

**Transplant Service**

Heart & Lung Transplant  
UCSF Box 0115  
500 Parnassus Ave., MUW 420  
San Francisco, CA 94143  
tel: 415.353.4145  
fax: 415.353.4166

Kidney & Pancreas Transplant  
UCSF Box 0116  
400 Parnassus Ave., Suite A701  
San Francisco, CA 94143  
tel: 415.353.1551  
fax: 415.353.1939

Liver Transplant  
UCSF Box 0116  
400 Parnassus Ave., Suite A701  
San Francisco, CA 94143  
tel: 415.353.1888  
fax: 415.353.8917

Transplant Administration  
UCSF Box 0354  
8000 Marina Blvd., Suite 600  
Brisbane, CA 94005  
fax: 415.353.4237

TTY: 415.885.3889

[www.ucsfhealth.org](http://www.ucsfhealth.org)

**Informed Consent for Living Liver Donor Evaluation**

I am thinking about donating a part of my liver to a patient at UCSF that has life threatening liver disease and needs a liver transplant. They have been placed on a waiting list for a liver transplant from a deceased donor. I am asking to be evaluated as a potential liver donor to donate a portion of my liver to provide a transplant. It is important that I understand the risks and benefits of living liver donation before I consent to being evaluated as a potential 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 long-term outcomes after surgery
- The recipient's expected and potential long-term outcomes (recipient may not survive even after receiving a donor liver)
- The living donor evaluation and surgery process is entirely voluntary, and I may choose to opt out at any time for any reason

This process is known as informed consent. This consent form provides detailed information about being a donor that will be discussed with me. I will need to provide informed consent if I wish to proceed with medical evaluation for living liver donation. In providing my consent to undergo evaluation as a possible donor, I understand that I am giving the transplant team at UCSF permission to do the tests that are necessary to decide if I am a suitable candidate to be a living liver donor. If I am found to be a suitable candidate, and I decide to proceed with liver 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 undergoing surgery.

I also understand that I cannot receive any payment in exchange for being a donor. It is illegal in the United States for a potential living liver donor to sell a portion of his or her liver. I cannot be forced to be a donor or forced to be evaluated as a possible living liver donor. My signature on this form affirms that I am not being forced to be a liver donor and I am not donating in exchange for anything of value including, but not limited to cash, property, and vacations. I am asking for this evaluation of my own free will.

**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 liver, 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 Evaluation Process**

Liver transplantation using a living liver donor involves two steps. The first step is a medical evaluation to decide if it is possible for me to be a living liver donor. Going through this step does not guarantee that I will be able to donate part of my liver. If it is determined that I am healthy and a good match with my recipient, I can then go on to the second step. The second step is having surgery to remove a portion of my liver that will be transplanted into the recipient.

An initial medical evaluation will be done to find out if I can donate. This first phase will include blood tests to determine my blood type and check for overall health and liver function.

In addition to the tests to look at my overall health, I will need to have more tests to measure the size, blood vessels and bile ducts, and condition of my liver:

- Ultrasound of my liver and blood vessels (a test that uses sound waves to evaluate blood flow to the liver)
- Computed Tomography (CT) scans to look at the anatomy and measure the volume of my liver. This test uses intravenous (IV) dye to take pictures of my liver.
- Magnetic resonance scan (MRI) of my liver (a test that uses radio waves and IV dye to study the blood vessels and bile ducts of the liver).

I may also have testing to look at my heart function:

- An echocardiogram, which uses sound waves to look at my heart and its function
- An exercise test to see how my heart functions under stress

For some donors, more tests may be needed. These may include:

- A liver biopsy (a test in which a needle is used to remove a small portion of the liver, this tissue is then looked at under a microscope.);
- An angiogram (a test in which a needle is inserted into a blood vessel in the leg and IV dye is used to take pictures of the blood vessels of the liver).
- Additional blood tests for those donors identified as being at increased risk for HIV, HBV and HCV transmission according to the U.S Public Health Service (PHS) Guideline.

Each test will be explained to me before it is done and I may need to sign additional separate consent forms for some tests.

