This checklist contains elements typically reviewed as part of OPTN routine survey activities of living donor recovery hospitals. Use of this checklist is not an OPTN obligation and does not guarantee an assessment of compliance with OPTN obligations upon a site survey. This checklist is intended to guide the development of center-specific processes and tools.

Living Donor Informed Consent Checklist

The living donor recovery hospital is responsible for obtaining and documenting informed consent prior to organ recovery. Informed consent requirements apply to living kidney, liver, pancreas, intestine, and lung donors and must include all of the components listed below. Documentation of informed consent must be maintained in the living donor medical record.

All Living Donors

✓	**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 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.)
✓	**Disclose to living donors:**
	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.
	4. 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.
	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 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 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 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

Living Kidney Donors – Additional Requirements

✓	**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 have a 25-35% permanent loss of kidney function after donation. b. 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. 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: • Decreased kidney function • Acute 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

Living Liver Donors – Additional Requirements

✓	**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 all living donors.

Outcomes Data

✓	**If the recovery hospital and the recipient hospital are the same:**
	Then the recovery hospital must provide the living donor with both national and that hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) program-specific reports, including all the following information: 1. National 1-year patient and transplanted organ survival 2. The hospital's 1-year patient and transplanted organ survival 3. Notification about all Centers for Medicare and Medicaid Services (CMS) outcome requirements not being met by the transplant hospital

✓	**If the recovery hospital and the recipient hospital will not be the same and the recipient hospital is known:**
	Then the recovery hospital must provide the living donor with both national and the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR program-specific reports, including all the following information: 1. National 1-year patient and transplanted organ survival 2. The recipient hospital's 1-year patient and transplanted organ survival 3. Notification about all CMS outcome requirements not being met by the recipient hospital
✓	**If the recovery hospital and the recipient hospital will not be the same and the recipient hospital is not known:**
	Then the recovery hospital must provide the living donor with national transplant recipient outcomes from the most recent SRTR reports, including national 1-year patient and transplanted organ survival.