

Iowa Methodist Transplant Center
Living Donor
Informed Consent for Evaluation of Donation

You are considering donation of a kidney to another person. This document is to inform you about the process for donation of a kidney. It is part of a process called “the Informed Consent Process”. It is important that you read this document and ask questions about any of the information that you do not understand.

Signing this consent means that you have been provided education on becoming a living kidney donor and have had the opportunity to ask questions on the topics listed below. You will have additional opportunities to ask questions during your donor evaluation appointment and at any time in the future.

You will be given a copy of this signed consent and the Transplant Center will keep the original copy in your transplant record.

The purpose of kidney transplantation is to give a healthy kidney to a person who has kidney disease. Kidney transplantation has been performed successfully since the 1950’s. A kidney may come from a living donor or, alternatively, from a person who recently died (deceased donor). Persons waiting for a kidney transplant may be on dialysis which provides the function of the kidney by a machine.

Evaluation Process

Your evaluation will consist of procedures, laboratory tests and assessment by health care professionals. It is done to determine your medical suitability for kidney donation and to provide you with information and the opportunity to discuss questions and concerns.

Going through the evaluation does not guarantee that you will be able to donate your kidney. Also, you may choose to stop the donation process at any time.

You will meet with the following members of the transplant team:

- A **Transplant Surgeon** will meet with you to discuss if kidney donation is an appropriate option. He/she will also discuss the significance of donating your kidney, the risks of the surgery, and the possible complications during and after donation.
- A **Nephrologist** is a doctor who specializes in kidney disease. The Nephrologist will assess the function of your kidney and the safety of your donation.
- An **Independent Living Donor Advocate (ILDA)** is not affiliated with the Transplant Center. He/she will call you during the referral process prior to any testing and then provide an assessment during the evaluation phase. The ILDA will be involved in all phases of donation and is independent of the decision to transplant. He/she will be available to you throughout the process and following donation and serves to promote your best interests and advocate for your rights. The ILDA ensures that you have the information necessary to make a decision that is informed and free from coercion.

- The **Transplant Coordinators** provide education and coordinate the evaluation process. The Transplant Coordinators are also responsible for informing you about your rights and responsibilities before and after kidney donation. Coordinators are available to answer your questions so that you are fully informed about the kidney donation process.
- The **Registered Dietician** performs a nutritional assessment and provides nutrition education to patients. The dietician will meet with you pre and post donation to help with dietary needs.
- The **Pharmacist** provides education regarding surgery-related medications, as well as medications you are currently taking. The transplant pharmacist is also a resource to the entire transplant team and provides drug information and education about complex drug interactions.

A psychosocial evaluation by the following individuals will occur. They will help determine if you are capable of giving informed consent, help you to discuss why you want to be a donor, and determine if you and your family will be able to handle the emotional, financial and physical stress of this type of surgery.

- A **Social Worker** will meet with you to evaluate your ability to cope with the stress of donation. The Social Worker will also help identify your support network, discuss any problems in obtaining health insurance or disability in the future and any resources that you may need.
- The **Clinical Psychologist** may meet with you to perform a screening in order to determine your suitability for donation. This process will address your psychological well-being and substance use history. Donors with a history of drug or alcohol abuse may be required to participate in a rehabilitation program and meet abstinence requirements prior to and after donation. This is done to ensure your safety and that of your potential recipient.
- There may be other professionals who will meet with you depending on your questions, your medical situation and/or your social or economic situations. Additionally, you may be referred to another doctor in order to complete the evaluation. For example, some patients need to be seen by a cardiologist (heart doctor) or a pulmonologist (lung doctor) to evaluate medical conditions.

Many different tests are done to determine if you are a suitable donor. Some of the following tests may be included in your evaluation process. Other tests may need to be done based on the results of these tests.

- Blood tests will be done to determine your blood type and to identify any possible reason that you might not be able to donate your kidney. These tests will screen for specific viruses, including HIV, Hepatitis B and C. Additional blood tests will be used to determine how well other organs are functioning.
- Urine testing is used to screen for the presence of urinary tract infections and to help determine how well your kidneys are currently functioning.
- A chest X-Ray will be done to identify any problems with your lungs.
- A DTPA Renal Scan will determine how well your kidneys function.
- A CT/Angiogram of your kidneys is done to determine the size and placement of your blood vessels.
- An EKG is a test that will check for problems with the electrical activity of your heart.

