Informed Consent for Liver Transplantation – High Risk Donors

The liver is the largest solid organ in your body. It has a very important role in many body functions such as regulating blood sugar and making proteins, hormones, vitamins, fats, and blood clotting factors. You should be aware that other treatments are available for advanced liver disease to relieve pain as well as reduce symptoms and other complications of liver disease. Transhepatic shunting (TIPSS) can decrease ascites, variceal bleeding and increase your quality of life. Fluid pills (diuretics) can decrease swelling. However, these interventions will not cure your underlying liver disease. It is not possible to live without a functioning liver. Successful transplantation provides the prospect of normal liver function and a return to health. If you are considered a candidate for liver transplant you would be placed on the national waitlist managed by UNOS/OPTN (United Network for Organ Sharing/Organ Procurement Transplant Network).

The risks of liver transplantation include the specific risks of surgery as well as the long-term risks of taking medications to prevent rejection (immunosuppression). The risks of surgery include all the known risks of major abdominal surgery, such as bleeding, infection, and complications of anesthesia. Liver transplantation is a long and complicated surgery. Other complications include stroke, heart attack, kidney failure, primary graft function, need for dialysis, or even death. There are many connections to the make during the liver transplantation. The hepatic veins, portal vein, hepatic artery and bile duct. There could be a problem with any of those connections including bleeding, narrowing, clotting, or leakage. If a problem occurs, then it could require further surgery. In the worst case the liver may fail for unknown reasons. If one of the blood vessels clots, then it could result in the loss of the liver transplant and require emergency transplantation.

The success of the liver transplant depends on many factors: your physical condition, the original disease process causing your own liver to fail, and the ability of your immune system to tolerate the new liver.

Rejection is a problem with all transplants and usually happens in the early weeks or months following a transplant. These rejection episodes are expected. Rejection of the transplanted liver is always a risk. You will have to take special medicines called immunosuppressive drugs to help your body tolerate your new liver. Some of these drugs are given though an IV when you first get your liver or during a rejection period. There are other standard immunosuppressive medications you will receive in varying combinations. You will need to take them daily, indefinitely. These are not experimental drugs, but they do have some side effects. These side effects include lowering of the body’s defense so that the chances of contracting viral, bacterial, and fungal infections are increased.

All patients on immunosuppressive drugs have a greater risk for developing cancers (e.g. lymphomas and skin cancers). If these drugs are used in larger doses, severe infections, bleeding from the gastrointestinal tract and pneumonias may develop. Viral, bacterial, or fungal infections can be acquired or re-activated from donor or recipient sources.

Complications may occur from the use of medications. Steroids can cause joint problems, stomach ulcers, cataracts in the eyes, and diabetes; mycophenolate and sirolimus can cause bone marrow depression (low white blood count) and gastrointestinal distress; sirolimus can cause the level of fats
(like cholesterol) in your blood to rise. Other medications such as cyclosporine and tacrolimus can cause tremors, increased blood pressure, development of diabetes and in high doses cause kidney problems.

Transplant recipients who become pregnant have an associated risk of birth defects and premature births with some of the medications. The long-term effects of many of these drugs are not fully known.

**Donation After Cardiac Death (DCD)**

Some people with non-survivable injuries to the brain never become brain dead because they retain some minor brain stem function. If such individuals made the decision to be donors or their families are interested, organ donation may be an option. The option of donating organs after cardiac death or “non-heart beating” donation may be presented to you once they have consent from the donor family. Donation in such cases entails taking the patient off the ventilator, typically in the operating room. Once the patient’s heart stops beating, the physician declares the patient dead and organs can be removed. Donor after cardiac death (non-heart beating is associated with biliary complications and delayed graft function.

**Hepatitis B core or Hepatitis C Donors**

Depending on your hepatitis serologies (Hepatitis B core or Hepatitis C) you may be offered organs from donors that test positive with the same type of virus. Transplant professionals do all within their ability to minimize the risk of disease or cancer transmission from donor to recipient. The risk is very small but can never be zero.

**Center for Disease Control (CDC) High Risk Donors**

You have the option to take organs from donors classified as CDC (Center for Disease Control) high risk. These donors have tested negative for HIV, but this definition has been made to define high risk behavior. High risk behavior is defined as:

1. Men who had sex with another man in the last 5 years
2. Intravenous drug use in the last 5 years
3. Persons with hemophilia or related clotting disorders who have received human derived clotting factor concentrates
4. Men or women who have had sex in exchange for money or drugs in the last 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 injection or through contact with an open wound, non-intact skin, or mucous membranes.
7. Inmates of correctional institutions
The majority of these donors are from standard criteria donors (donors under the age of 60). By agreeing to take an organ that is CDC high risk does not necessarily mean that you will receive a liver from a CDC high risk donor, additional post-transplant testing will take place.

**Other Risks**

Organ donors with a recent known malignancy are not used for organ transplantation, with the exception of benign skin cancers, and donors that have had brain tumors. Donors with brain tumors carry a very low risk of transmission and will be considered as other risk donors for the purposes of consent. Any donor that is offered to you as “other risks” will be discussed with you prior to transplantation.

Occasionally, research studies are conducted on patient outcomes following transplantation. This may include forwarding information about your transplant process and the type of immunosuppression used, to the federal government to be used for research purposes.

We ask that you sign the following statement to indicate (1) that you read and understood the information; (2) that your questions have been satisfactorily answered and explained; and (3) that you wish to take part in this procedure.

I have read and understand the above information and I agree to receive a liver transplant as treatment for my liver failure. I understand that success cannot be guaranteed and that the liver may be rejected or may need to be removed in case of non-function or life-threatening infection. I understand and accept the risks of immunosuppressive therapy. I have the option at any time during this process to choose not to receive an offered liver.

**REVIEW OF INFORMED CONSENT**

× ______________________  × ______________________

(Signature of Patient/Guardian)  Date

× ______________________  × ______________________

(Physician Signature)  Date