Saint Francis Kidney Transplant Program  
Issue Date: 5-12-15

**Living Donor Informed Consent Education**

**Confidentiality**
- I understand that communication between the Transplant Center and me will remain confidential. I may discuss my progress with my recipient if I choose.
- Information about my medical evaluation and test results will not be discussed with the potential kidney transplant recipient unless I give permission.
- I understand that it may be necessary to discuss some of the results of my evaluation if the results could have impact on the outcome of the transplant. This will only be done with my permission. If I do not give my permission, the donation will not proceed.
- I understand that my medical evaluation could reveal conditions that the transplant center must report to governmental authorities such as Hepatitis C, HIV or other infectious diseases with mandatory reporting requirements.
- Disclosure of any infectious disease or malignancy, will also be reported through the Organ Procurement and Transplantation Network (OPTN) Improving Patient Safety Portal.

**The Donor Team members and their roles.**
I will be evaluated for my acceptance as a kidney donor. This process will include testing and evaluation by members of the living donor team. The team members include:
- The RN Living Donor Coordinator is a Registered nurse that helps to guide me through the evaluation, hospitalization and long term follow up. The nurse will teach me what I need to know before and after my kidney donation. These meetings will give me a chance to ask questions and will help me to understand what to expect.
- A Transplant Nephrologist is a doctor that treats kidney disease. This doctor will provide my medical clearance for donation as this specialty will be able to discuss the long-term consequence of donation.
- The Transplant Living Donor Surgeon is the doctor that does the surgery. He will meet with me to discuss risks associated with surgery and any problems from the surgery that I may have after I donate my kidney.
- A Transplant Social Worker is a member of the transplant team that will meet with me to review the issues I may face before and after my kidney donation. A psycho-social assessment will be completed. This will include the support I may need before and after donation.
- The Independent Living Donor Advocate is an individual who works with only the living donor. Their role is to promote my best interest and advocate for my rights. The donor advocate will ensure that I understand about the risks and complications related to kidney donation. The Living Donor Advocate will assist me in discussing my questions with the physicians and other members of the transplant team.
- A Transplant Dietitian is someone who is educated in nutrition and weight control.
- Appointments with other doctors may be needed in order to clear me for donation. For example, I may need to be seen by a cardiologist (heart doctor) or a pulmonologist (lung doctor). I understand that my past medical history and evaluation testing help the team identify when I will need to see any other doctors.

**The Evaluation Process.**
- I made the first call to the Transplant Center asking to be considered for living kidney donation. I completed a telephone health assessment interview. I was given/read information about giving a kidney and how the transplant program works. I discussed my questions/concerns with the RN Living Donor Coordinator.
- I will meet/have met with the RN Living Donor Coordinator to discuss concerns and questions. I will have my blood drawn for ABO compatibility and a crossmatch.
I will meet with the Transplant Social Worker for a psycho-social evaluation. I will have a chance to ask additional questions. I will have a chance to talk about emotional issues related to donation. I will have a chance to talk about how donation will affect my family.

I will meet with the Independent Living Donor Advocate, Lynne Reyna or Thomas Mefford. He/she will ensure that I understand the information I have been given and that I am giving the kidney with no expectation of any payment. In addition, I know I may decide not to give the kidney at any time in the process.

If I am compatible, I will make an appointment to have further testing, which includes:

- Blood pressure check
- Chest x-ray
- EKG
- Kidney Ultrasound
- Abdominal CT Angiography
- Urinalysis
- 24-hour urine collection and several blood tests
- I will be asked for additional testing depending on my age and sex. These screening tests include:
  - Pap smear
  - Mammogram
  - PSA
  - Colonoscopy (if applicable)
  - Stress test of my heart (if applicable)

The following risks are associated with the evaluation:
- Allergic reaction 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 the donor’s expense.

After I have completed this testing my results will be sent to a Nephrologist (kidney specialist). This doctor will meet with me to:
- Review the results
- Perform a complete history and physical
- Decide if additional studies are needed
- Inform me of the risk of donating one of my kidneys
- Determine if I am a candidate to donate a kidney

I will have a test that takes pictures of my kidneys. The purpose of this test is to assist the Donor Surgeon in evaluating me as a potential donor. The healthcare team will explain this procedure to me.

After my evaluation is completed, I will meet with the Transplant Donor Surgeon and a Transplant Nephrologist (kidney doctor). The transplant team will decide if I am a candidate for donation. I may be asked to have additional testing.

If I am deemed not a candidate for donation at Saint Francis Kidney Transplant Program, I may be evaluated by another transplant program that may have different selection criteria.

**Surgical Procedure (I will be asked to sign a separate full surgical consent prior to donation)**

The surgical procedure(s) will be explained in terms that I understand, by W. Jason Cook, M.D., which includes:
- Risks associated with surgery
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- Risks and effects of general anesthesia
- Possible need for blood transfusion and the risks involved with the use of blood or blood products
- Expected post-surgical course and discomforts
- Termination of the surgery with any indication that I may be at risk for complications during the surgery
- I understand that no assurance can be given that the procedure(s) will be successful and the recipient may have increased risk factors that are not disclosed to me.
- I understand that my blood type and the recipient’s blood type will be verified prior to surgery, and these results will be maintained as part of the recipient’s transplant medical record, and will not be released.

**Alternative Treatment for recipient**
I understand the following alternatives are available for the recipient:

- To remain on current End Stage Kidney Disease Treatment(s)
- To switch to another End Stage Kidney Disease Treatment
- To seek donation through the national United Network for Organ Sharing (UNOS) deceased donor waitlist
- To terminate all treatments
- To find another potential living donor

I also understand that a deceased donor kidney may become available before my evaluation is complete or a living donor transplant takes place.