Some donors may require additional testing such as:

- a kidney biopsy (a test in which a needle is used to remove a tiny piece of kidney tissue which is looked at under a microscope)
- an angiogram (a test in which a needle is inserted into a blood vessel in the leg and dye is used to take pictures of the blood vessels of the kidneys)
- a Mag 3 scan (a scan to look at the individual function of each kidney).

Each test will be explained to you before it is done, as well as any potential risks and you will be asked to sign a separate consent form.

Risks associated with the evaluation process for living donation include:

- allergic reactions to contrast
- discovery of reportable infections
- discovery of serious medical conditions
- discovery of adverse genetic findings
- discovery of certain abnormalities that will require more testing at your expense or create the need for unexpected decisions on the part of the transplant team
- health information obtained during the 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.

Surgical Procedure

At the time of surgery, the surgical procedure and the risks will be discussed with you and you will be asked to sign a separate consent for surgery.

During the surgery, you will be put under general anesthesia. This means that you will be given medication by an anesthesiologist to put you to sleep, block pain and paralyze parts of your body. You will also be placed on a machine to help you breathe. Prior to your surgery, the anesthesiologist will talk with you in more detail regarding any risks associated with anesthesia.

At Iowa Methodist Kidney Transplant there are two different types of laparoscopic nephrectomy procedures being performed.

1. The primary laparoscopic approach is the Robotic-Assisted Laparoscopic nephrectomy. Three small incisions are made in the abdomen (less than one inch in diameter) that are big enough for the robotic probes to be inserted. There is also a small incision made in the abdomen to help remove the kidney. After the kidney is removed the abdominal incisions will then be closed.
2. In the Hand Assisted Laparoscopic Nephrectomy procedure, a small abdominal incision is created for the surgeon to place a hand into the abdomen. Two other small abdominal incisions are made just large enough to insert surgical equipment. Your kidney will be removed through the incision with the help of the surgeon's hand. Your abdomen will then be closed.

There is the remote chance that your surgery might have to be converted to an "open procedure". This means that if the surgeon is unable to remove the kidney with the laparoscopic approach then he would have to make an incision about 6-8 inches on your side to get the kidney out. This is only done if all other attempts to remove the kidney fail.

Risks Associated with Donation

There are possible surgical, medical, and psychosocial risks associated with living donation. These may be temporary or permanent and include, but are not limited to the following:

- a) Potential medical or surgical risks:
 - death
 - scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other issues typical of any surgical procedure
 - abdominal symptoms such as bloating, nausea, or development of a bowel obstruction
 - death and other complications may be impacted by age, obesity, hypertension, or other pre-existing conditions.

- b) Potential psychosocial risks:
 - problems with body image
 - post-surgery depression or anxiety
 - feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies - the transplant recipient may have risk factors for complications or death that are not disclosed to you as the donor
 - changes to your lifestyle from donating a kidney.

- c) Potential financial risks:
 - personal expenses of travel, housing, child-care costs and lost wages related to your donation might not be reimbursed; however, resources may be available to help with these donation costs
 - need for life-long follow up at your expense
 - loss of employment or income
 - negative impact on your ability to obtain future employment
 - negative impact on your ability to obtain, maintain, or afford health insurance, disability insurance, and life insurance
 - future health problems experienced following your donation may not be covered by your recipient's insurance.

Potential surgical risks may be temporary or permanent and include but are not limited to decreased kidney function and kidney failure with the need for dialysis or kidney transplant for the donor.

Early operative risks include but are not limited to:

- wound or urinary tract infections
- pneumonia
- abdominal or bowel symptoms such as bloating or nausea may occur - there may be some increased risk with the use of over the counter medications and supplements
- bowel injury or obstruction.
- blood clots in the legs or lungs
- injury to the spleen
- decreased kidney function
- acute kidney failure and the need for dialysis or kidney transplant in the living donor in the immediate post-operative period.

