I am thinking about donating one of my kidneys to a person who has kidney disease. This patient’s doctors have decided that the best treatment for him/her is to receive a kidney transplant. He or she is being evaluated for transplant and at this time is considered to be a likely transplant candidate. I am asking to be evaluated as a potential kidney donor.

I have been given information on being a living kidney donor from the Maine Transplant Program at Maine Medical Center. I have read the Pre-Transplant Handbook and have had the opportunity to ask questions on the topics listed below. I will have additional opportunities to ask questions of the transplant team during my donor evaluation appointment and at any time in the future.

In order for me to decide whether or not I wish to consent to the living donor surgery, it is important that I understand the risks and benefits of:

1. The living donor evaluation
2. The living donor surgery
3. The possible short and long term outcomes after donating a kidney.
4. The possible short and long term outcomes for any person receiving a kidney transplant.

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

THE EVALUATION PROCESS

In order to be considered as a living kidney donor, I must undergo a complete medical evaluation. Some of the details of the examination are outlined below. The medical evaluation will determine if it is possible for me to be a living kidney donor. If the Maine Transplant Program decides that I am healthy and a good match with the potential recipient, and I consent to continue, I can then have surgery to remove one of my kidneys to be transplanted into the potential recipient.

I understand that by completing the evaluation process for donor surgery does not guarantee that I will be able to donate my kidney. If it is determined that I am not a candidate for donation in the Maine Transplant Program, I may pursue donation at another Transplant Center that uses different selection criteria. I understand that the Evaluation Process will involve at least two visits to the Maine Transplant Program. I understand that there is no reimbursement available from the transplant program for travel, food, lodging, or time off work. Other sources of financial aid may exist, and I can discuss these with the financial counselor or social worker at the program.
During the evaluation, the kidney transplant team will discuss my suitability for living kidney donation. The transplant team includes a nephrologist, surgeon, social worker, pharmacist, nutritionist, Independent Living Donor Advocate, and possibly a psychiatrist. The kidney transplant team will let me know the result of the discussion(s). If I am approved to donate, the surgery and its associated risks will be discussed with me and I will be asked to sign a consent form for the surgery. I will receive instruction on pre- and post-operative care during my evaluation and after my surgery. My health and safety will be the primary focus at all times.

**Components of the Evaluation Include:**
- Initial blood testing to determine whether I am a match for my intended recipient or to a recipient of my blood type if this is a “non-directed” donation.
- Medical evaluation
- Psychosocial evaluation by a social worker
- Nutritional assessment
- Pharmacy review of my medical records and/or assessment
- Assessment by an Independent Living Donor Advocate
- Assessment and/or review by a financial counselor
- Psychiatric evaluation (if my donation is non-directed, i.e. I do not know the potential recipient of my kidney) or it recommended by the transplant team

**Medical Evaluation**

A living donor must undergo a medical evaluation according to UNOS Policy 14.4: Medical Evaluation Requirements for Living Donors and a psychosocial evaluation as required by Policy 14.1: Psychosocial Evaluation Requirements for Living Donors. Each medical evaluation test will be explained to me before it is done. Some tests have risks and these risks will be discussed with me before I undergo the test. I may be asked to sign a separate consent form for these tests. Other potential short or long term risks of donation will be reviewed with me during the living donation class. I understand that as a result of this medical testing I may learn that I have a serious medical condition that could prevent me from being a living donor, or may affect my long-term health.

The medical evaluation tests may include, but are not limited to:
- Genetic testing, done through blood testing to see if I am a match to my intended recipient, or to a recipient of my blood type if this is a “non-directed” donation.
- A result of this testing is that I may discover adverse genetic findings which I was previously unaware and/or abnormalities or medical conditions that may require more testing at my own expense, OR create the need for unexpected decisions on the part of the transplant team.
- Blood and urine test to determine if I have normal kidney function.
- Blood test to determine if I have any early signs of diabetes.
• Blood test to be sure I do not have any infectious disease or health conditions that could be passed on to the recipient. 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.
• Chest x-ray.
• CT angiogram to measure the size of the kidneys and see the position of the blood vessels to and from the kidneys. (This is a test that uses IV contrast, also called dye. I could have an allergic reaction to the contrast dye).
• Electrocardiogram (ECG).

The following tests may be ordered, however MOST potential donors do not need them as part of the donor evaluation:

• 24 hour urine study to determine if my kidneys have a tendency to make stones.
• Ultrasound of my abdomen or pelvis to clarify something found on the CT angiogram. Examples include but are not limited to: cysts in the liver or kidneys, cysts in the ovaries in women, abnormal blood vessels in the liver.
• Heart stress test.

A psychosocial evaluation will be performed during the evaluation. The primary reasons for this evaluation are to decide if I am capable of giving an informed consent; to discuss the reasons why I want to be donor; to decide if my family and I will be able to hold up under the emotional, financial and physical stresses of this type of surgery.

