



**Clinical Transplant Services
Kidney/Pancreas Transplant Program**

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Informed Consent for the Living Kidney Donor

I have volunteered to consider donating a kidney through the Transplant Program at Oregon Health and Science University. I have been provided with and have read written educational materials regarding living kidney donation including: the consent process, medical and psychosocial evaluation, pre and post-operative care and required follow-up after living kidney donation. I have also been given and have read written materials detailing the risks and benefits of living kidney donation and the lifestyle recommendations after donation.

I understand that donating a kidney involves undergoing major surgery that will not benefit me medically. Because of this, it is very important that I am fully educated about all aspects of kidney donation. The regulatory agency that oversees transplant in the United States (currently UNOS-- the United Network for Organ Sharing) requires that I acknowledge the following:

The voluntary nature of donation:

1. I understand that kidney donation is a gift offered freely with no expectation of financial reward to the donor from the recipient or from the Transplant Program. I have offered to donate a kidney free of coercion (pressure) or inducement (material incentive). I have not been offered anything of value including but not limited to money, property, or vacations in exchange for donation. I understand that it is a federal crime for any person to knowingly acquire, obtain or otherwise transfer a human organ for anything of value.
2. I can change my mind about donation at any time in the process up to and including the day of surgery. If I do withdraw from donation, that decision will be protected and confidential; my recipient will be informed only that OHSU determined that I was not an acceptable donor.

Independent Living Donor Advocate

1. I understand that OHSU is required to provide me with an Independent Living Donor Advocate who is not involved in the care of transplant recipients. My advocate's role is to serve as my representative in the donor process. S/he is available to me during my evaluation, admission to the hospital for surgery, immediate post-operative period and during my long-term follow-up after donation to:
 - a. Review all elements of informed consent, discuss and answer any questions I may have. If my advocate cannot answer my questions, s/he will refer me to another donor team member who can.
 - b. Insure that my rights as a donor are protected, including the right to feel free of feelings of pressure to donate or of undue emotional responsibility. Should I choose to withdraw as a donor, my advocate will assist with this.
 - c. Represent my interests and perspective to the donor team.

Evaluation Process

1. I understand that as a donor candidate I will undergo extensive medical and psychosocial testing and evaluation as required by the regulatory agency that oversees transplant. That evaluation involves certain risks:
 - a. Allergic reaction to the contrast given with a CT scan
 - b. Discovery of infections (for example tuberculosis) that must be reported to local, state, or federal public health authorities
 - c. Discovery of underlying serious medical conditions
 - d. Discovery of adverse genetic findings unknown to the living donor
 - e. Discovery of certain abnormalities that require more testing at the living donor's expense or that create the need for unexpected decisions on the part of the transplant team.

Risks of donation

1. I understand that there are surgical, medical, psychosocial and financial risks associated with donation. These risks may be temporary or permanent and include, but are not limited to, *all* of the following:
 - a. Potential Medical Risks:
 - i. Kidney function is reduced by donation. On average, a donor has a 25%-35% permanent loss in kidney function due to donation.
 - ii. The risk of End Stage Kidney Disease (ESRD or kidney failure) does not exceed that of the *general* population with the same demographic profile (for example: age, race, gender). However, the risk of a living kidney donor developing ESRD may exceed that of healthy non-donors with medical characteristics similar to those of living kidney donors.
 - iii. The medical evaluation of a young living kidney donor cannot accurately predict their lifetime risk of developing Chronic Kidney Disease (CKD or kidney insufficiency) or ESRD. This is because CKD generally doesn't develop until mid-life (40 or 50 years of age) and ESRD generally develops after the age of 60.
 - iv. Living kidney donors may be at higher risk of developing CKD if they sustain damage or cancer in their remaining kidney. The development of CKD and subsequent progression to ESRD may be faster with only one kidney.
 - v. Dialysis or transplant would be required if the living donor developed ESRD.
 - vi. Current UNOS practice is to prioritize prior living kidney donors who later become kidney transplant candidates themselves.
 - vii. The risks of preeclampsia or gestational hypertension (high blood pressure with pregnancy) are increased in women who become pregnant after donation.
 - b. Potential Surgical Risks:
 - i. Death
 - ii. Scars, incisional hernia, wound infection, blood clots, bleeding, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure.

