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STANFORD HEALTH CARE
STANFORD, CALIFORNIA 94305



**CONSENT • EVALUATION FOR KIDNEY
LIVING DONORS**

Addressograph or Label - Patient Name, Medical Record Number

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This document is to provide you with information regarding the adult **LIVING KIDNEY DONOR EVALUATION** process. It is important that your physician(s) have a discussion with you or your legally designated representative regarding the risks, benefits and alternatives of living donor transplant. In addition, it is important that you review this entire document. If you do not understand the risks, benefits and alternatives discussed in the contents of this document, you should ask questions so that you can make a fully informed decision about your health.

Evaluation of the Donor

As part of the evaluation process, the **LIVING KIDNEY DONOR** will be asked to undergo a medical history and physical examination, laboratory and diagnostic testing and a psychosocial evaluation. The evaluation process includes meeting with members of the transplant team. The transplant team may consist of a nurse coordinator, transplant physician, transplant surgeon, anesthesiologist, social worker, financial coordinator, psychiatrist, registered dietician, independent living donor advocate, transplant pharmacist, along with other individuals.

1. I understand the donor evaluation and donation processes, including all the procedures required for medical and psychosocial clearance.
2. I understand that I will receive a thorough medical and psychosocial evaluation. The medical evaluation will be conducted by a physician and/or surgeon experienced in living donation to assess and minimize risks post donation, and will include a screen for any evidence of occult kidney disease, infectious disease and medical co-morbidities which may cause kidney disease. The psychosocial evaluation will be conducted by a psychiatrist, psychologist, or social worker with experience in transplantation to determine my decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion.
3. After you complete your evaluation, the transplant multidisciplinary selection committee will review the results of your pertinent tests, procedures and consultations to determine whether or not you are a suitable **LIVING KIDNEY DONOR** for the potential transplant recipient. The transplant hospitals will determine who is a candidate for transplant based on their hospital specific protocols and clinical judgment. Potential donors will not move forward with donation if a concern arises related to medical, physical, emotional or financial reasons. If you do not currently meet the criteria, you may be deferred or declined. You will be notified of the selection committee's decision. Once you are determined to be suitable for donation, you will be asked to review the situation and reconsider your decision to be a living donor carefully. If you are still in agreement, a date for surgery will then be scheduled. In the case that you are ruled out as a potential kidney donor, you may be evaluated by another transplant program.
4. I understand that I will be contacted by an Independent Living Donor Advocate to verify that I receive all information related to donation and that I would like to proceed with donation. The Living Donor Advocate will promote and protect the interest of any potential living donor. The Living Donor Advocate will be available to discuss issues related to donation prior to and after donation.

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The result of the medical history and physical examination, and laboratory and diagnostic testing, will be discussed with you, including how any current health issues or medication regimen could be affected by your donation or recovery from donation. In addition, your suitability for donation, relevance of any psychosocial issues to donation, financial responsibilities resulting from donation, and follow-up testing that may be required after donation will be discussed with you.

Surgical Procedure

- Living Donor Nephrectomy

This operation consists of removing one of your kidneys along with the length of renal artery, renal vein and ureter for transplantation into the recipient. This operation can be done using a traditional open incision or a laparoscopic trans-abdominal operation.

The open approach consists of making an incision in the flank (your side) to create access to the kidney, its blood vessels and ureter. Removal of part of the 12th rib may be necessary. With the laparoscopic approach, the operation is done with small instruments and a camera which has been inserted into the belly after it has been inflated with air. Inflating the belly allows a good view of the interior organs. Three or four half-inch incisions are made in the belly to insert the instruments. A larger incision is made below the navel to take the kidney out of the body. With the laparoscopic approach, there is a 1-2% chance to need to convert to an open approach.

- Post-operative Care and Recovery

After the surgery, you will be sent to the recovery room and from there to the surgical ward. Pain is managed with intravenous patient-controlled analgesia (PCA), epidural anesthesia, or oral medication. You will be allowed to drink and eat gradually, as tolerated. You will begin getting out of bed and walking around. You will be discharged from the hospital when you are able to eat and walk and any pain is adequately controlled. You will be seen in clinic one to two weeks after the operation. At that time, you will undergo repeat blood testing in addition to physical examination. Most donors can go back to work at four to eight weeks following donation.

Potential Risks

As part of the evaluation process, you will have multiple opportunities to discuss with the transplant team the potential risks associated with kidney donation.

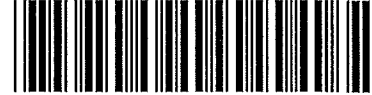
I am subject to the medical, psychological, and financial risks associated with being a living donor. These risks may be transient or permanent and include, but are not limited to all of the following:

Potential Medical and Surgical Risks

1. Risk of death
2. My morbidity and mortality may be impacted by age, obesity, hypertension or other donor specific pre-existing conditions.

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3. I am aware of the potential for decreased kidney function in kidney donors. Every kidney donor will experience a decrease in the kidney function compared to pre-donation. The amount will depend upon the potential donor's age and history. The anticipated change in kidney function has been discussed with me. On average, donors will have 25-35% permanent loss of kidney function at donation.
4. The reported risk of mortality for kidney donation averages 1 death per 3,000 donor operations.
5. Potential for organ failure and the need for dialysis in the immediate post-operative period or a future organ transplant for a donor
6. Potential for other medical complications and other consequences typical of any surgical procedure including long-term complications currently unforeseen
7. Bleeding
8. Hernia
9. Wound infection
10. Blood clots
11. Pneumonia
12. Nerve injury
13. Scars
14. Pain
15. Fatigue
16. Abdominal or bowel symptoms such as bloating, nausea, and developing bowel obstruction
17. Scrotal edema for male donors
18. The risk of preeclampsia or gestational hypertension is increased in pregnancies after donation
19. Increased risk of complications with the use of over-the-counter medications and Supplements
20. All living donors may be at higher risk for Chronic Kidney Disease (CKD) if they sustain damage to the remaining kidney. Development of CKD and progression to End Stage Renal Disease (ESRD) may be more rapid with only one kidney; dialysis is required when ESRD occurs.

Long-Term Risks

Donation should not be taken lightly. Serious thought should be given to the future consequences of your overall health before donating a kidney. Long term medical implications of organ donation have not been fully identified. Studies have shown that previous donors may be at greater risk to lose protein in the urine and develop high blood pressure. Chronic kidney disease generally develops in mid-life (40-50 years old) and end-stage renal disease (ESRD) develops after age 60. Although risk of end-stage renal disease 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. Current practice is to prioritize

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prior living kidney donors who become kidney transplant candidates. Medical evaluation of a young potential donor cannot predict lifetime risk. It has been reported that some donors have had difficulty obtaining life and/or health insurance after donation.

Inherent risks associated with evaluation for living donation

1. Allergic reaction to contrast used for some radiology studies
2. Discovery of reportable infections
3. Discovery of serious medical conditions
4. Discovery of adverse genetic findings unknown to the donor
5. Discovery of certain abnormalities that will require more testing at the donor's expense or create the need for unexpected decisions on the part of the transplant team.

Potential Psychosocial Risks

1. Problems with body image
2. Post-surgery depression, anxiety, or emotional distress
3. Feelings of emotional distress or bereavement in case of transplant recipient rejection and need for re-transplantation
4. Transplant recipient having a recurrence of disease
5. Transplant recipient death
6. Impact of donation on the donor's lifestyle
7. The recipient outcome may not be equivalent in a paired exchange