The risk of death from this procedure in the United States is very low. It is most commonly the result of a blood clot in the lung.

All efforts are made to avoid these issues postoperatively such as:

- having you out of bed and walking within a few hours after surgery
- breathing exercises
- using mild blood thinners to prevent clots
- using special leg devices while you are in bed to promote good circulation.

Late risks are more associated with your chances of developing problems from having only one kidney and this is uncommon.

- There are slightly increased risks of hypertension, protein in the urine, and kidney dysfunction in some studies
- For the majority of donors the loss of the kidney is of no consequence long term.

Despite this limited risk, it is important that persons who have donated a kidney maintain healthy lifestyles and obtain annual physicals to monitor their health.

Nationwide the risk of having some type of complication – minor or major – from this surgery is 2.2%. Most are minor and resolve on their own. Rarely do they require another surgery or procedure. The mortality rate (death) is less than 0.1% or 0.00036 deaths in 1000 donors. No donor deaths have occurred at this center. Data used to complete this section comes from a national database called the United Network of Organ Sharing (UNOS), www.unos.org.

On average, living donors will have a 25-35% permanent loss of kidney function after donation. Although risk of end-stage renal disease (ESRD) 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. When chronic kidney disease (CKD) or ESRD occurs in the general population, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. Therefore, medical evaluation of a young living donor cannot predict the lifetime risk of CKD or ESRD.

Living donors may be at higher risk of developing high blood pressure, CKD or ESRD if the remaining kidney undergoes some type of injury. The development of CKD and progression to ESRD may be faster with only one kidney. Dialysis or kidney transplant is required if the donor develops ESRD. Also, the risk of preeclampsia or pregnancy-related high blood pressure is increased in pregnancies after living kidney donation.

In the event that a living donor develops ESRD at any time during their life and is eligible for a kidney transplant, the current United Network for Organ Sharing (UNOS) policy gives priority to these donors who have become kidney transplant candidates.

Bleeding during or after surgery may require blood transfusions that can contain bacteria and viruses which cause infection. Although rare, these infections include, but are not limited to the Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

The incision is a potential site for infection as are the sites where tubes are placed in your body. Nerve damage may occur. This can happen from direct contact or from positioning of the arms, legs or back during the surgery. Nerve damage can cause numbness, weakness, paralysis and/or pain. In most cases the symptoms are temporary, but in rare cases they can last for a long time or become permanent.

There may be unforeseen risks in addition to the ones listed that we may not be aware of yet.

What happens after surgery when you after you leave the hospital?

- your incision will heal with a scar
- the visibility of the scar will vary
- your moods may be influenced by the outcome of the recipient
- although most patients have a positive feeling about their donation, up to 10 % of donors have been prescribed antidepressants to help cope with the process.

These issues should be addressed with your donation team.

Follow-up after Surgery

Medical follow-up is very important for your well-being. You will need to be seen in the transplant clinic at two weeks after surgery and four weeks after surgery. At six months, one year and two years after surgery you will be contacted by a transplant coordinator and current information on your health will be requested. We are required to report this information to the United Network for Organ Sharing (UNOS).

It is important that you continue to follow-up with your primary care provider every year for a routine physical examination, including blood pressure and lab work to check your kidney function.

It is important that with one kidney you should check with your doctor before taking over the counter medications as well as prescribed medications and to remind the doctor that you only have one kidney.

Any infection or cancer that that could affect the recipient’s care during the first two years after donation:

- may need to be reported to local, state or federal public health departments
- will be disclosed to the recipient’s transplant hospital
- will be reported to UNOS through the online “Improving Patient Safety” portal.

Are there medical benefits to being a living donor?

- there is no medical benefit to you by having this surgery
- a possible medical benefit of the evaluation is finding out about health problems that were unknown to you so that you may seek treatment.

Birth Control Pills/Hormone Replacements:

We will ask that you stop taking your birth control pills and or hormone replacements 6 weeks before your surgery. You will not be able to continue for an additional 6 weeks after donation. During this time we ask that you use 2 barrier forms of contraception to avoid pregnancy. You will not be able to donate if you are pregnant so please be very careful during this time so we will not have to cancel or delay your donation.

