



HARTFORD HOSPITAL KIDNEY TRANSPLANT PROGRAM INFORMED CONSENT FOR LIVING KIDNEY DONATION PROCESS

I have asked to be evaluated as a potential living kidney donor at the Hartford Hospital Transplant Program for the benefit of a patient with end stage kidney disease. The purpose of this informed consent is to enable the potential donor to understand all aspects of the donation process, especially the risks and benefits, including the evaluation process, the surgical procedure, post-operative care and required follow up. I am aware that I cannot be considered a suitable candidate for kidney donation for transplantation until the evaluation process described below is complete. I have been informed that transplant hospitals determine candidacy for transplantation based on existing hospital-specific guidelines or practices and clinical judgment. I understand that I may choose to stop the evaluation or donation process at any time in a way that is protected and confidential.

The Evaluation Process

I acknowledge that through my participation in meetings with the donor transplant team and the receipt of written educational materials regarding kidney donation and transplantation, I have been informed of the following aspects of the donor evaluation process:

- The consenting process
- Living Donors must undergo a thorough medical evaluation
- Surgical evaluation process;
- Eligibility criteria as a living donor for kidney transplant;
- Testing involved in performing my medical, surgical and psychosocial evaluation;
- Possible alternative donor organ sources;
- Donor and organ compatibility;
- Possible placement of the recipient on the OPTN/UNOS transplant waiting list for a deceased donor organ and range of wait times;
- The necessity of my participating in education to be prepared for surgery, recovery, and my care afterwards;
- Dietary evaluation, as needed;
- Psychosocial evaluation:
- The Independent living donor advocate (ILDA) evaluation; . The ILDA is available to assist during the consenting process.
- Information about insurance and potential financial issues associated with the living donation process

I have also been informed of the potential transient or permanent psychosocial risks of kidney donation, which may include, but are not limited to:

- Post-Traumatic Stress Disorder (PTSD),
- Post-surgery depression and/or anxiety,
- Guilt,
- Body image issues,
- Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies.
- The possible impact the donation may have on my lifestyle.

I have also been informed of inherent risks associated with the living donation evaluation including, but not limited to:

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



The Surgical Procedure

I acknowledge that through the above-mentioned meetings and educational sessions, I have been informed of:

- The nature and purpose of the kidney donor operation and the surgical techniques available to me such as a laparoscopic versus an open operation (this will be reviewed with me by one of the transplant surgeons) ;
- The need for anesthesia;
- The estimated surgical time;
- Post-surgical pain/discomfort and options for pain control after surgery;
- The estimated length of stay in the hospital and estimated recovery time;
- Potential restrictions in the post-operative period and return to full activities;
- Medications, testing and follow-up care required post-donation to promote my recovery;
- The reasonably foreseeable transient or permanent risks and consequences of kidney donation surgery, including the fact that my surgery and that of the transplant recipient may not achieve the desired outcome.

I have been informed specifically that there are both potential transient or permanent general risks to any operation as well as center specific risks which may include, but are not limited to:

- Anesthesia risks
- Blood clot in lungs or legs,
- Abdominal symptoms such as bloating, nausea, or developing bowel obstruction or perforation,
- Heart attack, arrhythmias, or cardiovascular collapse
- Pneumonia
- Hernia development
- Technical complications of blood vessels or ureter needing repeat operation,
- Pain
- Fatigue
- Scars
- Wound and/or systemic infections
- Diaphragm perforation
- Intra-abdominal adhesions
- Bleeding which may require blood transfusions and the risks involved with the use of blood or blood products
- Fluid collection
- Splenic injury
- Nerve injury
- Acute kidney failure and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period. Current practice is to prioritize prior living kidney donors who become kidney transplant candidates
- Decreased kidney function
- Death during or after surgery.

If I am a candidate for laparoscopic kidney surgery, I understand that this may require conversion to an open surgical procedure. I have been informed that it is not possible to list all possible complications related to the donor surgery and the surgery may be terminated based on my clinical condition during surgery. I understand that if I am determined to be a suitable kidney donor and I decide to continue with the donation process, the risks of surgery will be discussed with me once again and I will be asked to sign a specific informed consent form relating to the surgical procedure.



