LIVER TRANSPLANT CANDIDATE
CONFIRMATION OF EDUCATION AND INFORMED CONSENT FOR TRANSPLANT EVALUATION

A. PARTICIPATION

Your participation in the liver transplant evaluation process is completely voluntary. You are free to withdraw your decision to continue at any time. In addition, you have the right to refuse transplantation if and when you are found eligible and called in to receive a transplant.

University Hospital ("UH") is approved by Medicare to provide transplant services; however you should be aware that if you were to decide to have your transplant services in a facility that is not a Medicare-approved transplant center, it could affect your ability to have your immunosuppressive drugs paid for under Medicare Part B.

B. TREATMENT ALTERNATIVES

Persons with advanced liver disease and liver failure have several treatment options, based on the conditions affecting the liver and its related biliary system and severity of their illness:

- Liver Resection
- Liver Transplantation
- Radiofrequency ablation (RFA)
- Microwave coagulation therapy (MCT)
- Chemoembolization
- Alcohol injection
- Radiation
- Optimization of medical management

The benefits and risks associated with each of these options vary from patient to patient, depending upon a number of clinical and social factors. Your physician will discuss with you the specific benefits associated with each of these options.

C. THE EVALUATION PROCESS

The evaluation process determines if you are medically suitable to receive a liver transplant and includes an assessment to make sure that there are no psychological or social barriers to transplantation. The goal of the evaluation process is to make sure your health status is optimal and that you would be able to be safely transplanted. If a new health problem is found during the evaluation, you may be referred back to your primary physician or to an appropriate medical specialist. If a serious health problem is found, it is possible that you may be ineligible to receive a transplant.

1. Nursing assessment (Transplant coordinator) - will be my advocate throughout the transplant process, and will provide education regarding the evaluation process, listing for transplant and my responsibilities before and after transplant. This will provide me with an opportunity to ask questions and to become fully informed about the liver transplant process.

2. Review of required laboratory and diagnostic testing. Diagnostic testing may include:

    - Chest x-ray
    - Ultrasound with Doppler
    - CT scan of the abdomen
    - Magnetic Resonance Imaging (MRI)
    - Hepatic angiogram
    - Cholangiogram
    - Electrocardiogram (EKG)
    - Echocardiogram
    - Cardiac Catheterization
    - Pulmonary function tests
    - Upper / Lower endoscopy
    - Complete bloodwork
    - Hepatitis B, C, and HIV screening
    - Cancer screening (colonoscopy, prostate specific antigen (PSA) for men, PAP smear and or mammogram for women
    - Other tests may be recommended by your transplant physician as well

3. Tests will also need to be done to confirm your blood type, which is necessary to determine compatibility with a liver donor should you become a transplant candidate.

Blood Group compatibility:

	Recipient	**Donor must be:**
Blood type	A	A or O
Blood type	B	B or O
Blood type	O	O
Blood type	AB	A or B or AB or O

4. All patients entering into the liver transplant process will need to meet with the members of the multi-disciplinary team. These team members include our transplant physicians, transplant surgeons, social workers, transplant dieticians, transplant pharmacists and financial counselors. There may be other team members required to meet and discuss your care as well, depending on the results of your workup.

5. During the evaluation process, you will also participate in education and discussions regarding the following:

    a. Risks and benefits of transplantation
    b. Medication regimen
    c. Post-transplant follow up visit schedule
    d. Participation of your family and support
    e. How and when to communicate with the office regarding your status
    f. A discussion of the possible psycho-social risks including possible emotional, financial, and physical stressors from receiving a transplant

D. SELECTION COMMITTEE

Once your evaluation has been completed, the final step to becoming a liver transplant candidate at University Hospital involves formal consideration by a selection committee. This multidisciplinary team includes Hepatologists, transplant surgeons, social workers, financial coordinator, dietitian, nurse coordinators, psychiatrists, cardiologist, an anesthesiologist and other specialists as needed.

Patients accepted for transplantation are placed on the waiting list. Sometimes, patients are not accepted for a transplant. In some of those cases, the team may need more information, such as additional work-up studies or assessment, before they can be listed. In either case, a physician and a nurse coordinator discuss the decision with the patient and explain what lies ahead.

E. ACTIVATION ON THE WAITING LIST

You will be placed on the United Network for Organ Sharing (UNOS) liver transplant waiting list when all of the evaluations and diagnostic tests have been completed, reviewed, and it is determined that your current medical and social condition meets established criteria for a liver transplant. You will be sent an official letter from the transplant coordinator informing you that you are now active on the transplant waiting list. In addition, your referring or primary care physician (if applicable) will be notified.

