future pregnancies. One recent study⁴ found higher risks of gestational hypertension or preeclampsia among a cohort of female living donors after kidney donation compared with healthy non-donor controls, with rates of gestational hypertension or preeclampsia similar to prior studies^{5,6} comparing pregnancy outcome in groups of women after versus before donation.

While the methods and magnitudes of effects have been debated, a 2015 American Society of Transplantation consensus statement⁷ recommended that required education for potential living donors include this new information on ESRD risk and pregnancy risk. Newly proposed Kidney Disease Improving Global Outcomes (KDIGO) clinical practice guidelines for the evaluation of living kidney donors that recently underwent public comment include similar recommendations⁸. Additionally, since the initial implementation of the living donor informed consent policies, the SRTR developed living donor program

¹ Mjoen G, Hallan S, Hartmann A, Foss A, Midtvedt K, Oyen O, Reisaeter A, Pfeffer P, Jenssen T, Leivestad T, Line PD, Ovrehus M, Dale DO, Pihlstrom H, Holme I, Dekker FW, Holdaas H.. Long-term risks for kidney donors. *Kidney international*. 2014;86(1):162-7.

² Muzaale AD, Massie AB, Wang MC, Montgomery RA, McBride MA, Wainright JL, Segev DL. Risk of end-stage renal disease following live kidney donation. *JAMA*. 2014;311(6):579-86.

³ Grams ME, Sang Y, Levey AS, Matsushita K, Ballew S, Chang AR, Chow EK, Kasiske BL, Kovesdy CP, Nadkarni GN, Shalev V, Segev DL, Coresh J, Lentine KL*, Garg AX*. *Co-senior authors. Kidney-Failure Risk Projection for the Living Kidney-Donor Candidate. *The New England Journal of Medicine*. 2016;374(5):411-21.

⁴ Garg AX, Nevis IF, McArthur E, Sontrop JM, Koval JJ, Lam NN, Hildebrand AM, Reese PP, Storsley L, Gill JS, Segev DL, Habbous S, Bugeja A, Knoll GA, Dipchand C, Monroy-Cuadros M, Lentine KL. Gestational hypertension and preeclampsia in living kidney donors. *The New England Journal of Medicine*. 2015;372(2):124-33.

⁵ Ibrahim HN, Akkina SK, Leister E, Gillingham K, Corder G, Guo H, Bailey R, Rogers T, Matas AJ. Pregnancy outcomes after kidney donation. *Am J Transplant*. 2009;9(4):825-34.

⁶ Reisaeter AV, Roislien J, Henriksen T, Irgens LM, Hartmann A. Pregnancy and birth after kidney donation: the Norwegian experience. *Am J Transplant*. 2009;9(4):820-4.

⁷ LaPointe Rudow D, Hays R, Baliga P, Cohen DJ, Cooper M, Danovitch GM, Dew MA, Gordon EJ, Mandelbrot DA, McGuire S, Milton J, Moore DR, Morgievlch M, Schold JD, Segev DL, Serur D, Steiner RW, Tan JC, Waterman AD, Zavala EY, Rodrigue JR. Consensus conference on best practices in live kidney donation: recommendations to optimize education, access, and care. *Am J Transplant*. 2015;15(4):914-22.

⁸ KDIGO Clinical Practice Guideline on the Evaluation and Follow-up Care of Living Kidney Donors: Public Review Draft, November 2015. <http://kdigo.org/home/guidelines/livingdonor/> 2015

specific reports in 2015. This is another development that the Committee considered when determining whether the informed consent policies should be modified.

This proposal also includes minor clarifications to *Policy 13: Kidney Paired Donation (KPD)*. These clarifications are intended to make KPD match run eligibility requirements for potential KPD donors consistent with *Policy 14: Living Donation*. For example, current KPD policy (*Policy 13.6.B: Requirements for Match Run Eligibility for Potential KPD Donors*) requires the transplant hospital registering the potential KPD donor to affirm that this donor has undergone all age appropriate cancer screenings as defined by the American Cancer Society. However, *Policy 14.4.B Living Donor Medical Evaluation Requirements* allows for cancer screening protocols from either the American Cancer Society or the U.S. Preventive Services Task Force. Additionally, KPD policy only references the medical evaluations and not the psychosocial evaluations required by *Policy 14: Living Donation*. The KPD policies should be updated for consistency. These clarifications will require programming to change labels in fields that must be submitted in order to be entered into an OPTN KPD match run. The changes to KPD policy only apply to the OPTN KPD program.

The proposal includes some related clarifications and elimination of OPTN Bylaws addressing living donor informed consent and independent living donor advocate requirements. Historically, recovery hospitals were required to develop and follow center-specific protocols for living donor informed consent and independent living donor advocates. Both of these requirements are now superseded by current living donor informed consent and independent living donor advocate policies.

Why should you support this proposal?

The proposed policy changes will help ensure that living organ donors receive education and disclosure of information that is relevant and appropriate for their informed consent, given the current state of knowledge in the field.

How was this proposal developed?

In 2010, a Joint Societies Policy Steering Committee ((comprised of members from the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), and the North American Transplant Coordinators Organization (NATCO), Health Resources Services Administration (HRSA) and OPTN/UNOS)) 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 develop 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, approved by the OPTN/UNOS Board of Directors on November 12, 2012, and became effective on February 1, 2013.

Informed consent requirements for living liver donors were also based on recommendations from a Joint Societies Policy Steering Committee. During review of these recommendations, the Living Donor 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 Living Donor Committee considered this option because it understood that informed consent requirements for 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. Consequently, the project was expanded to address informed consent requirements for these other types of living donors. The Committee declined to expand these requirements to all living donors, notably vascular composite allografts (VCAs), due to the rapid innovation in that field and instead worked with the VCA Committee to develop a guidance document for the informed consent of potential living VCA donors.

In both March and September 2014, the Committee discussed new research on the impact of end stage kidney disease after living kidney donation. The Committee opined that the research was too preliminary to propose changes to current informed consent requirements, but the Committee wanted to continue to consider this research in the future.

The proposed consent requirements for living liver donors were distributed for public comment between March 14 and June 13, 2014. The proposed extension of the consent requirements to liver and other types of donors was approved by the OPTN/UNOS Board on November 13, 2014, and became effective on February 1, 2015.

On October 2015, the Committee considered if existing informed consent policy requirements should be revised to include new disclosures addressing:

- The emerging evidence related to ESRD risk after living kidney donation
- The increased risk of preeclampsia or gestational hypertension in pregnancies after donation
- Living donor follow-up rates included in PSRs beginning in 2015

Additionally, the Committee considered policy revisions to clarify requirements that program site surveys (performed by UNOS staff) have identified as frequently misunderstood or poorly understood by living donor recovery hospitals. UNOS site surveyors had identified that living donor recovery hospitals frequently had questions regarding what information could be shared about a potential living donor with a transplant candidate and vice versa.

In May 2016, the OPTN/UNOS KPD workgroup, comprised of members of the OPTN/UNOS Kidney Transplantation Committee, Living Donor Committee, and other professionals with experience in the field, reviewed the proposed changes, as modifications to the informed consent requirements would also impact existing KPD policies. The KPD workgroup was asked to provide feedback on any concerns with the proposed policy modifications. The Committee considered all feedback from the KPD workgroup and made minor changes to the proposed policy language based on feedback from the KPD workgroup.

On June 8, 2016, the Committee reviewed final proposed draft policy language and supported sending the proposal for public comment.

Prior to the public comment period, the draft policy language was provided to the leadership of AST, ASTS and NATCO because the proposed policy changes would impact medical care. Under a prior agreement, the transplant professional societies are afforded an opportunity to provide early comment on any proposed policy that will impact patient care.

In late June and early July, NATCO, AST, and ASTS provided written responses regarding aspects of the proposed modifications to current informed consent requirements and proposed new informed consent requirements. In response, the Committee supported changes to some to the proposed policy language which are summarized in the following table.

Policy	Current or Originally Proposed Policy Language	Feedback from AST, ASTS or NATCO	Committee response for changing the proposed requirement
14.1 A:3.	A review of the living donor's history of smoking, alcohol, and drug use, abuse and dependency	A review of the living donor's history of smoking, alcohol, and drug use, as well as any concerns for a substance use disorder." Suggest modifications to reflect the current language used in the DSM 5.	The language was changed to reflect current terminology used in the DSM 5 regarding diagnostic term for abuse and dependency

Policy	Current or Originally Proposed Policy Language	Feedback from AST, ASTS or NATCO	Committee response for changing the proposed requirement
Table 14.1	Any transplant candidate may have risk factors for increased morbidity or mortality that are not disclosed to the donor	We suggest that this be retained.	The concept is retained but has been repositioned and now reads "Any transplant candidate may have an increased likelihood of adverse outcomes (including but not limited to graft failure, complications, and mortality) that is not disclosed to the donor"
Table 14.1	Transplant hospital determine candidacy for transplantation based on hospital specific protocols and clinical judgement	This was noted as unnecessary and only adding administrative burden.	Language was clarified. The disclosure does not create new administrative burden, as the only new requirement is for the center to document that they have explained this concept to the donor. While it may seem intuitive and unnecessary to members of the transplant community, potential donors may not understand the selection process for candidate selection and some do have concerns as to whether or not the transplant candidate is "a good/suitable candidate" to receive a transplant and how that is determined.
Table 14.1	Have the donor commit to post-operative <u>donation</u> follow-up	Will this exact language be required for compliance? Will post-operative still be acceptable in patient materials, etc.	Per UNOS Member Quality both phrases would be acceptable and in compliance if the new policy language is adopted
Table 14.2	On average, living donors may have a 25 -35% permanent loss of kidney function after donation	The word may is misleading – suggest "will" or "should expect to"	The revision describes reduction in kidney function that living kidney donors will experience, on average, after donation
Table 14.2	Risks of preeclampsia or gestational hypertension may be increased in pregnancies after donation	Suggest restricting this to woman of child bearing age to prevent this being so heavily scripted and tailor it more to individuals. (women less than 60, pre-menopausal)	Disclosure will be limited to female potential living donors

The Committee did not support changing some proposed policy language based on recommendations from the transplant professional societies, but will reconsider those recommendations based on public comment during the post public comment period. The recommendations that will be reconsidered during the post public comment period are summarized in the following table.

Policy	Current or Originally Proposed Policy Language	Comment or suggested change recommended by AST, ASTS or NATCO	Committee response for not changing the proposed requirement at this time
Table 14.2	The risk of ESRD for living kidney donors does not exceed that of the general population with the same demographic profile, <u>risk of ESRD for living kidney donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors</u>	This is an administrative burden. 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 is already mandated as is the precise loss of function. There is question regarding what this new language adds here.	Three studies published after February 2013 report a small but clinically significant increase in the risk of kidney failure after donation compared to risk among non-donors who also have similar baseline health status – i.e., in contrast with studies controlling only for demographics, these studies provide comparisons that are more similar to living donors. The new language discloses what is now known about the potential for elevated ESRD risk attributable to donation
Table 14.4	When the recipient hospital is not known	The table describes a requirement to provide national recipient outcomes "when the recipient hospital is not known". Please provide an example of when/how that could occur.	The scenario is within a Donor Exchange. Disclosure of national statistics are required, but not transplant hospital statistics, because hospital statistics are not known. This revision reflects feedback from member centers to reduce barriers to donor exchange practice

Policy	Current or Originally Proposed Policy Language	Comment or suggested change recommended by AST, ASTS or NATCO	Committee response for not changing the proposed requirement at this time
Table 14.4	The recovery hospital's living donor six-month, one-year and two-year follow-up rates"	<p>We appreciate the goal of improving program follow-up rates, but do not feel that the potential donors would benefit from getting this information, and are concerned that this information might distract donors from the more important components of informed consent.</p> <p>The root cause is not that centers don't want to do it, it is more often that donors don't want to pursue follow up. It is already mandated that donors are informed of required follow up. A suggestion was made to include evidence that sharing this information with donors may impact their decision making process in your proposal if this is the case.</p> <p>The wording also states that the donor f/u rates are reported by SRTR, which they are not. Is there are plan to report them on SRTR?</p>	<p>The SRTR recently added live donor follow-up rates to PSRs. The Committee, including participating living donors, felt it was important to inform potential donors that this new information is available. The rationale is that investment in follow-up reflects an investment in post-donation care. There are no data available that such disclosure improves donor safety. Similarly, there are also no data to show that the root cause is primarily that donors don't want to pursue follow-up.</p> <p>Center-specific follow-up rates are available to the general public but only some donors may discover this information on their own. This would put remaining donors at a disadvantage because they would have less information. It is important that all donors be able to have available equivalent levels and types of information.</p> <p>Additionally, the Committee feels the disclosure is ethically appropriate to support informed decision-making.</p> <p>SRTR program-specific reports are publicly released twice a year, and provide the information that should be disclosed to satisfy the proposed policy⁹.</p> <p>To assist transplant programs in monitoring their follow-up performance, transplant programs can submit an OPTN data request to obtain both follow-up rates and detailed follow-up information for their living donors. By Fall 2016, these same reports will be updated monthly and available to transplant centers on demand through the Data Services portal in UNET</p>

On July 27, 2016, the Committee meet by web conference and approved the proposed policy language for supported sending the proposal for public comment.

⁹ URL to All Center reports is: <http://srtr.org/csr/current/Centers/Default.aspx>
Then choose Organ (Kidney or Liver) and then Center, Then item 12 in dropdown, or Table D1 in PDF

How well does this proposal address the problem statement?

