



Hartford Hospital Liver Transplant Program

Informed Consent for Living Liver Donation Evaluation/Process

I have asked to be evaluated as a living liver donor in the Hartford Hospital Liver Transplant Program for the benefit of a patient with end stage liver disease. This individual's medical team has determined that the best treatment for him/her is to receive a liver transplant. He/she has been placed on the list for a deceased donor liver transplant. The purpose of this document is to enable me, the potential donor, to understand all aspects of the evaluation and donation process including the risks and benefits, the donation and transplant surgical procedure and the long-term outcomes after living donor surgery. This process is called informed consent.

I understand that all phases of the living donation process are performed in adherence to Hartford Hospital guidelines.

I am aware that I cannot be considered a suitable candidate for living liver donation until the evaluation process described below is completed and I have been accepted by the **Hartford Hospital Liver Transplant Program Multidisciplinary Living Liver Donor Team**. I also attest that I am doing this because I have a vital/significant, emotional relationship with my intended recipient, I am doing this of my own free will and there is no financial incentive or motivation for my decision to be evaluated as a liver donor.

I understand that I can choose to stop the evaluation and consent process at any time as my physical and emotional safety is of primary importance. I am aware that Hartford Hospital must provide me with an **Independent Living Donor Advocate (ILDA)**, whose only role is to assist me with the informed consent process and be my advocate during this evaluation. He/she may recommend that I not be a living donor if medical or psychosocial concerns arise during the evaluation process. I also have been informed that going through this evaluation does not guarantee that I will be able to be a donor.

I understand it is important that I provide, to the best of my knowledge, accurate and complete information about my past and present medical and psychosocial history to the my Living Liver Donor Team. I understand I must read, understand and sign this consent form for the process to go forward.

Liver transplantation from a living liver donor has two phases. The first phase is the medical and psychosocial evaluation as required by OPTN/UNOS guidelines and the second phase is the surgery itself that involves removing a portion of my liver and transplanting it into the potential recipient.

Patient initials_____



Evaluation Educational Process

I acknowledge that through my participation in meetings with the Living Liver Donor Team and the receipt of written educational materials and personal instruction from them regarding living liver donation and transplantation I will be educated on the following:

- (1) The donor medical and surgical evaluation process
- (2) The short and long-term risks and benefits for me.
- (3) The short and long-term risks for the recipient including the fact that the recipient may not survive even after receiving a portion of my liver.
- (4) The eligibility criteria to be a living liver donor
- (5) The testing involved in performing my medical, surgical and psychosocial evaluation
- (6) What makes a donor and recipient liver compatible –such as blood group, liver size
- (7) Alternative donor organ sources
- (8) That the recipient will be placed on the OPTN/UNOS liver transplant waiting list for a deceased donor organ and may be transplanted before my evaluation is complete or the transplant takes place. He/she will remain on the list if I am not able to be a donor (I have been told what the range of waiting times for the recipient may be)
- (9) The necessity of having many tests, procedures and meeting with members of the Transplant Team. I am aware I will have visits with other health care providers. All these consultations, tests and procedures will help the Team decide if being a living liver donor is the right decision for me. It will also help them determine if I am healthy enough to safely undergo the living donor surgery, which is considered major abdominal surgery.
- (10) That I must participate in an extensive educational process to prepare me and my family for the surgery, recovery and after care
- (11) Who my independent living donor advocate (IIDA) is and what their role is in my donor evaluation
- (12) The financial and insurance implications of being a living liver donor
- (13) That I may stop this evaluation process at any time

Independent Living Donor Advocate and Team Members

In order for my Donor Team to assess my health in a comprehensive and accurate manner, they require several things from me.

- Accurate and complete information
- Full disclosure of my history of any past or present smoking, drug and/or alcohol use
- I will be expected to report any changes in my physical or mental health
- I will be expected to report truthfully that I understand my plan of care and what is expected of me pre and post donation
- I will be expected to follow my treatment plan and the schedule recommended
- I will be expected to keep appointments or cancel and reschedule them in a timely manner
- I will be responsible for my actions and my decisions regarding donation

Patient initials_____



- I will be expected to report truthfully that I understand the financial aspects of being a liver donor-what is covered by the recipient's insurance, out-of-pocket costs to me and what my financial risks and liabilities may be

Donor Evaluation Testing

I have been informed that comprehensive testing is done to determine if I am a suitable liver donor.

I understand some of the following tests may be included in my evaluation process and other testing may be done on an as-needed basis depending on results of these tests. My risk of complications and death may be impacted by obesity, hypertension or other pre-existing conditions I may have.

