Informed Consent for Liver Transplant Patients

Evaluation Process

You will be evaluated with consultations, lab tests and various procedures to determine the medical appropriateness of liver transplant. You will meet with many members of the transplant team who may include:

- The **Transplant Coordinator** provides education regarding the transplant evaluation process, listing for transplant and patient responsibilities before and after transplant. This meeting is intended to provide you with an opportunity to ask questions and to become fully informed about the liver transplant process.

- A **Hepatologist** is a physician who specializes in liver disease. The hepatologist will assist in the medical management of your liver disease and work with the transplant team to determine if you are medically suitable for a transplant.

- A **Transplant Surgeon** will meet with you and discuss the appropriateness of a transplant based on the information obtained during your evaluation. The surgeon will also discuss the significance of undertaking a liver transplant, the various types of livers available, and the risks of the surgery and the possible complications after your transplant.

- An **Anesthesiologist** will meet with you and review your medical records to determine the need for any additional workup to determine your risk from anesthesia.

- A **Social Worker** will meet with you to evaluate your ability to cope with the stress of transplantation and your ability to follow a rigorous treatment plan, both before and after transplantation. The social worker will also help to identify your support network.

- A **Financial Coordinator** will discuss the costs associated with your transplant and with the medications you will require after transplant. They will work with you to help you understand your insurance coverage. It is important that you understand the costs that may not be covered by insurance.

- A **Psychiatrist/Psychologist** may conduct a more in-depth evaluation and assessment. Some patients with a history of drug or alcohol abuse may be required to participate in a rehabilitation program as well to meet abstinence requirements prior to and after transplant listing.

- A **Registered Dietitian** may perform a nutritional assessment and provides nutrition education to patients.

- Some patients may be referred to another service for consultation. For example, many patients need to be seen by a nephrologist (kidney doctor), pulmonologist (lung doctor), or a cardiologist (heart doctor) to assess for other medical conditions.

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Many different tests are done to determine if you are a suitable transplant recipient. Some of the following tests may be included in your evaluation process. Remember, other tests may need to be done based on the results of these tests.

- Blood tests help to determine the extent and/or cause of your liver disease. Other tests will determine your blood type for organ matching and screen for your immunity to or the presence of specific viruses, including HIV. Additional blood tests may be used to determine how well other organs are functioning.

- A chest x-ray helps your physician identify any problems with your lungs.

- A urine test is used to screen for the presence of urinary tract diseases as well as drugs and alcohol in your system.

- An EKG, echocardiogram and/or stress test will show how well your heart is beating and the function of your heart valves. This will help your physicians decide if your heart function is strong enough for transplant surgery.

- A CT scan or MRI determines the extent of your liver disease, the presence of any tumors, and verifies the circulation to your liver.

- A liver biopsy may be requested by your transplant team. During a liver biopsy a needle will be used to remove a tiny portion of your liver. This is an outpatient procedure. A microscopic examination of the tissue will provide information to your physicians regarding the cause and severity of your liver disease.

- An ultrasound of your liver and abdomen helps assess the size, shape, and circulation of your liver.

- Pulmonary function tests may be required; especially if you have a history of smoking or a history of lung disease. This is a breathing test to analyze your lung capacity.

Surgical Procedure

Liver transplantation is a life-saving therapy; however, the potential benefits cannot result from surgery alone and are dependent upon you following the rigorous treatment plan prescribed by your physicians. You must be aware of the potential risks and complications outlined in this document that can result in serious injury, and death. Your physicians cannot predict exactly how your body will respond to a liver transplant. It is never fully known how the condition that caused your underlying liver disease will affect your transplanted liver. The operation is complex and the risks are high. The overall success rate, roughly defined as the patient surviving with the transplant liver for at least one year, is about 85-90%. In other words, the chance of dying following a liver transplant is about 10-15% in the first year. The success rate varies according to how sick the patient is prior to the transplant surgery with sicker patients having a lower chance of a successful outcome.

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Livers are allocated according to the policy of United Network for Organ Sharing (UNOS). The livers are primarily allocated according to how sick a patient is. Being placed on the waiting list for a liver transplant does not guarantee the availability of a liver or receiving a transplant.

The Transplant Operation

When a donor organ becomes available, you will be called and you must come to the hospital right away. If the organ is considered an extended criteria organ your surgeon will review this with you and assist you in making your decision. It is at this point that the surgeon has a clear picture of the risks associated with this particular organ versus the risk of waiting for the next available donor and can base the specific recommendations on this information. You always have the option to decline an organ.

