CONSENT FOR DECEASED HEART DONOR ORGAN OPTIONS

The shortage of heart donors and the ever-increasing waiting list has prompted the transplant community to look at different types of 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 donor organs you are willing to consider if they become available.

There are different types of heart donors available. Our Program may offer Standard Criteria Donors, Extended Criteria Donors and Hepatitis B positive donors, which are described separately below. This form only summarizes the differences between these different types of donor organs and the associated risks and benefits of each type. This consent form specifically addresses the risks associated with the donor organ. A separate consent form addresses the overall risks associated with heart transplantation.

1. **Standard Criteria Donors**

Standard Criteria Donor organs have been procured from donors who have died due to a fatal brain injury and who are between 1 and 45 years of age. These donors have either none or not more than one of risk factors associated with heart disorders, such as, high blood pressure, diabetes and/or history of stroke or bleeding in or around the brain.

These organs, as a general matter, present lower risk of serious complications after transplant and a higher chance of functioning well and for a longer period of time than non-standard donor organs. However, there is no guarantee that Standard Criteria Donor organs don’t have inherent risk factors.

You have the right to refuse this standard-criteria donor heart when it is offered. This refusal will not 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 Standard Criteria Donors 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 a Standard Criteria Donor heart.*

(       ) initials

2. **Extended Criteria Donors**

The ideal donor heart comes from someone age 45 or less whose body weight is 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 harvest. Because of the scarcity of heart donors, however, it is sometimes necessary to use organs that do not meet these ideal standards. These are called **Extended Criteria Donors**, and they may have one or more of the following conditions:

- 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 harvest to implant of more than 4 hours
- Structural heart disease (leaky valves, for example)
CONSENT FOR DECEASED HEART DONOR ORGAN OPTIONS

Historically, the Heart Transplant community has tried to avoid using these organs because of concerns about reduced short and long-term survival. However, there is growing evidence today that these conditions may only have a small impact, if any, on the outcome of your transplant. Data is not available from which to predict outcomes for each of the above criteria individually because of the small number of donors in each category. However, pooled data from donor populations meeting a variety of these extended criteria suggests that, when handled appropriately, a recipient should do just about as well with an Extended Criteria Donor heart as he/she would with a Standard Criteria Donor heart, and certainly better than he/she would with no transplant at all.

Being listed for an Extended Criteria Donor heart may shorten the wait time for your transplant. Waiting times get longer every year, and while options exist to keep you alive until a suitable donor is available, a successful outcome cannot be assured.

If you are listed for an Extended Criteria Donor Heart you may still get a Standard Criteria Donor Heart if it becomes available.

You have the right to refuse this Extended Criteria Donor Heart when it is offered to you and you may remove yourself from this list at any time at no penalty. This refusal will have no impact on your status on the OPTN/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 Extended Criteria 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 Extended-Criteria Donor heart.

( ) initials

3. 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. 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 dire situations with out prior exposure or vaccinations. However, receiving a heart from this type of donor presents a small risk of getting the Hepatitis B virus from the donor, but the risk of transmission is very low. Patients who contract Hepatitis B may be successfully treated or may experience liver failure and require a liver transplant to survive. Hepatitis B does not affect the heart; it is a liver infection.

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 Hartford Hospital Transplant 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 not impact your status on the UNOS transplant wait list for a Standard Criteria heart.

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

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)

- Chagas Disease - Recent travel of donor or donor originally from South America with risk of exposure to *Trypanosoma Cruzi*
- 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 ≤ 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). ( ) initials

I affirm that 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 an Extended Criteria Donor and/or Hepatitis B 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.

______________________________  ____________________________
Patient’s name  Signed by patient, parent, or patient’s legal representative

Date: _____________ Time: ______________

M.D.  Date: _____________ Time: ______________
(Physician responsible for treatment and/or procedure)

Interpreter responsible for explaining procedures and special treatment:

______________________________  Date: _____________ Time: ______________
Interpreter

UPDAtED CONSENT AND VERIFICATION OF SURGEON PERFORMING PROCEDURE:

______________________________  M.D.  Signed: ____________________________
(Patient or legally authorized representative)

Date: _____________ Time: ______________  Date: _____________ Time: ______________

PATIENT UNABLE TO SIGN PRIOR TO SURGERY BECAUSE:
________________________________________________________________________________________

______________________________  M.D.  Date: _____________ Time: ______________

______________________________  Date: _____________ Time: ______________
Witness