- An initial work up will be done to determine if I can donate. This will include a health care assessment along with some blood and urine tests. I will also have a chest x-ray and EKG. If this testing is acceptable then I will enter the second phase of testing.
- An EKG, echocardiogram and possibly a nuclear stress test.
- A MRI/MRA/MRCP.
- A liver ultrasound
- An abdominal CT may be performed
- A liver biopsy may be needed
- If I have any other medical issues I may need some additional testing
- If I am overweight, I could be asked to lose weight.
- I also am aware I will have to be abstinent from alcohol, tobacco and all recreational drugs both before and after donation. If I am on oral birth control pills these will need to be stopped for a period of time prior to donation.
- After completing the evaluation process the members of the Multidisciplinary Living Liver Donor Team will meet to present my results and determine if I meet the Hartford Hospital selection criteria for living liver donation.

I understand that all potential donors are screened several times for communicable disease, high risk behavior and problems that may affect the donated organ and could affect both my health and the recipient's health. There can be unforeseen factors such as me having an undetected infectious disease, undetected malignancy/cancer or some other undetected disease that may affect the success of the transplant or the recipient's health. There is no guarantee to me or the potential recipient, that the evaluation process will uncover every potential communicable disease.

Psychosocial risks

I have been informed of the potential transient or permanent psychosocial risks of liver donation. I understand that my quality of life may be affected by donation. This can include, but is not limited to; insomnia, anxiety, depression, preoccupation with my overall health or my liver health, suicidal thoughts, body image issues, post-traumatic stress disorder (PTSD), feelings of guilt, emotional distress or bereavement if the recipient experiences complications, recurrent disease or even death. If I am

Patient initials_____



feeling anxious, overwhelmed or in any way emotionally distressed, I will reach out to my Donor Team for support and assistance. I am aware that my social worker, psychologist and others will be available for support should I or my family members need help.

I have been made aware that liver donation may not only affect my daily activities and life style but it can also affect my relationships. My relationship with the recipient or my family and friends can change following donation. Sometimes they become richer and more fulfilling, but there are instances where these relationships become strained and lead to estrangement or the ending of the relationship.

Risks of the Donor Evaluation

I understand that part of the evaluation process is intended to discover the possibility of present and future liver disease or other medical conditions. I understand that despite this evaluation, I still may develop liver disease or other illnesses within my lifetime that could require treatment. I have been informed of the inherent risks associated with the living donor evaluation including, but not limited to, an allergic reaction to contrast media, discovery of reportable infections, discovery of a serious medical condition, discovery of adverse genetic findings that were previously unknown to me and discovery of conditions/abnormalities that will require more testing, at my expense, or create the need for unexpected decisions on the part of the transplant team. I understand that a benefit of the donor evaluation may be finding out about health problems I do not know I have but may need treatment for. However, my ability to get health and life insurance in the future may be affected by finding out about these health problems.

Risks of Surgical Procedure

The surgery that I will have is called a **partial hepatectomy** (the surgical removal of a part of my liver) with removal of my gall bladder. This surgery is most commonly done to treat liver disease such as benign or cancerous liver tumors. Partial hepatectomy can be done safely. But with any major surgery, there are risks involved, even the risk of death.

I understand that if the surgical team believes that I am at any risk during the surgery or that the segment of my liver is not right for transplantation, the surgery will be stopped and I will be closed and returned to the post-operative recovery area. This happens in the United States in at least 5% of donor operations.

I understand that abdominal surgery carries many **general risks** that include; anesthesia complications, fever, pneumonia, urinary tract infections, bloating, nausea, ileus (slow or absent bowel activity), bowel obstruction or perforation, heart attack, arrhythmias, cardiovascular collapse, wound infection, numbness or discomfort at the incision site- which can become chronic, systemic infection, hernia development, intra-abdominal adhesions, nerve damage due to positioning, pain, fatigue, scars, diaphragm perforations, bleeding that may require blood transfusions and the risks involved with the use of blood or blood products, injury to other organs in the abdomen, fluid collection, blood clots in my legs that can

Patient initials_____



break free and move through the heart to my lungs (pulmonary embolism). I understand that a pulmonary embolism is a serious complication that can cause death. To prevent them I will be given a mild blood thinner prior to surgery and special mechanical boots or sleeves will be placed on my legs to try and prevent these dangerous blood clots.

