

University of Washington Medical Center Living Kidney Donor Program
PATIENT EDUCATION ACKNOWLEDGEMENT FOR MEDICAL/SURGICAL EVALUATION AS A LIVING KIDNEY DONOR

I have been given the option to undergo medical, surgical and psychosocial evaluation to determine if I am a candidate for donating one of my kidneys for transplant to a designated transplant candidate. This process is called **living kidney donation**. My candidacy for donation is based on existing hospital guidelines, practices and clinical judgment.

Living kidney donation involves three phases. The first phase is a thorough medical, psychosocial and surgical evaluation to determine if I am a suitable living kidney donor. This phase includes extensive education regarding donation. If it is determined that I am approved as a suitable donor and I agree to continue, I will enter into the second phase. In the second phase, I will undergo surgery for the removal of one of my kidneys for transplant to a designated transplant candidate. The third phase is post-donation follow up care.

Because I have no obvious medical conditions that would make it impossible for me to be a living kidney donor, I have been given the option to proceed with the living donor evaluation. I understand that my willingness to participate in the medical, surgical and psychosocial evaluation for living kidney donation does not guarantee that I will be able to donate or obligate me to donate my organ for transplantation.

I am willing to donate. I understand that I will be free of any inducement and coercion to donate my kidney. I understand that I may discontinue the donor consent evaluation process and decline to donate at any time, and my choice not to donate will be protected and confidential. An Independent Donor Advocate is available to assist me during this consent process.

I understand that living donation involves risks to me, and I will receive no medical benefit from donating a kidney. Additionally, I am aware that there are alternate procedures or courses of treatment for the transplant candidate, including dialysis or deceased donor transplantation.

Confidentiality

I understand that this transplant center (recovery hospital) will take all reasonable precautions to provide confidentiality for me and the transplant candidate. I will sign a hospital release of information form when asked to share my medical information with other entities deemed necessary for my care or the transplant candidate's health care. The potential candidate may have risk factors for increased illness and death that are not disclosed to me.

Clinical Information regarding Transplant Candidate Care

Our living donor team can only provide you information regarding the transplant candidate with permission by the transplant candidate. Personal health information collected during the transplant candidate's evaluation is confidential and protected under privacy law. Your physician can explain the transplant candidate's 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 you

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Any infectious disease or malignancy pertinent to transplant and transplant candidate's care discovered during the first two years of post-operative follow-up care will be disclosed to me, the transplant candidate's transplant center, UNOS Patient Safety Portal, and may need to be reported to local, state or federal public health authorities.

MEDICAL, PSYCHOSOCIAL & SURGICAL EVALUATION PROCESS

My evaluation as a potential living donor will be coordinated if my preliminary screening is acceptable by the Living Donor team at UWMC. I understand that this medical, surgical and psychosocial evaluation process may take 2 to 6 months to complete. I understand that this process will include a 30-day cooling off period which starts at the beginning of HLA testing so I may further consider living kidney donation/surgery before making a decision to donate.

The Living Donor team members outlined below will perform my medical evaluation, as well as participate in my pre and post-operative care.

An **Independent Donor Advocate (IDA)**, a licensed clinical social worker, must be provided to me throughout the consent process, medical evaluation, psychosocial evaluation, pre & post-operative care, and post-operative follow-up to promote my best interest and advocate for my rights. The IDA is independent of the transplant candidate's care team. The IDA will assist me throughout the donor process with obtaining and understanding information regarding the risks associated with being a living donor. The IDA will be available to me to discuss any concerns or questions I may have throughout the donor evaluation and post-donation. The IDA will make sure that I feel comfortable moving forward with the living donation process and that I do not feel any pressure to donate. The IDA will be my voice at the donor selection conference.

The **Living Donor Nurse Coordinator** provides medical education through all three phases of the donation process including: consent process, medical evaluation, psychosocial evaluation, pre & post-operative care, and post-operative follow-up. The nurse coordinator facilitates the medical and surgical work-up, the surgery, and follow-up care. Meeting with the nurse coordinator is intended to provide me with an opportunity to ask questions and to become fully informed about the process, required testing and results of testing performed.

