



Boston Medical Center Division of Transplant Surgery

Informed Consent to be Considered as a Living Kidney Donor

You are considering having major surgery in order to give one of your kidneys to another person. Please read the following information and ask any questions before agreeing to undergo this procedure.

The purpose of kidney donation is to give a healthy kidney to a person who has end stage renal disease. A successful kidney transplant may eliminate the need for dialysis and prevent many of the complications associated with kidney failure and dialysis. Live donor kidney transplantation is a desirable alternative for a person who is waiting on the deceased donor waiting list and possibly on dialysis as well.

In order for you to make this decision to donate you must understand the risks and benefits to make an informed decision. This process is known as informed consent. This informed consent provides information about the kidney donation surgery, the possible risks and complications and a review of your recovery process.

We are required to provide organ transplantation information to the United Network for Organ Sharing (UNOS). This includes the name, birth date, gender, social security number, and blood type of the donor, the donor's relationship to the recipient, and some blood test results. The identifying information is not accessible to the public or to researchers.

It is important that you understand that we treat you as a separate and distinct patient from your potential recipient throughout the evaluation process. We do not share any information about your medical evaluation, diagnostic test results, or your progress in the evaluation with anyone, unless you give written permission. In addition, transplant candidates may have risk factors for increased mortality and morbidity that will not be disclosed. We recommend that you identify someone, other than your potential recipient, to be available with you through the evaluation period. All of your medical records will be kept entirely confidential.

Living kidney donation is a voluntary and altruistic act. It is important that you are coming to us willingly, free from inducement, coercion, or pressure. You must not be receiving anything of value in order to persuade your decision to donate. The sale of organs is illegal. 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. You may decline to donate at any time.

Evaluation Process

You will undergo a complete medical and psychosocial evaluation to determine if you are eligible to be a living donor as outlined by BMC and UNOS policies. You will be asked about your medical, surgical, social and psychiatric history. You will be asked about "Increased Risk Behaviors" which is mandated by the 2013 'PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation' These questions will be asked by two different transplant team members at two separate visits.

The members of the donation team include:

- The **Living Donor Coordinator** conducts initial screening and education about the donation process. This person will be your guide throughout the evaluation process and is the keeper of your living donor evaluation record.
- A **Nephrologist** is a physician who is responsible for the thorough medical evaluation you will undergo to ensure you are medically suitable to donate. The nephrologist's role is to make sure that you have no medical conditions that could make donation prohibitively risky for you and that you do not have any diseases that could be transmitted to your recipient.
- A **Living Donor Surgeon** is a specially trained surgeon who will meet with you to discuss the surgical procedure. The surgeon will discuss the risks and possible complications of the donation and will examine you to determine your appropriateness, from a surgical standpoint, for donating one of your kidneys.
- A **Social Worker** will identify your social support network and evaluate your ability to cope with the stress of donation. The social worker will also discuss the potential negative impact the donation may have on your health, finances, and the ability to obtain life insurance.
- A member of the **Pharmacy** staff will review your current list of medications and identify any potential hazards associated with drug-drug interactions. The pharmacist will make appropriate recommendations of medications that are safe and ones to avoid.
- **Independent Living Donor Advocate (ILDA)** will be provided by the hospital. This is a professional who is not part of the transplant team but is trained and available to answer questions associated with the transplant process and provide support. You will meet with the ILDA who will help explain the donation process and ensure that your best interests remain the top priority.
- A **Psychiatrist** will conduct an in-depth evaluation and assessment of your psychosocial history and the relationship between you and the intended recipient. The psychiatrist will also discuss many of the things that are discussed by the social worker. They will also evaluate your comprehension of the donation process and explain what you may experience medically and psychologically after donation.
- A **Dietitian** will perform a nutritional assessment and provide nutrition education. If you need to lose weight prior to donation, the dietitian can develop an appropriate nutrition plan for you.
- Some potential donors may be referred to other services for consultation. For example, some patients may need to see a pulmonologist (lung doctor) or a cardiologist (heart doctor).

