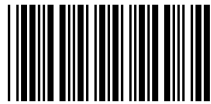
Hartford HealthCare
Hartford Hospital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HEART TRANSPLANT PROGRAM
INFORMED CONSENT FOR TRANSPLANT PROCESS

I am being considered as a candidate for heart transplantation with the Hartford Hospital Transplant Program. The purpose of this informed consent is to summarize information I have been given about the transplant process, including the evaluation process, surgical procedure and risks involved. I am aware that I cannot be considered a suitable candidate for transplantation until the evaluation process is complete.

The Evaluation Process

I acknowledge that I have signed Consent for Evaluation for Heart Transplant ______

I acknowledge receipt and review of the following educational and informational documents:

____ Heart Transplant Manual

____ Questions and Answers for Transplant Candidates and Families about Multiple Listing and Waiting Time Transfer

____ Post-Transplant Care Education (Infectious Disease Education)

The Surgical Procedure

I acknowledge that through the above-mentioned meetings and educational sessions, I have been informed of:

(1) the nature and purpose of the transplant operation;
(2) the psychosocial risks including but not limited to: anxiety, depression, post-traumatic stress, financial burden;
(2) the waiting list and range of wait times;
(3) the treatment available to me while waiting for transplant;
(4) the need for anesthesia;
(5) the estimated surgical time;
(6) post-surgical pain/discomfort and options for pain control after surgery;
(7) the estimated length of stay in the hospital and estimated recovery time;
(8) potential restrictions in the post-operative period and return to full activities;
(9) medications, testing and follow-up care required post-transplant to prevent rejection and care for my transplant;
(10) the known risks and consequences of the transplant surgery, including the fact that the transplant surgery may not achieve the desired goal.

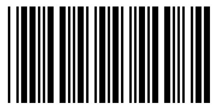
I have been informed specifically that the risks of the transplant surgery may include but are not limited to:

- early failure of the transplant organ requiring mechanical circulatory support,
- anesthesia risks,
- pneumonia,
- blood clots,
- kidney failure,
- wound infection,
- bleeding,
- fluid collection,
- re-operations or re-transplantation,
- rejection,
- stroke,
- death.

I have been informed of other possible complications related to the transplant surgery not listed above.

I understand that if I am accepted as a transplant candidate at Hartford Hospital, the risks of surgery will be discussed with me once again and I will be asked to sign a specific informed consent form relating to the surgical procedure.

Patient Initials ________



INFORMED CONSENT FOR TRANSPLANT PROCESS

Alternative Treatments

Alternative treatments and the risks and benefits of such alternatives have been discussed with me. I understand that these alternatives include long term medical management of heart failure and/or mechanical circulatory support, and that I may seek further information about these alternatives at any time.

Risks and Complications

Potential risks of heart transplantation therapy include, but may not be limited to:

1. Infection, organ rejection, organ failure, malignancy, death, heart attack, hypertension, increased cholesterol, diabetes, weight gain, depression, insomnia, anxiety, osteoporosis, kidney failure, and other potential side effects that may be caused by immunosuppression (medications taken to prevent organ rejection)
2. Extended and repeated hospitalization which may be caused by, but not limited to, infection, fever, medication reaction or inability to take medications, biopsy, organ transplant rejection, abnormal test results, or abnormal laboratory values.
3. Smoking and alcohol consumption increasing my risk of additional complications including cancer, lung and/or heart disease, organ transplant injury and early death.

I have been informed of the need to take medications for the rest of my life and of the common side effects of these medications. I have also been informed of the need for frequent lab tests after transplant and that I will need to have regular medical check-ups with the transplant program as needed but at least annually for the remainder of my life. The potential need for heart biopsy and risks of biopsy have been reviewed with me. I understand that alternatives to heart biopsy such as ALLOMAP testing may be considered after the first year.

I have been informed of the SRTR data, which includes national and Hartford Hospital transplant center-specific outcomes for heart transplantation.