Potential Financial Risks

1. Personal expenses of travel, housing, and lost wages related to live donation, which might not be reimbursed
2. There may be resources available to help defray some of the donation related cost
3. Child care costs
4. Possible loss of employment or income
5. Negative impact on the ability to obtain future employment
6. Negative impact on the ability to obtain, maintain or afford health, disability, and life insurance
7. Lack of coverage by recipient's insurance for health problems experienced by living donors following donation
8. Need for life-long follow up at the donor's expense

Lack of Medical Benefit for Donor

1. I will undertake the risks and receive no medical benefit from the operative procedure.
2. I will not and may not receive valuable consideration (including monetary or material gain) for agreeing to be a donor

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Alternative Treatments

There is a risk of failure immediately or later after transplantation due to a technical complication, rejection of the transplanted kidney or other reasons.

I am aware that there are alternate procedures or courses of treatment for the recipient including:

1. Chronic dialysis
2. Deceased donor transplantation. All transplant candidates are placed on the UNOS waiting list. If a deceased donor organ becomes available prior to the living donor procedure, deceased donor transplantation will be offered. It will be the recipient's decision whether to proceed with deceased donor transplantation or living donor transplantation.
3. Another living donor coming forward.

Disclosure of Medical Information

1. It is important to remember that any communication between you and the transplant center/ recovery center will remain confidential unless specifically allowed to be released pursuant to federal HIPAA regulations or applicable state law. We are required to provide information about all organ transplantation to the United Network for Organ Sharing (UNOS). 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. This information is kept in order to determine how many live kidney donor transplants are done, how many are successful, and complications that happen. UNOS assigns a case number to the transplant recipient and the donor, and the identifying information is not accessible to the public or to researchers.
2. The transplant center will take all reasonable precautions to provide confidentiality for the donor and recipient.
3. My medical evaluation could reveal conditions (such as HIV and certain infectious diseases) that the transplant center must report to governmental authorities.
4. My medical information may not be revealed to a potential recipient unless I authorize such.
5. If I have a condition that might harm a recipient, the medical team in charge of the evaluation will not allow the donation to occur.
6. I have been informed that any infectious disease or malignancy pertinent to acute recipient care discovered during the first two years of follow-up care:
 - Will be disclosed to me
 - May need to be reported to local, state, or federal public health authorities
 - Will be disclosed to the recipient's transplant center, and
 - Will be reported through the Organ Procurement and Transplantation Network (OPTN) Improving Patient Safety Portal.
7. I have been informed that health information obtained during 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.

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8. I have been informed that the transplant center is required to report living donor adverse events to the UNOS. The reportable events include abortion of the living donor organ recovery procedure after receiving general anesthesia, death within 2 years of donation, listing on the kidney UNOS wait list within 2 years of donation, organ recovered but not transplanted into any recipient, organ recovered and transplanted into someone other than the intended recipient.
9. I have been informed that the transplant center is required to obtain and store a living donor blood specimen for ten years, only to be used for investigation of potential donor-derived disease.

National and Transplant Center-Specific Recipient Outcomes for Adult Kidney Transplantation:

The Scientific Registry of Transplant Recipients (SRTR) provides detailed information about every solid organ transplant program in the United States and reports updated information twice a year. By visiting the SRTR website (www.SRTR.org), you can access information about our program published by the SRTR, such as transplant volume, waitlist size, transplant rate, and post-transplant patient outcomes. On SRTR's website, select the organ and then enter "Stanford Health Care" in the search box to view our program information. You may contact our program at 650-725-9891 for any additional questions or assistance with the use of SRTR website.

National statistics from SRTR dated **January 9, 2024** show that one year after transplantation **96.27%** of kidney transplant recipients are alive and **94.09%** of transplant kidneys are functioning. The results at Stanford Health Care published by the SRTR are:

Observed one year patient survival	<u>97.07%</u>	Observed one year graft survival	<u>97.42%</u>
Expected one year patient survival	<u>96.49%</u>	Expected one year graft survival	<u>95.22%</u>

National and Transplant Center-Specific Recipient Outcomes for Living Donor Adult Kidney Transplant Recipients:

National statistics from SRTR report dated **January 9, 2024** show that one year after live kidney donor transplantation **98.54%** of transplant recipients are expected to be alive after transplantation, and **97.65%** of transplant kidneys from living donors are functioning.

