This document explains the process of having a liver transplant evaluation and being placed on the waiting list. It is important that you read and understand this document, in order to provide informed consent to proceed with evaluation and potential listing for liver transplant. Signing this document does NOT mean that you are being placed on the wait list for liver transplant, however it indicates that you have been educated on the process of evaluation, listing, and liver transplantation.

**Evaluation Process:**
An evaluation for a liver transplant involves having many tests, procedures, and visits with many members of the transplant team. This is necessary to determine if liver transplant is the right treatment for you.

**Transplant Team Members:**
The **Transplant Coordinator** provides education regarding the transplant evaluation and listing processes, and reviews your responsibilities before and after transplant. They will also manage your evaluation schedule and follow up on your testing results.

A **Transplant Surgeon** will meet with you to discuss the significance of having a liver transplant, the transplant procedure: including the risks of the surgery and the possible complications after your transplant. Your evaluation testing results will be reviewed to determine your medical recommendations.

A **Transplant Hepatologist** will meet with you and discuss the disease processes that have contributed to your liver failure and will manage your medical care. They will assess your past and current medical conditions, review testing results, and determine if additional evaluation testing is needed to assess if you are a candidate for liver transplant.

A **Transplant Midlevel Provider (Physician’s Assistant or Nurse Practitioner)** will meet with you during your evaluation to help manage your medical care. They will assess your past and current medical conditions, review testing results, and determine if additional evaluation testing is needed to assess if you are a candidate for liver transplant.

A **Social Worker** will meet with you to evaluate your social support system, your coping ability, and your past psychosocial history. You will need to identify a primary care partner, or someone to support you before and after transplant. Their responsibilities will be reviewed with you by the social worker.

A **Financial Coordinator** will meet with you to discuss your insurance and prescription drug coverage, out of pocket costs and will assist with any financial concerns or needs that may arise.

A **Transplant Dietitian** will meet with you and assess your nutritional status. If you are overweight or underweight, our transplant dietitian will counsel you regarding healthy habits to improve your nutritional status.

You may also need to be seen by other consulting services such as (but not limited to): a nephrologist (kidney doctor), pulmonologist (lung doctor), or a cardiologist (heart doctor), to assess other medical conditions before determining your candidacy for liver transplant.

Please initial indicating you understand the above information and have had an opportunity to get your questions answered.

*Patient Initials: __________*  *Date: ____________ Time: ________*
Tests and Procedures:
Some of the following tests may be included in your evaluation process to help determine if you are a candidate for liver transplant. 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 performed include determining your blood type for organ matching and screening tests for immunity to or the presence of specific viruses, including HIV. Additional blood tests may be used to determine how well other organs are functioning.

- You will also have an HIV or AIDS blood test.
  1. AIDS, or Acquired Immune Deficiency Syndrome, is a disease that causes the body to lose its natural immunity to certain infections.
  2. AIDS is caused by the HIV virus. The HIV virus can be transmitted from person to person through sexual contact, exposure to or sharing of contaminated intravenous needles and through exposure to infected blood or its components. Certain behaviors, including sharing drug needles, practicing unprotected sex (without a condom) or any exchange of infected blood, semen or vaginal fluids, increases a person’s risk of acquiring HIV.
  3. When infected by a virus, the body produces substances called antibodies to fight off the infection. The blood test shows if you have antibodies to HIV, the virus that causes AIDS.
  4. A screening test (called the ELISA test) will be performed on a sample of your blood. If that test shows that you have HIV antibodies, an additional confirmation test (called the Western Blot) will be done on the same blood sample to make sure the first test was correct.
  5. Accuracy and reliability of the HIV test is uncertain. (HIV antibody testing is considered to be quite accurate but not 100%). A negative test means that you are probably not infected with the virus, but does not conclusively exclude the possibility of infection with the virus. A positive test usually means you have been exposed to the virus but does not mean you have AIDS or will develop AIDS in the future. In addition, false positives may occur. Your physician or designee will notify and explain the results to you.
  6. State law requires newly identified positive HIV test results to be reported to the state Department of Health. Saint Luke’s Health System, to the best of its ability, will not disclose the results of these tests to others except to the extent required by law.

- 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 assist your physicians in deciding if your heart function is strong enough for transplant surgery. Depending on the results, some patients may require further testing (cardiac catherization).

Please initial indicating you understand the above information and have had an opportunity to get your questions answered.
Patient Initials: __________ Date: ____________ Time: __________
An ultrasound of your liver and abdomen helps us know the size, shape, and blood supply to and from your liver. It also checks for the presence of any tumors in the liver.