Under Organ Procurement and Transplantation Network (OPTN) policy, you can be listed at more than one transplant center (multiple-list) as long as you don't choose two transplant centers in the same local area. As with any transplant listing, you must be evaluated and accepted by a transplant center. You should also check with your insurance provider to see if there are costs associated with multiple listing that may not be covered. In addition, you would need to maintain current lab results and contact information for each transplant program where you are listed.

It may take a few weeks to several months for a suitable liver to become available to me. The waiting time depends on my blood type, my body size, and the urgency of my medical condition. Patients who are critically ill are given priority in the allocation of organs, within a designated geographic area.

While waiting for a donor organ, I must continue medical therapy with periodic visits to see the transplant team. My nurse coordinator will provide me with phone numbers where I may call should I have any questions. They will also provide me with the answering service number to contact the team after hours. I must provide the nurse coordinator with a telephone number where I can be reached. If I require hospitalization before the transplant, I may be admitted either to a hospital near my home or to University Hospital. We ask that either you or your family member notify our team if you are hospitalized at another facility. I must be prepared to travel to the hospital the moment a liver becomes available. I may be called to the hospital while the liver is en route to University Hospital. The transplant surgeon will check the condition of the donor organ, and if the liver is not in transplantable condition, I will be sent home until the next opportunity arises.

In general, patients are not removed from the waiting list once they are placed on it, unless: (1) there is a serious deterioration in the patient's health that significantly reduces the likelihood of a successful transplant; (2) the patient is unable or refuses to comply with the required medication regimen; (3) the patient asks to be removed from the waiting list; (4) the patient has a positive drug or alcohol test, or (5) other circumstances occur that significantly reduce the likelihood of a successful transplant.

Each patient will be provided with a pamphlet entitled ***"Questions and Answers for Transplant Candidates about Multiple Listing and Waiting Time Transfer"*** for detailed information pursuant to OPTN and UNOS policy.

F. RIGHT TO REFUSE TRANSPLANTATION

I have a choice not to have a liver transplant. If I do not wish to have a transplant, the alternative is continued medical treatment for the various symptoms and complications of liver disease, but my condition is likely to worsen and limit my life expectancy. If I choose to have a transplant, I will continue to receive medical treatment while I remain on the transplant waiting list.

G. THE TRANSPLANT SURGICAL PROCEDURE

What happens before the surgery?

You will meet the transplant surgeon or surgical resident who will discuss the technical aspects of the operation with you and will ask you to sign a surgical informed consent and consent for blood and blood products. The transplant surgeon or surgical resident by virtue of their training and expertise has the ability to discuss risks, benefits, alternatives and any donor high risk factors with you and / or family prior to signing the surgical consent form.

Once you are taken into the operating room, the doctors will begin placing monitors on you to watch your heart and lung function before, during, and after surgery. In preparation for surgery, the team will start a few intravenous lines where the anesthesia team will give you medications, and monitor how you are tolerating the surgery. The anesthesia team will put you to sleep prior to the surgery by administering anesthesia medications. Once you have gone to sleep, an airway tube is placed in your mouth that goes down your throat and into your windpipe (trachea) to help you breathe. The tube is attached to a ventilator that will breathe for you during the procedure.

What happens during surgery?

I understand a liver transplant operation takes an average of about 6-8 hours. This is done through a long incision in the upper part of my stomach. During the operation doctors will remove my diseased liver and replace it with a liver from a donor. Most patients receive about 5-10 bags of blood during the operation. I will be under a general anesthetic and be sleeping throughout the operation. When I wake up I will have a tube in my mouth to help my breathing. This is usually removed within 1-3 days. Until the breathing tube comes out and my condition is stable, I will remain in the Intensive Care Unit. Usually, the new liver begins to work very shortly after it is in the patient's body but takes a few days to become stable. Generally, patients stay in the hospital for 1-2 weeks after the transplant operation. It is possible, especially if I am very ill to begin with or I develop some complications that I may need to stay in the hospital for a longer time.

<u>What happens after surgery?</u>

After the transplant operation is completed, you will be brought directly to the Surgery Intensive Care Unit (SICU) where you will stay until the transplant physician and surgeon decides that you can be transferred to the next level of care. An SICU stay can last for 1 or more days, each patient can progress at different rates requiring more time in the SICU.