Several tests are done to determine if you can be a suitable donor. Remember, further tests may be required based on the results of these tests and your medical and psychosocial evaluation. Any health information obtained during the evaluation is subject to the same regulations as all records and could reveal health conditions that must be reported to local, state, or federal public health authorities.

Blood tests are done to determine your blood type and matching with the recipient. Your blood counts and chemistries will be checked. Testing for the presence of current or previous infections, including HIV, Hepatitis B, and C, Herpes, Syphilis, Epstein - Barr virus, Cytomegalovirus, Tuberculosis, West Nile Virus (between May and November), and other infections, will be performed.

Additional testing includes:

- A chest x-ray.
- A urine test is done to screen for the presence of urinary tract infection and disease. You will also need to perform at least two 24 hour collection of your urine for us to calculate your kidney function. You will also undergo a urine drug screen.

- An EKG (echocardiogram) or stress test will be performed. This will help your physicians decide if your heart function is strong enough for surgery.
- A CT scan will be done to identify the anatomy of your kidneys.
- Pulmonary function tests may be required, especially if you have a history of smoking or lung disease. This is a breathing test to analyze your lung capacity.

There is no comprehensive way to screen potential living donors for all transmissible diseases. Transmissible diseases and malignancies may be identified after transplant.

Once you have completed your workup your case will be presented to our Living Donor Selection Committee. A complete review of all your testing and consults will be done to determine if it is safe for you to donate a kidney. Once you have been approved for donation by the Committee, your surgery will be scheduled.

You may also be turned down as a donor. If this happens you will be told the reason why you cannot be a donor. This reason is not revealed to the recipient. You will be referred to a specialist or back to your primary care doctor if needed. You also have the option to be evaluated by another transplant program but the recipient would also need to be evaluated at this other program as well. Another transplant program may have different selection criteria.

Alternative Treatments

Your intended recipient can wait on the deceased donor list for a kidney transplant as an alternative to living donor kidney transplant. If the intended recipient is on dialysis, they would remain on dialysis. A deceased donor kidney may become available for the recipient before your evaluation is complete or a live donor transplant occurs and your intended recipient could receive this deceased donor kidney.

Right to Withdraw

You have the right to stop your donor consent or evaluation process at any time during the process in a way that is protected and confidential. The ILDA will be available to assist the donor during the consent process, at your request.

None of your health information will be shared with your recipient by the transplant team without your written permission. The transplant team will not allow the recipient to know the reason for you not becoming a donor. **YOU MAY STOP AT ANY TIME, FOR ANY REASON.** The ILDA is available to assist you in this process.

National and Transplant Center-Specific Outcomes

The results for kidney transplants at Boston Medical Center are excellent and meet all standards set forth by the United Network of Organ Sharing.

The latest Scientific Registry of Transplant Recipients (SRTR) results for Boston Medical Center can be found by visiting www.srtr.org. You will also be provided a paper copy of the most recent SRTR data. This information will be discussed with you by one of our staff.

Notification of Medicare Outcome Requirements not Being Met by Center

Transplant centers must meet specific outcome requirements and are required to notify you if they do not meet those requirements. Boston Medical Center meets all requirements for transplant centers.

Transplantation by a Transplant Center Not Approved by Medicare

If your recipient has a transplant at a facility that is not approved for transplantation by Medicare, the recipient's ability to have immunosuppressive drugs paid for under Medicare Part B could be affected.

Waiting Time Transfer and Multiple Listing

The recipient has the option of being listed for transplant at multiple transplant centers as long as they are in different regions. The recipient may also transfer waiting time to a different transplant center without loss of the accrued waiting time. Wait times vary in different regions.

Concerns or Grievances

The United Network for Organ Sharing 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 a problem you may be experiencing with your transplant center or the transplantation system in general. The toll-free patient services line number is 1-888-894-6361.

Acceptance Criteria

These are the general criteria on which we will base our decision to accept you as a living kidney donor.

- Age 18 years and older
- Healthy individual, free of renal, infectious and medical disease processes
- Willing to donate
- Free of coercion or inducement
- Be able to comprehend the donation process and give informed consent

Relative Contraindications:

These are conditions or circumstances in which you may not be able to be a living kidney donor.

