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**INFORMED CONSENT**  
**HEART DONOR ORGAN OPTIONS**

The shortage of heart donors has prompted the transplant community to look at different types of heart organ donors to meet the needs of our patients on the waiting 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 heart donor organs you are willing to consider if they become available.

At the current time the Hartford Hospital Transplant Program may offer Standard Criteria Donor organs, Hepatitis B positive donor organs, donor organs which are at increased risk for transmission of diseases according to the Public Health Service, and organs which are positive for either the antibody for Hepatitis C or infected with Hepatitis C. These are described in detail separately below.

Donors are evaluated and screened according to UNOS (United Network of Organ Sharing) Policy. There is no comprehensive way to screen donors for all transmissible diseases. Malignancies and diseases may be identified and transmitted after transplant. Donor evaluation and screening results may impact your post-transplant evaluation, screening and management.

This form only summarizes the differences between these different types of donor organs and the associated risks and benefits of each one. There is a separate consent form which addresses the overall risks associated with heart transplantation.

The ideal donor heart comes from someone age 45 or less and whose body weight is close to yours (not less than 70% of yours), functions normally, has no structural abnormalities, has no evidence of coronary artery disease, and can be implanted within 4 hours of its procurement. Because of the scarcity of "ideal" heart donors, it is necessary to consider a donor heart that does not meet these ideal standards, such as the following:

- Donor age > 45
- Undersized donor
- Wall motion abnormalities or (Left Ventricular Ejection Fractions) EF<45%
- Inotrope requirement (Medications that improve blood pressure.)
- Coronary Artery Disease
- Potential time from procurement to implant of more than 4 hours
- Structural heart disease (leaky valves, for example)

If you are offered a donor heart with any of these conditions, the risks associated with this heart will be discussed with you in detail at the time of your organ offer. You have the right to refuse this organ when it is offered to you. This refusal will have no impact on your status on the OPTN/UNOS transplant wait list.

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**The following are conditions which may be present in a donor heart:**

1. **Hepatitis B Positive Donors**

These organs are from donors who may have had active Hepatitis B or who have been exposed to Hepatitis B in the past. Agreeing to accept a donor organ with this condition does not exclude you from standard criteria organs – it is only to expand the donor pool that you will be eligible for.

Hepatitis B does not affect the heart; it is a liver infection. (Ideally, in order for you to receive a heart from this type of donor you must have received the Hepatitis B immunizations or have become immunized from a prior Hepatitis B exposure and have had a blood test to prove that you are immune to the Hepatitis B virus.) Hearts from Hepatitis B positive donors should generally be used in patients with prior Hepatitis B infection or successful immunization; however, these hearts may be used in emergent situations without prior exposure or vaccinations, Receiving a heart from a donor with this condition presents a small risk of getting the Hepatitis B virus. And although the risk of getting this infection is very low, if you contract Hepatitis B from a donor heart you may be successfully treated or may experience liver failure and require a liver transplant to survive. )

If you agree to accept a heart from a Hepatitis B positive donor you will need to have extra blood tests after transplant at various intervals to test for the Hepatitis B virus. You may also be required to take extra medications to treat or prevent you from acquiring the Hepatitis B virus.

If you receive a heart from a Hepatitis B positive donor, the Program will monitor the status of your liver after transplant by blood tests, which measure liver function and Hepatitis B viral loads.

If you are listed for a Hepatitis B positive donor heart you may still get a standard criteria donor heart if one becomes available.

You may remove yourself from the list for a Hepatitis B positive donor heart at any time and at no penalty. You have the right to refuse a Hepatitis B positive donor heart when it is offered to you. This refusal will have no impact your status on the UNOS transplant wait list.

**I have been given the opportunity to ask questions and have been told I can ask questions at any time. I understand the benefits and risks of the Hepatitis B positive donor and I agree to be on the list for this type of heart transplant.**

**Initials** \_\_\_\_\_

**I do not wish to be placed on the wait list for the Hepatitis B positive donor heart.**

**Initials** \_\_\_\_\_

**2. Hepatitis C Positive Donors**

**Hepatitis C with NAT – (past infection with Hepatitis C)**

Hepatitis C can be transmitted from a donor whose blood tests show that he/she has Hepatitis C Virus (HCV) antibodies. Agreeing to accept an HCV organ does not exclude you from standard criteria organs – it is only to expand the donor pool that you will be eligible for.

- A. I understand that I may be accepting an organ that has been infected with Hepatitis C Virus in the past (HCV antibody +) but there is no active virus at the time of transplant and the RNA is negative (NAT - , no active infection). The risk of getting HCV is very low.

**I have been given the opportunity to ask questions and have been told I can ask questions at any time. I understand the benefits and risks of the Hepatitis C Antibody Positive, NAT negative donor and I agree to be on the list for this type of heart transplant.**

Initials \_\_\_\_\_

**I do not wish to be placed on the wait list for the Hepatitis C Antibody Positive, NAT negative donor .**

Initials \_\_\_\_\_

**Hepatitis C with NAT + (Active infection with Hepatitis C)**

- B. I understand that I may be accepting an organ from a donor who has the Hepatitis C Virus and that transmission is greater than 90% if the patient has virus in their blood or is RNA positive (NAT +) for Hepatitis C virus. I also understand that I will undergo post-transplant treatment for Hepatitis C if I become infected and it has a 97% to 100% cure rate if I take the medication as prescribed.

**I have been given the opportunity to ask questions and have been told I can ask questions at any time. I understand the benefits and risks of the Hepatitis C Antibody Positive, NAT Positive donor and I agree to be on the list for this type of heart transplant.**

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**I do not wish to be placed on the wait list for the Hepatitis C Antibody Positive, NAT Positive donor.**

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I may remove myself from the list for a Hepatitis C-positive donor organ at any time and with no penalty. I have the right to refuse a Hepatitis C-positive organ when it is offered to me. This refusal will not affect my status on the UNOS transplant wait list.

### 3. PHS Increased Risk Donors

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)

- 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 men with have sex with men (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 these 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.

**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).**

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- 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 may have contracted Chagas Disease .**

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I understand the risks and benefits associated with organs from each type of donor described above, and that I have indicated my wishes as to the types of donor organs I am willing to consider accepting if offered to me. I understand that I may refuse any organ when offered without affecting my status on the UNOS transplant wait list. Additionally, if I indicated a willingness to accept an organ from a Hepatitis B positive donor, a Hepatitis C positive donor, a PHS increased risk positive donor; I understand that I may remove myself from any or all of these lists at any time without affecting my status on the UNOS transplant wait list for a Standard Criteria donor heart.

\_\_\_\_\_  
*Printed Name of Patient Or Authorized Representative*

\_\_\_\_\_  
*Signature of Patient Or Authorized Representative*

\_\_\_\_\_  
*Date*

\_\_\_\_\_  
*Time*

\_\_\_\_\_  
*Relationship*

\_\_\_\_\_  
*Printed Name of Provider Obtaining Consent*

\_\_\_\_\_  
*Signature of Physician Obtaining Consent*

\_\_\_\_\_  
*Date*

\_\_\_\_\_  
*Time*

Interpreter responsible for explaining procedures and special treatment:

\_\_\_\_\_  
*Interpreter*

\_\_\_\_\_  
*Date*

\_\_\_\_\_  
*Time*

Patient unable to sign because:		
Physician Signature:	Date:	Time: