



Transplant Services

Living Kidney Donor Consent for Evaluation

You are considering having a major surgery for the purpose of donating one of your kidneys for someone who has kidney disease. This is a very important decision that requires a lot of thought. The following information is provided to all potential living donors to inform them of all aspects of the living donation process and surgery and potential outcomes from living donation. It is important that you read and understand this information before beginning your evaluation for living kidney donation, and that you know the risks and benefits of the evaluation process.

1. You have been provided a living donor teaching booklet which contains information about the UPMC Pinnacle Transplant program. This teaching booklet provides an overview of the donor surgical procedure, potential risks and benefits of living donation, and living donor transplant, use of blood products, expected post-op course, and the expected post-donation appointment schedule.
2. Transplant is a form of treatment for organ failure and is not a cure for the transplant recipient. While statistically kidney transplant recipients live longer and most report having an improved quality of life after transplant, live kidney donation should NOT be thought of as a matter of life or death.
3. Transplant hospitals determine candidacy for transplantation based on existing hospital specific guidelines, practices, and clinical judgment.
4. A transplant candidate may have an increased likelihood of adverse outcomes (including but not limited to transplant failure, complications, and death) that:
 - a. exceed local or national averages.
 - b. do not necessarily prevent transplantation.
 - c. are not disclosed to the living donor.
5. In some cases, an intended recipient may have risk factors for increased complications or death that cannot be disclosed to you due to confidentiality reasons. The transplant center can disclose to the living donor certain information about candidates only with permission of the candidate, including:
 - a. The reasons for a transplant candidate's increased likelihood of adverse outcomes.
 - b. Personal health information collected during the transplant candidate's evaluation which is confidential and protected under privacy law.
6. A deceased donor kidney may become available for an intended recipient before the donor evaluation is completed, or before the living donor transplant occurs.
7. The decision to donate a kidney is your own personal decision and should be free from undue pressure or coercion from others. Participation in the living donation evaluation process is completely voluntary and you are free to withdraw your decision to donate at any time in the process.
8. You will be provided sufficient time to reflect on your decision to donate and will not be pressured to move forward at any time.

9. Communication between the donor and the transplant center will remain confidential and may not be shared with the intended recipient. Communication between the recipient and the transplant center is also confidential and will not be shared with the potential donor.
10. The potential transplant recipient has other forms of treatment available to him/her. These include but may not be limited to the following:
 - a. Continue to follow with their nephrologists for medical management if pre-dialysis.
 - b. Remain on dialysis.
 - c. Remain on the transplant list until a deceased donor organ becomes available for transplant.
11. If you decide not to proceed with donation, the transplant center can provide you with a nonspecific statement of unsuitability for donation at any time throughout the donation process. Once this statement is provided you can no longer be considered for donation at this center.
12. If you are unable to donate or decide not to donate, the transplant team will support your decision about how you wish to communicate this information to the potential recipient. The potential recipient may only be informed of this decision with your consent. In addition, your medical information will not be revealed to the intended recipient without your permission. The transplant center will encourage you to communicate your donation status with the potential recipient as it may impact their decision to pursue other potential living donors, if available.
13. You will receive a thorough medical and psychological evaluation by a physician and social worker experienced in living donation to assess the individualized risks associated with the donation process.
14. In addition to the transplant team members, an Independent Living Donor Advocate (ILDA) will be assigned to you. The ILDA will discuss any concerns about the donation process. The ILDA is not part of the transplant team and is specifically meant to be an advocate for me throughout the donation process.
15. A standard set of selection criteria will be used to determine candidacy for living kidney donation at this center. The following conditions must be met to be considered for living kidney donation at this transplant center:
 - a. Body Mass Index (BMI) less than or equal to 35.
 - b. Clearance from a cardiologist (heart doctor) if requested.
 - c. Blood pressures within an established range.
 - d. Normal heart function.
 - e. Normal results of tests such as EKG, chest x-ray, lab results and routine health screenings.
 - f. Creatinine clearance acceptable for donation based on age and other medical criteria.
 - g. Appropriate psychosocial support system.
16. The following conditions may prevent you from being a candidate for living kidney donation at this center:
 - a. Current or history of high blood pressure.
 - b. Current or history of cancer.
 - c. Current or history of diabetes.
 - d. Presence of autoimmune diseases.
 - e. Liver cirrhosis.
 - f. Infectious diseases such as, but not limited to, HIV/AIDS, Hepatitis C, and Hepatitis B.
 - g. Inadequate social support system.