A CT scan or MRI of the abdomen helps determine the extent of your liver disease, the presence of any tumors, and checks the blood supply to and from your liver.

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

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 how well your lungs are working.

**Decision Making Process:**
After you have completed all of the tests the physicians request, your case will be discussed by the entire team, at the Liver Transplant Selection Meeting. The decision about your need for a liver transplant and your overall suitability to undergo a liver transplant will be decided by the team – no one person makes the decision. We will consider the medical, surgical, financial, and psychological aspects of your case.

**Selection Criteria:**

**Indications for a Liver Transplant**
- Advanced liver disease (cirrhosis) with complications or decompensation.
- Acute liver failure – sudden failure of the liver in a patient who did not have chronic liver disease.
- Hepatocellular carcinoma – Unresectable primary tumor of the liver, within Milan criteria.
- Patients with other types and stages of liver cancer are considered for transplantation on a case by case basis.
- Primary graft failure – failure of a liver transplant within a few days of a transplant.
- Incapacitating or life threatening complication that would be improved or eliminated with transplantation.
- Medically suitable for surgery

**Relative Contraindications to Liver Transplant**
- Extrahepatic malignancy – cancer that has spread outside the liver
- Intrahepatic infections – infections within the liver
- Multiple uncorrectable congenital anomalies – abnormal anatomy since birth
- Severe hypoxemia due to right to left shunting - lack of enough oxygen due to severe lung damage
- Pulmonary hypertension – very high pressure in the blood vessels between the heart and the lungs
- Age > 70 years
- Inadequate financial resources
- HIV positive persons
- Body mass index > 35 percent which is obese
- Re-transplantation – a second transplant
- Recent history of substance abuse

*Please initial indicating you understand the above information and have had an opportunity to get your questions answered.*

*Patient Initials: __________ Date: ____________ Time: ________

Patient Label
Absolute Contraindication to Liver Transplant

- Active alcohol / substance abuse
- Uncontrolled extra hepatic sepsis – uncontrolled severe infection outside the liver
- Advanced Cardiopulmonary Disease – severe heart and/or lung disease
- Inadequate support mechanisms
- AIDS
- Active non-adherence – failure to follow the teams recommendations on any aspect of your care such as diet, exercise, appointments, medications

Waiting List:
Being placed on the waiting list for a liver transplant does not guarantee the availability of a liver or receiving a transplant. There is a chance that while you are waiting for a liver to become available you may become too sick to undergo the liver transplant surgery. Some of the complications that may arise while awaiting a liver transplant are:

- Encephalopathy - With severe liver disease, toxic substances normally removed by the liver, collect in the blood affect the function of brain cells. This can cause confusion, loss of memory, or changes in mood and behavior. In severe cases, it can result in coma.

- Ascites- When the liver is damaged, fluid may collect in places such as the belly. This can happen as a result of increased blood pressures within and around the liver due to liver scarring. This can become severe enough that we will need to remove some of the fluid with a needle, with a special procedure called a paracentesis. Removing this fluid will only temporarily resolve the ascites and symptoms, until it re-accumulates.

- Spontaneous Bacterial Peritonitis – This occurs when the build up of fluid [ascites] in the abdomen becomes infected. If you develop pain in your abdomen, fever, mental confusion and generally do not feel well, you should contact your doctor or coordinator for advice. This is a very serious complication, which usually needs urgent medical attention.

- Variceal bleeding- Liver failure can cause increased pressure in one of the main veins of the liver. This causes the development of large, swollen veins (varices) within the esophagus [food pipe] and stomach. The varices can rupture or burst easily, causing a large amount of blood loss. This is a medical emergency and you should call 911 immediately if you vomit blood or pass a large amount of blood in the stool.

- Hepatorenal Syndrome- Liver disease can cause decreased kidney function. Usually kidney function will get better when your liver function improves after liver transplant. In rare cases, if you have to be on kidney dialysis for a long period of time before your liver transplant, your kidneys may not get better.

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Patient Initials: __________ Date: ____________ Time: ________
Re-evaluation While on the Waiting List:
You will be followed very closely while on the waiting list. It is important that you keep all your appointments, take all medications as prescribed, follow the recommended diet and exercise program, maintain your health insurance, and comply with our recommendations regarding alcohol and other drug use. There is a chance that while awaiting a liver to become available you may become too sick to undergo a liver transplant surgery.

Clinic Visits and Blood Tests:
All transplant candidates have routine follow-up visits/physical examinations in the pre-transplant clinic as necessary according to your Model for End Stage Liver Disease (MELD) score and medical status. Education will be continued on each visit based on individual patient needs. Medication lists and history of present illness will be updated with each visit. Your compliance with your appointments is critical to keep your status on the waiting list.

