I am thinking about donating a part of my liver to a patient who has end stage liver disease. This patient’s doctors have decided that the best treatment for him or her is to receive a liver transplant. He or she already has been placed on a waiting list for a deceased donor liver transplant. I am asking to be evaluated as a potential living, partial liver donor.

In order for me to decide whether or not I wish to consent to the living liver donor surgery, I should understand enough about the risks and benefits of

1. the living donor evaluation,
2. the living donor surgery, itself,
3. the long-term outcomes after the living donor surgery, and
4. the recipient transplant surgery (recipient may not survive even after getting a donor liver)

to make an informed decision. This process is known as informed consent. This consent form provides detailed information about the donor surgery (operation) that will be discussed with me. I understand that I will need to sign this consent form if I wish to proceed with medical evaluation for living liver donation.

Liver transplantation using a living partial liver donor involves two steps. The first step is a MEDICAL and SURGICAL evaluation to decide if it is possible for me to be a living liver donor. If it is decided that I am healthy and a good match with the potential recipient, and I consent to continue, I can then go on to the second step. The second step is having surgery (an operation) to remove a portion of my liver that will be transplanted into the potential recipient. I understand that by going through the medical and surgical work-up for donor surgery does not guarantee that I will be able to donate a portion of my organ. I understand that I may choose to stop the donation process at any time.

I also understand that I cannot receive any payment in exchange for being a donor.

EVALUATION PROCESS
An initial evaluation will be done to find out if I am able to safely donate. This will involve health care assessment along with laboratory blood and urine tests and a consultation with one of the surgeons. I will also have an electrocardiogram (EKG) and a chest x-ray. If the initial screening tests show that I can possibly be a donor, then I will enter the second phase of the evaluation. This involves a variety of tests and consultations that more thoroughly evaluate my health (such as heart, lung and kidney evaluations) and to determine the size, blood flow and condition of my liver. These tests may include, but are not limited to:

- Magnetic resonance scan of my liver: MRI/MRA (a test using magnetic waves to study the blood vessels and bile ducts of my liver).
- Ultrasound of the liver and blood vessels (a test using sound waves to evaluate blood flow to the liver);
• CT scan to measure the volume of the liver (a test that uses IV contrast, also called dye, to figure out the weight of my liver);
• a liver biopsy (a test in which a needle is used to remove a small piece of my liver. The 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 dye is used to take picture of the blood vessel of the liver).

Not every potential donor will need all of these tests. Each test will be explained to me before it is done. Some test will have risks (the CT scan with dye, the liver biopsy or the angiogram). 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.

One benefit of the donor evaluation is finding out about health problems that I did not know I had but may need treatment for. My ability to get health and life insurance in the future may be affected by finding out about these health problems.

A psychosocial evaluation will be performed. There are three main reasons for this assessment:

1. to decide if I am capable of giving an informed consent
2. to discuss my reasons why I want to be a donor
3. to decide if my family and I will be able to hold up under the emotional, financial and physical stress of this type of surgery.

There will be a detailed discussion with me about the complications that can happen, including death to either me or to the liver transplant recipient, as a result of the evaluation or transplant procedures. There are support systems in place at Vanderbilt University Hospital to help me and/or my family go through this process. These systems will be available to my family and me at any time during the living liver transplant process.

During the evaluation process, I will be seen by and Independent Donor Advocate Team (IDAT). This team is hired by Vanderbilt University Hospital to look after my health, safety and interests throughout the liver donation process. The IDAT will help me decide if there are any medical or psychosocial problems that would stop me from becoming a donor. The IDAT will not be involved in the care of the potential recipient.

I understand and agree that, after the living liver donor operation, my health insurance company may identify me as having pre-existing liver disease and/or abdominal related problems. As a result of having this living donor transplant surgery, future liver disease or abdominal related problems may not be covered by my insurance. If these problems are not related to the surgery and are not covered by my health insurance, I will be responsible for all costs. I understand and agree that both my future health, disability, and life insurance premiums may be higher due to this donation. I understand and agree that I may also not be able to get health, disability, and life insurance in the future if I lose my current insurance or if I am now not insured.
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.

At any time during the evaluation process, or prior to the surgery, I am free to decide, for any reason, that I no longer wish to become a donor.

I understand and agree that the recipients’ insurance will be billed for the donation surgery hospitalization. If there is a denial of claim, my donors insurance may be billed. I will not be responsible for out of pocket expenses for the donation surgery hospitalization.

