Living Kidney Donor
Informed Consent Checklist

OPTN policy changes for living donation take effect February 1, 2013. These changes will create national standards for evaluation and informed consent of all living kidney donors. Programs may use this checklist tool to review their informed consent process and determine if it contains all the required as specified in OPTN Policy 12.0. The 'OPTN Reference' column indicates throughout the checklist which specific policy section applies.

	Required documentation in the donor chart	OPTN Reference
Living kidney donor consent		**Policy 12.2**
	Written assurance by potential donor that he/she:	**Policy 12.2 a (Also 12.4)**
	• Is willing to donate	
	• Is free from inducement and coercion	
	• Has been informed that he/she may decline to donate at any time	
	• Has been informed that transplant centers must:	
	○ Offer donors an opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential	
	○ Provide an independent donor advocate (IDA) to assist the potential donor during this process	
	Instruction about all phases of the living donation process (teaching or instructional material can include any media, one-on-one or small group interaction)	**Policy 12.2 b (Also 7.3.2)**
	• Consent	
	• Medical and psychosocial evaluations	
	• Pre and post operative care	
	• Required post operative follow up	
	• Presented in a language in which donor is able to engage in meaningful dialogue	
	Disclosure that the recovery hospital will take all reasonable precautions to provide confidentiality for the donor/recipient	**Policy 12.2 c**
	Disclosure that it is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for valuable consideration	**Policy 12.2 d**
	Disclosure that recovery hospital must provide an independent donor advocate (IDA)	**Policy 12.2 e**
	If the recovery hospital and recipient hospital are the same:	**Policy 12.2 f**
	• Recovery hospital must provide the potential donor data from the most recent SRTR center-specific reports:	
	○ National 1-year patient and graft survival rates	
	○ Hospital's 1-year patient and graft survival rates	
	○ Notification about all CMS outcome requirements not being met by the transplant hospital	
	If the recovery hospital is not the same AND the recipient hospital is known:	
	• Recovery hospital must provide the potential donor data from the most recent SRTR center-specific reports:	
	○ National 1-year patient and graft survival rates	
	○ Recipient hospital's 1-year patient and graft survival rates	
	○ Notification of all CMS outcome requirements not being met by the recipient hospital	
	Education about expected post-donation kidney function and how chronic kidney disease and end-stage renal disease might potentially impact the donor in the future to include:	**Policy 12.2 g**
	• On average, donors will have 25-35% permanent loss of kidney function at donation	
	• Baseline risk of ESRD does not exceed that of members of general population with same demographic profile	
	• Donor risks must be interpreted in light of known epidemiology of both CKD or ESRD	
	○ CKD generally develops in midlife (40-50 years old)	
	• ESRD generally develops after age 60	
	• Medical evaluation of young potential donor cannot predict lifetime risk	
	Donors may be at higher risk for CKD if they sustain damage to the remaining kidney. Development of CKD and progression to ESRD may be more rapid with only 1 kidney	
	Dialysis is required when reaching ESRD	**Policy 12.2 g**
	Current practice prioritizes prior living kidney donors who became kidney transplant candidates	
	Disclosure of alternate procedures or courses of treatment for the recipient, including deceased	**Policy 12.2 h**

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	donor transplant	
	• A deceased donor kidney may become available for the recipient before donor evaluation is complete or transplant occurs	**Policy 12.2 h**
	• Any transplant candidate may have risk factors for increased morbidity or mortality that are not disclosed to the potential donor	
	Disclosure that donor will receive a thorough medical and psychosocial evaluation	**Policy 12.2 i**
	Disclosure that health information obtained during the evaluation is subject to the same regulations as all records and could reveal conditions that must be reported to local, state, or federal public health authorities	**Policy 12.2 j**
	Disclosure that the recovery hospital is required to report living donor follow up information at 6 months, 1 year, and two years	**Policy 12.2 k (Also 12.8.3)**
	• Potential donor must commit to post operative follow up testing coordinated by the recovery hospital	
	Disclosure that any infectious disease or malignancy pertinent to acute recipient care discovered during the potential donor's first two years of follow up care:	**Policy 12.2 l**
	• Will be disclosed to the donor	
	• May need to be reported to local, state or federal public health authorities	
	• Will be disclosed to their recipient's transplant center, and	
	• Will be reported through the OPTN Improving Patient Safety Portal	
Living kidney donor evaluation consent		**Policy 12.2.1**
	Written documentation that the potential donor was informed of the following:	
	• He/she must undergo a medical and psychosocial evaluation as required by Policy 12.3	
	• The transplant hospital may refuse the potential donor. He/she must be informed that he/she could be evaluated by another transplant program with different selection criteria	
	• The following are inherent risks associated with evaluation for living donation:	
	o Allergic reactions to contrast	
	o Discovery of reportable infections	
	o Discovery of serious medical conditions	
	o Discovery of adverse genetic findings unknown to the donor, discovery of certain abnormalities that will require more testing at the donor's expense or create the need for unexpected decisions on the part of the transplant team	
	Disclosure that these risks may be transient or permanent & include but are not limited to:	
	• Potential medical or surgical risks:	
	o Death	
	o Scars, pain, fatigue, and other consequences typical of any surgical procedure	
	o Decreased kidney function	
	o Abdominal or bowel symptoms such as bloating and nausea, and developing bowel obstruction	
	o Kidney failure and the need for dialysis or kidney transplant for the donor	
	o Impact of obesity, hypertension or other donor-specific medical conditions on morbidity and mortality of the potential donor	
	• Potential psychosocial risks:	
	o Problems with body image	
	o Post-surgery depression or anxiety	
	o Feelings of emotional distress or bereavement if recipient experiences any recurrent disease or in the event of the recipient's death	
	o Impact of donation on the donor's lifestyle	
	• Potential financial impacts:	
	o Personal expenses of travel, housing, child care, lost wages related to donation might not be reimbursed; however, resources may be available to defray some donation-related expenses	
	o Need for life-long follow up at the donor's expense	
	o Loss of employment or income	
	o Negative impact on the ability to obtain future employment	
	o Negative impact on the ability to obtain, maintain, or afford health, disability, and life insurance	
	o Future health problems experienced by living donors following donation may not be covered by the recipient's insurance	

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