Other Tests and Consultations:
Regular screening of the abdomen with ultrasound, CT scanning or MRI imaging may be done every 6 months to a year, as patients with cirrhosis are at higher risk for developing liver cancer. For those already diagnosed with a liver cancer (hepatocellular carcinoma or HCC) a CT scan or abdominal MRI is done every 2-3 months. Patients who have a TIPS (transjugular intrahepatic portosystemic shunt) which is a device that is sometimes placed in the liver to improve blood flow, an abdominal sonogram with doppler study may be required every 3-6 months for the first year of the TIPS placement, then based on the medical status of the patient. Cardiology evaluation and follow-up may be done every year or more frequently for those with pulmonary hypertension and/or cardiac disease.

Hospitalization Outside Saint Luke’s Hospital:
Any surgeries, hospitalizations, and changes in medical status should be reported to your transplant coordinator immediately. If hospitalized in another institution, you must make sure to have your doctor in charge of the care call us to inform us about your medical status. They may want to transfer you to Saint Luke’s Hospital. This is critical information that enables us to fully participate in your medical care. Ideally, if you require hospitalization we would like it to be at Saint Luke’s Hospital, so we can watch your liver condition carefully.

Healthy Life Style:
While waiting for a liver transplant, it is important to maintain your overall health by eating a proper diet (low salt), exercising, not smoking, not drinking any alcohol at any time, taking your prescribed medications, and seeing your regular doctors (dentist, gynecologists, primary doctors, gastroenterologists, etc.). Medical care of transplant candidates is a collaborative effort between the patient, their family, transplant team and the referring/primary care physician. As the patient, YOU are the most important member of the team!

Demographic Information:
It is very important that we have current and correct contact numbers for you. On each visit, you must review your contact information with us. If any of your information changes, you must call us immediately. If we do not have correct contact information to reach you, you may miss out on a liver offer.

Please initial indicating you understand the above information and have had an opportunity to get your questions answered.

Patient Initials: __________ Date: ____________ Time: ________
Health Insurance:
Your Financial Coordinator is verifying health insurance coverage and will discuss with you any out of pocket costs associated with the transplant process and medications following your transplant. It is important that you maintain uninterrupted insurance coverage and do not let it lapse while awaiting your liver transplant. If you change companies or lose insurance there may be a delay in your ability to be transplanted. Please discuss any possible changes with your Financial Coordinator before you actually make the change.

Organ Donor Risk Factors:
With so many people waiting for liver transplants, there is an effort in this country to consider and use all possible donor organs. 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. All potential organ donors undergo extensive testing prior to donation. Donors are tested so we know how well their liver is working. They are also tested to see if they have any infections or cancer. Even with this testing, there is a potential risk that you may contract infectious diseases or cancer if they cannot yet be detected in the donor. Additionally, the Center for Disease Control and Prevention (CDC) has defined some organ donors as High Risk Donors based on their history which may suggest socially high risk behaviors.

High Risk Organ Donors:
You may be offered a liver from a donor who has been deemed “high risk for viral transmission” This type of donor had been identified by the Center for Disease Control (CDC) guideline as potentially being at high risk for transmitting HIV, the virus that causes AIDS. The following is a list of the reasons why a particular donor is deemed high risk.

1. Men who have had sex with another man in the preceding 5 years.
2. Persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 5 years.
3. Persons with hemophilia or related clotting disorders who have received human-derived clotting factor concentrates.
4. Men and women who have engaged in sex in exchange for money or drugs in the preceding 5 years.
5. Persons who have had sex in the preceding 12 months with any person described in items 1-4 above or with a person known or suspected to have HIV infection.
6. Persons who have been exposed in the preceding 12 months to known or suspected HIV-infected blood through percutaneous inoculation or through contact with an open wound, non-intact skin, or mucous membrane.
7. Inmates of correctional systems. (This exclusion is to address issues such as difficulties with informed consent and increased prevalence of HIV in this population.)
8. Persons whose history, physical examination, medical records, or autopsy reports reveal other evidence of HIV infection or high-risk behavior, such as a diagnosis of AIDS, unexplained weight loss, night sweats, blue or purple spots on the skin or mucous membranes typical of Kaposi's sarcoma, unexplained lymphadenopathy lasting greater than 1 month, unexplained temperature greater than 100.5 F (38.6 C) for greater than 10 days, unexplained persistent cough and shortness of breath, opportunistic infections, unexplained persistent diarrhea, male-to-male sexual contact, sexually transmitted diseases, or needle tracks or other signs of parenteral drug abuse.