If I am a woman of childbearing age, I understand that transplantation may complicate pregnancy especially during the first year after transplant. I understand that pregnancy may injure my transplant and even cause transplant organ failure and/or death. Prior to becoming pregnant, I agree to inform the transplant team of my wishes to discuss risks and benefits.

I understand that all donors and myself are screened for communicable diseases or problems that may affect the organ and my health. There is no guarantee as to whether any and all contagious diseases have been detected. There may be unforeseen factors including previously undetected diseases (including but not limited to: bacterial and fungal infections, human immunodeficiency virus (HIV), Hepatitis, Tuberculosis); or cancers that may affect the success of my transplant or my health. I understand that other information related to the donor, such as the donor's history and the condition of the organ(s) used may also affect the success of my transplant or my health.

Deceased donors are evaluated and screened according to UNOS Policy. There is no comprehensive way to screen deceased and living donors for all transmissible diseases. Malignancies and diseases may be identified and transmitted after transplant. Donor evaluation and screening results may impact post-transplant evaluation, screening, and management of the candidate.

Patient Initials ________

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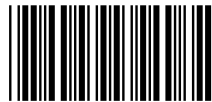
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INFORMED CONSENT FOR TRANSPLANT PROCESS

Insurance Issues

I have been informed that if my insurance changes, transplantation and its complications may not be covered. Also, my insurance may not cover future health problems related to transplantation. If these treatments/problems are not covered by my health insurance, I will be responsible for all costs. I understand that transplantation may affect my ability to obtain health, disability, or life insurance, and that future insurance premiums may be higher or I may be unable to get health, disability or life insurance in the future.

I have been told that if my transplant is not performed in a Medicare-approved transplant center, Medicare may not pay for immunosuppressive drugs needed after transplant.

I agree to inform the transplant team immediately both before and after transplant of any insurance changes or difficulties in obtaining medications.

Patient Initials______

General

I have been informed and have received information about waiting time transfer and multiple listing options.

I will receive a letter of notification concerning my status at the end of this evaluation process indicating that either:

a. I have been accepted as a candidate and I am active on the OPTN/UNOS waitlist.
b. I am not an acceptable candidate for transplantation at the Hartford Hospital Transplant Program at this time, and the reason(s) for this decision.

I understand that the Hartford Hospital Transplant Program may remove candidates for transplantation from its waitlist if future developments (including but not limited to: changes in medical condition, inability to comply with pre-transplant care requirements) cause an individual to no longer be a suitable candidate for transplantation under the program's patient selection criteria. I understand that I will be notified if such a determination is ever made about me.

I have the right to refuse transplant at any time, but if I accept transplantation, I agree to comply with the Hartford Hospital Transplant Program policies and guidelines as long as I am under the care of this program. I agree to return for follow-up visits as necessary and as required by the Hartford Hospital Transplant Program, even though this may require additional time and expense.

I have the right to notify the Organ Procurement and Transplantation Network (OPTN) at 1-888-874-6361, if I have any concern or grievance about my care or the Hartford Hospital Transplant Program.

I have been given the opportunity to ask questions and have received answers to these questions. I have been told I can ask questions at any time.

I affirm that I understand the purpose, benefits, risks and alternatives to transplantation. I understand that no guarantee has been made to me as to the availability of an organ for transplant within the estimated wait time or the results that may be obtained if I do receive a transplant.

Patient Initials______

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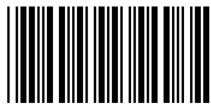
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INFORMED CONSENT FOR TRANSPLANT PROCESS

______________________________	______________________________
Printed Name of Patient /Authorized Representative	**Signature of Patient/Authorized Representative**
Date	**Time**
Printed Name of Transplant Staff	**Signature of Transplant Staff**
Date	**Time**
Printed Name of Interpreter if necessary	**Signature of Interpreter if necessary**
Date	**Time**

PATIENT UNABLE TO SIGN [❑] BECAUSE:

____

____________________________________ Transplant Staff

Date:________Time:_________