

**UNIVERSITY HEALTH SYSTEM IN PARTNERSHIP WITH
UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER IN
SAN ANTONIO, TEXAS**

LIVING LIVER DONOR INFORMED CONSENT FOR DONATION PROCESS

(University Health System Transplant Programs Revised version of recommendations by the
U.S. Department of Health and Human Services Advisory Committee on Organ Transplantation)

I am being given the choice to undergo surgery to remove a part of my liver, which will be transplanted into a potential recipient.

In order for me to make this decision, I must understand enough about its risks and benefits to make an informed decision. This process is known as informed consent. This consent form provides information about the surgery that will be discussed with me. Once all my questions have been answered, I will sign this form showing that I am, of my own free will, choosing to donate a part of my liver.

I understand that I will not receive any payment or anything of value from the potential recipient or the transplant center if I agree to be a donor.

I am free to ask any questions and I am free to change my mind and remove my consent at any time.

SURGERY

Interrupted 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 that the segment of my liver is not right for transplant, the surgery will be stopped. This happens in the United States at least 5% of the time.

Risks

The surgery that I will have is called a partial hepatectomy (the surgical removal of a part of my liver). This surgery is most commonly used to treat liver diseases. Partial hepatectomy can usually be done safely. With any major surgery, there are risks involved, including the risk of death. Partial hepatectomy in a well person carries less risk than when it is done to treat someone who is sick with liver disease.

My gallbladder will be removed during this surgery. The gallbladder is not needed for adequate bowel function. Some people who have their gallbladder removed have periods of diarrhea and cramping, which will usually resolve in two-three months.

There are always risks with any surgery, but a surgery that will remove between 25-70% (25-30% for pediatric recipient, 55-70% for adult recipient) of the liver carries significant risk. Pain, bleeding, infection, bile duct injury, liver failure, and/or injury to other areas in the abdomen, as well as death, are potential risks. Other risks include postoperative fevers, pneumonia, heart attack, stroke, and urinary tract infection. We try to minimize the risk of these problems with our preoperative evaluation of your health.

Patients who have abdominal surgery are also at risk to form blood clots in their legs. These blood clots can break free and move through the heart to the lungs. In the lungs, the blood clot may cause a serious problem called pulmonary embolism. Pulmonary embolism is usually treated with a blood thinner. In some cases, these clots can cause death. There are special devices used to keep blood flowing in the legs during surgery to try to prevent the blood clots from forming. **The risk of blood clots is higher if you smoke cigarettes.**

There are also risks that are specific only to liver surgery. During the pre-surgery evaluation, the transplant team tries to find out what your liver looks like so that they can decide what piece can safely be taken out. For the living liver donation, 25-30% of the liver will be removed for a pediatric recipient and 55-70% will be removed for an adult recipient. Removal of a portion of the liver may cause the remaining liver to not work as well for a period of time. The part of the liver left behind will begin to grow back within a few weeks and get better. **A person who has a piece of his/her liver removed can develop liver failure.** In some cases, this liver failure may require a liver transplant to treat. This is a very rare event, about 2 transplants per 1000 living liver donor surgeries. At UNIVERSITY HOSPITAL, this has occurred 0 TIMES.

The most common liver related problem (complication) is a bile leak. The reported rate of this happening ranges from 5-15%. At this center, this occurs about 10% of the time. Most bile leaks get better without having to have another surgery. A leak may require you to have tubes placed that pass through the skin and into the liver or a fluid collection near the liver to drain bile into a bag worn outside the body for a period of time. This often can be done without having surgery.

Biliary strictures (narrowing of the large ducts that drain the liver) can also occur after this surgery. Since this will be a long-term problem and living liver donor transplants are so new, there is not enough data to know how often this will occur. Early data shows that this problem should be rare. Some of them can be fixed without surgery.

Another rare event that may happen is injury to the spleen during the surgery. If this occurs, the spleen will be removed. The spleen helps to prevent bacterial infections, most commonly pneumonia. Getting a vaccination for pneumonia can usually prevent these infections. These infections can also be treated with antibiotics. If the infections are not treated, they can cause death.

Across the country, the risk of having some type of problem, minor or major, from this surgery is 15-30% (about 2 in 7 cases). At this center, 20% of donors have had problems after surgery. All of these problems have been considered minor by our doctors. Most problems are minor and get better on their own. Rarely do they require another surgery or procedure. **Living liver donor transplants are still very new so there may be risks that are not yet known.**

So far in the United States, the mortality rate (death) has been about 0.2% or 2 deaths in about 1000 donors. ZERO donor deaths have occurred in this center.

General Anesthesia

This surgery will be done under general anesthesia. There are a number of known possible risks with any surgery done under general anesthesia. An anesthesiologist will explain these to me and I will need to sign a separate consent for anesthesia.