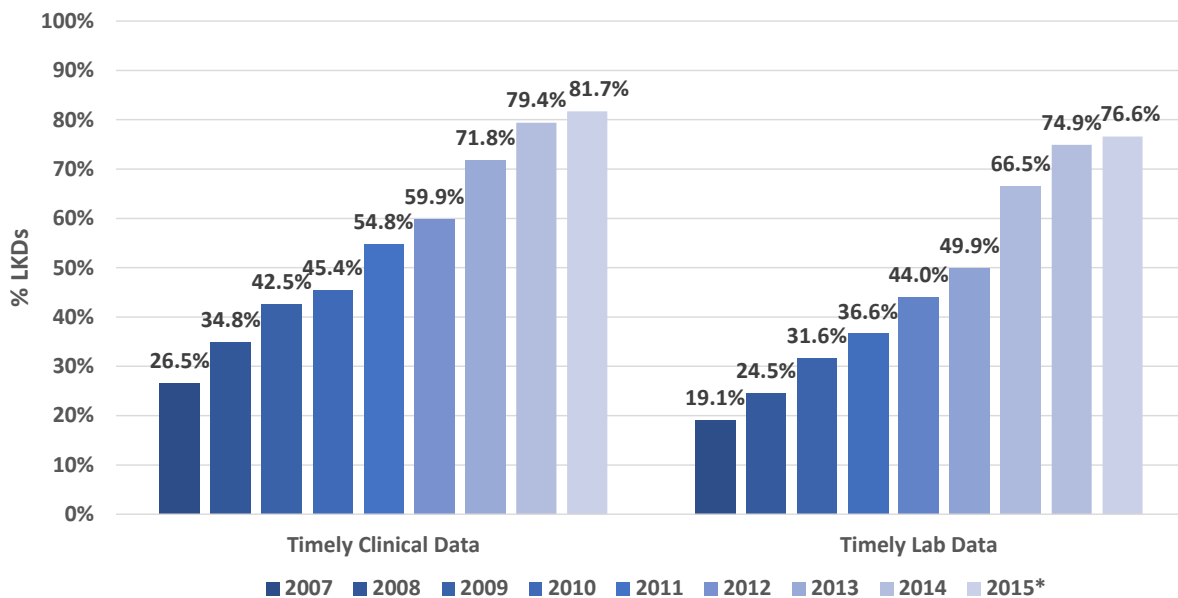
Several consensus statements have been published affirming basic principles governing the informed consent of potential living kidney donors¹⁰. These principles include ensuring that potential donors are capable of making the decision to donate, willing to donate, free of coercion or undue pressure to 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.

As with any research study, each of the new studies on post-donation health outcomes has limitations. The studies of post-donation ESRD in particular have been intensely debated, perhaps because the message that donation may increase ESRD risk was viewed as potentially controversial. Historically, potential living kidney donor have been told they would not have an increased risk of ESRD. In terms of OPTN/UNOS policy, the proposed solution does not require disclosure of a specific statistic or risk estimate (which could change as research continues and would lead to rapidly outdated policy), but instead includes the requirement that recovery hospitals address the concept with potential donors.

Living Donor Follow-up

Figure 1 illustrates the improvement over time in national transplant center follow-up rates for Living Kidney Donors (LKD), the policy requiring LKD follow-up was implemented in 2013, and the graph reflects a noticeable increase in the reporting for both clinical data and lab data. Over 80 percent of LKDs in the January 1 – June 30, 2015, cohort had timely and complete clinical data reported on the 6-month Living Donor Follow-up form, compared with about 60 percent of LKDs in the 2012 cohort (pre-policy implementation). Almost 77 percent of LKDs in the January 1 – June 30, 2015, cohort had timely and complete 6-month laboratory data reported, compared with just under half of LKDs in the 2012 cohort. Numbers in Figure 1 reflect timely data rates calculated with patient status date; dates for laboratory tests were added to the data collection forms in April 2015.

