Methodist Dallas Medical Center

Informed Consent to Donate a Kidney for Transplantation
Paired or Non-Directed Donor

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 as successful as deceased donor kidney transplantation.

We are required to provide information about all organ transplants to the Organ Procurement and Transplant Network (OPTN). 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.

It is important that you understand that you may withdraw from the process at any time, for any reason.

_____ _____ **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 a GloFil test will be done to make sure that you have adequate kidney function.

- Pulmonary function tests may be required, especially if you 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 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.

_____ _____ **Matching**
Patient Employee

Transplant hospitals must view organ offers and respond to these offers through the match system. The transplanting physician at the receiving transplant hospital is responsible for ensuring the medical suitability of organ offered for transplant to potential recipients, including whether the donor and candidate blood types (and donor subtype if applicable) are compatible or intended incompatible. Potential donors must be at least 18 years old and not be currently registered for any other candidate registered in the OPTN KPD program. KPD donors do not choose their match. KPD donors or candidate may decline a match.

Additionally, it is possible that the:

- KPD donors could help more than one candidate receive a transplant
- Paired donors may have to wait to find a match
- Paired donors might have to wait longer to donate after a match has been identified because of logistical issues
- Paired candidate might not receive a transplant because of an unexpected issue with the matched donor's kidney found during or after the surgery
- Paired donor's kidney might not be transplanted or the paired donor's matched candidate might not receive a transplant because of unexpected events
- KPD program's remedy for failed KPD exchanges and that the remedy does not include any additional priority for the paired candidate on the deceased donor waiting list
- Personal expenses of travel, housing, childcare costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation related costs
- Paired donor's paired recipient and the paired donor's matched recipient might not have equal outcomes
- Paired donor's name appearing on the matched candidate's insurance estimation of benefits Donor's kidney could be lost in transport, and other potentially negative consequences related to shipping a kidney
- Paired donors may require re-evaluation including multiple blood draws for crossmatching

_____ _____ **Bridge Donors**
Patient Employee

If you are or become a bridge donor, it is possible that:

- You may need to have another medical evaluation at a future time
- You may need to be available to provide blood on multiple occasions for crossmatching

You may decide the amount of time you are willing to wait for donation and our center will document your wishes in your medical record. You may revise this decision at any time

As a bridge donor, you can choose to continue as a bridge donor or you may choose to donate to a candidate waiting for a deceased donor kidney. You may decline to donate at any time, for any reason.

_____ _____ **Surgical Procedure**
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.

_____ _____ **Unexpected Surgical Events**
Patient Employee

An event may occur in the operating room that makes it necessary to stop a donor procedure. In this case, one recipient would not receive a kidney. If a donor or recipient surgery has begun, this surgery will continue even if another surgery in the match must stop.

If it is necessary to stop a recipient surgery, a kidney would be available. This kidney would be given to a recipient on the deceased donor waiting list according to Organ Procurement and Transplantation Network (OPTN) policy.

_____ _____ **Risks of Shipping a Kidney**
Patient Employee

The living donor kidney will be shipped via ground and/or air transportation to the recipient transplant center. This form of transportation has the risk of courier delay, flight cancellation, or flight delay which would extend the cold ischemic time of the kidney. Cold ischemic time is the amount of time an organ spends being preserved after recovery from the donor. Too much cold ischemic can affect the quality of the organ for transplant. With clear-cut, organized plans, the risk is decreased. There is the risk of problems outside the transplant center's control such as a plane crash, terrorist activity, and natural disaster. There is risk of damage to the kidney during transport which would be discovered at the time of inspection of the kidney at the recipient's transplant center.

_____ _____ **Alternative Treatments**
Patient Employee

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

Alternative treatments or therapies 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 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

_____ _____
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 preexisting 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.

Miscellaneous Risks

_____ _____
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 may 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 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 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, receive, 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).

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.

_____ _____ **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 do not significantly differ compared to national data. If your kidney will be transplanted at another transplant hospital, you will be provided the most recent national and program specific SRTR data reports for the facility where your kidney will be transplanted. This will be provided prior to the donation.

_____ _____ **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. If your kidney will be transplanted at another transplant hospital, you will be provided the Medicare standing of the facility where your kidney will be transplanted. This will be provided prior to the donation.

_____ _____ **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 Medical Center or 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.

_____ _____ **Meetings Between Matched Donors and Recipients**
Patient Employee

The transplant program can help facilitate communications and/or meetings between matched donor and recipients if all parties consent. MDMC policy states that physical meetings will not occur until 48 hours after donation and transplantation. Other centers participating in an exchange may have different policies and timelines for communication between the donors and recipients._

_____ _____ **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 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 1-866-678-6411.

I am willing to participate in a three way match	Yes	No
I am willing to participate in a chain	Yes	No
I am willing to be a bridge donor	Yes	No

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 Staff Name & Initials Date

_____ _____
Transplant Social Worker Name & Initials Date