**Potential Medical Risks**

- Surgical complications
  - Wound infection
  - Pneumonia
  - Blood clot formation
  - Incisional hernia
  - Scars
  - Pain
  - Fatigue
  - Decreased kidney function
  - Abdominal or bowel symptoms such as bloating, nausea or developing bowel obstruction
- Obesity, high blood pressure and other medical conditions can negatively affect your long-term health post-donation.
- On average, donors will have a 25-35% permanent loss of kidney function at donation
- Baseline risk of end stage renal disease does not exceed that of members of the general population with the same demographic profile
- Chronic kidney disease normally develops at 40-50 years of age and end stage renal disease, requiring dialysis, normally develops after age 60. For young donors, it is difficult to predict whether or not they will develop kidney disease later in life.
- If you develop kidney disease or injure your remaining kidney, your decline in kidney function may be more rapid with only one kidney.
- Arrhythmias
- Kidney failure which could result in the need for dialysis.
- Need for organ transplant later in life (current practice is to prioritize prior living kidney donors who become kidney transplant candidates)
- Death
Potential Psychosocial Risks
- Depression
- Anxiety
- Anxiety regarding dependence on others
- Feelings of guilt
- Stress disorder
- Problems with body image
- Feelings of emotional distress or bereavement if the transplant recipient experiences any recurrent disease or in the event of the transplant recipient’s death.
- Impact of the donation on the donor’s lifestyle

Risk of Rejection to Recipient
- I understand that despite tissue typing, crossmatching, and pre-operative testing, there is a chance the recipient may reject my donated kidney.

Potential Financial Risks
- The pre-transplant donor evaluation costs and hospital charges will be billed to the transplant program, which in turn bills Medicare through the Kidney Acquisition Fund. Any services not covered by Medicare will be billed to the recipient’s insurance. This includes the surgeon’s fees and any physicians’ billing after the donation. The recipient’s Medicare will cover medically documented complications directly related to donation for at least one year from the date of transplant. After that time, Medicare may require additional documentation of the relationship to the donation.
- My future health problems following donation may not be covered by the recipient’s insurance.
- My insurance carrier may not cover the donation procedure and future health problems related to the donation.
- Need for life-long follow-up at the donor’s expense
- Personal expenses of travel, housing, childcare costs, and lost wages related to live donation might not be reimbursed; however, there are resources that may be available to defray some donation-related costs if you qualify.
- Loss of employment or income
- Negative impact on the ability to obtain future employment
- Attempts to obtain, maintain or afford medical, disability and life insurance in the future may also be at risk. There is also the possibility that I may be denied coverage.
- If the transplant is not provided in a Medicare-approved transplant center, it could affect the transplant recipient’s ability to have his/her immunosuppressive drugs paid for under Medicare Part B.

All of the above potential risks may be temporary or permanent

General Obligations for Living Kidney Donor
- I understand that I cannot receive anything of value (cash, property, vacations) as payment in exchange for being a donor as this is a federal crime, subject to a $50,000 fine or 5 years in prison.
- I understand that my donation is voluntary and free from inducement and coercion.
- It is my right to opt out of donation at any time during the evaluation/donation process.
- I understand that I will undertake risk and will receive no medical benefit from the donor nephrectomy.
- I understand that Lynne Reyna or Thomas Mefford, is my donor advocate. He/she is independent of the kidney transplant center. As my advocate, he/she will ensure that I understand the risks and
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complications related to kidney donation and had the opportunity to discuss my questions with the physician. He/she will also be available to assist me if I chose to opt out. Either can be reached at (918) 494-1140.

- I will immediately notify the transplant center of any changes in my medical condition which might affect my availability or suitability as a living kidney donor candidate, including, but not limited to:
  - Admission for observation or treatment to a hospital;
  - Blood transfusions
  - Outpatient surgery
  - Pregnancy
  - Change in weight of more than 10 pounds
  - Any other significant changes in my medical condition.
  - I will immediately notify the transplant center of any of the below changes
  - Change of address or phone number
  - Change in employment or marital status
  - Change in health care benefits

After Donation

After donation, I fully understand that I have the responsibility to comply with the discharge instructions and medical follow-up set forth by the transplant team. I agree to the following:

- Regular lab work and visits according to physician orders.
- Follow the transplant discharge instructions
- Follow any additional instructions specific to my recovery
- I will follow up for basic testing at the transplant center for the following time schedule: 6 months, 1 year and 2 years. This data will be provided to Organ Procurement and Transplantation Network / United Network for Organ Sharing (OPTN/UNOS) to assist in monitoring the results of living donation
- If any infectious disease or malignancy is discovered during the 2-year follow up period it may need to be reported to the recipient’s transplant center and/or government authorities and/or OPTN/UNOS and will be disclosed to the donor.
- Follow-up with my Primary Care Physician (PCP) for a medical exam every year following my nephrectomy as part of good health maintenance. I understand that the cost of the PCP will be my responsibility.

My signature below constitutes my acknowledgement that:

- I have read the above information or the information has been read to me.
- The explanations referred to above were made and understood by me.
- I have been given the opportunity to ask any questions that I might have and my questions have been answered to my satisfaction.
- All blanks or statements requiring completion or insertion were filled in and inapplicable paragraphs, if any, were stricken before signed.

United Network of Organ Sharing (UNOS)

- I give permission that personal information, including my name and social security number, can be entered into the national data system of UNOS.
- Should I have any questions or concerns, I can call UNOS toll free at the following number, 1-888-894-6361.