- High blood pressure requiring 1-2 medications
- Body Mass Index > 35 percent
- History of gestational diabetes
- Mild/Moderate controlled psychiatric disease
- Hepatitis C positive
- Hepatitis B Core Antibody positive

Absolute Contraindications

These are conditions or circumstances in which you cannot be a living kidney donor.

- Diabetes
- High blood pressure requiring 3 or more meds or uncontrolled high blood pressure
- Severe psychiatric illness
- Significant cardiac disease
- Active illicit drug use
- Chronic lung disease
- Untreated or recent history of cancer (depending on type)
- HIV positive
- Hepatitis B Surface Antigen positive
- Incarceration with scheduled deportation

Benefits of a Living Donor Kidney Transplant

There are a number of advantages to a recipient of a kidney from a living donor. Studies have shown that people who receive a kidney from a living donor typically receive a better quality organ because it is coming from a younger, healthier person. A kidney from a living donor is immediately transplanted into the recipient

but a deceased donor kidney is stored and often transported long distances. Kidneys from living donors function, on average, about twice as long as kidneys from deceased donors. The transplant can also be planned as “elective” surgery and can be done when the recipient is in the best possible health. In some cases, if a recipient has a living donor he or she can have a transplant before starting on dialysis. This can be very important to the recipients overall health and long-term survival. Although lifesaving, dialysis can cause many health problems and the longer the patient stays on dialysis the greater the risk of developing these problems. In addition to the benefit to the recipient, every time a kidney transplant is done with a living donor kidney there is one less person on the waiting list for a deceased donor kidney. This contribution to the pool of donors helps others waiting on the list indirectly.

Risks Associated with the Evaluation Process

The following are inherent risks associated with evaluation for living donation. These risks may be short term or permanent, and include but are not limited to:

- o Allergic reactions to contrast used during the CT scan
- o Discovery of reportable infections that you may not have known about
- o Discovery of serious medical conditions that you may not have known about
- o Discovery of adverse genetic findings or other abnormalities that will require more testing at your own expense or create the need for unexpected decisions on the part of the transplant team.

Living Kidney Donor Surgery

The surgery is performed under general anesthesia and usually takes approximately 2 to 3 hours. The surgery is usually performed laparoscopically (minimally invasive with a camera). You will be positioned on your side to facilitate removing the kidney. You will likely have 3 to 4 small incisions on your abdomen to insert the camera and surgical instruments and to remove the kidney. You will have an IV tube and a urinary tube in place after surgery. Most donors remain in the hospital for 2 days. You will have a healing period of approximately six weeks when you may not be able to work depending on your job. You should not lift more than ten pounds. For the most part, donors are usually pain-free one week after the laparoscopic surgery; some people continue to have pain for a longer period but this is unusual. If you develop any complications after the surgery the recovery period may be longer.

Your Kidney Function After Donation

A human body is able to function normally with one working kidney. However, each donor and donation experience is different. On average, donors will have 25-35% permanent loss of kidney function at donation. Your risk of End Stage Renal Disease after donation is not greater than other people who are like you in age, race, or sex.

Chronic Kidney Disease generally develops in midlife (40-50 years old), and End Stage Renal Disease generally develops after age 60. Medical evaluation of young potential donor cannot totally predict lifetime risk. Donors may be at higher risk for Chronic Kidney Disease if they sustain damage to the remaining kidney. Development of Chronic Kidney Disease and progression to End Stage Renal Disease may be more rapid with only 1 kidney. Dialysis or kidney transplant is required when reaching End Stage Renal Disease.

Your health may be affected. You may experience decreased kidney function, kidney failure and the need for dialysis or kidney transplant following donation. Obesity, hypertension or other donor-specific medical

conditions may impact your morbidity and mortality. These medical risks may be short term or permanent and any risk cannot be predicted.

Current practice prioritizes prior living kidney donors who become kidney transplant candidates.

Surgical Risks

The surgery that you are having is called a live donor nephrectomy (removal of one healthy kidney). You will sign a separate consent for the surgery with the Donor Surgeon. There are potential surgical risks associated with living donation. These risks may be short term or permanent.