During the transplant surgery you will be put under general anesthesia, which means you will be given medications to put you to sleep, block pain and paralyze parts of your body. You will also be placed on a machine to help you breathe. The anesthesiologist will talk with you in more detail about the risks of anesthesia. The transplant surgeon will make an incision in your abdomen. Through this incision your liver and gallbladder will be removed and a donated liver graft (without a gallbladder) will be placed into your abdomen.

During the surgery you may be placed on veno-veno bypass. If this is required, your surgeon will make an incision in your underarm or neck and groin for the placement of intravenous tubes. These tubes will be connected to a machine that will allow your blood to bypass your liver during surgery. The transplant surgeons will decide if this machine will be used based upon your condition.

Drains will be put into your body to allow fluids to be removed and to help you heal. Special mechanical boots or sleeves around your legs will be used to keep blood flowing through your legs to try to prevent dangerous blood clots. You will be in the operating room approximately 4-12 hours.

Post-Surgical Care and Recovery

After the surgery you will be taken to the intensive care unit where you will be closely monitored. You will be on a machine to help you breathe and you will have many tubes and drains in place. Intermittent pressure boots or sleeves around your legs will be used to prevent blood clots.

Immediately following the surgery, you will experience pain. This will be carefully monitored and controlled. Most transplant recipients have a significant reduction in the pain two to three weeks after surgery.

When your medical condition has stabilized you will be transferred to the transplant floor. Your length of stay in the hospital will depend on the rate of your recovery. You will remain in the hospital as long as your physicians feel hospitalization is necessary. Most patients stay in the hospital for approximately one week. The hospitalization time

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can vary depending on the severity of your illness prior to transplant or complications after surgery.

After you leave the hospital you will still be recovering. For the first 4-6 weeks you will have some restrictions on your daily activities. If you experience any post-operative complications your recovery time may be longer. During the recovery period the transplant team will follow your progress. You will need to be monitored on a long-term basis and you must make yourself available for examinations, laboratory tests and scans of your abdomen to see how well your transplanted liver is working. Biopsies may be done routinely and as needed to diagnose possible complications including rejection or recurrent liver disease.

The transplant team will see you regularly for three to six months post transplant. Every effort is made to transition your routine medical care to your primary care physician. You will be followed in the transplant clinic for life. For most patients this involves frequent lab work and a yearly clinic visit. Patients who develop complications may need to be seen more often by the transplant team.

Alternative Treatments

Alternative treatments or therapies may be available for your medical condition. Please discuss your condition and any possible alternative therapies with your health care team.

Potential Medical/Psychosocial Risks

There are inherent risks in all surgeries, especially surgeries conducted under general anesthesia. Many complications are minor and get better on their own. In some cases, the complications are serious enough to require another surgery or medical procedure.

Bleeding during or after surgery may require blood transfusions or blood products that can contain bacteria and viruses that can cause infection. Although rare, these infections include, but are not limited to, the Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

There may be a delay in the function of your transplanted liver. Such a delay may increase the length of your hospital stay and increase the risk of other complications. There is a possibility that the transplanted liver will not function. When this occurs a second transplant is needed. You will be placed on the UNOS waitlist in the highest priority category allowed. If a second liver does not become available death may occur.

The chance of primary non-function (liver not working right after surgery) is about 3%. Re-transplantation is required emergently for cases of primary non-function.

Hepatic artery thrombosis occurs in a small percentage of liver transplants. This is a clot that develops in one of the major blood vessels going to your liver. Hepatic artery thrombosis can cause liver failure, liver abscesses and/or biliary strictures. Most patients that develop hepatic artery thrombosis will require a second operation; some will require re-transplantation.

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Some patients experience biliary complications such as leaks and strictures (narrowing). Most bile leaks get better without the need for surgery. Occasionally, tubes need to be placed through the skin to aid in the healing process. In some cases surgery is necessary to correct the bile leak. Some transplant patients have a long term complication of biliary strictures. A biliary stricture is a narrowing of the ducts transporting bile. Some of the strictures can be repaired by non-surgical means such as insertion of tubes, but some will require surgical repair.

Your original disease may recur after transplant. Diseases that may recur include autoimmune disease, hepatocellular carcinoma (HCC), and Hepatitis B. For certain diseases, such as hepatitis C, recurrence is universal. Sometimes a second transplant may be indicated. Unfortunately some patients may not be appropriate candidates for a second transplant. In certain incidences, we may elect to use for transplantation livers from donors who had a history of hepatitis B or C. We generally offer these livers to recipients who already have a diagnosis of hepatitis B or C.