Please initial indicating you understand the above information and have had an opportunity to get your questions answered.

Patient Initials: __________ Date: __________ Time: ________

Patient Label
High Risk Organ Donors (continued):
The transplant coordinator on call will identify the donor as high risk and discuss the donor history with you before you are asked to make a decision about accepting the organ for transplant. If you refuse the organ, it will not affect your status on the UNOS waitlist.

Allocation of Donor Livers:
Deceased donor livers are allocated according to the policy of United Network for Organ Sharing (UNOS). One of the main responsibilities of UNOS is to develop and implement new policies that will ensure that limited donor organs are allocated to patients that are medically in the greatest need of a liver transplant. Deceased donor livers are primarily allocated according to how sick a patient is. The MELD scoring system was developed as a way to identify how sick a person with liver disease is. It essentially predicts the likelihood of death within 3 months for people with end-stage liver disease. The idea behind MELD is that livers will be allocated more fairly because they will go to the sickest patients first or the most in need first. Time on the waiting list plays a much lesser role than it used to.

A MELD score is calculated based on certain labs values.

- Total Bilirubin-this is the main indicator of the liver’s ability to rid the body of toxins. An increase bilirubin level in the bloodstream is what makes the skin and eyes appear yellow (jaundiced). Elevations in bilirubin may cause to you itch. Normal range for total bilirubin is 0.1-1.2 mg/dl.

- Creatinine-is the end product of metabolism used to monitor kidney function. This value increases when kidney function decreases as the result of advanced liver disease. Factors such as bleeding and fluid shifting due to liver disease and diuretic therapy put stress on the kidneys. Most often this is corrected following liver transplantation. The normal range for creatinine is 0.6-1.2 mg/dl

- INR-this is a laboratory value that is used to help determine the liver’s ability to make clotting factors and it assesses the patient’s risk for bleeding. If elevated or prolonged, it is an indication that liver disease is progressing. Normal INR range is less than 1.2.

Your Meld score will be reassessed and recertified with UNOS based on the following schedule. It is very important that these labs are updated in time to follow the appropriate schedule for your current MELD score. If you do not get your blood tests done at the appropriate times, you will not maintain your current status on the UNOS waiting list.

Please initial indicating you understand the above information and have had an opportunity to get your questions answered.

Patient Initials: __________ Date: __________ Time: _______
Allocation of Donor Livers (continued):

### Adult Candidate Reassessment and Recertification Schedule

<table>
<thead>
<tr>
<th>Status</th>
<th>Recertification Schedule</th>
<th>Laboratory Values Must Be No Older Than</th>
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<tr>
<td>Status 1 A</td>
<td>Every 7 days</td>
<td>48 hours</td>
</tr>
<tr>
<td>MELD Score 25 or greater</td>
<td>Every 7 days</td>
<td>48 hours</td>
</tr>
<tr>
<td>MELD Score &lt;= 24 but &gt; 18</td>
<td>Every 1 month</td>
<td>7 days</td>
</tr>
<tr>
<td>MELD Score &lt;= 18 but &gt;= 11</td>
<td>Every 3 months</td>
<td>14 days</td>
</tr>
<tr>
<td>MELD Score &lt;= 10 but &gt; 0</td>
<td>Every 12 months</td>
<td>30 days</td>
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</tbody>
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**Hepatocellular Carcinoma (HCC):**
If you have a liver tumor, you will be required to have a CT or MRI repeated every couple of months as directed by your Transplant Coordinator. Depending on the size and number of tumors you have, you may be eligible for prioritization on the UNOS waiting list. This can give you a higher priority than your MELD score calculated using your lab results. If you do not repeat your scans as scheduled, you will not maintain your current status on the waiting list. It is necessary for many patients to undergo treatment for the tumor while they wait for a liver transplant. It is possible that the size or number of your tumors will increase and you may no longer meet the indications for a liver transplant at our center.

**Source of Organs:**

**Organs From Brain Dead Donors:**
Brain dead donors are maintained on a breathing machine so the heart continues to beat and maintain blood flow in the body.

**Organs From Donors Who Die of a Cardiac Death:**
A Donation after Cardiac Death or DCD liver is a liver from a donor who has died of a cardiac death or heart death. This means the heart has stopped beating, they are not on a breathing machine and blood flow has stopped. Livers may be used from donors whose heart has stopped beating. This means there is no blood circulating through the liver for a short period of time before it is recovered. Many of these livers can function very well; however, there is an increased risk of certain complications after the transplant. Your doctor will discuss the risks and benefits of considering this type of organ with you and together you will make a decision.

Please initial indicating you understand the above information and have had an opportunity to get your questions answered.