Donor nephrectomy can be done safely, but, with any major surgery, there are risks involved, even the risk of death. Bleeding during or after surgery may require blood transfusions or blood products that can contain bacteria and viruses that can cause infection. Although very rare, these infections include, but are not limited to the Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

Despite the use of compression boots during surgery blood clots may develop, on rare occasion, in your legs and break free and move to the lungs. In the lungs, they can cause serious interference with breathing, which can lead to death. Blood clots are treated with blood-thinning drugs that may need to be taken for an extended period of time. This scenario of blood clot formation is very unusual.

There is a risk of infection with any surgery. Infections in the sites where tubes are placed in your body (tubes to help you breathe, tubes in your veins to provide fluids, nutrition and to monitor important body functions) can cause pneumonia, blood infections and local infections.

Damage to nerves may occur. This can happen from positioning of the arms, legs or back during the surgery. Nerve damage can cause numbness, weakness, paralysis or pain. In most cases these symptoms are temporary, but in rare cases they can last for extended periods or even become permanent.

Other possible complications include: injury to structures in the abdomen, such as organs and blood vessels, pressure sores on the skin due to positioning, burns caused by the use of electrical equipment during surgery, damage to arteries and veins, pneumonia, heart attack, stroke, and permanent scarring at the site of the abdominal incision, and the need for blood transfusion. Also, risks include death from surgical donation, scars, pain, fatigue, hernia and other consequences typical of any surgical procedure, and/or abdominal or bowel symptoms such as bloating and nausea, and bowel obstruction.

Surgical risks may be transient or permanent and include but are not limited to: Decreased kidney function or Acute kidney failure and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period.

Psychosocial Risks

Along with surgical risks there may be psychosocial risks associated with kidney donation such as depression after transplant if the procedure doesn't go well or if the recipient doesn't have a good outcome. There may also be anxiety about post operative pain and recovery and potential loss of work or productivity. Some individuals may feel pressure to donate and there can be anxiety associated with this. Even post traumatic stress disorder (PTSD) has been reported in the post donation setting.

The Independent Living Donor Advocate is made available to the patient to help deal with many of these issues and our screening referral with psychiatry would also help identify these issues.

There are potential risks associated with living donation. These risks may be short term or permanent, and are considered psychosocial risks, and include but are not limited to:

- Problems with body image
- Post-surgery depression or anxiety
- Feelings of emotional distress or bereavement if recipient experiences any recurrent disease or in the event of the recipient's death
- Impact of donation on the donor's lifestyle
- Personal expenses of travel, housing, child care, lost wages related to the donation process might not be reimbursed; however, resources may be available to defray some donation-related expenses
- Need for life-long follow up at the 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 living donors following donation may not be covered by the recipient's insurance.

Recipient Organ Failure

It is possible that the donor kidney, on very rare occasions, may not work or may be rejected by the recipient's immune system. This may require that he or she be placed on the UNOS waiting list to wait for another kidney. During the waiting time the recipient may need dialysis.

Insurance/Pre-existing Conditions

All expenses associated with the transplant process will be covered by the recipient's insurance. After living kidney donor surgery your health insurance company may identify you as having a pre-existing kidney disease or abdominal related problems. Future kidney disease or abdominal related problems may not be covered by your insurance because you have been a living kidney donor. If these problems are not related to the surgery and are not covered by your recipient's insurance company, you may be responsible for all costs.

Future health insurance, disability, and life insurance premiums may be higher as a result of live kidney donation. You may not be able to get health, disability, and life insurance in the future if you lose your current insurance or if you are not currently insured.

Financial Considerations

You may incur personal expenses for travel, housing and lost wages related to live donation. Resources may be available to offset some of the donation related cost which our social worker can discuss with you. There is a possible loss of employment or the donation surgery could affect your ability to obtain future employment.