A **Transplant Nephrologist** (a physician who specializes in kidney care) meets with me to determine if I am a good medical candidate for donation. The nephrologist will review my medical history and ask many questions about my health and what infections I may have been exposed to. The nephrologist will review my family history to determine if I am a suitable candidate for donation. After donation, the UWMC nephrologist follows my kidney function for at least two years.

A **Transplant Surgeon** meets with me to discuss whether donation is an option for me, based on the results of my testing. The surgeon will also discuss the significance of having the surgery, the donation procedure itself, the risks of the surgery and the possible complications during my recovery period and after my donation.

The **Patient Care Coordinator (PCC)** coordinates testing, procedures and appointments for my evaluation and surgery. The PCC provides detailed instructions about testing, procedures and appointments that are performed at outside facilities and at University of Washington Medical Center.

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The **Social Worker**, a licensed clinical transplant social worker, will complete a full psychosocial evaluation, including review of my mental health and alcohol/drug use. The purpose of this evaluation is to determine if I understand the emotional, financial and physical stressors I may experience as a kidney donor. This interview will also allow me to become acquainted with the support systems available at the UWMC. The social worker can also recommend options for assistance with expenses not covered as part of the donation (e.g., housing and transportation). Support of the transplant social worker will be available throughout the living kidney donor process to help with stress-related problems for me and my family.

A **Psychiatrist/Psychologist** may conduct a more in-depth psychiatric evaluation and assessment. Some patients with a history of drug or alcohol abuse may be required to participate in a rehabilitation program and/or to abstain from substance use prior to and after donor surgery.

A **Registered Dietitian** performs a nutritional assessment and provides nutritional education for kidney health. The dietitian evaluates the donor pre, peri-operative, and post-donation.

A **Transplant Pharmacist** performs a medication review, discusses allergies and provides pharmacological education for future kidney health. The pharmacist evaluates the donor pre, peri-operative, and post-donation.

EVALUATION TESTING: MEDICAL & SURGICAL

Physical Examination and Laboratory Tests

I will undergo a thorough physical examination that includes, but is not necessarily limited to: a complete medical history, kidney function testing (24-hour urine collections and/or nuclear scan), histocompatibility testing, blood tests, such as HIV and Hepatitis, as well as electrocardiogram (EKG) and chest x-ray. Depending upon my past medical history and age, additional tests may be needed. If the results of these tests are acceptable, I will undergo further tests to measure the size, blood supply and condition of my kidney.

Abdominal CT Scan

I will undergo a CT scan, which is a special x-ray that includes injection of a contrast dye for detailed imaging of my kidneys. The surgeon will use the CT scan to determine which kidney will be removed for donation and the best surgical method (laparoscopic or open) for the donor nephrectomy (surgery for the removal of my kidney). This is a low risk procedure with contrast dye that may include an allergic reaction. If I have had any allergic reactions to dye, shellfish, eggs or iodine, I must inform Living Donor Program staff so they can request radiology review and prepare appropriately.

Test Results

The results of all tests will be discussed with me. If it is determined that I am a suitable candidate for living kidney donation, I will be asked to carefully, once again, consider my decision to be a living kidney donor.

SURGICAL PROCEDURE

During the surgical evaluation, the surgeon will provide education regarding the nephrectomy.

