Methodist Dallas Medical Center
Informed Consent to Donate Kidney for Transplantation

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

The purpose of kidney transplantation is to give a healthy kidney to a person who has kidney disease. A successful kidney transplant may prevent the need for dialysis and the complications associated with kidney failure. For many years, the kidney that was transplanted had to come from a person who had died, from a "deceased donor." But there have not been enough deceased donors for the number of people who need a kidney transplant. Live donor kidney transplantation is now as successful as deceased donor kidney transplantation.

We are required to provide information about all organ transplants to the United Network for Organ Sharing (UNOS). This includes the name, birth date, sex, social security number, blood type of the donor, the donor's relationship to the recipient, and some blood test results. UNOS then assigns a case number to the transplant recipient and the donor. The identifying information is not accessible to the public or to other researchers.

Information about your medical evaluation, diagnostic test results, etc., will not be discussed with the potential kidney transplant recipient unless you give written permission. It is your option to discuss this information with the potential recipient.

_____ _____ **Evaluation Process**
Patient Employee

As part of the evaluation process, you will receive a thorough medical and psychosocial evaluation. You will be evaluated with consultations, lab tests, and various diagnostic procedures to determine the appropriateness of kidney donation. You will meet with many members of the transplant team who may include:

- The **Transplant Coordinator** provides education regarding the transplant donor evaluation process and patient responsibilities before and after donation. This meeting is intended to provide you with an opportunity to ask questions and to become fully informed about the kidney donation and transplant process.

- A Transplant **Nephrologist** is a physician who specializes in kidney disease. The Transplant Nephrologist assesses medical suitability for donation, discusses the significance of donation, manages donation-related medical needs before and after donation, participates in care during the hospital admission, and follows donors during clinic appointments at specific time periods post-discharge.

- A **Transplant Surgeon** will meet with you during the evaluation and/or prior to surgery to discuss the appropriateness of donation based on the information obtained during your evaluation. The Transplant Surgeon evaluates surgical suitability for donation, discusses the significance of donation (including the risks, benefits, and surgical complications), performs the donation operation, and provides post-operative care for a defined period of time following surgery.

- An **Anesthesiologist** may meet with you and review your medical records to determine the need for any additional workup to determine your risk from anesthesia.

- A **Transplant Social Worker** will meet with you to evaluate your ability to cope with the stress of donation. The social worker will also help to identify your support network. They will discuss any possible costs associated with your donation. They will work with you to help you understand your insurance coverage. It is important that you understand the costs that may not be covered by insurance.

- A **Psychiatrist/Psychologist** may conduct a more in-depth evaluation and assessment of your psychosocial history and the relationship between you and the intended recipient.

- A **Registered Dietitian** will perform a nutritional assessment and provide nutrition education.

- An **Independent Living Donor Advocate** will meet with you to make sure you are fully informed of the donation process and the care required after donation. As a donor recovery hospital, we are required to have an individual serve in this position; this individual is here solely to protect your rights as a donor and respond to any questions or concerns you may have as a donor. If your donation occurs at another facility, that facility is also required to provide an Independent Living Donor Advocate.

- Some potential donors may be referred to another service for consultation. For example, some patients need to be seen by a pulmonologist (lung doctor) or a cardiologist (heart doctor) to assess for other 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. Remember, other tests may need to be done based on the results of these tests.

- Blood tests are done to determine your blood type and identify any possible reason that you might not be able to donate one of your kidneys. These tests will screen for your immunity to or the presence of specific viruses, including HIV. Additional blood tests may be used to determine how well other organs are functioning.

- A chest x-ray helps your physician identify any problems with your lungs.

- A urine test is used to screen for the presence of urinary tract diseases.

- A CT scan will be done to identify the blood flow to and from your kidneys.

- A 24 hour urine collection or GloFil will be done to make sure that you have adequate kidney function.

- Pulmonary function tests may be required, especially if you are have a history of smoking or a history of lung disease. This is a breathing test to analyze your lung capacity.

The following are inherent risks associated with evaluation for living donation: 1) allergic reactions to contrast; 2) discovery of reportable infections; 3) discovery of serious medical conditions; and 4) discovery of adverse genetic findings unknown to you. Evaluation testing may also reveal certain

abnormalities that will require more testing at your expense or create the need for unexpected decisions on the part of the transplant team.

After completion of a partial or full evaluation, your case will be presented to the Selection Committee. If you are denied participation as a donor at Methodist Dallas Medical Center, you have the option of being evaluated by another transplant program that may have different selection criteria.