Additional Considerations

I have been informed of the need to participate in follow-up care with the transplant program. I have been informed of the benefit, need and importance of post-donation follow-up at a minimum of, 6, 12 and 24 months. These appointments are necessary to monitor my health and to obtain data for research. I have been informed that it is required, at a minimum, to submit Living Donor Follow-up forms addressing my health information at 6 months, 12 months, and 24 months post donation to United Network for Organ Sharing (UNOS). To obtain this health information, the transplant program will contact me to arrange testing with the transplant program or with my primary care physician. This testing includes but is not limited to blood pressure readings, urine tests, blood tests, and a history and physical. I understand the importance of this health information and agree to participate in my post-donation follow-up care. If I chose to follow-up with my primary care physician the transplant program will supply me with data forms to be completed by my physician.

I understand that all donors and myself are screened several times for communicable diseases, increased risk behaviors and problems that may affect the donated organ and my or the recipient's health. There is no guarantee as to whether any and all contagious diseases have been detected. There may be unforeseen factors including undetected infectious disease (bacterial and fungal infections, human immunodeficiency virus (HIV), TB, or cancers or any other previously undetected disease that may affect the success of the transplant or my or the recipient's health.

I understand that Hartford Hospital will take all reasonable precautions to provide confidentiality to both myself and the recipient.

I am aware that health information obtained during my evaluation will be subject to the same regulations as all records and could reveal conditions that the transplant program must report to local, state or federal public health authorities. Also, I have been informed that any infectious disease or malignancy pertinent to acute recipient care discovered during the potential donor's first two years of post-operative follow-up care; will be disclosed to the donor; may need to be reported to local, state or federal public health authorities; will be disclosed to their recipient's transplant center; and will be reported through the OPTN Improving Patient Safety Portal.

If I am a woman of childbearing age, I understand that:

- Donation surgery should postpone my becoming pregnant for at least a year.
- Pregnancy may stress my remaining kidney and that I will need to consult with my primary care provider and my obstetrician prior to pregnancy.
- I understand that the risks of preeclampsia or gestational hypertension may be increased in pregnancies after donation.

I am also aware that I must maintain good overall health post donation and I understand the impact of age, obesity, hypertension, or other donor-specific medical conditions on my morbidity and mortality.

I understand that part of the evaluation process is intended to discover the possibility of present and future kidney and other medical illnesses. I understand that despite this evaluation, I still may develop kidney disease or other illnesses within my lifetime that could affect my remaining kidney. These conditions, if they were to occur, may require me to take medication or need dialysis in the future.



I understand expected post-donation kidney function and how chronic kidney disease (CKD) and end-stage-renal-disease (ESRD) might potentially impact my future which may include;

- Donors will have on average a 25%-35% permanent loss of kidney function after donation.
- Although baseline risk of ESRD does not exceed that of members of the general population with the same demographic profile, the risk of ESRD for living kidney donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors
- The medical evaluation of a young potential donor cannot predict lifetime risk of CKD or ESRD; CKD generally develops in midlife 40-50 years of age; ESRD generally develops after age 60; development of CKD and progression to ESRD may be more rapid with only one kidney;
- 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 one kidney.
- Dialysis is required when reaching ESRD; however, current practice is to prioritize prior living kidney donors who become kidney transplant candidates.

I understand that if the Hartford Hospital Transplant Program refuses me as a potential donor, I may be evaluated by another transplant program that may have different selection criteria.

Alternative Treatments

Alternative treatments and the risks and benefits of such alternatives for the transplant recipient have been discussed with me. I understand that these alternatives include dialysis for the possible recipient and accepting of an organ from a deceased donor from the OPTN/UNOS wait list. A deceased donor organ may become available before I complete my evaluation or donation surgery occurs. I may seek further information about these alternatives at any time. If I decide not to donate my kidney, the potential recipient may be placed on or remain on the OPTN/UNOS wait list for a deceased donor organ and will continue to receive care from his/her health care providers

I have been informed that kidney transplantation for the recipient is elective and not a cure for kidney disease.