Blood Transfusions

I may need blood transfusions during this surgery, although transfusions are usually not necessary during the surgery. It may be possible to bank my own blood before the surgery. I may need more blood than I have banked. During this surgery and after care, **I clearly consent to the use of stored blood or blood products if it is needed.** I have been fully informed of the associated risks with the use of blood or blood products. Although the blood is carefully checked for HIV, Hepatitis and other diseases, there is still a very small risk that I will be infected.

Post-Surgical Course/Discomforts

I understand that after my surgery, drains will be temporarily placed in my body to help me heal. After the surgery, I will go to an intensive care unit (hospital floor) where I will be closely watched. There is a chance that I could be placed on a machine to help me breathe after surgery. I will feel pain (for example: gas pains, sore throat, soreness, backaches, incisional pain etc.) after the surgery. I also understand that I may become confused for a short time because of the medications I will be given. At some point I will be moved to a less acute floor.

I will remain in the hospital as long as needed, depending on how fast I get better. Usually, donors are discharged 5-10 days after surgery. For the most part, donors are usually pain-free three weeks after the surgery; some people continue to have pain for longer. The recovery period at home is 6-12 weeks. Should I have any problems, the recovery period may be longer. Most donors return to their usual activities in 6 weeks. They usually return to their most demanding activities in 3-4 months. You should be able to drive within 2-3 weeks.

I understand and agree that a team of doctors at the UNIVERSITY HEALTH SYSTEM/ UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER will follow me. I will be given appointments to see my doctors and have blood work and possible scans of the abdomen to see how my liver is doing. Blood work testing will usually be done several times in the first few weeks after discharge and once or twice a year for the next 10 years. Other testing may be done as required if problems are identified.

Insurance/Pre-existing Conditions

I understand and agree that, after the living liver donor surgery, my health insurance company may identify me as having a pre-existing liver disease and/or abdominal related problems. **Future liver disease or abdominal related problems may not be covered by my insurance because I have been a living liver donor.** If these problems are not related to the surgery and are not covered by my insurance company, I will be responsible for all costs.

I understand and agree that my insurance may be billed by this hospital for denial of claims before the recipient's insurance can be billed. I understand and agree that both future health, disability, and life insurance premiums may be higher due to this donation. **I understand that 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 not now insured.**

RECIPIENT ORGAN FAILURE

It is possible that the donor segment of my liver may not work or may be rejected by the recipient's immune system. This may require that he or she be placed on the Organ Procurement and Transplantation Network (OPTN) list to wait for another liver. During the waiting time, death may occur.

ALTERNATIVES

The alternative to living liver donation is cadaveric liver donation, using a liver from a donor who is declared brain dead. Should I decide not to donate a portion of my liver the potential recipient will continue to receive care by the liver transplant team at UNIVERSITY HOSPITAL/UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER. His or her name will remain on the Organ Procurement and Transplantation Network (OPTN) liver transplant waitlist and he or she will wait for a cadaveric donor organ or another living liver donor to become available. The details of this process will be described to me.

RECIPIENT BENEFITS

I understand that, by my donation, the recipient will receive a benefit. For the most part, this benefit includes a decrease in waiting time on the list, which might have an effect on his/her recovery. Graft failure in the recipient occurs 5-10% of the time and may lead to a repeat transplant or death. This has happened in this center 1 TIME. Liver transplant recipients die for some reason with both cadaveric and living donor transplant about 10-15% of the time.

DONOR BENEFITS

I understand that there is no medical benefit to me by having this surgery. A possible medical benefit of the evaluation is finding out about health problems that I did not know that I had so that I may seek treatment.

CONFIDENTIALITY

Hospital personnel who are involved in the course of my care may review my medical record. They are required to maintain confidentiality as per law and the policy of this hospital. If I do become a donor, data about my case, which will include my identity, will be sent to the OPTN and may be sent to other places involved in the transplant process as permitted by law.

ADDITIONAL INFORMATION

I understand that I may obtain more information about living liver donor transplants from the www.unos.org web page. UNIVERSITY HEALTH SYSTEM/UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER IN SAN ANTONIO transplant program will contact me from time to time after the surgery to learn about any concerns I might have about my health, insurance, employment and overall well being.

SIGNATURES

I, _____, certify by my signature below that:

I have had the surgery and the risks of the surgery explained to me by my doctor, _____, and understand the risks involved in the surgery.

I have read, or had read to me, this informed consent form.

I have had the chance to ask any questions I have about the surgery and they have all been answered.

I understand that I may withdraw my consent at any time prior to the surgery.

I, _____, certify by my signature below that I would like to proceed with the surgery:

Printed Name of Potential **Donor**

Printed Name of Potential **Recipient**

Signature

Date