<u>What happens after discharge?</u>

After you are discharged home, you will receive follow-up care in the Transplant Clinic. Before you leave the hospital, your team will give you a date and time to report to the transplant clinic. Initially, you will have twice weekly office visits. It is important for you to keep your scheduled appointments to ensure that you are doing well. In addition to my willingness to follow the medical regimen, I will need the support of at least one other individual to help me with my care after the transplant, especially in the first few months.

If you choose to move out of the area, please contact your coordinator first, who can assist in setting up appointments with a transplant center in your new hometown.

H. MEDICAL / SURGICAL RISKS AND COMPLICATIONS

1. There is no guarantee that the donor organ will be successfully transplanted or that, once transplanted, it will be free from complications. The following is a list of known complications of liver transplant:

    a. **<u>Second transplant:</u>** The new liver I get may not work (1 in 30 chances) in which case I will need another transplant during my stay in the hospital (Rejection or Primary Graft/Donor Liver Failure). Sometimes, the blood vessels taking blood into my liver may clog up, in which case I may need another transplant (1 in 30 chances).

    b. **<u>Infections</u>:** Overall, there is a 1 in 2-3 chance that I will have some infection. The important ones are: a) infection in the operation cut (1 in 5-10 chances); b) pneumonia (1 in 10 chances); and c) urine infection (1 in 5-10 chances).

    c. **<u>Additional Operations</u>:** There is a 1 in 5-10 chance that I might need additional operations for bleeding, infections or other problems inside my stomach.

    d. **<u>Organ Rejection:</u>** There is a 1 in 2-3 chance that I will develop rejection; however, most rejections are reversible. Rejection may occur at any time after the transplant, sometimes without any symptoms of illness. That is why it is extremely important for liver transplant recipients to not miss having their liver function blood tests. If the patient's liver tests become abnormal, he or she may need a liver biopsy, in which a small sample of the liver is obtained by a small needle. The elevation in the liver tests may be due to rejection or various infections, such as hepatitis.

    e. **<u>Side Effects of Medications</u>:** After the transplant I will be taking anti-rejection and other medications. Side effects may occur from those medications. These have been explained to me in the transplant patient handbook. The important side effects are: a) high blood pressure,

b) diabetes, c) kidney impairment, d) infections, e) decreases in white blood cell and platelet counts, and f) headache, hand tremors, etc.

f. **Recurrence of Original Disease:** a) If I have Hepatitis C, there is an 80 % chance it will affect the new liver; b) if I have Hepatitis B, I will need to take monthly injections or intravenous infusions; c) if my clotting is excessive, I will need to take a blood thinner; d) if I have primary biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC), or autoimmune hepatitis, that disease may come back in my new liver.

g. **Cancer:** If I am receiving a liver transplant for a cancer in my liver, it may come back after the transplant. You will be monitored closely after transplant, checking for recurrence. Also, if I had a cancer in another part of my body before the transplant it may also grow back. Even if I had no cancer before, transplant patients are at an increased risk of developing cancers in general.

Liver transplant recipients should call their transplant coordinator or go to their hospital immediately for treatment if they are experiencing rejection symptoms. The quicker treatment is received, the more successful it is likely to be.

While most of these problems are treatable, the possibility of death does nevertheless still exist. There is a 1 in 20 chance of dying after the transplant operation. Survival statistics (included in this packet) will be reviewed by your transplant coordinator.

There are potential long term transplant complications of transplant as well, that can include, but are not limited to, chronic rejection, complications related to long term immunosuppression such as osteoporosis, renal insufficiency or renal failure, infection, or a development of new onset diabetes.

2. Risks of Acquiring Disease from Donor

While all efforts will be extended to minimize this risk by screening the donor for potentially dangerous infections and health risks, there remains the risk of acquiring an infection or cancer unknown to the program at the time of transplant.

As with any transfer of blood, blood products or tissues from one individual to another, there exists the possibility of transferring disease from the donor to the recipient even with screening, such as HIV, hepatitis B virus (HBV), hepatitis C virus (HCV), cancer or malaria if the donor is infected, but the infection is not detectable at the time of donation. (For example, known high-risk behaviors in the donor's background). While low, the risk for infection is not zero percent from any potential organ donor.