I am aware I may need blood transfusions during the surgery. It may be possible to donate a few units of my own blood before surgery. However, I could require more blood than I banked. For this reason, I hereby agree to the use of any blood or blood products that my doctors think are necessary for my safety. I have been fully educated on the potential risks associated with such transfusions. Although all blood is screened for HIV, hepatitis and other infectious diseases, I am aware there is a small chance I could be infected with something that was not detected.

I also understand that there are also **specific risks** associated with liver surgery and particularly a partial hepatectomy and these include; bile leaks, bile duct stricture, technical complications involving the blood vessels in the liver, decreased liver function or failure that could require an urgent liver transplant and the possibility of death during or after surgery.

The most common complication after a partial hepatectomy is a bile leak. The chance of this happening is about 5-15%. Most bile leaks get better without another surgery and can be treated with an endoscopic procedure that places a plastic drain (stent) to decompress the area or a soft tube that diverts the leaking bile and allow the area to heal. Sometimes the bile is drained outside the body via a tube into a bag that is removed once the leak stops. Bile duct strictures (narrowing) can also occur after surgery, but are much less common. This can usually be treated by endoscopic placement of a stent that dilates the narrow area in the bile duct.

Based on national statistics, I understand my risk of having some type of complication, either major or minor, is approximately 15-40%. Most of these problems are minor and will get better on their own and rarely require a procedure or corrective surgery.

During the evaluation, the Donor Team will evaluate my liver function and size to determine if a piece of my liver can safely be donated, I understand between 25-60% of my liver may be removed. The doctors will determine what part of my liver will be donated. It will be either a left lateral lobe hepatectomy, a left lobe hepatectomy or a right lobe hepatectomy. I realize that in most cases for an adult recipient, the right lobe is used which is approximately 60% of the liver. I have been informed that removing a portion of my liver will temporarily decrease my liver capacity and function and that the potential for transient liver dysfunction depends on the total amount of my liver that is removed for donation. The remaining part of my liver will grow in a few weeks but usually not to its original size. I understand the blood vessels and bile ducts removed with not grow back and I cannot donate a portion of my liver a second time. I understand that I could develop liver failure after the donation surgery. This could require an emergency liver transplant for me or even death. This is a **very rare** complication and occurs in approximately 2 out of every 1000 (0.2%) living liver donor surgeries.

Patient initials_____



The Surgical Procedure

I understand that through my participation in meetings with the living donor team and reading the donor education notebook I will receive information on:

- 1.) The nature and purpose of the liver donor operation
- 2.) The risk and benefits of general anesthesia
- 3.) The estimated surgical time
- 4.) Post-surgical pain and options for pain control after surgery
- 5.) The estimated length of my hospital stay and estimated recovery time
- 6.) Post-operative restrictions and estimated time to return to full activities
- 7.) Medications I may be given, follow up testing and care post-donation to promote my recovery
- 8.) The reasonable foreseeable transient or permanent risks and consequences of liver donation surgery, including the fact that my surgery may not achieve the desired outcome

I have specifically been informed that there are potential medical, surgical, psychosocial and financial risks that can be transient or permanent. There are risks associated with any abdominal operation as well as certain specific risks associated with the liver donation surgery.

I will meet with my donor surgeon on at least two occasions. They will discuss the specifics of the surgery with me, estimated surgery time, the length of my hospital stay, post-operative restrictions and when I can return to normal activity levels. They will also review the potential risks and complications of liver donation with me. This will be documented in a consultation form that we will both sign.

During the transplant surgery I will be put under general anesthesia, which means I will be given medications to put me to sleep, block pain and paralyze parts of my body. I will also be placed on a ventilator (breathing machine) during the surgery. I will meet with an anesthesiologist for a consult prior to surgery and then again on the day of surgery. The anesthesiologist will go over a specific consent for anesthesia with me.

Post-Surgical Care and Recovery

After the surgery I will be taken to the intensive care unit where I will be closely monitored. I may still be on a machine to help me breathe and I will have many tubes and drains in place. Intermittent pressure boots or sleeves will be placed on my legs to prevent blood clots.

Immediately following the surgery, I understand I will experience pain. This will be carefully monitored and controlled. The goal of pain control is to keep me as comfortable as possible so I can move, take deep breaths and begin the recovery process. I may also be a little confused as a result of the medications.

Patient initials _____



When my medical condition has stabilized I will be transferred to the transplant floor. My length of stay in the hospital will depend on the rate of my recovery. I will remain in the hospital as long as my physicians feel hospitalization is necessary. Most patients stay in the hospital for a period of 4 to 7 days.