### **Independent Living Donor Advocate**

The UCSF Liver 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 of whether 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 liver 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 a portion of my liver 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 liver transplant. It will also include the 1-year survival rate for the new liver 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 transplant coordinator. I can also visit the following websites for further information:

Scientific Registry for Transplant Recipients (SRTR) [www.srtr.org](http://www.srtr.org)

Organ Procurement and Transplantation Network (OPTN) [www.optn.org](http://www.optn.org)

United Network for Organ Sharing (UNOS): [www.unos.org](http://www.unos.org)

### **Suitability for Donation**

During the evaluation process, I will be seeing a coordinator (nurse or nurse practitioner) who is not involved in the care of the recipient. The multidisciplinary liver transplant team and my assigned coordinator will determine whether I am suitable as a donor. 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 with me. I will have the opportunity to ask any questions I may have, and I will be asked to sign a separate consent form for the surgery. At all times, my health and safety will be the primary focus.

If I am not a suitable donor, 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 liver 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.

Additionally, a deceased donor organ or another living donor organ may become available for the recipient before my evaluation is complete or before my liver donation surgery occurs.

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 liver is rejected or the recipient dies. There is a possibility that the recipient's original disease could return, even in the liver I donated. 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**

Either the right lobe or the left lobe of my liver will be removed and implanted in the recipient. The portion of my liver selected for donation depends on the size of my liver as well as the recipient's need and the blood supply to the liver and bile duct anatomy. Both segments (the remaining section of my liver, and the portion received by the patient) will regenerate and grow to fit the needs of each individual.

Depending on which part of my liver is removed, the incision is either straight up and down, or across the abdomen. Typically, the gallbladder is removed. The surgeons isolate the blood vessels and bile duct to the portion of the liver to be removed. The liver is then divided by tying off small blood vessels and bile ducts until the liver is separated. The blood vessels and bile duct is then divided and the piece of liver removed. The surgeon then closes the incision with self-absorbing sutures.

I will have a catheter (tube) to drain my bladder, potentially but rarely a tube to drain my abdomen, and several intravenous lines for administration of medications and to ensure I do not become dehydrated. These tubes are mostly removed after 24 -36 hours, leaving one remaining intravenous line until I am discharged. Typically, a donor remains in the hospital from four to seven days after surgery.

### **Interruption/Termination of Surgery**

The evaluation process of me and my 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 of significant complications or that the segment of my liver is not right 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 anesthesia. There are a number of known possible risks with any surgery done under 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 of red blood cells or other blood products 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 patient in 500,000 patients) that I will be infected. I will need to give consent to the use of stored blood or blood products, in case they are needed during my surgery or postoperative care.

### **General Risks of Surgery**

This surgery will remove part of my liver. Pain, fatigue, bloating, 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. My risk of complications may be higher for me than other people depending on my age, whether I'm obese, have high blood pressure, or other pre-existing conditions.

My surgeon will tell me if my gallbladder is to be removed during this surgery. The gallbladder is not needed for my body to function normally. Some people who have their gallbladders removed have periods of diarrhea and cramping, which may last for 2-3 months.

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 patients in 100 patients. 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 patients will develop a hernia.

I may develop infections in my lungs (pneumonia) or bladder. These infections would need to be treated with antibiotics. One or two patients in 100 patients will get one of these infections.

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

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 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.

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

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 piece of their liver, this risk is very low, less than 1 patient in 1000.

### **Risks Specific to Liver Surgery**

Removal of a portion of the liver will temporarily reduce the overall function of my liver. The liver is expected to grow back.

A person who has a piece of their liver removed can develop liver failure. This liver failure can be transient (temporary) or permanent. In some cases, this liver failure may require treatment with a liver transplant. It is expected that 1 donor out of 3000 will need to have a liver transplant.

The most common complication after this surgery is a bile leak. This happens to approximately 2 donors in 100. Most bile leaks get better without having to have another surgery. When necessary, the radiologists need to put a tube into the bile leak. This tube passes through the skin to drain bile into a bag worn outside the body, usually for a few weeks.

Narrowing of the bile ducts that drain the liver can also occur after this surgery. Since living liver donations are so new, there is not enough data to know how often this will occur, but it is probably 1 donor in 100 donors.