There are other risks associated with liver transplants. Infections from bacteria, viruses, or fungi, acute rejection, side-effects from drugs that suppress the immune system are all possible complications. Side-effects from immune-suppressing drugs include kidney problems, gastrointestinal complaints, blood count abnormalities, nerve damage, high blood pressure, weight gain, diabetes, and others. There may be a need for repeated liver biopsies, surgeries, and other procedures, or a prolonged intensive care unit or hospital stay after a liver transplant.

There is a slight increase in the risk of certain kinds of cancer (including skin cancer and post-transplant lymphoproliferative diseases or lymphoma) because of the immunosuppressive medications.

Miscellaneous risks:

Despite the use of compression boots, blood clots may occasionally develop in the legs and can break free and occasionally move through the heart to the lungs. In the lungs, they can cause serious interference with breathing, which can lead to death. Blood clots are treated with blood-thinning drugs that may need to be taken for an extended period of time.

The risk of infection is higher for transplant recipients than other surgical patients because the treatments needed to prevent organ rejection make the body less capable of fighting infection. Also, liver disease itself decreases the body's ability to fight infection. The abdominal incision for the liver transplant and any incision needed for the liver bypass machine (neck, underarm, and groin) are potential sites for infection. Infections in the sites where tubes are placed in your body (tubes to help you breathe, tubes in your veins to provide fluids, nutrition and to monitor important body functions) can cause pneumonia, blood infections and local infections.

Damage to nerves may occur. This can happen from direct contact within the abdomen or from pressure or positioning of the arms, legs or back during the surgery. Nerve damage can cause numbness, weakness, paralysis and/or pain. In most cases these

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symptoms are temporary, but in rare cases they can last for extended periods or even become permanent.

Other possible complications include: injury to structures in the abdomen, pressure sores on the skin due to positioning, burns caused by the use of electrical equipment during surgery, damage to arteries and veins, pneumonia, heart attack, stroke, and permanent scarring at the site of the abdominal incision.

National and Transplant Center-Specific Outcomes

National Statistics from the Scientific Registry of Transplant Recipients (SRTR) (www.ustransplant.org) show that one year after transplantation approximately 89% of liver transplant recipients are alive and approximately 79% are alive 3 years after transplant. The donated liver (the "graft") is functioning approximately 85% of the time at 1 year after transplant and approximately73% of the time at 3 years after transplant. The results at Jackson Memorial Hospital meet or exceed these standards and do not significantly differ from the expected survival rates and comply with Medicare's outcome requirements. You will be provided a copy of our actual results in clinic. New results are published every January and July.

Notification of Medicare Outcome Requirements not Being Met by Center

Specific outcome requirements need to be met by transplant centers and we are required to notify you if we do not meet those requirements. Currently, Jackson Memorial Hospital meets all requirements for transplant centers.

Organ Donor Risk Factors

Certain conditions in the donor may affect the success of your liver transplant such as the donor's history and the condition of the organ when it is received in the operating room for your surgery. Additionally, there is a potential risk that you may contract HIV and other infectious diseases if they cannot be detected in the donor.

Right to refuse transplant

You have the choice not to undergo transplantation. If you choose not to have a transplant, treatment for your liver disease will continue. If you do not undergo the transplant surgery, your condition is likely to worsen and limit your life expectancy.

Transplantation by a Transplant Center Not Approved by Medicare

If you have your transplant at a facility that is not approved by Medicare for transplantation, your ability to have your immunosuppressive drugs paid for under Medicare Part B could be affected.

After you have a liver transplant, health insurance companies may consider you to have a pre-existing condition and refuse payment for medical care, treatments or procedures. After the surgery, your health insurance and life insurance premiums may increase and remain higher. In the future, insurance companies could refuse to insure you.

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Waiting Time Transfer and Multiple Listing

Once listed for transplant, you have the option of being listed for transplant at multiple transplant centers and the ability to transfer your waiting time to a different transplant center without loss of the accrued waiting time.

Concerns or Grievances

The United Network for Organ Sharing provides a toll-free patient services line to help transplant candidates, recipients, living donors, and family members understand organ allocation practices and transplantation data. You may also call this number to discuss a problem you may be experiencing with your transplant center or the transplantation system in general. The toll-free patient services line number is 1-888-894-6361.

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I have provided this information to the prospective liver transplant patient.

Nurse Coordinator: _____ Date: _____

Patient: _____ Date: _____

Family Member: _____ Date: _____

Relationship: _____ Date: _____

Physician: _____ Date: _____