- h. On-going substance abuse.
- i. Diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality.
- j. Suspicion of donor coercion.
- k. Age less than 18.
- l. Mentally incapable of making an informed decision.

17. There are risks associated with the evaluation for living donation. These include:

- a. Allergic reaction to contrast dye that is required for evaluation.
- b. Discovery of any infectious disease, such as Hepatitis or tuberculosis (TB) which are required to be reported to local, state or federal public health authorities, to the recipient's transplant center and reported through the Organ Procurement and Transplantation Network (OPTN) Improving Patient Safety Portal.
- c. Discovery of serious medical conditions.
- d. Discovery of adverse genetic findings unknown to the potential donor.
- e. Discovery of certain abnormalities that require more testing at the donor's expense and create the need for unexpected decisions on the part of the transplant team.

18. Health information obtained during the evaluation will be 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. UPMC Pinnacle will take all reasonable precautions to provide confidentiality for living donors and transplant recipients.

19. When the required studies and consultations have been completed, the donor information will be presented, reviewed, and discussed by the Transplant Selection Committee, which includes surgeons, nephrologists, transplant coordinators, social workers, and financial coordinators. This committee will determine your fitness and readiness for living kidney donation. The Selection Committee has the right to deny your request for donation either temporarily, for a designated length of time, or permanently based on evidence that donation or the potential outcomes might not be of benefit or could jeopardize your health and well-being either now or in the future. In addition, you may be denied as a donor if something is discovered during the evaluation that could potentially harm the recipient after transplant of your kidney. If you are found not to be a suitable donor at this center, you can be evaluated at another transplant center.

20. There are both benefits and risks associated with living kidney donation. The potential benefits of living donation are not a guarantee and doctors cannot ensure that you will live longer than if you had not been a living kidney donor. The risks of living donation may be short term or permanent. These benefits and risks include, but are not limited, to the following;

a. Benefits:

- i. Emotional benefit from the donation process.
- ii. Discovery of health problems that were not identified prior to this process which will allow a potential donor to seek treatment.

b. Medical or Surgical Risks:

- i. Post-surgical wound infection or pneumonia.
- ii. Pain after the surgery.
- iii. Fatigue after the surgery.
- iv. Blood clot in the legs.
- v. Complications that require re-operation.
- vi. Blood transfusion.

- vii. Irregular heart rhythms or cardiac complications.
- viii. Hernia at the incision sites.
- ix. Abdominal discomfort or bowel symptoms such as bloating, nausea and development of a bowel obstruction.
- x. Numbness or tingling or pain around the incision sites.
- xi. Nerve injury typical of any surgical procedure.
- xii. Complications from anesthesia up to and including multi-organ failure and death.
- xiii. Increased risk with use of over-the-counter medications or supplements.
- xiv. Development of acute or chronic kidney failure and the need for dialysis or kidney transplant in the immediate post operative period.
- xv. Long term health and/or longevity may be impacted by age, obesity, hypertension or other medical conditions that may occur after donation.

c. Psychosocial Risks:

- i. Depression after donation.
- ii. Sense of loss after donation.
- iii. Generalized anxiety.
- iv. Altered body image, including scars.
- v. Altered lifestyle after donation.
- vi. Post-traumatic stress disorder (PTSD).
- vii. Difficulty dealing with the need to depend on others for assistance while recovering from surgery.
- viii. Feelings of emotional distress or grief if the outcome for the recipient is not positive. This may include, but is not limited to:
 - a. Rejection or need for continued dialysis due to non-function.
 - b. Need for re-transplant.
 - c. Reoccurrence of the disease that caused the kidney failure.
 - d. Recipient death.

d. Financial Risks:

- i. Personal expenses such as 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. Loss of income or employment.
- iii. Need for lifelong follow-up at the donor's expense.
- iv. Donation may negatively impact the ability to obtain employment.
- v. Donation may negatively impact the ability to obtain, maintain, or afford health, disability and life insurance.
- vi. Future health problems that may develop following donation may not be covered by the recipient's insurance or the donor's health insurance. If covered by the donor's health insurance, these services may affect the maximum lifetime benefits under an insurance policy or policies.

21. There is no medical benefit to you from the donor operation.

22. Every living kidney donor will experience a decrease in their kidney function compared to pre-donation. The amount will depend upon the potential donor's age and medical history. Information specific to you will be shared with you after the medical evaluation is completed.

