



## Hartford Hospital Liver Transplant Program Consent for Acceptance of Liver Allograft

The shortage of liver donors and the ever-increasing number of patients on the waiting list has prompted the transplant community to look at different types of organ donors to meet the needs of our patients on the wait list. The purpose of this consent form is to summarize information you have been given about the different types of organ donors and allow you to indicate the type(s) of donor organs you are willing to consider if they become available. Signing this form does not require you to accept the organ but will allow you to be considered for a wider pool of donors. Your Transplant Team will work with you throughout this process to help you make the decision that is right for you.

### Classification of Organ Donors

There are four general types of liver donors available: *Standard Criteria Donors*, *Extended Criteria Donors*, *Donors after Cardiac Death*, and *donors at increased risk for disease transmission*. This form only summarizes the differences between these types of donor organs and the associated risks and benefits of each type. This consent form specifically addresses the overall risks associated with the donor organ.

**1. The Public Health Service (2013) has identified certain organs as being at higher risk of transmitting infectious disease** when they are used for transplant. Receiving any donor organ carries a risk of receiving an organ with compromised function and/or the transmission of diseases despite appropriate screening and negative findings. These infectious diseases include but are not restricted to human immunodeficiency virus (HIV), Hepatitis C (HCV) and Hepatitis B (HBV). If your donor is considered high risk under the criteria, your Transplant Team will discuss this with you in detail at the time of the organ offer. You will then be able to make the best decision for you at the time. The following is a list of donor behaviors that place a recipient at higher risk for transmission of an infectious disease as determined by the Public Health Service (2013).

### Public Health Service donors at increased risk behaviors:

- People who have had sex with a person known or suspected to have HIV, HBV or HCV infections in the preceding 12 months.
- Men who have had sex with other men in the preceding 12 months.
- Women who have had sex with a man with a history of MSM behavior in the preceding 12 months.
- Persons who report non-medical intravenous, intramuscular or subcutaneous injection of drugs in the preceding 12 months.
- People who have engaged in sex in exchange for money or drugs in the preceding 12 months.
- People who have had sex with a person who had sex in exchange for money or drugs in the preceding 12 months.
- People who have had sex with a person that has injected drugs by IV, IM or sub-Q route for non-medical reasons in the preceding 12 months.
- People who have been in lockup, jail, prison, or a juvenile correctional facility for more than 72 hours in the preceding 12 months.
- People who have been newly diagnosed with or have been treated for syphilis, gonorrhea, chlamydia or genital ulcers in the preceding 12 months.
- People who have been on hemodialysis in the preceding 12 months. **Donors who meet this criteria are at increased risk for HCV infection only.**
- A child who is  $\leq$  to 18 months of age and born to a mother known to be infected with or at increased risk for HIV, HBV, or HCV infections.



- A child who has been breastfed within the preceding 12 months and the mother is known to be infected with, or at increased risk for HIV infection.
- When a deceased potential organ donor's medical/behavioral history cannot be obtained or risk factors cannot be determined, the donor should be considered at increased risk for HIV HBV and HCV infection because the donor's risk is unknown.
- When a deceased potential organ donor's blood is diluted (because of transfusions or intravenous fluids), the donor should be considered at increased risk for HIV HBV and HCV infection because the donor's risk for infection is unknown.
- Chagas Disease -Recent travel of donor or donor originally from South America with risk of exposure to Tripanosoma Cruzi

I have been given the information regarding the donors who are at higher risk for disease transmission as identified by the Public Health Service 2013.

( ) initials

**2. Liver Standard Criteria Donors (SCD)**

Standard criteria donor organs come from donors who have died due to a fatal brain injury and have been declared "brain dead" by neurological criteria but have had blood circulation continued until the liver is obtained for transplant. These donors have no known significant medical history that would affect their liver or any prior exposure to transmittable diseases. These would include, but are not limited to, HIV, HCV or HBV. They are also ABO blood group compatible with you. You will receive the entire liver (as compared to a segmental liver described below). These organs in general present a lower risk of serious complications and have a higher chance of functioning well after transplant for a longer period of time when compared to the other three types of donated organs.

You always have the right to refuse a SCD when it is offered. However, if the Transplant Team is concerned about the reason for your refusal we may need to have a more in depth discussion of the reason for you declining the offer to be sure that you remain mentally and physically ready for transplantation.