The most commonly transmitted virus is cytomegalovirus (CMV). In general, there is minimal impact if the recipient has already been exposed to CMV, it is estimated that 75% of the population has had exposure to CMV. In those cases where the recipient has not been previously exposed to CMV, there is a high probability of developing CMV disease unless antiviral therapy is given in the early post-operative period. Even with antiviral therapy, however, there is a chance of developing CMV disease. In most cases, this can be treated successfully. Similar, although not identical, problems can be seen with many other infections such as Epstein Barr virus, hepatitis, parvovirus B19, West Nile virus. The small risk of transmitting viral infections should be discussed with your physician at the earliest possible opportunity to insure that all questions you have may be answered.

In addition to viral infections it is also possible to transmit bacterial infections. As with viral infections, all efforts are made to minimize this risk. The probability of transmitting bacterial infections is lower than the probability of transmitting viral infections. Most of those infections are treatable with standard antibiotics.

Lastly, there are rare reports of malignancies and non-viral/non-bacterial infections being transmitted from a donor to a recipient. These occur in only a handful of cases each year nationally and while they are known to happen it should not be a cause for undue concern.

Occasionally, an appropriate donor may become available for you that may be considered at an increased risk for HIV, Hepatitis B or C disease transmission. These organs are used routinely by transplant centers across the country, and University Hospital considers many of these potential organs to be of good quality for transplantation.

After an organ offer is made for you and the organ procurement organization (OPO) deemed that the donor has any of the following 10 risk criteria, the Transplant Coordinator will discuss with you the possible risks associated with transplantation of that specific organ.

The following are risk criteria (during the 30 days before organ procurement):

- *Sex (i.e., any method of sexual contact, including vaginal, anal, and oral) with a person known or suspected to have HIV, HBV or HCV infection.*
- *Men who has had sex with another man*
- *Sex in exchange for money or drugs*
- *Sex with a person who had sex in exchange for money or drugs*
- *Drug injection for nonmedical reasons*
- *Sex with a person who injected drugs for nonmedical reasons*
- *Incarceration (confinement in jail, prison, or juvenile correction facility) for ≥ 72 consecutive hours*
- *Child breastfed by a mother with HIV infection*
- *Child born to a mother with HIV, HBV, or HCV*
- *Unknown medical or social history*

In the event of an emergency situation during a transplant, vessels recovered from a previous organ donor may need to be used in life-saving circumstances. These vessels can potentially come from an organ donor that has any of the following risk criteria as stated above. All efforts will be made by the transplant team to limit this from happening, but in the event of a life-saving situation, they could be used as part of your transplant procedure. It is important that you understand what PHS Increased Risk donors are, and we are here to help if you have additional questions or concerns.

All recipients of a transplant are required to undergo routine testing for HIV and Hepatitis B and C infections after transplant. This testing will be done at least once within 4-6 weeks after transplant, and again for Hepatitis B at one year after your transplant. If you develop any signs or symptoms of liver injury

after transplant, you will be required to be tested for those viruses again. Agreeing to move forward to transplantation is an agreement on your part to submit to that testing.

I. Psychosocial Risks

1. Major surgery such as a transplant may have psychological impact on patients and their families.
2. Your illness and subsequent transplant may alter your daily routine, dietary habits, and strain your financial resources.
3. The stress of the surgery may make it difficult for you to comply with the lifestyle changes that may be needed.
4. You should be aware that this psychological impact can be manifested in the following ways:
    i. Depression
    ii. Anxiety
    iii. Post traumatic-like stress disorder
    iv. Sleep disorders
    v. Guilt
5. Please let us know if you are having difficulty coping with life after a transplant and we will work with you to find ways to help you with your adjustments.

J. Financial Risks

Transplantation is an expensive undertaking that requires a serious commitment. It represents partnership between you, your physicians, and the transplant team. Therefore, it is important for you to understand the terms and conditions of your current insurance and to keep the transplant team apprised of any changes that may occur with your coverage. The Financial Coordinator and Transplant Social Worker will explain the financial considerations involved in transplantation and verify your health insurance coverage both initially and periodically. However, it remains your responsibility to be aware of any changes to you plan and coverage.

K. Transplant Program Coverage Plan

The transplant program has at least one transplant surgeon and transplant physician available 365 days per year, 24 hours/day, & 7 days /week. A surgeon / physician is readily available in a timely manner to be on hospital premises to address urgent patient issues and to facilitate organ acceptance, recovery, and transplantation. The transplant surgeons and transplant physicians on call for the program will not be simultaneously on call for another transplant program or designated as the primary surgeon and or physician at another OPTN – approved transplant program.