A dietary assessment will be performed during the evaluation to be sure that I have good eating habits and to guide me on how to best maintain good health in the future should I donate a kidney.

A pharmacist will review my medical chart and/or meet with me during the evaluation to determine whether I have any medication issues that would be important to be aware of or make me an unsuitable candidate for donating a kidney.

The Transplant Program is required to provide me with an Independent Living Donor Advocate. This person is not involved in the care of the potential recipient and is there to look after my safety and interests throughout the kidney donation process. This person is there to help me decide whether or not I want to continue the process and potentially donate a kidney. He/she is available to me at any time during the consent process according to UNOS Policy 14.2: ILDA Requirements.

I understand that there are many factors that should be considered in deciding whether or not to donate a kidney. The information in this form does not exhaust the factors that should be considered. As I proceed with my donor evaluation, other considerations not mentioned in this form may come to light. I understand that if I
enter into a kidney exchange program I will need to sign a separate consent form at that time. I understand that another informed consent will be required prior to surgery. I understand that this form will contain additional information about the surgery that I may wish to consider. This consent is for the evaluation process only.

Possible complications of the evaluation process and donation and transplant surgery, including my death or the death of the kidney recipient, will also be discussed. There are support systems in place at the Maine Transplant Program to help me and/or my family go through this process. These systems will be available to me and/or my family at any time during the living kidney transplant process.

I understand that if I agree to be a non-directed kidney donor, I will not be able to decide who receives my kidney. This decision is made according to the Organ Procurement Transplantation Network. If I agree to be a non-directed donor, I will be required to undergo evaluation by the recipient’s transplant program before I will be able to proceed with the surgery. The recipient’s transplant program will evaluate my health using their own criteria and may choose to accept or decline my kidney for donation based upon their criteria.

I understand that the Maine Transplant Program and the potential recipient’s transplant program will take all reasonable precautions to provide anonymity for me and for my recipient should we enter into a kidney exchange program. At the same time I understand that there is a possibility that my identity may be disclosed on a recipient’s insurance Estimate of Benefits form.

I understand that I can stop the donor consent process or evaluation process at any time for any reason, and that the Maine Transplant Program will keep this information protected and confidential.

RECIPIENT BENEFITS AND RISKS

I understand that the recipient will benefit from my donation. These benefits include decreased time on the kidney waiting list, a kidney that will likely function longer, and a kidney that may function better as compared with one from a kidney waiting list. A transplant candidate may have risk factors for increased problems with maintaining their transplanted kidney or for morbidity and mortality I will not be aware of. Any transplant candidate may have an increased likelihood of adverse outcomes (including but not limited to graft failure, complications, and mortality) that: exceed local or national averages; do not necessarily prohibit transplantation; or are not disclosed to the living donor.

I understand that other procedures or courses of treatment are available to the recipient, including deceased donor transplantation and that a deceased donor organ may become available for the recipient before my evaluation is complete or the living donation surgery occurs. I understand that transplant hospitals determine candidacy for transplantation based on existing hospital specific guidelines and criteria, practices, and clinical judgement.
DONOR BENEFITS

I understand that there is no medical benefit to me by having this surgery. A possible medical benefit of the evaluation is finding out about health problems that I did not know I had so that I may seek treatment. I also understand that the testing done to determine if I can be a donor is covered by the recipient’s insurance. If a health problem is found, I will be sent back to my primary care physician for medical follow-up and treatment of the health problem which will not be covered by the recipient’s insurance.

DONOR RISKS

The following are inherent risks associated with the evaluation for living donation:

- Allergic reactions to contrast
- Discovery of reportable infections
- Discovery of serious medical conditions
- Discovery of adverse genetic findings unknown to the living donor
- Discovery of certain abnormalities that will require more testing at the living donor’s expense or create the need for unexpected decisions on the part of the transplant team

There are surgical, medical, psychosocial and financial risks associated with living donation that may be temporary or permanent and include, but are not limited to all of the following:

A. Potential Medical or Surgical Risks:
   i. Death
   ii. Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue and other consequences typical of any surgical procedure
   iii. Abdominal symptoms such as bloating, nausea, and developing bowel obstruction
   iv. Decreased kidney function
   v. Acute kidney failure and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period
   vi. The morbidity and mortality of the living donor may be impacted by age, obesity, hypertension, or other donor-specific pre-existing conditions.
   vii. For female donors, the risks of preeclampsia or gestational hypertension are increased in pregnancies after donation