Figure 1: Percent of Living Kidney Donors Nationwide with Timely Clinical and Lab Data on 6-Month Living Donor Follow-up Form 2007-2015*



*January 1 – June 30, 2015

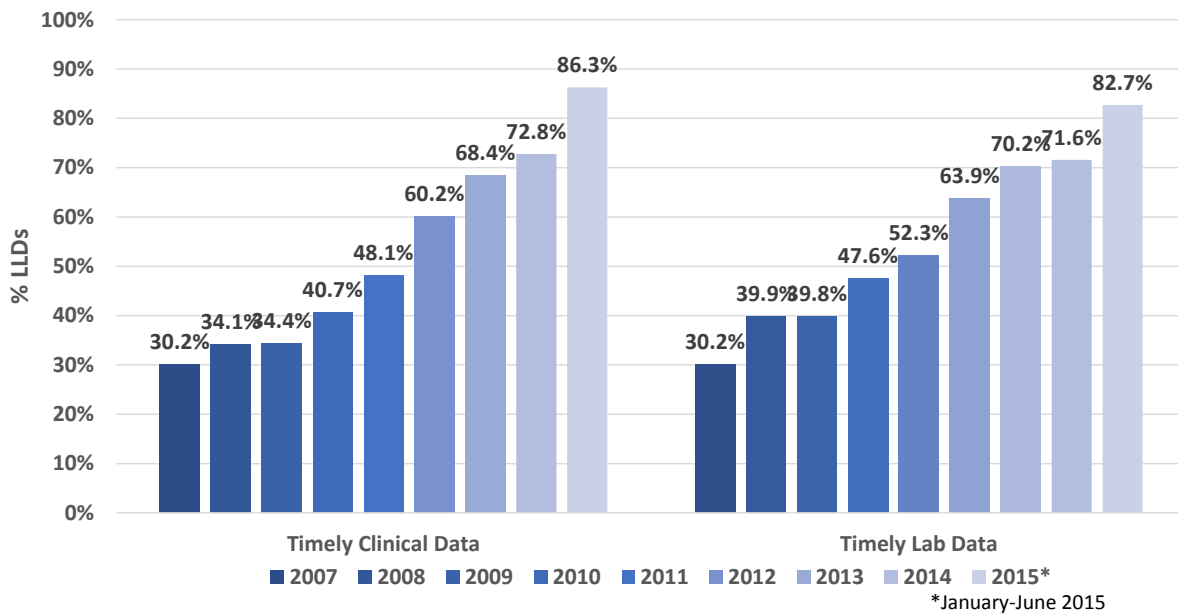
Source: OPTN data are current as of March 2016; however, the 2015 counts may change subject to delays in reporting.

While the living liver donor (LLD) follow-up policy applies to hospitals performing LLD recovery and transplantation, its general scope was similar to the previously enacted requirements for LKD recovery

¹⁰ (Adams et al., 2002; Ethics Committee of the Transplantation Society, 2004; Abecassis et al., 2000; Pruett et al., 2006)

and transplantation. The mandatory reporting requirement applies only to LLDs who donated beginning in September 2014. Figure 2 illustrates the notable increase in national rates of timely and complete clinical data from the 2014 (pre-policy) LLD cohort (72.8%) to the January 1 – June 30, 2015 cohort (86.3%). There was a similar increase in timely and complete laboratory data from 2014 (71.6%) to the January 1 – June 30, 2015 cohort (82.7%). Numbers in Figure 2 reflect timely data rates calculated with patient status date; dates for laboratory tests were added to the data collection forms in April 2015.

Figure 2: Percent of Living Liver Donors Nationwide with Timely Clinical and Lab Data on 6-Month Living Donor Follow-up Form 2007-2015*



Source: OPTN data are current as of March 2016; however, the 2015 counts may still change subject to delays in reporting

Which populations are impacted by this proposal?

The new informed consent requirements would apply to all living kidney, liver, lung, intestine, and pancreas donors. The proposal would have no impact on vascularized allograft donors or transplant candidates.

Table 1. Living Donors in the US by Volume and Type of Donor January 1, 2010 – December 31, 2015

Year of Donation	Kidney	Liver	Lung	Intestine	Pancreas
2010	6278	282	0	1	0
2011	5773	247	2	1	0
2012	5619	246	2	0	0
2013	5723	252	2	1	1
2014	5538	280	0	1	0
2015	5627	359	0	2	0

How does this proposal impact the OPTN Strategic Plan?

Increase the number of transplants: There is no impact to this goal.

Improve equity in access to transplants: There is no impact to this goal.

Improve waitlisted patient, living donor, and transplant recipient outcomes: The proposal clarifies some existing informed consent requirements and proposes new informed consent requirements to reflect the current state of knowledge. Providing potential living donors with a thorough and best possible informed process should improve living donor outcomes.

Promote living donor and transplant recipient safety: There is no impact to this goal.

Promote the efficient management of the OPTN: There is no impact to this goal.

How will the OPTN implement this proposal?

No instructional resources for the proposed changes to the informed consent requirements are anticipated.

The related proposed changes to KPD policy would only require programming to change labels in the system to reflect the proposed clarifications.