I understand that 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
- Are not disclosed to the living donor.

I understand that the hospital can disclose to the living donor certain information about the recipient only with the permission of the recipient that includes:

- the reason for a transplant candidates increased likelihood of adverse outcomes
- personal health information collected during the candidate's evaluation , which is confidential and protected under privacy law.

Financial Issues

I have been informed and understand the financial provisions for the kidney donor evaluation, the coverage for the operation, associated hospitalization and recovery is based on the recipient's insurance coverage which will be shared with me prior to any surgery.

I have also been informed that there is a possibility that future health care problems I may experience related to donating a kidney **may not be covered by my recipient's insurance** or if covered, may affect my maximum lifetime benefits. If these problems are not covered by my health insurance, I may be responsible for all costs.

I understand that the medical evaluation or donation may impact my ability to obtain, maintain, or afford health, life, and disability insurance; and there is the possibility of denial of coverage.

I understand that I may request a meeting with a financial coordinator in order to answer any further questions I may have regarding financial or insurance issues relating to the donation.



I have been told that if the transplant surgery for which I am acting as a donor is not performed in a Medicare-approved transplant center, Medicare may not pay for immunosuppressive drugs needed by the recipient post-transplant. I agree to inform the transplant team immediately both before and after surgery of any significant insurance changes.

I have been advised and understand that The National Organ Transplant Act of 1985, states it is a federal crime to receive financial gain from organ donation and will impose criminal penalties of up to \$50,000 and five years in prison on any person who “knowingly acquires, receives, obtains or otherwise transfers any human organ for valuable consideration for use in human transplantation. Valuable considerations are considered as anything of value such as cash, property or vacations.

I understand that there are out-of-pocket expenses associated with the living donation process, including, but not limited to, travel, housing, child care cost, and lost wages. However, resources may be available to defray some of the donation-related costs. Under the National Transplant Act, if recipients are financially able they are allowed to reimburse the donor for out-of-pocket expenses incurred during the donation process, including travel, housing, food and lost wages. Other potential financial impacts of living donation may include:

- Need for life-long follow-up at my expense,
- Loss of employment or income
- A negative impact on the ability to obtain future employment.

General

I have been informed and have received information about national and Hartford Hospital transplant center specific outcomes related to kidney transplantation for recipients provided through the Scientific Registry for Transplant Recipients (SRTR). I have been informed as to whether the latest reported outcome measures in the SRTR report comply with Medicare outcome requirements. I have also been informed of the available national and Hartford Hospital transplant center outcomes which specifically pertain to living donors.

I am aware that it is possible that my donated kidney may not work or may be rejected by the recipient’s immune system.

I understand that at any point during the evaluation process or prior to surgery, I am free to decide, for any reason that I no longer wish to become a donor. I have been offered several opportunities to discontinue the donor consent or evaluation process in a way that would be protected and confidential. If I proceed with the donation procedure, I agree to comply with the Hartford Hospital Transplant Program policies. I agree to return for follow-up visits at minimum of 6, 12 and 24 months, even though this may require additional time and expense. I understand that the Hartford Hospital Transplant Program will request that reports of my health records from my primary care or other physicians be sent to the transplant program indefinitely. I agree to permit the transplant program to receive information from my other health care providers as may be necessary to monitor my post-donation health and comply with any living donor data reporting obligations. I am aware that information related to my donation and transplantation will be furnished to OPTN/UNOS for national data recording.

I understand that my communications with the Hartford Hospital Transplant Program concerning all aspects of the evaluation and donation process are confidential and protected by state and federal privacy laws. Such information shall only be used or disclosed as permitted under such laws and applicable hospital policy, or with my authorization.

I have the right to notify the Organ Procurement and Transplantation Network at 1-888-894-6361, if I need further information or if I have any concerns, grievances or complaints about my care or the Hartford Hospital Transplant Program.