Patient Initials: __________ Date: ____________ Time: ________
The Organ Offer:
When a donor liver becomes available we will contact you and discuss the offer with you. We will make a decision together. If you accept the liver, you will most likely need to come to Saint Luke’s Hospital immediately. If the liver is from an extended criteria donor your surgeon will review this with you and assist you in making your decision. If the liver is from a High Risk Donor 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 of this particular organ versus the risk of waiting for the next available donor liver. You always have the option to decline an organ offer. If the organ is determined to be unusable once we see it, you will be discharged home. You will remain on the UNOS waiting list for future liver offers.

The Transplant Operation:
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 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 anesthesia prior to the surgery.

Once you are asleep, IV lines and a urinary catheter will be placed. You will have a tube placed through the nose to the stomach to drain the contents of the stomach and prevent vomiting.

The transplant surgeon will make a relatively large incision in your abdomen. Through this incision your liver and gallbladder will be removed and the donated liver graft - without a gallbladder - will be placed into your abdomen.

During the surgery you may be placed on veno-veno bypass. This allows the blood to bypass the liver during the surgery. If this is required, the surgeon will place catheters into the big vein in your neck and groin. These tubes will be connected to a machine that will allow your blood to bypass your liver during surgery. It is normal to have some blood or fluid loss after the surgery.

Special mechanical boots or sleeves will be placed around your legs to keep blood flowing through your legs to try to prevent dangerous blood clots.

You will be in the operating room approximately 3-6 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 in an ICU setting for the first couple of days until you have recovered from the anesthesia, your liver is working and there are no signs of complications.

Immediately following the surgery, some pain and discomfort is normal. The nursing staff will be carefully monitoring this and will be giving you medication to control it. Most transplant recipients have a significant reduction in the pain within two to three days after surgery. Getting out of bed and starting to walk will greatly help.

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 7-10 days. The hospitalization time can vary depending on the severity of your illness prior to transplant or complications after surgery.

Please initial indicating you understand the above information and have had an opportunity to get your questions answered.
Patient Initials: __________ Date: __________ Time: ________
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 very closely. 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 of your liver may be done as needed to diagnose possible complications including rejection or recurrence of your original 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 clinic visit every 6-12 months. Patients who develop complications may need to be seen more often by the transplant team.

**Alternative Treatments:**
Alternative treatment 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:**
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 the physicians and multidisciplinary team. However, even then, there are risks and complications to having a liver transplant. You should be aware of the potential risks and complications outlined in this document that can result in serious injury, and even 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 itself is complex and the risks remain high for many patients. 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.

**General Surgical Risks:**
There are risks associated with 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).

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

Other possible complications include but are not limited to: 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.

*Please initial indicating you understand the above information and have had an opportunity to get your questions answered.*

**Patient Initials:** __________ **Date:** ____________ **Time:** ________

Patient Label
Early Complications of Liver Transplant:
Liver transplantation is a complex surgery where complication can occur. It is important to be aware of the possible complications. There is no way to predict what if any complications each individual patient may get. Early detections of a complication are directly related to the success of treating them. Many complications can be picked up early on blood tests or by your physician even before you develop any symptoms. Therefore, regular check-ups and blood work, even when you are feeling well is extremely important.

Delayed Graft Function
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 ever function normally. When this occurs a second transplant may be needed. You will be placed on the UNOS waitlist in the highest priority category allowed for a second liver transplant. If a second liver does not become available death may occur.

Primary Graft Non Function
There is a chance of primary graft non-function. This is when the liver does not work at all after the transplant. The reason this happens is not known and it is not possible to predict who this may happen to. An immediate re-transplantation is required in cases of primary graft non-function.

Hepatic Artery Thrombosis
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 or narrowing. Most patients that develop hepatic artery thrombosis will require a second operation to remove the blood clot; some patients will require re-transplantation.

Portal Vein Thrombosis
This is a blood clot that develops in one of the major veins going to the liver. This can happen early after the transplant or many months to years after the transplant. If it happens early, it can cause the blood to back up in the liver causing the liver transplant to fail and a re-transplant will be required.

Biliary Complications
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 may develop 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, and balloon dilatation, but some may require surgical repair.

Rejection
Rejection occurs when your immune system sees your new liver as foreign (not a part of your body) and tries to attack it. Your body deals with this "foreign" body the same way it deals with germs, by attacking it and trying to destroy it. You will be taking medications for the rest of your life after transplant to try to prevent rejection from happening. There are two types of rejection that we are concerned about in liver transplant - acute rejection and chronic rejection.