How will members implement this proposal?

Transplant Hospitals

Living donor recovery hospitals would need to update their informed consent policies or procedures to address the new or modified informed consent requirements.

Will this proposal require members to submit additional data?

No, the proposal does not require additional data collection. Clarifications to the KPD policy require label changes for existing programming in the system.

How will members be evaluated for compliance with this proposal?

At living donor recovery hospitals, site surveyors will continue to review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital has provided each of the required informed consent elements to the living donor as part of the informed consent process.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The Committee will continue to request feedback from UNOS living donor program site surveyors regarding if members understand informed consent requirements and are compliant with informed consent requirements.

Policy or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal 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

- 43 • Whether the potential KPD donor has undergone all medical evaluations as required
44 in *Policy 14: Living Donation*
- 45 • Whether the potential KPD donor has had all ~~age-appropriate~~ cancer screenings as
46 ~~defined by the American Cancer Society~~ required in *Policy 14: Living Donation*
- 47 • KPD status: active, inactive or removed. A donor must have current active status in
48 the OPTN KPD program to be eligible for a match run-
- 49
- 50 b. Clinical information, including *all* of the following:
- 51 • The number of anti-hypertensive medications the potential KPD donor is currently
52 taking
- 53 • Systolic and diastolic blood pressure with date (either 24-hour monitoring or two
54 measurements)
- 55 • Creatinine clearance or glomerular filtration rate (GFR), date, and method
- 56 • Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results
- 57
- 58 c. Donor choices, including *all* of the following:
- 59 • Whether the potential KPD donor would be willing to travel, and, if so, the
60 transplant hospitals to which the potential KPD donor would be willing to travel or
61 the distance the donor is willing to travel
- 62 • Whether the potential KPD donor is willing to ship a kidney
- 63 • Whether the potential KPD donor is willing to donate a left kidney, right kidney, or
64 either kidney
- 65 • Whether the KPD candidate-donor pair and the transplant hospital are willing to
66 participate in a three-way exchange or a donor chain
- 67 • Whether the potential KPD donor and the transplant hospital are willing for the
68 potential KPD donor to be a bridge donor
- 69
- 70 d. Donor HLA as defined in *Policy 13.5.C: HLA Typing Requirements for OPTN KPD*
71 *Donors*
- 72
- 73 5. The potential KPD donor must be paired to an active and eligible candidate registered in the
74 OPTN KPD program or be a non-directed donor
- 75 6. The transplant hospital registering the potential KPD donor must submit a response for all
76 previous match offers for the potential KPD donor in the OPTN KPD program, including reason
77 for refusing offers
- 78 7. The potential KPD donor must not be in a pending exchange in the OPTN KPD program

79

80 **14.1 Psychosocial Evaluation Requirements for Living** 81 **Donors**

82 **14.1.A Living Donor Psychosocial Evaluation Requirements**

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

85

86 The living donor psychosocial evaluation must be performed by a psychiatrist, psychologist, or
87 masters prepared social worker, or licensed clinical social worker prior to organ recovery.
88 Documentation of the psychosocial evaluation must be maintained in the living donor medical
89 record and include *all* of the following components:
90

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

113

114 **14.2 Independent Living Donor Advocate (ILDA)** 115 **Requirements**

116 **14.2.A ILDA Requirements for Living Donor Recovery Hospitals**

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

119 For any living ~~kidney~~ donor who is undergoing evaluation for donation, the living donor recovery
120 hospital must designate and provide each living donor with an ILDA who is not involved with the
121 potential recipient evaluation and is independent of the decision to transplant the potential
122 recipient. The ILDA may be one person or an ILDA independent living donor advocate team with
123 multiple members. An ILDA team must designate one person from the team as the key contact
124 for each living donor. All ILDA requirements must be completed prior to organ recovery.
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127 The ILDA must:

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- 129 1. Function independently from the transplant candidate's team.
- 130 2. Advocate for the rights of the living donor.
- 131 3. Fulfill the qualification and training requirements specified in the recovery hospital's protocols
132 regarding knowledge of living organ donation, transplantation, medical ethics, informed
133 consent, and the potential impact of family or other external pressure on the living donor's
134 decision about whether to donate. ~~Document that each requirement has been met.~~
- 135 4. Review and document whether the living donor has received information on each of the
136 following areas and assist the donor in obtaining additional information from other
137 professionals as needed about the:

- 138 a. Informed consent process as described in *Policy 14.3: Informed Consent*
- 139 *Requirements*
- 140 b. Evaluation process according to *Policies 14.1.A: Living Donor Psychosocial*
- 141 *Evaluation Requirements* and *14.4.A: Living Donor Medical Evaluation Requirements*
- 142 c. Surgical procedure
- 143 ~~d. Medical risks according to *Tables 14-1 through 14-5*~~
- 144 ~~e. Psychosocial risks according to *Tables 14-1 through 14-5*~~
- 145 ~~fd. Follow-up requirements, and the benefit and need for participating in follow-up~~
- 146 ~~according to *Policies 18.1: Data Submission Requirements, 18.5.A: Reporting*~~
- 147 ~~*Requirements after Living Kidney Donation, 18.5: Living Donor Data Submission*~~
- 148 ~~*Requirements, and 18.5.C: Submission of Living Donor Death and Organ Failure 18.6:*~~
- 149 ~~*Reporting of Living Donor Adverse Events*~~
- 150 ~~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:

- 153 1. The composition of the ILDA team, if the hospital uses a team.
- 154 2. The qualifications and training (both initial and ongoing) required for the ILDA. Minimum
- 155 qualifications must include knowledge of living organ donation, transplantation, medical
- 156 ethics, informed consent, and the potential impact of family or other external pressures on the
- 157 potential living donor’s donation decision. Document that each requirement has been met.
- 158 3. The duties and responsibilities of the ILDA, which must include at least the functions and
- 159 duties listed ~~throughout according to *Policy 14.2.A: ILDA Requirements for Living Donor*~~
- 160 ~~*Recovery Hospitals.*~~
- 161 4. The process the living donor recovery hospital will provide for the ILDA to file a grievance
- 162 when necessary to protect the rights or best interests of the living donor.
- 163 5. The process the living donor recovery hospital will use to address any grievance raised by
- 164 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 14-54. 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 <u>living</u> donor’s signature on a document that confirms that the donor: <ul style="list-style-type: none"> • <u>1.</u> Is willing to donate • <u>2.</u> Is free from inducement and coercion and • <u>3.</u> Has been informed that he or she may decline to donate at any time

The recovery hospital must:	These elements of informed consent :
<p>Provide to living donors</p>	<ol style="list-style-type: none"> 1. An opportunity to discontinue the <u>living donor</u> consent or evaluation process in a way that is protected and confidential. 2. The ILDA must be available to assist the <u>living donor</u> during the consent process, according to <i>Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements</i>. 3. Instruction about all phases of the living donation process, which includes: <ul style="list-style-type: none"> • Consent • Medical and psychosocial evaluations • Pre- and post-operative care • Required post-operative follow-up according to <i>Policy 18.5: Living Donor Data Submission Requirements</i>. <p>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 <u>living donor</u> is able to engage in meaningful dialogue with recovery hospital's staff.</p>

<p>Disclose to living donors</p>	<p>The recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient.</p> <ol style="list-style-type: none"> 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. 1. b. Any transplant candidate may have risk factors for increased morbidity or mortality that are not disclosed to the donor. <u>5. Transplant hospitals determine candidacy for transplantation based on existing hospital specific guidelines or practices and clinical judgment.</u> <u>6. The recovery hospital will take all reasonable precautions to provide confidentiality for the living donor and recipient.</u>
<p>Disclose to living donors</p>	<ol style="list-style-type: none"> <u>7. Any transplant candidate may have an increased likelihood of adverse outcomes (including but not limited to graft failure, complications, and mortality) that:</u> <ul style="list-style-type: none"> <u>• Exceed local or national averages</u> <u>• Do not necessarily prohibit transplantation</u> <u>• Are not disclosed to the living donor</u> <u>8. The recovery hospital can disclose to the living donor certain information about candidates only with permission of the candidate, including:</u> <ul style="list-style-type: none"> <u>• The reasons for a transplant candidate's increased likelihood of adverse outcomes</u> <u>• Personal health information collected during the transplant candidate's evaluation, which is confidential and protected under privacy law</u> <u>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.</u> <u>10. The recovery hospital is required to:</u> <ol style="list-style-type: none"> a. Report living donor follow-up information, at the time intervals specified in <i>Policy 18.5: Living Donor Data Submission Requirements</i>. b. Have the donor commit to post-operative donation follow-up testing coordinated by the recovery hospital. <u>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:</u> <ol style="list-style-type: none"> 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 <u>12. 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 14.1: Psychosocial Evaluation Requirements for Living Donors</i>.</u> <u>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.</u> <u>14. The following are inherent risks associated with evaluation for living donation:</u> <ol style="list-style-type: none"> a. Allergic reactions to contrast b. Discovery of reportable infections c. Discovery of serious medical conditions d. Discovery of adverse genetic findings unknown to the living donor