The results at Stanford Health Care published by the SRTR are:

Observed one year patient survival	<u>100.00%</u>	Observed one year graft survival	<u>100.00%</u>
Expected one year patient survival	<u>98.73%</u>	Expected one year graft survival	<u>97.74%</u>

Notification of Medicare Outcome Requirements Not Being Met by Center:

Specific outcome requirements need to be met by transplant centers and we are required to notify you if we do not meet those requirements. Currently, Stanford Health Care

- meets all requirements for transplant centers
- does not meet the following requirements:

If the recipient has the transplant at a facility that is not approved by Medicare for transplantation, the transplant recipient's ability to have immunosuppressive drugs paid for under Medicare Part B could

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be affected. In addition, future health problems of the donor may not be covered by the donor's or recipient's insurance, and the donor's ability to secure health, disability or life insurance may be compromised.

Donation Follow Up

I commit to post-operative follow-up testing coordinated by the transplant center for a minimum of two years at 6, 12, and 24 months, so I should expect to be contacted by the transplant program regarding current health status for at least two years following donation.

1. I understand that the 6, 12, and 24 month follow up information is required to be reported by the transplant center to the United Network for Organ Sharing.
2. I understand that I will not be responsible for the cost of this follow-up care.
3. I understand that living donor follow-up is the best method for the collection of information on the long-term health implications of living donation.
4. I may not receive valuable compensation for post donation follow-up care.
5. Need for life-long follow-up will be at my own expense
6. Future health problems may not be covered by the recipient's insurance.

Right to Refuse Donation:

You have the right to opt out of donation at any time during the donation evaluation or consent process in a way that is protected and confidential. The independent living donor advocate will be available to assist you during this process.

I understand the following as explained to me by my medical team:

Donation as a Personal Choice

1. I am willing to donate, free from inducement and coercion.
2. I have sufficient time to reflect after consenting to donate.
3. I may decline to donate at any time.
4. I have the option of a general, nonspecific statement of unsuitability for donation should I wish not to proceed with donation.
5. My decision to proceed with the donation can only be disclosed if I authorize it.

Donation as an Educated Decision

1. I have been provided information that explains all phases of the living donation in my native language including medical and psychosocial evaluation, pre- and post-operative care, and required post-operative follow up.
2. I have been provided education that discusses what remaining organ function will be left after the donation and what the potential health impact is after donation.
3. I have been provided the information about the national and center-specific recipient outcomes from the most recent report produced by the Scientific Registry of Transplant Recipients. This

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information includes, but is not limited to: 1 year patient and graft survival, national 1 year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center.

4. 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 but does not necessarily prohibit transplantation. These are not disclosed to the donor without explicit consent from the transplant recipient in compliance with federal privacy laws.
5. The recovery hospital 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, and
 - b. personal health information collected during the transplant candidate's evaluation, which is confidential and protected under privacy law.

I have received this information as well as other education materials, including the living kidney donation media produced by the American Society of Transplant Surgeons (ASTS), from the transplant team on _____, prior to evaluation. I have been given the opportunity to read the information and ask questions. I have been informed by the staff of the Stanford Transplant Program that 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. I understand the information that has been provided to me.

Potential Donor:

DATE TIME SIGNATURE (Patient /Legal Designated Representative)

PRINT NAME RELATIONSHIP TO PATIENT

If an interpreter participated in the informed consent discussion:

PRINT SHC in-person interpreter name Video or TEL Interpreter ID# Language

Nurse Coordinator:

DATE TIME RN SIGNATURE PRINT NAME

Transplant Physician/Surgeon:

DATE TIME PHYSICIAN SIGNATURE PRINT NAME