



INFORMED CONSENT
HEART DONOR ORGAN OPTIONS

The purpose of this form is to summarize the education and information that you have received from the transplant team. This form only summarizes the differences between the types of donor organs and the associated risks and benefits of each one. There is a separate informed consent form which describes the overall risks associated with heart transplantation.

Organs are categorized by the risk associated with them. With respect to transplantation of a heart, the following risk categories, explained below, are relevant:

- Standard Criteria Donor,
- Extended Criteria Donor,
- Hepatitis B positive,
- Hepatitis C positive,
- Public Health Service (PHS) particular risk, and
- Donation after Circulatory Death organs.

Donors are evaluated and screened according to United Network of Organ Sharing (UNOS) Policy, however, there remains a possibility for transmission of diseases and malignancies from donor to recipient. Diseases and malignancies may be identified and transmitted after transplant as discussed with you and as explained in the informed consent form for heart transplant.

1. Standard Criteria Donors (SCD):

Standard criteria organs come from donors (Standard Criteria Donors, or SCD)

- Age 45 or less years and optimally matched to your height and weight;
- Potential time from procurement to implant of less than 4 hours;
- Who have been declared “brain dead” by neurological criteria but have had normal range blood pressure until the heart is obtained for transplant;
- Without known medical history that would affect their heart function and structure;
- Without known exposure to transmissible diseases, including but not limited to human immunodeficiency virus (HIV), hepatitis B (HBV) or hepatitis C (HCV); and
- ABO blood group compatible with you.

These organs, in general, present a lower risk of serious complications and have a higher chance of functioning after transplant for a longer period of time compared to the other types of donated organs described below.

You always have the right to refuse a SCD organ if it is offered. However, if the Transplant Team is concerned about the reason for your refusal, we may 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 have been provided with all outcome information regarding the above category requested by me and the risks associated with this type of donor. I agree to be on the waitlist for a Standard Criteria Donor heart transplant.

Patient initials _____



2. Extended Criteria Donors (ECD):

Because of the scarcity of Standard Criteria heart donors, you may consider a heart from a donor that does not meet the standard criteria (an Extended Criteria Donor, or ECD), such as the following:

- Donor age more than 45 years;
- Not optimally matched to your height and weight;
- Suboptimal heart function and/or structure;
- Inotrope (medication) requirement to maintain heart function;
- Coronary artery disease;
- Time from procurement to implant of more than 4 hours; or
- Structural heart disease (leaky valves, for example) that may be correctable.

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 UNOS transplant waitlist.

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 have been provided with all outcome information regarding the above category requested by me and the risks associated with this type of donor. I agree to be on the waitlist for an Extended Criteria Donor heart transplant.

Patient initials _____

I do not wish to be on the waitlist for an Extended Criteria Donor heart transplant.

Patient initials _____

The following are conditions that may be present in a donor heart that I receive by transplant:

3. Hepatitis B Positive Donors:

In order for you to receive a heart from a hepatitis B positive donor, you must have documentation that you 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 (HBV). Receiving a heart transplant from a donor with hepatitis B presents a small risk of disease transmission to the recipient. Although the risk of getting this infection is very low, if you receive a heart from a hepatitis B positive donor, you may still require long-term treatment to prevent an active HBV infection. Agreeing to accept an HBV positive organ does not exclude you from standard criteria organs; it is only to expand the donor pool that you will be eligible for.

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 hepatitis B positive donors. I have been provided with all outcome information regarding the above category requested by me and the risks associated with this type of donor. I agree to be on the waitlist for a hepatitis B positive heart transplant.

Patient initials _____



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I do not wish to be on the waitlist for a hepatitis B positive heart transplant.

Patient initials _____

4. Hepatitis C Positive Donors:

Inactive infection with hepatitis C (Nucleic acid testing (NAT) negative):

I understand that I may be offered an organ from a donor that has been infected with hepatitis C virus in the past (i.e., HCV antibody positive), but there is no active HCV infection at the time of transplant, and the ribonucleic acid testing is negative (NAT negative). The risk of contracting HCV is low in this case. Agreeing to accept an HCV positive organ does not exclude you from standard criteria organs; it is only to expand the donor pool that you will be eligible for.