Please initial indicating you understand the above information and have had an opportunity to get your questions answered.
Patient Initials: __________ Date: ____________ Time: ________
Early Complications of Liver Transplant (continued):

Acute Rejection
Although you will be taking immunosuppressive medications for life to prevent rejection, you may still develop rejection. Rejection happens most often in the first 3 to 6 months after transplant but it can occur at any time. A large majority of all transplant patients experience at least one rejection episode at some time. Generally, if the rejection is diagnosed early, it can be treated with stronger medications. The only way to diagnose rejection is with a liver biopsy. Sometimes you may need to be hospitalized for rejection and sometimes we can treat it as an out-patient. Signs and symptoms of rejection include:

- Fever over 100.9. degrees
- Flu like symptoms: chills, aches, fatigue, nausea, vomiting & diarrhea.
- Pain or fullness over the area of your transplant.
- Yellowing of the skin and eyes

Chronic Rejection
This is rejection that occurs over time. It is scarring of the liver tissue that is not reversible. It can take a long time for chronic rejection to develop and to damage the liver. Sometimes we may adjust your medication to slow down the process but there is no definitive treatment for chronic rejection. The causes of chronic rejection are not totally understood but it may be caused by not taking the correct does of immunosuppression, or from missing doses of your immunosuppression.

Recurrent Liver Disease
Your original liver disease may recur after liver 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. Your physician and coordinator will discuss your liver disease and the possibility of recurrence in the transplanted liver in more detail with you.

Infection
The most common types of infections that transplant patients get are the same as everyone else, like the common cold, or bronchitis, for example. But the infection can last longer and be more serious in transplant patients. The type of infections that we are most concerned about after your transplant are called opportunistic infections. These may be caused by viruses, fungi or bacteria and may affect people who do not have a “normal” immune system. The organisms that cause opportunistic infections can be present in the environment or may be in our body in controlled numbers. In people who are not immunosuppressed the numbers of these organisms are controlled by the body’s natural immune system. This system involves tissues, organs and physiological processes used by the body to identify a protein as abnormal or foreign and prevent it from causing harm. Your white blood cells, antibodies and the lymphatic system are involved in this process.

Please initial indicating you understand the above information and have had an opportunity to get your questions answered.
Patient Initials: _________ Date: ___________ Time: _______
Early Complications of Liver Transplant (continued):

Signs and Symptoms of Infection
Because of your immunosuppressive medication, symptoms of infection might be less obvious. Even mild symptoms should be reported to your transplant coordinator.

- Fever 100.4 degrees or higher
- Flu-like symptoms (chills, aches, fatigue, dizziness, nausea, vomiting)
- Cold symptoms persisting longer than one week
- Chest discomfort, cough or shortness of breath
- Abdominal pain, tenderness over the transplant site, diarrhea
- Pain, burning or increasing frequency of urination
- Redness, warmth, swelling or drainage from a skin wound
- Headache
- Myalgia (muscle aches and pains)
- Tiredness and weakness

You are at a slightly higher risk for getting the flu than the general population, but the severity may be worse. You are more likely to pick up a secondary infection, like a sinus infection or bronchitis. The incidence of transplant recipients getting pneumonia is about the same as the general population. Just like the flu vaccine, pneumonia vaccine is safe and effective in transplant recipients.

Opportunistic Infections:
The type of infections that we are most concerned about after your transplant are called opportunistic infections. These may be caused by viruses, fungi, or bacteria and may affect people who do not have a “normal” immune system. The organisms that cause opportunistic infections can be present in the environment or may be in our body in controlled numbers. In people who are not immunosuppressed, the numbers of these organisms are controlled by the body’s natural immune system. This system involves tissues, organs and physiological processes used by the body to identify a protein as abnormal or foreign and prevent it from causing harm. Your white blood cells, antibodies, and the lymphatic system are involved in this process.

Some of the more common opportunistic infections are reviewed below.

1. Cytomegalovirus (CMV)
   CMV is very common in the general population, but is dormant with little or no affect in a person with a healthy immune system. The virus can be activated when you are transplanted or in some cases you may receive the virus from your donor. This virus is treatable and you will be screened periodically post transplant to verify that it has not activated.

2. Herpes (HSV)
   There are other viral infections, including herpes simplex (“cold sores”) and herpes zoster (“shingles”) which transplant patients are more susceptible to developing. Similar to CMV, much of the adult population has had exposure to the herpes viruses in the form of cold sores, shingles or chicken pox. In some cases the virus, which usually remains dormant, will be reactivated due to your immunocompromised state.

Please initial indicating you understand the above information and have had an opportunity to get your questions answered.