Surgical Procedure

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Patient Employee

For surgery, you will be medicated with general anesthesia, the surgeon will place three small holes in your abdomen for a camera and surgical instruments, and one incision will be made to remove your kidney. Your abdomen will then be stitched closed. Additional vessels may be removed at the time of your surgical procedure but can only be used for the transplant surgery or a surgical modification in the original intended recipient of your donated kidney. Your signature indicates that you consent to the removal of additional vessels and subsequent use of those vessels in the original intended recipient of your donated kidney.

You will have a small IV tube and a urinary tube in place after surgery. Most donors remain in the hospital for 2 days. You will probably feel more tired than usual for one to three months after the surgery. You will have a healing period of approximately 3 to 6 weeks during which you should not work or lift more than ten pounds. You also should not lift more than 20 to 25 pounds until three months after surgery.

Alternative Treatments

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Patient Employee

Transplant hospitals determine candidacy for transplantation based on existing hospital specific guidelines or practices and clinical judgement.

Alternative procedures or courses of therapy other than transplantation may be available for kidney disease, including initiating or remaining on dialysis and receiving a kidney transplant from a deceased donor. Additional alternatives can be discussed with you by the Transplant Nephrologist.

A transplant recipient may have an increased likelihood of adverse outcomes (including but not limited to graft failure, complications, and mortality that exceed local or national averages and do not necessarily prohibit transplantation. Personal health information collected during the transplant recipient's evaluation, which is confidential and protected under privacy law. These risks may not be disclosed to you without the consent of the recipient.

A deceased donor kidney might become available for the recipient before the donor evaluation is completed or the living donor transplant occurs. The transplant candidate might have risk factors for increased morbidity or mortality that are not disclosed to you as the potential donor.

Potential Medical/Psychological/Financial Risks

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Patient Employee

There are inherent risks in all surgeries, especially surgeries conducted under general anesthesia. These risks may be transient or permanent. In some cases, the complications are serious enough to require another surgery or medical procedure. Medical or surgical risks include but are not limited to: death; scars, hernia, pain, fatigue, and other consequences typical of any surgical procedures; decreased kidney function; abdominal or bowel symptoms such as bloating and nausea and developing bowel obstruction; and acute kidney failure and the need for dialysis or kidney transplant for the donor in the immediate post-operative period. Medical conditions such as age, obesity, hypertension, or other donor specific

pre-existing conditions may have an impact on morbidity and mortality of the donor; these risks will be discussed with you in further detail by the Transplant Nephrologist or Transplant Surgeon.

Bleeding during or after surgery may require blood transfusions or blood products that can contain bacteria and viruses that can 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).

Risks of preeclampsia or gestational hypertension are increased in pregnancies after donation.

Emotional and psychological issues before and after donation vary. Potential psychosocial risks include but are not limited to: problems with body image; post-surgery depression or anxiety; and feelings of emotional distress or bereavement if the transplant recipient experiences any recurrent disease or in the event of the transplant recipient's death. There may also be an impact on your pre-donation lifestyle. Should you experience these, please notify your Transplant Surgeon, Transplant Nephrologist, Transplant Coordinator, Transplant Social Worker, or Independent Living Donor Advocate.

On average, donors will have a 25-35% permanent loss of kidney function at donation. Although the risk of End Stage Renal Disease (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 Chronic Kidney Disease (CKD) and ESRD. When Chronic Kidney Disease (CKD) or ESRD occurs, CKD generally develops in mid-life (40-50 years) but ESRD usually doesn't develop until after age 60. The medical evaluation of a young potential donor cannot predict lifetime risk of CKD or ESRD. Living Donors may be at higher risk for CKD if they sustain damage to the remaining kidney and development of CKD and subsequent progression to ESRD may be more rapid with only one kidney. Dialysis is required when reaching ESRD and current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to OPTN policy.

Financial complications may occur related to time off from work for medical testing, the surgical procedure, and post-operative recovery. Potential financial impacts may result from: 1) personal expenses of travel, housing, childcare costs, and lost wages related to donation that might not be reimbursed; 2) loss of employment or income; 3) need for life-long follow-up at your own expense; 4) a negative impact on your ability to obtain future employment; and 5) negative impact on your 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. Financial assistance may be available to you as a living donor to defray some donation related costs. Please ask our Financial Coordinator, Transplant Social Worker, or Independent Living Donor Advocate any questions you may have related to financial risks.

Miscellaneous Risks

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Patient Employee

Despite the use of compression boots, blood clots may occasionally develop in the legs and can break free and occasionally move through the heart 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.

There is a risk of infection. The abdominal incision is a potential site for wound infection. Infections in the sites where tubes are placed in your body (tubes to help you breathe, tubes in your veins to provide fluids and nutrition and to monitor important body functions) can cause pneumonia, blood infections and local infections.