**I have been given the opportunity to ask questions and have been told I can ask questions at any time. I understand the risks and benefits of Standard Criteria Donors.**

I agree to be on the list for a Standard Criteria Donor \_\_\_\_\_  
(Patient initials) (Date)

**3. Liver Extended Criteria Organ (ECD)**

Extended criteria donor organs are obtained from donors with medical risk factors that may result in less than optimal liver function and increased risks of death and complications. These factors are defined as:

- Donor over age 65
- Fatty Liver-greater than 30% macrosteatosis
- Segmental liver graft (liver split into 2 segments)
- Hepatitis C positive serology , NAT negative – 16% risk of transmission unless you already have HCV
- Hepatitis C positive serology , NAT positive – 100% risk of transmission unless you already have HCV  
(Additional consent formed needs to be signed)
- Hepatitis B positive serology (HBV core Antibody)
- Central nervous system or history of other (non-skin) cancers
- ABO incompatible donors



I understand that a liver from an Extended Criteria Donor has a higher chance for delayed or impaired liver function which may require additional medical management, prolonged hospital stay, another liver transplant and even death when compared to a Standard Criteria Donor. In addition, livers from donors who have been exposed to or have Hepatitis B or C can transmit the virus to the recipient and are usually used in recipients who are already infected with the Hepatitis C virus, are immune to the Hepatitis B virus or in life threatening situations. ABO incompatible donors are considered in life-threatening situations but can result in higher rates of rejection and graft versus host disease that may be fatal. Additionally, these livers may increase the overall risks of the transplant surgery and side effects of the post-transplant medications.

If a Standard Criteria liver becomes available for you, being listed for an Extended Criteria liver will not affect you in any way. You will still be offered any Standard Criteria livers that you are eligible for. You have the right to refuse any Extended Criteria liver that is offered to you with no penalty or change in your OPTN/UNOS wait list status.

***I have been given the opportunity to ask questions and have been told I can ask questions at any time. I understand the risks and benefits of Extended Criteria Donors.***

I agree to be on the list for an Extended Criteria Donor and have indicated above my choices

\_\_\_\_\_  
(Patient initials) (Date) (Time)

I do not agree to be on the list for an Extended Criteria Donor

\_\_\_\_\_  
(Patient initials) (Date) (Time)

#### **4. Donor after Cardiac Death (DCD)**

These organs are from individuals that have an irreversible and devastating injury for whom further medical care is futile. The patient's family and physicians have decided that life support will be discontinued. These patients are not brain dead by neurologic criteria but will be declared dead once life support is discontinued and the heart stops. Once this happens it is possible to recover organs for transplantation.

I understand that Donor after Cardiac Death livers have a higher chance for bile duct injury, delayed or impaired liver function which may require additional medical management, prolonged operative time and hospital stay, another liver transplant and even death when compared to a Standard Criteria Donor. Additionally, these livers may increase the overall risks of the transplant surgery and side effects of the post-transplant medications.

If a Standard Criteria Donor becomes available for you, being listed for a Donor after Cardiac Death liver will not affect you in any way. You will still be offered any Standard Criteria livers that you are eligible for. You have the right to refuse any Donor after Cardiac Death liver that is offered to you with no penalty or change in your OPTN/UNOS wait list status.

***I have been given the opportunity to ask questions and have been told I can ask questions at any time. I understand the risks and benefits of Donor after Cardiac Death livers.***

I agree to be on the list for a Donor after Cardiac Death liver

\_\_\_\_\_  
(Patient initials) (Date) (Time)

I do not agree to be on the list for a Donor after Cardiac Death liver

\_\_\_\_\_  
(Patient initials) (Date) (Time)



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Livers for an Extended Criteria Donor or a Donor after Cardiac Death may shorten your waiting time for a transplant and studies have shown that a transplant from an Extended Criteria Donor is better than no transplant at all. Patients in these studies lived longer than those who never received a transplant at all. Unfortunately as wait times get longer and longer each year, some patients will die while waiting for a transplant. Your Transplant Team will have an ongoing discussion with you about your risks of dying while awaiting transplant. You should be aware that this risk can change over time as your condition either improves or worsens.

I affirm that I fully understand the risk and benefits of each type of organ described above and I have indicated my wishes as to the types of organs I am willing to consider. I fully understand that this in no way commits me to accept any specific Extended Criteria or Donor after Cardiac Death organ and that I can change my mind at any time without affecting my status on the

OPTN/UNOS transplant wait list . If and when a liver becomes available to me, my Transplant Team and I will make a determination together about the liver's suitability for me. I realize that because there are more people waiting for livers than there are liver donors, there is no guarantee that any liver will become available to me.

\_\_\_\_\_  
Provider Printed Name

\_\_\_\_\_  
Patient or Legally Authorized Representative Printed Name

\_\_\_\_\_  
Provider Signature

\_\_\_\_\_  
Patient or legally authorized representative Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Date

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Time

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Interpreter's Signature (if needed)

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

**NOTE: THIS DOCUMENT MUST BE MADE PART OF THE PATIENT'S RECORD**