23. The goal of the medical evaluation is to limit potential risk to the donor and to reduce the risk for kidney failure in the future. Although the real risk of donation in a multi-ethnic population is not known, UNOS data shows the following:
 - a. The risk of dying from living donor surgery is 0.03%. (Extremely low).
 - b. The risk of kidney failure and the need for dialysis or transplant is less than 1%, (between 0.10 to 0.52%). This risk may be higher for African Americans.
 - c. For those donors who do develop kidney failure, where the date of donation is known, the average length of time from donation to placement on the transplant list is 20 years.
 - d. According to a study done in Sweden, the risk of kidney failure in living donors is less than 1 % (0.05%) after 30+ years for their specific population.

24. Education regarding expected post donation kidney function and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) may potentially impact a donor's future health has been provided. This includes:
 - a. Female living donors who become pregnant after donation are at risk for preeclampsia or gestational hypertension.
 - b. On average, donors will have a 25-35% permanent loss of kidney function at donation.
 - c. Although the risk of ESRD for living donors does not exceed that 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.
 - d. Donor risks are interpreted in light of the known course of both CKD and ESRD. When CKD or ESRD occur, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after the age of 60. The medical evaluation of young living donors cannot predict the lifetime risk of CKD or ESRD.
 - e. Donors may be at a higher risk for CKD if they sustain damage to the remaining kidney and this may progress more rapidly with only one kidney. Dialysis is required when reaching ESRD.
 - f. Current UNOS policy (Policy # 8.3) gives priority points to persons who have been prior living kidney donors.

25. It is very important for living donors to be active participants in their healthcare and treatment both now and after donation. All donors have the right to ask questions and obtain answers to their questions at any time.

26. The United Network for Organ Sharing (UNOS) requires all living organ donors to have post donation follow-up care by the transplant team at specific intervals, or if any problems occur in the interim. After donation surgery, donors need to be seen for post-donation visits with the transplant team at the following time frames: 4 weeks, 6 months, 1 year and 2 years post donation. This follow-up care is beneficial for the long term health of donors. Payment for long-term follow-up (after six months) may be your responsibility.

27. UNOS requires transplant centers to submit data on post-donation outcomes so that living donor data/results can be analyzed and outcomes evaluated. Any other release of information will require a donor to sign a consent form in accordance with UPMC Pinnacle confidentiality policies.

28. If a transplant is not performed in a Medicare approved transplant program it could affect the transplant recipient's ability to get immunosuppressant medications paid for under Medicare Part B. The UPMC Pinnacle Transplant Program is a Medicare approved transplant facility at the time of this consent.

29. Outcomes for transplant patients and transplanted kidneys performed at the UPMC Pinnacle Transplant Program are publicly available at the Scientific Registry of Transplant Recipients (SRTR). This

information can be found on the internet at www.SRTR.org. A copy of the national and this program's outcome results and data submission rates dated _____, has been provided to you. Your living kidney donor coordinator can assist you with any questions you have about the information on the SRTR website. Currently there are no national or center specific outcomes for living donors calculated by the SRTR.

30. Your intended recipient is under no social or financial obligation to you as a living donor. It is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for anything of value including, but not limited, to cash, property, and vacations
31. Costs related to the evaluation and hospitalization for living donation are covered by the recipient's insurance, or a Medicare fund specific for living donor costs. A donor's insurance should not be billed for care related to the donation process. Any bills related to the evaluation or donation process must be brought to the attention of the transplant team immediately so they can be addressed.
32. Any health issues identified during the evaluation process will be referred to the donor's primary health care provider for follow-up and management. In addition, these services will be billed to the donor's insurance.
33. The United Network for Organ Sharing provides a toll-free patient services line to help transplant candidates, recipients, family members/friends, living donors and/or donor family members understand information about transplantation and donation. Any potential donor may contact UNOS at the toll-free patient services line at 1-888-894-6361. This number may also be used to discuss a problem you may be experiencing with the transplant center or the transplantation system in general.

My signature on this form verifies that the above information was provided and explained to me. I agree to actively participate in the living donor evaluation process. **I understand that by signing this form I am NOT obligated to proceed with kidney donation and that I may opt out of the donation process at any time.**

_____ **I understand the benefit of the UNOS requirement for post donation care and agree to this followup.**

Patient Signature

Printed Name

Date

The Independent Living Donor Advocate reviewed this consent form with the potential living kidney donor by phone on _____. This information was discussed and reviewed with the potential living kidney donor before beginning the evaluation for living kidney donation.

ILDA Signature

Printed Name

Date