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Donor Nephrectomy Surgery

The surgical removal of one of your kidneys for transplant is called a donor nephrectomy surgery. Surgery for removing a healthy kidney (donor nephrectomy) is less risky than removing a kidney with a disease because you are a healthy individual. Donor nephrectomy can be performed safely, but as with any major surgery there are minor and major risks, including the risk of death either from anesthesia or surgery (0.03-0.06%)

Procedure

The donor nephrectomy entails the surgical removal of one of my kidneys to transplant in a designated transplant candidate. One of my kidneys will be removed using either a laparoscopic or open surgical procedure. Although most of our nephrectomies are through the laparoscopic approach, some are done by open procedure, either because of donor choice or anatomical considerations. With the laparoscopic approach, there are typically 3 to 5 small incisions (1 to 2cm) and one larger incision (7 to 8cm) to remove the kidney. For the open approach, there is one incision (8 to 9cm). There exists the possibility that an intended laparoscopic approach may require conversion to the open approach requiring a larger surgical incision. This occurs in less than 2% of the living donor procedures. This center does not recover extra vessels from a living kidney donor for transplantation.

RISKS RELATED TO LIVING DONATION

Living Donor Evaluations Risks

I understand that during the evaluation process I may be found to have a condition that may or may not be treatable. Risks of medical testing may include results that bring unexpected decisions for me and the medical team. Allergic reactions to contrast, discovery of reportable infections, serious medical conditions, adverse genetic findings or certain abnormalities could be uncovered by evaluation. This may result in additional testing and treatments that will be you or your insurance's financial responsibility, or create the need for unexpected decisions by the transplant team. Testing could reveal positive results for infections that must be reported by law to other health care agencies. Health information obtained during the evaluation is subject to the same regulations as all records. Your health information could reveal conditions that must be reported to local, state, or federal public health authorities. HLA testing may reveal unexpected identity or family relationships.

Psychosocial Risks

I understand that potential psychosocial risks related to donation include the following problems: 1) body image, 2) post-surgery depression or anxiety, 3) anxiety related to dependence on others, 4) feelings of guilt, 5) feelings of emotional distress, 6) bereavement (grief) if the transplant candidate's health is related to any recurrent disease or in the event of the transplant candidate's death or graft loss, 7) changes to your lifestyle from donation and 8) post-traumatic stress disorder (PTSD).

Surgical Procedure & Medical Risks

The overall frequency of major complications when this operation is performed in a healthy person and by trained surgeons is expected to be minimal. As with any surgery, the administration of general anesthesia carries a small risk for a healthy person. In general, complications can occur immediately following surgery, as well as later in the course of life.

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Examples of surgical risks associated with living donation, which may be temporary or permanent include but are not limited to all of the following:

1. Death
2. Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure
3. Abdominal symptoms such as bloating, nausea, vomiting, constipation and potential bowel obstruction
4. And the morbidity and mortality of the living donor may be impacted by age, obesity, hypertension, or other donor-specific pre-existing conditions

Other specific risks include but are not limited to: deep vein thrombosis (DVT), bleeding, pulmonary embolism, as well as injury to the blood vessels, kidney and surrounding organs can also result in complications. Damage to nerves may occur. This can happen from direct contact within the abdomen or from pressure or positioning of the arms, legs or back during the surgery. Nerve damage can cause numbness, weakness, paralysis and/or temporary pain. Some donors report feeling emptiness or occasional 'twinges' of discomfort in the area where the kidney was removed. For female donors, risks of preeclampsia or gestational hypertension are increased in pregnancies after donation.

The risk of substantial blood loss during donor nephrectomy surgery is approximately 0-2%. This may necessitate a blood transfusion. I acknowledge that I will be asked to agree to a blood transfusion with the risks associated if my doctors determine it is necessary.

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

Chronic kidney disease (CKD) and end stage renal disease (ESRD) may also potentially impact living donor in the future, to include:

- On average, living donors will have a 25-35% permanent loss of kidney function after donation
- 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
- 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 living donor develops ESRD
- Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to OPTN policy

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Potential Financial Impacts

I understand that during the evaluation process I may be found to have a condition that needs further evaluation and treatment. Evaluation and treatment for any of these conditions will be my financial responsibility.