B. Potential Psychosocial Risks:
   i. Problems with body image
   ii. Post-surgery depression or anxiety
   iii. Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies
   iv. Changes to the living donor’s lifestyle from donation
C. Potential Financial Impacts
   i. Personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed; however resources might be available to defray some donation-related costs
   ii. Need for life-long follow up at the donor’s expense
   iii. Loss of employment or income
   iv. Negative impact on the ability to obtain future employment
   v. Negative impact on the ability to obtain, maintain, or afford health insurance, disability insurance, and life insurance
   vi. Future health problems experiences by living donors following donation may not be covered by the recipient’s insurance

Information Regarding Post Donation and Life with One Kidney
A. On average, living donors will have a 25-35% permanent loss of kidney function after donation
B. Although 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 donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors.
C. Living donor risks must be interpreted in light of the known epidemiology of both chronic kidney disease (CKD) and end stage renal disease (ESRD). When CKD or ESRD occurs, CKD generally develops in the mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young living donor cannot predict lifetime risk of CKD or ESRD. Long-term medical risks of organ donation have not been fully identified.
D. Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD may be faster with only one kidney.
E. Dialysis is required if the living donor develops ESRD.
F. Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to UNOS Policy 8.3: Kidney Allocation Points.

CONFIDENTIALITY

Hospital personnel who are involved in the course of my care may review my medical record. They are required to maintain confidentiality as per federal law (HIPAA, 1996) and the policy of this hospital. If I do become a donor, information about my case, which will include my identity, will be sent to the Organ Procurement Transplant Network (OPTN) and may be sent to other places involved in the transplant process as permitted by law. Health information obtained during the living donor 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. I understand that the hospital will take all reasonable precautions to provide confidentiality for me and my recipient, and that the hospital may disclose to me certain information about the candidate/recipient only with permission of the candidate/recipient including the reasons for a candidate’s increased likelihood of adverse outcomes, and
personal health information collected during his/her evaluation which is confidential and protected under privacy law. Any information shared between the living donor candidate and the transplant program may not be shared with the potential kidney recipient and/or their families except as permitted by 45 CFR parts 160 and 164.

ADDITIONAL INFORMATION

I understand that I cannot receive any payment in exchange for being a donor and that under the National Organ Transplant Act (NOTA), it is a federal crime to knowingly acquire, obtain, or otherwise transfer any human organ for anything of value including, but not limited to cash, property, or vacations. NOTA specifically states “it shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.” The penalty of breaking this law is a fine of $50,000 or up to five years in prison, or both. This law does contain an exception permitting a person to acquire, receive, or otherwise transfer a human organ for reasonable payments associated with the organ removal such as travel, housing, and lost wages incurred by the donor.

I understand that the Transplant Program may refuse me as a living donor. If I am declined, the hospital must inform me that a different living donor hospital may evaluate me using different selection criteria. The Maine Transplant Program may contact me from time to time after the surgery to learn about any concerns I might have about my health, insurance, employment and overall well-being. I understand that the Maine Transplant Program is required to document my commitment to post donation follow up testing at intervals specified in UNOS Policy 18.5: Living Donor Data Submission Requirements: 6, 12, and 24 months. I understand that the hospital is required to report this follow up information to the UNOS per Policy 18.5.

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.

I understand that the Living Donor Program is required to provide me with a Living Donor Advocate who will advocate for my rights and make sure I understand the living donation process, including Informed Consent, the evaluation process, surgical procedure, and follow up requirements.

I understand that if a kidney transplant is not provided in a Medicare-approved transplant center it could affect the transplant beneficiary’s ability to have his or her immuno-suppressive drugs paid for under Medicare Part B.

Before you decide to donate a kidney with our Transplant Program, it is important for you to understand how our Program compares to others. We will provide you with a copy of the most current information on our transplant outcomes, and explain what the outcomes mean. This information also is available on the Scientific Registry for
Transplant Recipients (SRTR) website, www.srtr.org. If you have questions or need further assistance understanding kidney transplant outcomes, please contact a member of the Transplant Team. We also will provide you with data on our Program’s living donor outcomes and the outcomes of living donors nationally.

The United Network for Organ Sharing provides a toll-free patient services line to help transplant candidate, recipient 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. I understand that I may obtain more information about living kidney donor transplants at www.unos.org.

SIGNATURES

My signature certifies that I have decided to proceed with the evaluation to become a living kidney donor, having read the information contained in this consent form, having received the educational material provided, and having had the risks and benefits explained to me and my questions answered. I confirm that I am free from inducement, coercion and undue pressure to donate my kidney. I understand that I may discontinue the evaluation process at any time and this decision will be kept confidential and not shared with anyone unless I consent to share the information. I understand that at or near the completion of the evaluation, I will review and sign a Living Donor Rights form which provides further information on the donation process. I also understand that I will sign a separate consent form for the actual surgical procedure. Upon signing this form, I will receive a copy.

________________________________________  __________________________
Patient Signature                        Date

________________________________________  __________________________
Transplant Coordinator - received consent Date