Some donors will have abnormal or false-positive lab tests after donation that may trigger additional tests, which carry additional risks.

The risk of all types of complications at UCSF have been examined, and the risk is about 20%. Most complications do not need another surgery or procedure. However, living liver donor transplants are still very new, so there may be risks that are not yet known.

According to the best current estimates, the risk of death is about 2 deaths in 1000 donors.

### **Post-Surgery Recovery/Discomforts**

I will have significant pain after this operation. The pain medications that I receive will make the pain less but won't take it away completely. The pain medications may cause nausea, vomiting, constipation and possibly problems with breathing. There is a chance that I could be placed on a machine to help me breathe after surgery. I may become confused for a short time because of medications.

There are long term risks with narcotic medications including dependence, this will be discussed with me.

### **Subsequent Surgery**

If I donate a piece of my liver, I will not be able to donate another portion of my liver. I may be able to donate a kidney depending on several factors. If I need an abdominal operation later in life, there may be scarring that would make that more difficult.

### **Pregnancy**

There is no information to suggest that fertility is changed or that there are increased complications of pregnancy related to donation.

### **Post Donation Follow-up**

UCSF Medical Center Transplant services is federally mandated to collect certain clinical information and lab work at 6 months, 1 year, and 2 years post-donation. UCSF Transplant will reach out to me to collect this information and pay for the lab work, but it is my responsibility to return the clinical questionnaire and go to the lab within the required timeframe. This is a requirement to be a donor.

If I have an infectious disease or malignancy that is discovered after my donation that may impact the care of my recipient, it may need to be:

- Reported to local, state or federal public health authorities
- Reported to the recipient transplant center
- Reported to the OPTN through the patient safety portal

**Psychosocial Risks**

If I decide to donate a portion of my liver, 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 covers 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 cost of treatment of complications related to this surgery. I would be responsible for the cost of any care that the insurance won't pay for. Future insurance premiums may be higher due to this donation. My donation may negatively impact my ability to obtain, maintain, or afford health insurance, disability insurance or life insurance.

**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**

The alternative to living liver donation is deceased liver donation. If I decide not to donate a portion of my liver, the potential recipient will continue to receive care by the liver transplant team at UCSF Medical Center. Their name will remain on the liver transplant waitlist and they will wait for a deceased donor organ or another living liver donor to become available.

**Donor Benefits**

I understand there is no medical benefit to me if I decide to proceed with donating a portion of my liver.

**Recipient Benefits**

By my donation, the recipient will receive a benefit. This benefit is a decrease in waiting time on the list, which might have an effect on the recipient's recovery or prevent them from dying while waiting for a deceased donor liver transplant.

The recipient of my donated liver may have an increased risk of having a poor outcome (including graft failure, complications, and death) that may not be disclosed to me. The transplant hospital may only disclose these factors, or any of the recipient's personal health information, if they receive permission from the recipient.

The recipient of my donated liver may have more complications after the living donor transplant than with a deceased donor transplant. The donated segment of my liver may not work or may be rejected by the recipient's immune system. This may require that they be placed on the list to wait for another liver. The recipient could possibly die before another liver becomes available.

**Right to Opt out of Donation**

I understand that at any time during the evaluation or prior to surgery, I can discontinue the living donor consent or evaluation process in a way that is protected and confidential.

**Additional Information**

I understand that I can take my time in deciding if I want to pursue donating a portion of my liver and discuss it with my family and friends. I may obtain more information about living liver donor transplants from [www.unos.org](http://www.unos.org).

**Who to contact if I Have Any Questions or Problems?**

I am free to ask the transplant team questions. I can contact a transplant coordinator at 415-353-1888 or email [liver.livingdonor@ucsfmedctr.org](mailto:liver.livingdonor@ucsfmedctr.org)

**Documentation of Informed Consent**

*This consent has been reviewed in detail and I have received a copy. I have been informed about this program's purpose, procedures, possible benefits, risks and alternatives. I have had the opportunity to ask any and all questions related to living liver donor evaluation and surgery and those questions have been answered to my satisfaction. I understand that I may change my mind at any time and am under no obligation to proceed with living donor evaluation or surgery.*

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