I understand that there are additional potential financial impacts including but not limited to:

- 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
- Need for life-long follow up care at the living donor’s expense
- Loss of employment or income
- Negative impact on the ability to obtain future employment
- Negative impact on the ability to obtain, maintain, or afford health, disability and life insurance
- Future health problems experienced by you following donation may not be covered by the transplant candidate’s insurance

If questions surface, the financial counseling team will assist me in clarifying my concerns.

The sale or purchase of human organs is a federal crime. It is unlawful 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.

RECOVERY PERIOD

The in-hospital recovery period for donor nephrectomy in a healthy person is approximately 2 to 4 days. In addition, I should expect a recovery period at home of approximately 4 to 6 weeks. Should I experience surgical or postoperative complications, the recovery period may be longer.

Required Follow Up Post-Operative Care after Donation

I commit to regular preventative health care, a healthy lifestyle and agree to the mandated follow-up at the UWMC as recommended by the living kidney donor team for 2 years after donation. I will be asked to attend follow up appointments at 12 days, 6 months, 1 year, and 2 years after the donation. If it is not possible for me to attend follow-up appointments at UWMC, it will be necessary to have physical examinations with my primary care provider and laboratory testing which would include serum creatinine and urine testing. I will be asked to sign a release of records from my primary care provider to UWMC Living Donor Program in order to help follow my progress after donation. UWMC requests that I notify them if any medical issues occur which may be related to my donor surgery.

NOTIFICATION OF TRANSPLANT PROGRAM INACTIVATION (CLOSURE)

If any event were to occur that might impact our ability to provide donation or transplant services, UWMC staff will attempt to contact me regarding the type of program inactivation (closure) in a timely manner. This would be rare, but may include lack of required physician coverage, operational changes requiring temporary cessation of transplantation or a natural disaster. The inactivation may be short-term or long-term.

If the event is unplanned, the center’s disaster call list will be initiated once inactivation is determined. The designated individual(s) would initiate notification of patients. UWMC would use whatever means is available to contact me, such as telephone, email, text or mail. If a disaster is severe, UWMC will make arrangements for an out-of-the-hospital agency to assist UWMC with the notification.

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UNITED NETWORK for ORGAN SHARING (UNOS)

UNOS is the national agency that helps to keep track of all donors and transplant outcomes. Prior to having my kidney removed and transplanted into the intended transplant candidate, I understand that I will be registered into UNOS as a living kidney donor. The purpose of my registration is to track my health along with the health of all other living kidney donors after donation. This center is required to submit health information to UNOS about me at 6 months, 1 year, and 2 years post donation.

The United Network for Organ Sharing provides a toll-free patient services line to help transplant candidates, recipients, and family members understand organ allocation practices and transplantation data. This "Patient Information Letter" from the United Network for Organ Sharing (UNOS) has been provided to me at my clinic visit. It describes the services and information offered to patients by UNOS and the Organ Procurement and Transplantation Network.

National and Transplant Center-Specific Outcomes

Statistics about survival after kidney transplant are available from the Scientific Registry of Transplant Recipients (SRTR). UWMC will provide me with both national and the transplant candidate’s center 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

I can also review these statistics at www.srtr.org.

I will also be notified if Centers for Medicare and Medicaid Services (CMS) outcome requirements are not being met by the UWMC.

ALTERNATIVES

If I do not wish to be a living donor, my intended transplant candidate will continue to receive care from the kidney transplant team at UWMC. They will continue to be eligible for dialysis and deceased donor transplantation, plus other living donors can be evaluated. A deceased donor organ might become available for the transplant candidate before my evaluation is completed or the living donor transplant occurs.

The UWMC Living Donor Program may refuse me as a living kidney donor. If the living donor program determines I am not eligible to donate, I can be evaluated by another transplant program with different selection criteria.

This agreement acknowledges that the enclosed detailed information regarding living kidney donation has been provided to me. I have read the information and been given opportunity to ask questions. I understand the information that has been given to me. I would like to proceed with the evaluation process.

DONOR SIGNATURE	PRINT NAME	DATE
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WITNESS SIGNATURE	PRINT NAME	DATE
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