Program’s Inability to Perform Transplant Notification Process

In the event that a change occurs in our center’s ability to perform transplant, including Centers for Medicare & Medicaid Services (CMS), withdrawal of certification, voluntary withdrawal of program or waitlist activation, 90 day period of unavailability of key medical or surgical staff, all patients who are associated with the transplant program (evaluated patients, active UNOS waitlist patients and post-transplant patients) are notified within 30 days. You would be notified as quickly as possible or 30 days prior to CMS withdrawal of certification or voluntary withdrawal of program, regardless of your phase in transplant via a formal letter sent certified mail.

In the event of an internal or external emergency or disaster such as loss of all power, water or other utilities, terrorist attack or severe weather such as a hurricane, or any other reason that would limit our center’s ability to accept organs or perform organ transplant, the program will immediately notify you and/or your caregiver/family.

The notification will be made inclusive of the available methods for contacting you and your family including phone, and certified letters.

A follow up letter describing the event and any further direction or information will be sent ASAP to you after the initial notification. The Transplant coordinator of designee is responsible for this activity.

CONFIDENTIALITY

All communication between patients and University Hospital are confidential. Health Care System personnel who are involved in the course of your care may review your medical record. They are required to maintain confidentiality as per law and the policy of this Health Care System. If you do become a transplant candidate/recipient, appropriate medical information which will include your identity, will be sent to The Sharing Network and UNOS and may be sent to other places involved in the transplant process as permitted by law.

Liver Transplant Success Rates

In general, outcomes for transplant recipients are excellent. The data on this page represents current national and center-specific data obtained from the Scientific Registry of Transplant Recipients (SRTR).

National and Transplant Center Outcomes
(Release date: January 5, 2023)

Patient Survival

- ***Observed (Actual) Patient Survival:*** At University Hospital, **95.65%** (percent) of patients receiving liver transplants are alive at the end of one (1) year.
- ***Expected Patient Survival:*** At University Hospital, the expected patient survival (based on national experience with similar types of patients) would be **93.54%** (percent) at the end of one (1) year.
- ***National Patient Survival:*** In the United States, **93.73%** (percent) of patients receiving liver transplants are alive at the end of one (1) year.

Graft Survival

- ***Observed (Actual) Graft Survival***: At University Hospital, **95.72%** (percent) of the transplants were working at the end of one (1) year.
- ***Expected Graft Survival:*** At University Hospital, the expected percent of transplants working (based on national experience with similar types of patients) would be **92.37%** at the end of one (1) year.
- ***National Graft Survival****:* In the United States **91.89%** (percent) of the transplants were working at the end of one (1) year.

The differences between observed and expected patient and graft survival at University Hospital are not statistically significant. University Hospital meets all Medicare outcomes requirements.

Scientific Registry of Transplant Recipients (SRTR) publishes updated reports every six (6) months on activities at each transplant center and organ procurement organization in the United States. Please visit www.srtr.org.

University
HOSPITAL
Newark, NJ

CONFIRMATION OF EDUCATION AND INFORMED CONSENT FOR TRANSPLANT EVALUATION

I have been provided with a liver transplant patient handbook, ***A Patient's Guide to Liver Transplant Surgery at The University Hospital****,* which contains detailed information about the evaluation process and explains the many different types of tests and procedures that may be part of this evaluation and its contents have been explained to me.

I understand that I am only being evaluated for a transplant and that this is NOT equal to being accepted for a liver transplant or having my name put on the transplant waiting list.

I understand that at any time during this process I have the right to refuse transplantation.

I have been informed that I have the option to multi-list at another transplant center if I so choose.

I have read the ***"Confirmation of education and informed consent for transplant evaluation"*** and it has been presented and explained to me by the Pre-Transplant Evaluation Coordinator. All of my questions regarding the evaluation process, including the various consultations, tests and procedures, my visits with the transplant team, and my responsibilities have been answered to my satisfaction.

In accordance with OPTN policy, we are required to provide you with written information about multiple listing and transferal of waiting time. Your signature below confirms we have provided you the booklet from UNOS titled:
"Frequently asked questions about multiple listing and waiting time transfer".

If I have any questions, I may call my assigned pre-transplant coordinator.

______________________________	______________
Printed Name of Transplant Candidate	Date
______________________________	______________
Signature of Transplant Candidate	Date
______________________________	______________
Printed Name of Transplant Coordinator	Date
______________________________	______________
Signature of Transplant Coordinator	Date
______________________________	______________
Signature of Transplant Center Staff Providing Booklet	Date