I have been given the opportunity to ask questions and have been told I can ask questions at any time. I have been provided with all outcome information regarding the above category requested by me and the risks associated with this type of donor. 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.

Patient initials _____

I do not wish to be on the waitlist for a hepatitis C antibody positive, NAT negative heart transplant.

Patient initials _____

Active infection with hepatitis C (NAT positive):

I understand that I may be offered an organ from a donor who has hepatitis C virus, and that the transmission risk is greater than 90%. I also understand that I will undergo post-transplant treatment for hepatitis C if I become infected, and the treatment has a 97% to 100% cure rate if I take the medication as prescribed.

I may remove myself from the list for hepatitis C positive donor organ offers at any time and without penalty. I have the right to refuse a hepatitis C positive organ if it is offered to me. This refusal will NOT affect my status on the UNOS transplant waitlist.

I have been given the opportunity to ask questions and have been told I can ask questions at any time. I have been provided with all outcome information regarding the above category requested by me and the risks associated with this type of donor. 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.

Patient initials _____

I do not wish to be on the waitlist for the hepatitis C antibody positive, NAT positive donor heart.

Patient initials _____



5. Donors with PHS particular risk factors:

In 2020, the Public Health Service (PHS) identified certain transplanted organs as being at risk of transmitting infectious disease. Receiving any organ from such donors may carry a risk of compromised organ 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 B (HBV) and hepatitis C (HCV).

If a potential donor is considered at particular risk by these 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 characteristics, if present in the 30 days before organ procurement, that place a recipient at risk of transmission of an infectious disease as determined by the PHS:

- 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;
- Man 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 born to a mother with HIV, HBV or HCV infection;
- Child breastfed by a mother with HIV infection; or
- Unknown medical or social history.

I have been given information regarding donors with PHS particular risk factors for disease transmission and have had the opportunity to ask all my questions. I have been provided with all outcome information regarding the above category requested by me. I am aware of and accept the risks associated with this type of donor.

Patient initials _____

6. Donation after Circulatory Death (DCD):

These organs are from individuals who are not brain dead, but who have sustained irreversible and devastating injury for whom further medical care is futile. The clinical team and the patient's family and physicians have decided that life support will be discontinued. Once life support is discontinued and the heart stops, it is possible to recover organs for transplantation.

I understand that DCD hearts carry a higher risk for suboptimal function, also known as primary graft dysfunction (i.e., the heart ventricles do not function), and a potential need for temporary mechanical circulatory support after transplant. Organs from such donors have comparable outcomes to those received from brain dead donors.



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If a Standard Criteria Donor becomes available for you, being listed for a DCD heart will not affect you in any way. You will still be offered any Standard Criteria Donor hearts that you are eligible for. You have the right to refuse any DCD heart that is offered to you with no penalty or change in your UNOS waitlist status.

I have been given the opportunity to ask questions and have been told I can ask questions at any time. I have been provided with all outcome information regarding the above category requested by me and the risks associated with this type of donor. I understand the benefits and risks of the DCD donor, and I agree to be on the list for this type of heart transplant.

Patient initials _____

I do not wish to be on the waitlist for a DCD donor heart transplant.

Patient initials _____

Accepting an ECD, HBV positive, HCV positive or DCD donor heart offer may shorten your waiting time for a transplant. Your Transplant Team will have an ongoing discussion with you about your risks of dying while awaiting transplant. Your risk of death can change over time as your condition either improves or worsens.

I understand the risks and benefits associated with organs from each type of donor described above, and 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 waitlist. Additionally, if I indicated a willingness to accept an organ from a hepatitis B positive donor, a hepatitis C positive donor or a DCD donor, I understand that I may remove myself from any or all of these listing options at any time without affecting my status on the UNOS transplant waitlist for a Standard Criteria Donor heart.

Patient or Legally Authorized Representative (signature)		Date	Time
Telephone/Verbal Consent obtained from (print full name)		Date	Time
Relationship if not patient	<input type="checkbox"/> Official Interpreter Signature or ID #		
Resident/Fellow/Advanced Practice Provider (APP) Signature	Resident/Fellow/APP (Print full name)	Date	Time
ATTENDING Physician Signature	ATTENDING (print full name)	Date	Time
Witness (Provider or RN) Signature - mandatory for telephone consent		Date	Time