- iii. Abdominal symptoms such as bloating, nausea, and developing a bowel obstruction (blockage).
- iv. Decreased kidney function
 - v. Acute kidney failure and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period
 - vi. The risk of death and complications of the living donor may be affected by age, obesity, high blood pressure or other donor-specific pre-existing conditions. Each transplant center determines who is a candidate for living donation based on their own selection criteria.
- c. 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 a poor outcome (for example recurrent kidney disease, rejection or death)
 - iv. Changes to the living donor's lifestyle as a result of donation
 - v. If a donor has engaged in behaviors within the past year that increase his or her risk of contracting a communicable disease (i.e. HIV, Hepatitis B or Hepatitis C), that risk would need to be disclosed to the recipient. The recipient would then need to consent to accept the donor's kidney. If the donor does not feel comfortable with this, the donor can choose to withdraw from the donor process and neither the donor's behavior nor the fact that the donor withdrew will be disclosed to the recipient. The recipient will only be informed that the donor "does not meet the living donor criteria".
- d. Potential Financial Impacts of Donation:
 - i. Personal expenses such as travel, housing, childcare costs and lost wages related to donation might not be reimbursed. Resources to help cover some of these costs may be available
 - ii. The need for life-long follow-up at the living donor's expense.
 - iii. Loss of employment or income related to donation
 - iv. Negative impact on the living donor's ability to obtain future employment
 - v. Negative impact on the living donor's ability to obtain, afford or maintain 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

Recipient Considerations:

1. There are alternative procedures and treatments for the recipient including dialysis and receiving a transplant from a deceased donor (the Waiting List). Kidney transplantation may improve the recipient's quality and length of life.
2. A deceased donor organ may become available for the recipient candidate before the living donor's evaluation is complete or prior to the living donor surgery.
3. A Transplant Center determines recipient candidacy for transplantation based on existing center-specific guidelines or practices as well as their clinical judgment.

4. The Transplant Center will take all reasonable precautions to provide confidentiality for both the living donor and the recipient.
5. Any transplant recipient candidate may have an increased likelihood of adverse (poor) outcome (including but not limited to graft (transplant) failure, complications, and death) that exceed local or national averages but do not necessarily prohibit transplantation and are not disclosed to the living donor.
6. The Transplant Center can only disclose certain information about the recipient candidate to the living donor if the recipient gives permission to do so. Examples of this “certain information” include the reasons for that candidate’s increased likelihood of adverse outcomes as well as personal health information collected during the recipient’s transplant evaluation which is confidential and protected under privacy law.

Donor Considerations:

1. The Transplant Center will take all reasonable precautions to provide confidentiality for the donor and the recipient. Certain basic information regarding me such as my name, date of birth, blood type, tissue typing, whether I have had certain viruses in the past and my UNOS Donor ID number will be placed in the recipient’s chart for purposes of ensuring that the correct organ is transplanted.
2. 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 health authorities.
3. The Transplant Center is required to report living donor follow-up information to UNOS at specific time intervals, currently at 6, 12 and 24 months after donation. A living donor must commit to follow-up testing coordinated by the Transplant Center at those time points.
4. Any infections disease or malignancy (cancer) that the donor develops during the first two years after donation that is pertinent to the acute recipient care may need to be reported to local, state or federal public health authorities, will be disclosed to the recipient’s transplant hospital and will be reported to UNOS through the Patient Safety Portal.
5. The Transplant Center may refuse a living donor. If a living donor is declined by one Transplant Center, their recourse is to seek donation through another Transplant Center that may have different living donor selection criteria.

Other Issues:

1. I have been provided with both national and OHSU specific information about 1 and 3 year kidney transplant recipient patient survival as well as 1 and 3 year graft (transplanted kidney) survival. These statistics are also available at the Scientific Registry of Transplant Recipients (SRTR) web site: <http://www.ustransplant.org/csr/current/csrDefault.aspx>
2. I understand that OHSU is in good standing with the Center for Medicare and Medicaid Services and has no unmet requirements. If a transplant is not performed at a Medicare approved transplant center, it could affect the recipient’s ability to access transplant benefits through Medicare.
3. I understand that if I have concerns or grievances about the OHSU Transplant Center I can discuss them with my Independent Living Donor Advocate, the supervisor of the transplant program, the OHSU Patient Advocate Office or UNOS (888-894-6361).

4. I wish to continue in the process of evaluation as a potential living kidney donor. I understand that signing this consent does not in any way obligate me to donate and that I can change my mind about donation at any time without penalty for doing so.

Potential living kidney donor signature/date

Witness signature/date

Printed name

Printed witness name

Additional Issues for the Non-Directed Donor:

1. I understand that as a non-directed donor (someone who is donating a kidney but has not designated a particular recipient for that kidney), there are some additional considerations.
 - a. I understand that while every effort will be made to protect my anonymity, it is possible that the recipient may learn of my identity.
 - b. As a non-directed donor, I may choose to participate in a national Paired Exchange Program, start a transplant chain within OHSU or donate to a recipient on the OHSU Deceased Donor Waiting List according to established UNOS and OHSU protocols. I cannot influence who will receive my kidney.

Potential living kidney donor signature/date

Witness signature/date

Printed name

Printed witness name

I am on-site at Oregon Health and Science University completing my evaluation as a living kidney donor. I have reviewed the above, have had an opportunity to ask questions and had them answered and wish to continue in the donor process.

Potential living kidney donor signature/date

ILDA signature/date

Printed name

Printed ILDA name