SURGERY
Interrupted Surgery
My evaluation as a potential donor continues with the donation surgery. If at any point the surgical team believes that I am at high risk or that the segment of my liver is not right for transplantation, 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 type of surgery is most commonly used to treat liver diseases such as liver cancer or benign tumors. Partial hepatectomy can be done safely. But with any major surgery, there are risks involved. Partial hepatectomy in a healthy person carries less risk than when it is done to treat someone who is sick with liver disease.

If I will donate my right lobe (Adult to Adult) my gallbladder will be removed during this surgery. The gallbladder is not needed for my normal function. Some people who have their gallbladder removed have periods of diarrhea, cramping and intolerance to fatty food, which may last for two to three months.

Pain, bleeding, infection and/or injury to other organs in the abdomen, as well as, death are potential risks. Other risks include postoperative fevers, pneumonia, nausea, and urinary tract infection. Patients are also at risk to form blood clots in their legs that may cause a serious problem called a pulmonary embolism; there are special devices, i.e. plastics boots, used to keep blood flowing in the legs during and after surgery. There are also risks specific to liver surgery. The IDAT will evaluate your liver function and size to determine if a piece can safely be taken out. For living donation, 25-60% of the liver will be removed. The surgeons determines whether you will have a left lateral hepatectomy, left hepatectomy, or right hepatectomy based on the size of the 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 liver function will improve. But, 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).
A common complication after liver surgery is a bile leak which is caused from the cut surface of the liver. The risk of this happening is about 5-15%. Most bile leaks get better without having to have another surgery. A leak may be treated with tubes or drains that pass through the skin and into the liver to drain bile from the liver into a bag worn outside the body for a period of time. This often can be done without surgery.

Bile duct strictures (narrowing of the large ducts that drain the liver) can also occur after this surgery. If this does happen, some of them can be fixed without surgery by placing a stent (plastic tube) in the area of the stricture via an endoscopic procedure (through the mouth) or percutaneous procedure (through the skin).

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 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 complication, minor or major, from this surgery is 15-30%. These include infection, hernia, and swelling. Most problems are minor and get better on their own. Rarely do they require another surgery or procedure. However, some patients have developed incisional hernias or painful adhesions requiring surgery. 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 about 2 deaths in about 1000 donors. No living liver donors have died at 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 and I will need to sign a separate consent for anesthesia.

BLOOD TRANSFUSIONS
I may need blood transfusions during this surgery, although they are not usually necessary. 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. 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 further agree that after my surgery, drains will be placed in my body to help me heal. I will go to a unit (intensive care and then a regular 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, etc.) after the surgery. I also understand that I may become confused for a short time because of medications.
I will remain in the hospital as long as needed, depending on how fast I get better. Usually, donors are discharged 5 to 7 days after surgery. For the most part, donors are usually pain-free three weeks after the surgery; some people continue to have pain for a longer period of time. The recovery period at home is 4 to 6 weeks. Should I have surgical complications, the recovery period may be longer. Most donors return to their usual activities in 4 weeks. They usually return to their most demanding activities in 3 months.

I understand and agree that a team of doctors at Vanderbilt University Hospital will follow me. My follow-up care will include doctor appointments and having blood work and possible scans of the abdomen to see how my liver is doing.

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 the recipients’ insurance will be billed for this hospitalization. For denial of claims, the donors’ insurance may be billed. I will not be responsible for out of pocket expenses for the hospitalization. I understand and agree that both future health and life insurance premiums may be higher due to this donation. I understand and agree that I also may not be able to get health, disability, and life insurance in the future in 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 fail or may be rejected for some reason in the recipient. This may require that he or she be placed on the Organ Procurement and Transplantation Network (OPTN) list to wait for another liver. During this waiting time, death may occur.

ALTERNATIVES
The alternative to living liver donation is deceased liver donation, using a liver from a donor who has died. Should I decide not to donate a portion of my liver, the potential recipient will continue to receive care by the liver transplant at Vanderbilt University Hospital. His or her name will remain on the 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. The rate of this happening in this center is 5%.
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 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 transplant from the www.unos.org web page. Our office 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 have read this document. I understand the risk(s), benefit(s) and alternative(s) to living liver donation. I wish to proceed with the evaluation to find out if I may be a donor.

Printed Name of Potential Donor

______________________________  ____________________________
Signature        Date

Printed Name of Donor Team Member

______________________________  ____________________________
Signature of Donor Team Member        Date

Printed Name of Witness

______________________________  ____________________________
Signature of Witness        Date