After I leave the hospital I will still be recovering. For the first 3 to 6 weeks I will continue to have some restrictions on my daily activities. Most donors say they are relatively pain free in 3 to 4 weeks, although this can vary from person to person. During the recovery period the donor team will closely monitor my progress. I can return to all of my pre-operative activities once my surgeon has cleared me to do so (usually at 8-12 weeks). I realize I will require life-long follow-up and should adopt a liver-healthy lifestyle. This include, but is not limited to, maintaining a healthy weight, avoiding excessive alcohol intake and yearly follow up checks with my primary care physician.

If I am a woman of childbearing age, I understand that donation cannot occur during a pregnancy. If there is any possibility that I am pregnant at any time during the evaluation, surgical admission or the recovery period, I will inform the Transplant Team immediately. I also understand that pregnancy is not recommended during the recovery period.

Recipient Benefits/ Outcomes

I understand that, by my donation, the recipient will receive certain benefits. These include; a scheduled transplant (some patients on the waiting list never receive an organ), the ability to have surgery at a selected date and time and, most importantly, a decrease in waiting time for the transplant compared with waiting for a deceased donor. I understand that there are additional risks for the recipient related to receiving a living donor liver transplant including receiving only a partial organ and that it is a technically more difficult operation.

However, I understand that in spite of the donation, the recipient may fail to regain his/her former health. They could die from a complication of the surgery, their original liver disease could return (for example cancer, hepatitis or substance abuse) or they could reject the liver. It is possible that the amount of liver transplanted would be insufficient for the recipient (small for size). They might need to be placed on the OPTN/UNOS wait list for another liver. During the waiting time, death may occur. This loss could have a lasting psychological effect on me and it is important that I have the coping skills and support to help me deal with this loss.

National and Transplant Center-Specific Outcomes for Adult Liver Transplantation

I have been informed and received information about national and Hartford Hospital Transplant Center specific data outcomes related to liver transplantation provided through the Scientific Registry for Transplant Recipients (SRTR). I have been informed as to whether the latest reported outcome measures

Patient initials_____



comply with Medicare outcome requirements. I am aware of the available national outcomes that pertain to living liver donors. *(See attached form for most current SRTR data)*

Financial Issues

I have been informed and understand the financial provisions for the liver donor evaluation, the coverage for the operation, associated hospitalization and recovery is based on the recipient's insurance. This will be shared with me prior to any decision making on my part. I have also been informed that there is a possibility that future health care problems I may experience related to donating a portion of my liver **may not be covered by my insurance** or, if covered, may affect my maximum lifetime benefits. If these problems are not covered by my health insurance, I may be responsible for all costs.

I understand that the medical evaluation or donation may impact my ability to obtain, maintain, or afford health, life and disability insurance; and there is a possibility of denial of coverage. Another potential financial impact of being a living donor may include the loss of employment or income and a negative impact on my ability to obtain future employment.

I understand that being a living liver donor may result in insurance companies considering me to have a pre-existing condition or be at higher or unacceptable risk for coverage. My health insurance and life insurance premiums may increase and remain higher and some, insurance companies could refuse to insure me.

I have been told that if the transplant surgery for which I am the donor, is not done at a facility that is approved by Medicare, Medicare may not pay for immunosuppressive drugs needed by the recipient post-transplant. I agree to inform the transplant team immediately both before and after the surgery of any insurance changes. I understand, if necessary, that my insurance may be billed by Hartford Hospital for a denial of claim before the recipient's insurance can be billed.

I have been advised that the National Organ Transplant Act (NOTA) of 1985, states it is a federal crime to receive any financial gain from organ donation. The penalty for this is a fine up to \$50,000 and five years in prison for any person who "knowingly acquires, receives, obtains or otherwise transfers any human organ for valuable consideration for use in human transplantation." Valuable considerations are anything considered to be of value-for example, cash, stocks, property or vacations. I understand that there are out-of-pocket expenses associated with the living donation process. This includes, but is not limited to, travel, housing, child care, lost wages. However, under the National Organ Transplant Act, if recipients are financially able, they are allowed to reimburse the donor for out-of-pocket expenses incurred during the donation process, including travel, housing, food and lost wages. Other resources may also be available to help defray my expenses.

Patient initials_____



I understand I will meet with a Transplant Financial Coordinator to review my specific insurance situation. They and the social worker will also be available to answer any financial questions or concerns I have on an ongoing basis.

