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Informed Consent for Living Kidney Donor Evaluation

I am thinking of donating one of my kidneys to or on behalf of a patient at UCSF who has advanced and permanent kidney disease (failure). This patient's healthcare team has decided that the best treatment option for them is to receive a kidney transplant. I am asking to be evaluated as a potential kidney donor.

It is important that I understand the risks and benefits of kidney donation before I consent to being evaluated as a donor. This is known as "informed consent." It is also important that I understand the following information:

- The living donor evaluation process.
- The living donor surgical procedure, including post-operative treatment.
- The living donor's expected and potential short- and long-term outcomes after kidney donation.
- The living donor's responsibility to follow up with the transplant center after donation.
- The alternative treatments available to patients with advanced kidney failure.
- The kidney transplant recipient's expected and potential long-term outcomes.
- The living donor evaluation and surgery process is entirely voluntary, and I may choose to opt out at any time for any reason.

By providing my consent, I understand that I am giving the transplant team at UCSF permission to do the tests necessary to determine if I am a suitable candidate to be a living kidney donor. If I am found to be a suitable candidate and decide to proceed with kidney donation, I will have opportunities to learn more about the surgery and ask any questions I may have. I will need to sign additional consent forms prior to surgery.

I also understand that I cannot receive any payment in exchange for being a donor other than potential reimbursement for lost wages, travel and expenses related directly to donation. It is illegal in the United States for a potential living kidney donor to sell their kidney. I cannot be forced to be a donor or forced to be evaluated as a possible living kidney donor. By providing consent, I am affirming that I am

entering the evaluation process of my own free will, that I am not donating my kidney in exchange for anything of value including, but not limited, to cash, property and vacations.

Accuracy of evaluation

My safety is the top priority of the UCSF Transplant Team. It is vital that I disclose any and all medications that I am currently taking or have taken in the past, and any and all medical and/or psychiatric conditions that I currently have, or have had in the past. Failure to do so could put me in danger if I were to donate and will disqualify me from becoming a donor if the medical team learns that there is something that I failed to disclose. I agree that, in connection with providing accurate information to my physicians, I will review my medical history and, if necessary, ask my family about any significant family medical history they may be aware of.

Confidentiality

UCSF complies with state and federal confidentiality laws and is committed to safeguarding my confidential health information. Except where allowed by law, communication between me and UCSF will remain confidential. This includes, but is not limited to, sharing information about me with the potential recipient; no information will be shared with my potential recipient unless I give consent. Similarly, I cannot receive medical information about the recipient unless the recipient has given permission to share that information. Hospital staff who are involved in my medical care may review my medical record.

If I do become a donor, data about my case, which will include my identity, will be sent to the Organ Procurement and Transplantation Network (OPTN), the United Network for Organ Sharing (UNOS) and may be sent to other places involved in the transplant process as required or permitted by law.

I understand that some infections and health conditions that may be discovered during the donor evaluation process are required by law to be disclosed to the California Department of Public Health and other state and federal agencies, as applicable. Any infectious disease or malignancy discovered in the initial 2-year period after donation, that may affect the recipient of my Kidney, will be disclosed to the recipient transplant center and reported through the OPTN improving patient safety portal for the purpose of investigating potential disease transmission.

If I become a donor, a blood sample will be taken within 24 hours prior to my donation. This blood sample will be stored by UCSF Transplant Services indefinitely, but for a minimum of 10 years after my donation date. This blood sample will only be used in the investigation of potential disease transmission and will not be used for any other purpose. If I do not wish for my blood sample to be stored, I may opt out of becoming a living donor at any time during the evaluation process.

The Living Donation Process

There are three phases to the living donation process: the screening phase, the evaluation phase, and the surgical phase during which a kidney is removed from the donor. I understand that I may opt out of the evaluation at any point for any reason, and that my reason for opting out will be kept confidential unless I allow it to be disclosed.

Screening Phase:

This phase consists of a health history questionnaire, lab work and preliminary health testing. Completing this phase does not mean I am cleared to be a living donor. This testing determines only if I can move on to the evaluation phase.

Health Questionnaire

I will complete a questionnaire about my health that consists of simple questions about my past or present medical problems, medications I am taking (if any), and health habits. If this questionnaire shows that I can potentially be a donor, then the second step will begin. It is important that I answer all questions honestly and to the best of my knowledge.

Laboratory Testing

Several laboratory tests will be performed to screen my potential as a donor. These will include, but are not limited to the following:

- Blood samples that will determine my blood type, and check for medical diseases as well as infections such as the Hepatitis B and C viruses and the HIV virus
- Blood and urine samples that will be tested to make sure that I have normal kidney function
- Blood pressure measurements to assess my risk of future kidney problems
- Compatibility testing if I wish only to donate directly to a particular person. If I am open to donating to another person on behalf of my intended recipient or participating in an exchange program, the compatibility testing will be done later.

The results of these tests will be reviewed by the transplant team, if they are acceptable, I will be scheduled for the evaluation phase.

Evaluation Phase

This phase consists of thorough medical and psychological evaluation to determine if I can be a living kidney donor.

Physical Examination and Diagnostic Tests

I will be scheduled for testing that may include, but is not limited to:

- A complete physical evaluation and medical history review with a transplant physician or nurse practitioner. This provider will help determine if there are any medical problems, or problems involving social and psychological behavior that could prevent me from becoming a donor.
- Compatibility testing to determine if I can donate directly to my intended recipient, or if I can donate to another person on behalf of my intended recipient or participate in an exchange program.
- Chest x-ray to assess the health of my chest and lungs.
- Electrocardiogram to assess the health of my heart.
- Exercise stress test to assess the health of my heart.

- CT angiogram to ensure I have two healthy kidneys with adequate blood flow and to allow my surgeon to determine which kidney is most suitable for donation. This test requires contrast dye to be injected into my blood vessels while pictures are taken of my abdomen and kidneys. I must let the transplant team know if I have an allergy to contrast material.
- Ultrasound of my kidney and blood vessels – this is a test that uses sound waves to evaluate blood flow to the kidney.
- Nuclear Medicine GFR - a test that uses contrast material and imaging to evaluate kidney function.
- Psychosocial evaluation.
- Other tests or consultations as determined by the transplant team based on findings during the evaluation.

Not every potential donor will need all of these tests. Each test will be explained to me before it is done, and some tests will require separate consent. It is possible that these tests will find some problem with my kidneys that will make it unsafe for me to donate, even if all my other tests are normal.

Independent Living Donor Advocate

The UCSF Kidney Transplant Program has an Independent Living Donor Advocate (ILDA) whose primary responsibility is to protect and promote my interests as a living donor. The advocate will respect my decision to donate or not to donate and will make sure that I am fully informed and do not feel that I am being forced to be evaluated as a potential donor or to be a donor. I may contact the advocate at any time throughout the evaluation process and before surgery if I have any questions or concerns about donation.

I understand that I will meet with the ILDA and possibly a psychiatrist who are also part of the donor evaluation team. There are several main reasons for this work-up:

- To determine if I am capable of giving informed consent.
- To assess for potential risk factors which may affect my safety or the safety of my organ for donation.
- To discuss my reasons for wanting to be a donor.
- To evaluate if my family and I will be able to manage the emotional, financial and physical stresses of this type of surgery.
- To ensure that I understand the entire donation process including consent, the need for medical and psychological evaluations, care before and after surgery, and requirements for follow-up testing.
- To ensure I understand that complications that can happen, including death, to either me or to the kidney recipient as a result of the evaluation or the transplant procedures.

My donor evaluation team and the ILDA at UCSF Medical Center are available to help me and/or my family at any point during this process.

My donor evaluation team and I will also discuss results of the physical evaluation, as well as how any current health issues or medication regimen could be affected by donation or could affect recovery from the donation.

All results of the medical and psychosocial testing to see if I can donate my kidney will remain confidential with the members of my donor team. No results will be given out to any individual, including the potential recipient without my consent.

National and Transplant Center-Specific Outcomes

During the evaluation process, I will be given UCSF's most current outcome data as released by the Scientific Registry of Transplant Recipients (SRTR). The document will include UCSF's current 1-year survival rate for patients after they receive a kidney transplant. It will also include the 1-year survival rate for the new kidney after it is transplanted. The document will explain how these rates compare to the national average. If I need help understanding the report, I can contact my coordinator.

I can also visit the following websites for further information:

Scientific Registry for Transplant Recipients (SRTR) www.srtr.org

Organ Procurement and Transplantation Network (OPTN) www.optn.org

United Network for Organ Sharing (UNOS) www.unos.org

Suitability for Donation

During the evaluation process I will be guided by a transplant coordinator (nurse or nurse practitioner) who is not involved in the care of the recipient. The multidisciplinary kidney transplant team and my assigned coordinator will decide whether I can donate or not. My suitability is determined by protocols that take into account my current health condition, past medical history, psychosocial history, laboratory results, diagnostic testing and financial status as well as clinical judgement. I can request a copy of UCSF Transplant's minimum living donor selection criteria. If I am approved to donate, my surgeon will discuss the surgery and the risks, and I will be asked to sign a consent form for the surgery. At all times, my health and safety will be the primary focus.

If I am not approved to donate, I understand that I may choose to be evaluated for donation at another transplant center which may have different selection criteria.

Risks of Evaluation

The goal of living donor kidney transplantation is to benefit the recipient, but not harm the donor. Some tests will have risks, for example CT angiogram or regular angiogram require the injection of contrast material (dye) which may cause an allergic reaction. These risks will be discussed with me at the time the test is planned, and I will be asked to sign a separate consent form.

During the living donor evaluation, serious medical conditions, or adverse genetic findings that I was not aware of may be discovered. Discovery of certain abnormalities may require more testing at my expense or create the need for unexpected decisions by my donor evaluation team.

The information discovered during the evaluation may have implications for insurance coverage in the future. If this happens, my ability to get health and life insurance might be affected by the discovery of these health problems. All results will be available to me, and also become a part of my permanent medical record.

My recipient may have a higher chance of poor 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

UCSF can disclose to me certain information about my recipient's health but only with their permission, including:

- The reasons for the recipient's increased chance of poor outcomes
- Personal health information collected during the recipient's evaluation, which is confidential and protected under privacy law

Psychosocial Issues

How I feel about myself after the donation process may change and may be affected by several factors. I may experience a change in my body image related to the scar or pain from the surgery, depression or anxiety, or feelings of emotional distress or grief if the transplanted kidney is rejected or the recipient dies. There is a possibility that the recipient's original disease could return, even in the kidney I donated, or the recipient may die. I may experience an impact on my lifestyle due to the donation. It is also possible that the nature of my relationship with the recipient may change for the worse after donation. Lastly, the long-term effect of donation on my mental health has not been well studied, and therefore is not known.

Financial Responsibilities

It is important for me to understand that there are financial responsibilities resulting from donation, as well as expenses after the surgery. There could be expenses during the evaluation process leading up to the surgery and during recovery after the surgery, such as travel, housing, childcare and lost wages. There may be resources available to help defray these costs, however they may also be my responsibility in part or whole.

There is a possibility that I could lose my job if I need more time off than my employer allows, or if I use all my sick time from my employer. It is important that I have my employer approve the necessary time off for surgery and healing. It is possible that donation will have a negative impact on my ability to obtain future employment. It is possible that if I develop complications after the surgery, the recipient's insurance will not cover treatment, and if I do not have insurance, the cost of my medical care will be my responsibility. The yearly follow-up visits required to monitor my health after donation will also be my financial responsibility if I do not have insurance coverage.

The Surgical Procedure

Surgery - What to Expect

The donation surgery is called a nephrectomy (the surgical removal of one of my kidneys). A nephrectomy is a form of abdominal surgery (the abdomen is the part of the body that contains all the structures between the chest and the pelvis). The surgical procedure will be done under general anesthesia. It will most likely be done through small incisions using special instruments and a camera on a long scope (laparoscope). If, at any time, the surgical team is having problems and feels that my safety is at risk, a bigger incision will be made, and they will stop using the laparoscope. This happens in less than 1 in 400 donor surgeries at UCSF. If a bigger incision is needed, there may be more time required for my recovery.

During surgery, I will have a catheter (tube) to drain my bladder, possibly but rarely a tube to drain my abdomen, and several intravenous lines for administration of fluids and medications. These tubes are mostly removed after 24 hours. Typically, a donor remains in the hospital for 2 to 3 days after surgery.

Interruption/Termination of Surgery

The evaluation process of the potential donor and recipient does not stop when the surgery begins; it continues throughout the surgery. If, at any point, the surgical team believes that I am at risk or the kidney does not seem adequate for transplantation, the surgery will be stopped. The surgery may also be stopped if the recipient has issues that prevent the surgery from going forward. Stopping the donation during surgery happens in less than 1 % of donations.

Risks of General Anesthesia

The surgery will be done under general anesthesia. There are several known possible risks with any surgery done under general anesthesia. An anesthesiologist will explain these to me.

Blood Transfusions and Risk Involved with use of Blood or Blood Products

I may need blood transfusions during the surgery or after it. It may be possible to bank my own blood before the surgery, but I may need more blood than I have banked. In this case, blood will be used from the blood bank. Although the blood from the blood bank is carefully checked for HIV, Hepatitis and other diseases, there is still a very small risk (1 in 500,000) that I will be infected. I will need to give consent for the use of stored blood or blood products in case they are needed during my surgery or postoperative care.

General Risks of Surgery

Before I begin any donor testing, it is important that I understand the general risks of surgery, since this might influence my decision to undergo an evaluation. I understand that I will receive a more detailed list and discussion of the risks of the surgery if I am found to be a suitable donor, and I will sign another consent form to proceed with the surgery.

The surgery that I will have (a nephrectomy) is most commonly used to treat kidney diseases such as kidney cancer. A nephrectomy can be done very safely. However, as with any major surgery, there are risks involved. Pain, bleeding, infection, and/or injury to other areas in the abdomen, as well as death, are potential risks. Some complications may require additional surgery or hospitalization.

After the operation, there may be problems with healing that could lead to an infection in my wound. The risk of a wound infection is about 5 in 100. The infection may require the wound to be opened, antibiotics to be given, or both. Another potential problem with wound healing is a hernia, which is a hole in the abdominal wall. If a hernia develops, I may require an operation to correct it. It is expected that 5 patients in 100 will develop a hernia.

Any patient who has abdominal surgery will have scarring in the abdomen. This scarring may cause a blockage (obstruction) of my bowels. A surgery may be needed to fix the obstruction. One or two patients in 100 may develop a bowel obstruction.

Patients who undergo surgery have a risk of nerve injury that could lead to temporary or permanent pain or paralysis.

My risk of complications may be higher for me than other people depending on my age, and whether I'm obese, have high blood pressure, or other pre-existing conditions. I may develop infections in my lungs (pneumonia) or bladder. These infections would need to be treated with antibiotics.

Patients who have abdominal surgery are at risk of forming blood clots in their legs. These blood clots can break free and move through the heart to the lungs. In the lungs, the clot may cause a serious problem called pulmonary embolism. These clots are usually treated with a blood thinner. These clots can cause death.

Pneumatic stockings are used to keep blood flowing in the legs during and after surgery to prevent the blood clots from forming. It is important that I wear the stockings when I am in bed after surgery. It is estimated that 1-2 patients in 100 will have a blood clot.

In patients who undergo major surgery, there is a risk of heart problems that can lead to death. In healthy patients, such as those who donate a kidney, this risk is very low, less than 1 in 1000.

Risks Specific to Kidney Donation Surgery

There are temporary and permanent risks specific to kidney donation which include but are not limited to:

- Decreased kidney function. Kidney donors experience an average permanent loss of 25- 35% of kidney function after donation.
- Acute (sudden) kidney failure and the need for dialysis or kidney transplant in the immediate post-operative period (right after surgery).
- Potentially higher risk of chronic kidney disease (CKD) or end stage renal disease (ESRD) if the remaining kidney is damaged. Kidney disease may develop faster with only one kidney.
- Living kidney donors may have a higher risk of developing ESRD than healthy non-donors with similar medical characteristics.
- Dialysis is required to treat ESRD. Living kidney donors who develop ESRD will require dialysis, and potentially a kidney transplant. The current practice is to prioritize prior living kidney donors on the transplant waiting list.
- While many kidney donors go on to have safe and uncomplicated pregnancies, women who donate a kidney may have an increased risk of preeclampsia (elevated blood pressure and urine protein in pregnancy) or gestational hypertension (elevated blood pressure in pregnancy) in post-donation pregnancies.

When CKD or ESRD occurs, CKD generally develops in 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.

Post-Surgery Recovery/Discomforts

After my surgery, I will be taken to a hospital floor where I will be closely watched by the transplant team. There is a rare chance that I may need to be placed on a machine (ventilator) to help me breathe for a short time after surgery. After the surgical procedure, I will feel pain (for example: gas pains, sore throat, incision

soreness, shoulder pain, backaches, etc.). I might even experience fatigue, nausea, bloating and/or vomiting. I will receive pain medications after the surgery to try to reduce the amount of pain, but it will not take it away completely. There are risks with taking narcotic pain medication, including short-term side effects like itching, nausea, constipation, or confusion. There may be long-term risks of taking narcotic pain medication such as dependence. The transplant team at UCSF tries to minimize the use of narcotic pain medication to improve recovery; this will be discussed with me in further detail during my evaluation.

Follow-Up Care

My follow-up care will include appointments with a transplant nurse practitioner or other provider in the transplant clinic in the first two weeks after my surgery, with blood work to see how my kidney is doing. I also understand that longer term follow-up is needed, and this should be done by my regular health care provider. I should be seen by that provider within six months after the surgery and then yearly for the rest of my life. These visits are important to check on the health of my remaining kidney, and to look for any new medical problems that could damage it, such as high blood pressure or diabetes.

UCSF Transplant Services is federally mandated to collect health updates and lab work from me at 6 months, 1 year, and 2 years post-donation. UCSF will reach out to me to collect this information and pay for the lab work, but it is my responsibility to return the questionnaire and go to the lab when requested. This is a requirement to be a donor.

Long Term Risks of Kidney Donation

I understand that my life expectancy is not changed by being a kidney donor. My chance of developing kidney failure or needing dialysis after I donate is no higher than that of the general population but may be higher than healthy non-donors with similar medical characteristics to me. There is a slight chance of developing high blood pressure in the remaining years of my life, but it is not clear that this is directly related to the donation procedure.

Psychosocial Risks

If I decide to donate one of my kidneys, there will be different types of adjustments. My family and I can expect some ups and downs and emotional reactions related to the donation. Some possible side effects I may experience are: depression, post-traumatic stress disorder, a general feeling of anxiety, anxiety regarding dependence on others, and feelings of guilt. It is important that I notify my transplant team if I feel I may be experiencing any psychological side effects.

Financial Risks

The recipient's insurance will cover my care and medical expenses for a limited time after donation. This insurance may not cover any long-term medical problems that I develop. After surgery, insurance companies may not want to cover complications related to this surgery. I will

be responsible for the cost of treatment that insurance won't pay for. Future insurance premiums may be higher due to this donation. I also may not be able to get health, disability, and life insurance in the future if I lose my current insurance or if I am currently not insured.

Transplantation by a Transplant Center Not Approved by CMS (Medicare)

If the transplant is not provided in a Medicare-approved transplant center, it could affect the recipient's ability to have immunosuppressive drugs paid for under Medicare Part B. UCSF is a Medicare-approved transplant center. If at any time UCSF loses Medicare approval, I will be notified at least 30 days in advance.

Alternative Treatments

I understand that my recipient has several alternatives besides receiving a living donor kidney transplant including dialysis or deceased donor transplant.

Should I decide not to donate my kidney, the potential recipient will continue to receive care by the kidney transplant team at UCSF, their name will remain on the national kidney transplant waitlist, and he or she will wait for a deceased donor organ or another living donor to become available.

While all the testing is being done to prepare for living donor transplant, a deceased donor organ or another living donor organ may become available for the potential recipient, and they may get a transplant before my evaluation is complete. Additionally, the potential recipient may have risk factors for increased morbidity or mortality that have not been disclosed to me. Finally, the potential recipient may get too sick to safely undergo transplant, or even die.

Donor Benefits

I understand that I will receive no direct medical benefits from having this evaluation. A possible unexpected outcome of the evaluation is finding out about a health problem that I did not know I had but may need treatment for. I also understand there is no medical benefit to me if I decide to proceed with donating my kidney.

Recipient Benefits

I understand that by my donation, the recipient may receive a benefit. For the most part, this benefit includes a decrease in waiting time on the list for a kidney, which might improve their recovery and success rate after receiving a transplant. I also understand that a kidney transplant, while not immediately lifesaving, is likely to lead to a much better quality of life and a longer life for the recipient compared to dialysis.

It is possible that the transplanted kidney may not work or may be rejected by the recipient's immune system. Kidney transplant failure in patients who receive a kidney from a living donor occurs 3% of the time in the first year. 50% of the kidneys are still functioning after 15 years. If the kidney fails after transplant, the recipient will need to return to dialysis and could be listed for another transplant if they are still in reasonable health.

Right to Opt out of Donation

I understand that at any time 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. My decision will be kept confidential unless I give permission otherwise.

Additional Information

I understand that I can take my time in deciding whether or not to pursue kidney donation and discuss it with my family and friends. I can obtain more information about living kidney donor transplants from www.unos.org.

Whom Do I Call if I Have Any Questions or Problems?

I am free to ask the transplant team questions. I can contact a transplant coordinator at (415) 353-1551 or email living.donor@ucsfmedctr.org

Documentation of Informed Consent

This consent has been reviewed in detail and the patient has received a copy. They have been informed about this program's purpose, procedures, possible benefits, risks and alternatives. The patient has had the opportunity to ask any and all questions related to living kidney donor evaluation and surgery and those questions have been answered to their satisfaction. The patient understands that they may change their mind at any time and are under no obligation to proceed with living donor evaluation or surgery.

Informed consent has been obtained and the patient wishes to proceed.