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 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, 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.

_____ _____ **Right to Withdraw**
Patient Employee

By signing this consent form, you agree that you are willing to donate and are free from inducement and coercion. You have the right to withdraw your participation as a donor at any time during the process and the Independent Living Donor Advocate can assist you with the process if needed. If you wish, the transplant team can inform the recipient on your behalf in a way that is protected and confidential.

_____ _____ **Confidentiality**
Patient Employee

Methodist Dallas Medical Center will take all reasonable precautions to provide confidentiality for the donor and the recipient. With few exceptions, none of your health information will be shared with the candidate by the transplant team unless you have provided written consent. Health information obtained during your evaluation is subject to the same regulations as all medical records and could reveal conditions that the transplant center must report to local, state or federal public health authorities. Any infectious disease or malignancy pertinent to acute recipient care discovered during your first two years of post-operative follow-up care may need to be reported to local, state or federal public health authorities, will be disclosed to the recipient's transplant center (if the transplant does not occur at Methodist Dallas Medical Center), and will be reported through the Organ Procurement and Transplantation Network (OPTN) Improving Patient Safety Portal.

_____ _____ **Sale/Purchase of Human Organs**
Patient Employee

Please be aware that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, obtain, or otherwise transfer any human organ for valuable consideration for use in human transplantation (i.e. for anything of value including but not limited to cash, property, vacations).

_____ _____ **National and Transplant Center-Specific Outcomes**
Patient Employee

The most current data available from the Scientific Registry of Transplant Recipients (SRTR) describing both national and program specific patient and graft survival one year after transplant is represented in the attached document and does not significantly differ compared to the national data.

_____ _____ **Notification of Medicare Outcome Requirements not Being Met by Center**
Patient Employee

Specific outcome requirements must be met by transplant centers and we are required to notify you if we do not meet those requirements. Currently, Methodist Dallas Medical Center meets all requirements for transplant centers.

_____ _____ **Transplantation by a Transplant Center Not Approved by Medicare**
Patient Employee

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

After you donate one of your kidneys, health insurance companies may consider you to have a pre-existing condition and refuse payment for medical care, treatments or procedures. After the surgery, your health insurance and life insurance premiums may increase and remain higher. In the future, insurance companies could refuse to insure you for health, life, and/or disability insurance.

_____ _____ **Waiting Time Transfer and Multiple Listing**
Patient Employee

If listed for transplant, the recipient has the option of being listed for transplant at multiple transplant centers and the ability to transfer waiting time to a different transplant center without loss of the accrued waiting time.

_____ _____ **Post-Donation Follow-Up**
Patient Employee

Information about living donors is submitted to the United Network for Organ Sharing (UNOS) at the time of donation and at 6 months, 1 year, and 2 years after donation. This follow-up will require blood testing, urine testing, weight and blood pressure measurement, which can be coordinated at Methodist Dallas Medical Center or at a health care provider of your choice. This information is kept in order to determine how many live donor kidney transplants are done, how many are successful, and what the complications are. By proceeding with the evaluation and donation process, you agree that you are committed to post-operative follow-up testing coordinated by the living donor recovery hospital.

I understand that I may learn of an infectious disease or malignancy during the first two years of my medical follow up after donation. Any infectious disease or malignancy that is pertinent to acute care of the recipient discovered during the first two years of my follow up care may need to be reported to local, state, or federal public health authorities; will be disclosed to my recipient's transplant hospital; and will be reported through the OPTN Improving Patient Safety Portal. You may be asked to provide additional information or specimens. I understand that in accordance with UNOS policy, the Methodist Dallas Transplant Program is required to obtain and store a living donor blood specimen for ten years after the date of transplant, only to be used for investigation of potential donor-derived disease. This specimen must be obtained within 24 hours prior to organ recovery and documented in the living donor medical record.

_____ _____ **Concerns or Grievances**
Patient Employee

The OPTN provides a toll-free patient services line to help transplant candidates, recipients, living donors, and family members understand organ donation and transplant and organ and donation transplant policies. You may also call this number to discuss questions you may have with your transplant center or the transplantation system in general. The toll-free patient services line number is 1-866-678-6411.

My signature below indicates that I have reviewed the information in this Informed Consent. I have had the opportunity to ask questions and all questions or concerns have been addressed. As further questions arise, I will notify a member of the transplant team or the Independent Living Donor Advocate.

Patient Name & Initials	Date
Independent Living Donor Advocate Name & Initials	Date
Transplant Coordinator Name & Initials	Date
Transplant Social Worker Name & Initials	Date