There are potential financial risks associated with living donation. Future health problems experienced by living donors following donation may not be covered by the recipient's insurance. Personal expenses of travel, housing, child care, lost wages related to the donation process might not be reimbursed; however, resources may be available to defray some donation-related expenses. There may be a need for life-long follow up at the donor's expense. You may experience loss of employment or income. You may experience a negative impact on the ability to obtain future employment or on the ability to obtain, maintain, or afford health, disability, and life insurance.

Follow up care Requirements

As a living kidney donor you will be followed by Boston Medical Center immediately after surgery. By signing this consent you are agreeing to commit to post-operative follow up testing coordinated by Boston Medical Center. We will either see you again at 6 months, 1 year and finally at 2 years post donation or ask that you provide us with a name and contact information of the physician you chose to see in follow-up for these specific time frames. We will ask you/your physician to forward the results of your check-up and certain blood and urine tests to us so we may review them. It is a UNOS/OPTN requirement that we submit medical information on you for a period of 2 years after donation. By agreeing to be a living donor you agree to the follow-up plan and submission of clinical information.

Boston Medical Center is required to report any infectious disease or malignancy found in the recipient or donor during your first two years of follow up care to local, state and/or federal public health authorities. You and your recipient will be notified of any reportable findings. If your recipient is at another transplant center, this information will also be disclosed to that transplant center. It will also be reported through the OPTN Improving Patient Safety Portal.

Lifestyle Changes

You should maintain a healthy lifestyle after donation. Eat healthy and get plenty of exercise. As long as you do not have medical conditions that can affect kidney function, such as diabetes or high blood pressure, you are not at a higher risk of developing kidney problems than the general population. It will be very important for you to maintain a healthy life style and get annual medical check-ups – of course, everyone should do this regardless of being a living kidney donor but it is especially important for living donors. It is important that you maintain a normal weight after living kidney donation because obesity can increase your risk of developing high blood pressure and type-two diabetes. Having only one kidney could put you at greater risk of developing kidney failure in this setting. As part of the evaluation, you will undergo routine age appropriate testing for cancer. This is done to ensure you do not have a cancer that could be transmitted to the recipient.

You must notify all medical personnel in the future that you have donated a kidney.

BOSTON MEDICAL CENTER RECOGNIZES THAT A PATIENT MAY WITHDRAW CONSENT AT ANY TIME PRIOR TO TREATMENT REGARDLESS OF WHETHER A CONSENT FORM HAS BEEN SIGNED.

Boston Medical Center
Division of Transplantation

Informed Consent to be a Living Kidney Donor

I have received a copy of Informed Consent to be a Living Kidney Donor. I have read the information and I have been provided the opportunity to ask questions and to have my questions answered. **By signing below, I attest that that I am freely willing to donate and that I am free from intimidation, inducement and coercion in my decision. I also attest that I am not receiving anything of value or personal gain for donating my kidney, including money, possession or property.** I understand that I may stop the evaluations process and decline to donate at any time. I understand that I will be provided with an Independent Living Donor Advocate (ILDA) to assist me during the living donor evaluation process. I have been given information regarding all phases of the living donation process, including but not limited to:

- Consent
- Medical and psychosocial evaluations
- Pre and post operative care
- Required post operative follow up

The above information has been presented in a language in which I understand. I understand that the recovery hospital will take all reasonable precautions to provide confidentiality for the donor/recipient pair. I understand that it is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for valuable consideration (payment for the kidney).

I have been given the opportunity to have all of my questions answered to my satisfaction and that if I have any further questions, I may contact any member of the Living Donor Evaluation team.

I have read and understand the above document and have had any questions explained to my satisfaction. I acknowledge that I am the patient or I am the patient's legally authorized representative or surrogate and by signing below indicate that I herein voluntarily consent to the above procedure.

Sign Name: _____ Print Name: _____ Date: _____ Time: _____

Sign Name: _____ Print Name: _____ Date: _____ Time: _____
Parent/Guardian/Surrogate (if applicable)

Sign Name: _____ Print Name: _____ Date: _____ Time: _____
Provider/Physician/Witness (as applicable)

I interpreted the provider's explanation. (Interpreter must sign below, if applicable)

Sign Name: _____ Print Name: _____ Date: _____ Time: _____