The recovery hospital must:	These elements of informed consent :
<p style="text-align: center;">Disclose to living donors</p>	<p>e. Discovery of certain abnormalities that will require more testing at the <u>living donor's</u> expense or create the need for unexpected decisions on the part of the transplant team</p> <p>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, <i>all</i> of the following:</p> <p>a. Potential medical or surgical risks:</p> <ul style="list-style-type: none"> 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 <u>living</u> donor may be impacted by <u>age</u>, obesity, hypertension, or other donor-specific pre-existing conditions <p>b. Potential psychosocial risks:</p> <ul style="list-style-type: none"> 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 <u>living</u> donor's lifestyle from donation <p>c. Potential financial impacts:</p> <ul style="list-style-type: none"> 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 <u>living</u> 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

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Table 14-32: 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	<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"> On average, living donors will <u>may</u> have a 25-35% permanent loss of kidney function after donation. Baseline <u>Although</u> risk of ESRD for living kidney donors does not exceed that of the general population with the same demographic profile, <u>risk of ESRD for living kidney donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors.</u> 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. 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. Dialysis is required if the <u>living</u> donor develops ESRD. Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to <i>Policy 8.3: Kidney Allocation Points.</i>
Disclose to all living kidney donors	<p>Surgical risks may be transient or permanent and include but are not limited to:</p> <ul style="list-style-type: none"> Potential medical or surgical risks: Decreased kidney function <u>Acute kidney failure and the need for dialysis or kidney transplant for the living donor</u>
<u>Disclose to all female living kidney donors</u>	<u>Risks of preeclampsia or gestational hypertension may be increased in pregnancies after donation</u>

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Table 14-43: 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	<p>Surgical risks may be transient or permanent and include but are not limited to:</p> <ul style="list-style-type: none"> 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.

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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.*

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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 <i>all</i> the following information:
Are the same	The recovery hospital must provide the living donor with b Both national and that hospital's program-specific transplant recipient outcomes, and donor follow-up rates from the most recent Scientific Registry of Transplant Recipients (SRTR) program-specific reports.	<ul style="list-style-type: none"> • National 1-year patient and transplanted organ survival • The hospital's 1-year patient and transplanted organ survival • <u>The recovery hospital's living donor six-month, one-year and two-year follow-up rates</u> • 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, and donor follow-up rates from the most recent SRTR program-specific reports.	<ul style="list-style-type: none"> • National 1-year patient and transplanted organ survival • The recipient hospital's 1-year patient and transplanted organ survival • <u>The recovery hospital's living donor six-month, one-year and two-year follow-up rates</u> • Notification about all CMS outcome requirements not being met by the recipient hospital
<u>Will not be the same and the recipient hospital is not known</u>	<u>National transplant recipient outcomes from the most recent SRTR reports.</u>	<ul style="list-style-type: none"> • <u>National 1-year patient and transplanted organ survival</u>

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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 <i>all</i> 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

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

197 **E.6 Kidney Transplant Programs that Perform Living Donor Recovery**

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199 **A. ~~Potential~~ Living Donor Medical Evaluation**

200 The kidney recovery hospital must have the clinical resources available to assess the medical
201 condition of and specific risks to the ~~potential~~ living donor.
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203 **B. ~~Psychological~~ Living Donor Psychosocial Evaluation Assessments**

204 The kidney recovery hospital must have the clinical resources to perform a psychosocial
205 ~~assessment~~ evaluation of the ~~potential~~ living donor's ability to make an informed decision. ~~This~~
206 ~~psychosocial assessment should also confirm that the evaluation and donation are completely~~
207 ~~voluntary.~~
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209 **C. Independent Living Donor Advocate (ILDA)**

210 The kidney recovery hospital must have an ~~independent living~~ Donor Advocate (ILDA) who is
211 not involved with the evaluation or treatment decisions of the potential recipient, and is a
212 knowledgeable advocate for the ~~potential~~ living donor. The ILDA must be independent of the
213 decision to transplant the potential recipient and follow the ~~Protocols~~ that outline the duties and
214 responsibilities of the ILDA ~~as described in~~ according to *OPTN Policy 14.2: Independent Living*
215 *Donor Advocate (ILDA) Requirements.*
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217 The ~~goals of the IDA are:~~

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

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226 **~~G. Required Living Donor Protocols~~**

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

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

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

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

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F.8 Liver Transplant Programs that Perform Living Donor Recovery

B. Potential Living Donor Medical Evaluations

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~~ Psychosocial Evaluation Assessments

~~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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