Patient Initials: __________ Date: __________ Time: ________
3. Pneumocystic Carinii Pneumonia (PCP)
   All immunosuppressed patients are at risk for developing pneumocystic carinii pneumonia (PCP) which is a bacterial lung infection. The incidence of this infection is reduced by prophylactic treatment. The treatment includes Septra (Trimethoprim/Sulfamethoxazole), or Pentamidine Nebupent) for those who are allergic to sulfa containing drugs.

4. Toxoplasmosis
   Toxoplasmosis is a protozoan disease that affects the central nervous system in humans which could be potentially life-threatening to immunosuppressed patients. The organism is found in many mammals and birds. The incidence of this infection is reduced with proper precautions and can usually be treated with sulfadiazine and pyrimethamine.

Medications After Transplant:
You will be on a number of different medications after your liver transplant. Generally the doses of the medications are highest in the first 3-6 months and will be decreased over time after the transplant. You will be on immunosuppressive medications to prevent rejection, anti-infection medications to prevent infections and other additional medications to treat other medical conditions you may have. You will be on some medications for the rest of your life. Failure to take all your medications at the correct doses or even missing occasional doses of your medications could cause serious complications and even failure of your transplant.

Immunosuppressive Medications:
These are medications that work in combination to keep your body from rejecting your transplanted liver. The following are some of the medications you may be on and some of their side effects. It is important to remember that not every patient will get every side effect. Generally the side effects are dose related, meaning the higher the dose the greater the possibility of having side effects. However, over time, we will be able to reduce the dosage of your medications which should lessen the side effects.

Tacrolimus (Prograf)
 Potential side effects of Prograf:
• Nephrotoxicity (impaired kidney functions)
• Headaches, tremors, confusion, sleep disturbance, anxiety
• Hair loss
• Nausea, diarrhea
• Increased blood pressure
• Increased blood sugar (diabetes)
• Increased potassium levels
• Increased risk of infection

Myfortic or Mycophenolate Mofetil (CellCept)
Potential side effects include:
• Bone marrow suppression (decreased white blood cells, decrease red blood cells {anemia})
• Infections (especially viruses)
• Diarrhea (or other gastric {GI} issues)

Please initial indicating you understand the above information and have had an opportunity to get your questions answered.
Patient Initials: __________ Date: __________ Time: ________
Sirolimus (Rapamune)
Potential side effects of Sirolimus (Rapamune) include:
- Elevated cholesterol and triglycerides.
- Decreased platelets
- Decreased white blood cell count
- Increased cholesterol and triglycerides
- Skin rash
- Acne
- Joint Pain
- Low potassium levels
- Diarrhea

Prednisone
Potential side effects include:
- Weight gain
- Acne
- Sodium and fluid retention
- Elevated blood pressure
- Muscle weakness
- Osteoporosis (loss of bone mass)
- Increased cholesterol and triglycerides
- Increased blood sugar (diabetes)
- Cataracts
- Stomach ulcers, heartburn
- Mood swings
- Increased risk of infection
- Sun sensitivity
- Fragile skin

Other Medications:
You will be prescribed anti-infection medications to protect you from developing the opportunistic infections mentioned above. As your immunosuppressive medications are gradually reduced during the first year, we will be able to discontinue the anti-infection medications. You may also be on additional medications such as blood pressure medications, insulin if you are a diabetic and others depending on your overall health.

Health and Life Insurance:
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.

Please initial indicating you understand the above information and have had an opportunity to get your questions answered.
Patient Initials: __________ Date: ____________ Time: ________
Right to Refuse Transplant:
You have the choice not to undergo transplantation. If you choose to have a liver transplant, you have the right to refuse a particular liver offered. If you do refuse a particular liver, you will not lose your place on the waiting list. However, repeated refusals to accept healthy organs may indicate that you do not want a transplant and that you should be removed from the waiting list. If you do not undergo the transplant surgery, your condition is likely to worsen and limit your life expectancy.

Waiting Time Transfer and Multiple Listing:
If listed for transplant, you have the option of being listed for transplant at multiple transplant centers. You have the ability to transfer your waiting time to a different transplant center without loss of the accrued waiting time.

Sale of Human Organs:
Sale or purchase of human organs is a federal crime and it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. Organ trafficking, more commonly known as Transplant Tourism, is simply defined as obtaining an organ outside of the legitimate rules and regulations covering transplantation in this country and abroad. It involves buying an organ. This usually happens in countries other than the United States. Sometimes patients from the United States go to these countries and obtain their transplant. As stated above, it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. If you obtain a transplant in this way, this program will not provide post-transplant care to you.

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. We have provided you a handout from UNOS with their contact information.