Patient Relations

The Patient Relations Department at Hartford Hospital provides information to patients and their families about services at Hartford Hospital. They help people, like me, and their families interpret hospital policies and procedures, provide a formal mechanism for the investigation, resolution and recording of patient complaints and assure the observation of patient's rights, and handle certain special requests. I can reach the Patient Relations office at Hartford Hospital at (860) 972-1400.

I also have the right to notify the Organ Procurement and Transplantation Network at 1-888-894-6361, if I need further information or have any concern or grievance about the Hartford Hospital Transplant Program.

Follow Up

It is critical to my safety to attend follow up appointments at the Comprehensive Liver Center. This will allow my donor team to continually assess both my overall health and my liver health. If I proceed with the donation procedure, I agree to comply with the Hartford Hospital Transplant Program polices. I agree to return for follow up visits at a minimum of 3, 6, 12 and 24 months, even though this may require additional time and out-of-pocket expense. These appointments are necessary to monitor my health and obtain data for research. I am aware that post donation testing could reveal abnormal or false positive results that may trigger additional testing that have associated risks and cost.

I have been informed that it is required that the transplant program submit information related to my donation, the liver transplant and Living Donor Follow-Up forms to UNOS/OPTN at 6, 12 and 24 month post donation. This is required per OPTN/UNOS Policy 18.5. To obtain this information, they will contact me to arrange testing either at the transplant program or through my primary care physician. This testing includes, but is not limited to, blood pressure checks, lab work, liver imaging and a history and physical exam. I understand that the Hartford Hospital Living Donor Program will request reports from my primary care physician or other physicians involved in my healthcare be shared with them so they can monitor my health post donation and comply with these living donor data reporting obligations. I hereby authorize the Hartford Hospital Transplant Program to obtain these records indefinitely.

I understand that all records and communication between me and the Hartford Hospital Transplant Program, including all aspects of the evaluation and donation process, are confidential and protected by state and federal privacy laws. Such information shall only be used or disclosed as permitted under such laws and applicable hospital policy, or with my authorization.

Patient initials_____



I am aware that health information obtained during my evaluation will be subject to the same regulations as all medical records and could reveal conditions that the transplant program must report to local, state or federal public health authorities. I have been informed that any infectious disease or malignancy pertinent to the recipient's care that is discovered during my first two post-operative years will be disclosed to the recipient's transplant team. In cases of mandatory disease reporting, this would be reported to local, state and federal public health authorities. This will also be reported to the UNOS/OPTN Improving Patient Safety Portal.

I am aware that it is possible that my donated liver may not work and/or that the recipient may develop serious complications including death both during and after surgery. I am also aware that the reason that the recipient needs a liver transplant is that they have a serious medical condition and may have risks factors for increased morbidity or mortality that have not been disclosed to me.

I have been informed that it is not possible to list all potential complications related to the donor surgery and that my surgery may be terminated at any time, based on my clinical condition during surgery. I understand that if I am determined to be a suitable liver donor and I decide to continue with the donation process, the risks of surgery will be discussed with me again when I am meeting with the donor surgeon to sign the surgical consent for a living donor partial hepatectomy.

I understand what my expected post-donation liver function should be and how acute or chronic liver dysfunction/disease could potentially impact me.

At the end of this process, I understand I will receive either communication in-person or a formal letter of notification concerning my status indicating that either:

- a. I have been accepted as a living liver donor*
- b. I have been conditionally accepted and need to complete a specific course of action before being a donor*
- c. I am not an acceptable candidate for living liver donation and the reason(s) for this decision*
- d. I understand that if Hartford Hospital declines me as a potential donor, I may be evaluated by another transplant program that may have different selection criteria*

I attest that I have received all of the previously mentioned information from the Transplant Team, as well as, a copy of this document. I have been provided an opportunity to read the information and ask questions. I understand the information that has being provided to me.

Finally, I affirm that I am willing to proceed with the living donor evaluation process and am free from inducement and/or coercion. I understand the purpose, benefits, risks and alternatives to live liver donation and recipient transplantation. I understand there is no medical benefit to me by having this

Patient initials_____



6816

surgery, and that no guarantee has been made to me concerning the success of the transplant surgery for the recipient. I again state I am aware that at any point during the evaluation or prior to surgery, I am free to decide, for any reason, that I no longer wish to become a donor and can withdraw my consent and end this process in a way that is protected and confidential.

Signatures

Donor Signature _____ Date/Time _____

Donor Surgeon Signature _____ Date/Time _____

Printed Name _____

Donor Coordinator Signature _____ Date/Time _____

Printed Name _____

Patient initials _____