Privacy of Your Medical Information

Results of your physical evaluation and test results will not be discussed with the potential kidney recipient unless you give written permission. Your information will remain confidential, in accordance with the requirements of 45 CFR parts 160 and 164.

We are required to provide information about all organ transplants to UNOS. This includes name, birth date, sex, social security number, blood type, your relationship to the recipient, and blood test results. UNOS then assigns a case number to the transplant recipient and donor. The identifying information is not accessible to the public or to other researchers. This information is kept to determine how many living donor kidney transplants are done, what the success rates is, and what complications occur.

If the transplant recipient candidate gives permission, we may tell you the reasons for the recipient’s increased likelihood of adverse outcomes and/or any personal health information learned during the candidate’s evaluation that might affect the outcome of the transplant.

National and Transplant Center-Specific Outcomes

Statistics are from the Scientific Registry of Transplant Recipients (SRTR) www.srtr.org. The most recent one-year transplant recipient and transplanted organ survival data for both the nation and Iowa Methodist Medical Center Transplant Center will be given to you and discussed. Iowa Methodist Medical Center meets these standards and does not significantly differ from the expected survival rates. We are required to notify you if we do not meet these standards for survival rates. Our transplant center meets all requirements for Medicare certification. This is important for transplant recipients as it can help with payment for immunosuppressive drugs through Medical Part B.

Right to Withdraw

It is important to remember you have the right to withdraw as a living kidney donor at any time during the evaluation and donation process.

If you wish, the transplant team can inform the potential recipient of a reason for withdrawal, which will not affect your relationship with them. None of your health information will be shared with unless you have provided written permission to do so. We cannot share information with you about the potential recipient due to health privacy rules.

Right of Hospital to Refuse Donation

If the transplant team determines that you would not be a suitable candidate for donation, we will inform you of the possibilities for evaluation at other transplant centers that may use different selection criteria for donors.

Alternative Therapy for the Recipient

Alternative treatment therapies may be available for the recipient such as deceased donor transplantation, hemodialysis or peritoneal dialysis.

A deceased donor kidney may become available for the recipient before your living donor evaluation is complete or before the living donor transplant occurs.

The transplant hospital will determine whether or not a transplant candidate (recipient) is a candidate for transplantation based on specific written guidelines and practices and clinical judgement.

Any transplant recipient candidate may have an increased chance of unexpected outcomes (including, but not limited to kidney failure, complications, and death). These may exceed local or national averages and do not necessarily prohibit transplantation and are not disclosed to the donor.

How is this paid for?

- Your evaluation and hospitalization are paid by the recipient's insurance.
- It is important for you to know that you will not receive any payment for donating your kidney. There is a federal law forbidding payment in exchange for an organ or tissue for transplantation.
- If the recipient receives Medicare, it is important that the surgery is performed in a Medicare-approved transplant program.
- If the transplant is not performed in a Medicare-approved center, the recipient's immunosuppression may not be paid for by Medicare Part B.

Concerns or Grievances

The United Network for Organ Sharing (UNOS) provides a toll-free patient services line to help transplant candidates, recipients, living donors, and family members understand organ allocation practices and

transplantation data. You may also call this number to discuss any problems you may be experiencing with your transplant center or the transplantation system in general. The toll-free patient services line number is included in the attached UNOS patient information letter.

Living Donor

Informed Consent for Evaluation of Donation

I understand that I need to sign this consent form if I wish to proceed with medical evaluation for living kidney donation. I understand my signature does not commit me to donating my kidney. I may remove myself from the evaluation and donation process at any time prior to the transplant. A surgical informed consent will occur prior to surgery.

I understand that in the United States 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. I understand that compensation to the donor does not include the reasonable payments associated with the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ. I agree to abide by this and not enter into any illegal financial arrangement with potential living donor(s).

My signature on this document that confirms that I (the donor):

- **am willing to donate**
- **am free from inducement and coercion and**
- **have been informed that I may decline to donate at any time**
- **acknowledge that Iowa Methodist may not approve me as a kidney donor**
- **I will complete any post-donation follow-up as directed by the transplant center**

Patient

Date

Transplant Coordinator

Date

Transplant Surgeon

Date

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