Program Coverage Plan:
A transplant surgeon and/or a transplant physician are available 365 days a year, 24 hours a day, 7 days a week to provide coverage at all times. The assigned covering physician and/or surgeon are readily available in a timely manner (defined as within one hour of the hospital) to facilitate organ acceptance, procurement of organs, transplantation of organs, and address patient and living donor concerns.

Saint Luke’s Hospital Liver Transplant Program
Informed Consent to Evaluate & List for Liver Transplant

I have received a copy of the Informed Consent to Evaluate. I have met with the transplant team, discussed the following, have been provided the opportunity to ask questions, and have had my questions answered. The following information was discussed by the evaluating team:

Evaluation Process:
- Results of physical evaluation.
- Patient selection criteria and suitability for transplant.

Please initial indicating you understand the above information and have had an opportunity to get your questions answered.

Patient Initials: __________ Date: ___________ Time: ________

Patient Label
Evaluation Process (continued):

- Results of transplant-specific testing. I have received a list of needed tests, and understand that results will be communicated to my dialysis unit, if I am receiving dialysis treatment.
- Psychosocial issues that may affect my candidacy have been discussed.
- Financial responsibilities resulting from transplant have been discussed.
- I am aware that I will have to follow a strict medical regimen after transplant. Major side effects of this regimen have been reviewed.

Surgical Procedure:
I have received an overview of the transplant operation. I understand that I will have a more detailed discussion prior to transplant.

Alternative Treatments:
- I have been advised of alternatives to transplant.

Potential Medical or Psychosocial Risks:
- I understand that there are medical risks associated with transplant, including but not limited to wound infection, pneumonia, blood clot formation, organ rejection, lifetime immunosuppressant therapy and its attendant side effects, arrhythmias and cardiovascular collapse, multi-organ failure, and death.
- I understand that there are potential psychosocial risks associated with transplant, including but not limited to depression, post-traumatic stress disorder, generalized anxiety, anxiety regarding dependence on others, and feelings of guilt.
- I understand that future health problems related to the transplant may not be covered by my insurance carrier and that it is possible that my ability to obtain medical, life, and/or disability insurance in the future may be jeopardized and that denial of coverage is possible.

Organ Donor Risk Factors:
- I understand that organ donor risk factors could affect the success of the transplant or my health, including but not limited to donor’s history, condition or age of the organs used, or the potential risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor. I understand that at the time of an organ offer this information as it applies to that particular donor will be reviewed with me.

Please initial indicating you understand the above information and have had an opportunity to get your questions answered.

Patient Initials: __________ Date: ____________ Time: ________
Other:

• I am aware I have the right to refuse transplant and/or withdraw from the evaluation process at any time.

• I am aware that if my transplant is not provided by a Medicare approved transplant center it could affect my ability to have immunosuppressant’s paid for under Medicare part B. Saint Luke’s Hospital’s Liver Transplant Program has not yet been approved by the Center for Medicare Services. My transplant financial counselor has discussed with me my financial obligations related to transplant.

• I understand Saint Luke’s communication policies. Specifically, I understand that I will need to be seen on a regular basis by my transplant team. I understand that if I have not received a call from center by 6-12 months from this date I should call 816-932-4655.

• I am aware that I will receive a letter anytime my listing status changes, including when I am first placed on the list. My nurse coordinator has reviewed the procedures for contacting me when I get an organ offer. I understand that I must inform center of any significant changes in my health.

• I have provided Saint Luke’s Liver Transplant Team with my true, current, and accurate contact information. I understand if my contact information changes I must notify Saint Luke’s Liver Transplant Team immediately. This includes during periods of temporary relocation such as hospitalization, travel, etc.

• I acknowledge that I may list at more than one center. I have been told that I may call the United Network for Organ Sharing hotline and have received the UNOS letter with this number and instructions.

• I realize there is additional information in the consent to transplant that has not been covered above, and I have read or will read this information.

After review of the above I hereby consent to be listed for a liver transplant upon approval by the selection committee. I will notify the center if I wish to withdraw my consent.

I have received:

• Informed consent for evaluation and listing for liver transplant (total document 18 pages)
• A copy of the “multiple listing” brochure
• UNOS “hotline” letter
• Contact information for transplant center
• A list of tests I need prior to proceeding with the transplant process

Patient: _____________________________ Patient: ___________________________ Date: _____________ Time: ______

Name Printed      Signature

Care Partner: ___________________________ Care Partner: ___________________________ Date: _____________ Time: ______

Name Printed      Signature

Coordinator: ___________________________ Coordinator: ___________________________ Date: _____________ Time: ______