HEART RECIPIENT TRANSPLANT PROGRAM
INFORMED CONSENT FOR TRANSPLANT PROCESS

I have asked to be considered as a candidate for the Hartford Hospital Transplant Program for heart transplantation. 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 described below is complete.

The Evaluation Process

I acknowledge that through my participation in meetings with a transplant nurse coordinator, transplant social worker, and physician members of the transplant team and receipt of written educational and informational materials regarding transplants, I have been informed of the following aspects of the transplant evaluation process: (1) purpose of the evaluation process; (2) eligibility criteria for transplant; (3) testing involved in performing my medical and psychosocial evaluation; (4) possible donor organ sources; (5) donor and organ compatibility; (6) placement on the OPTN/UNOS transplant waiting list and range of wait times; (7) the necessity of my participating in ongoing education to be prepared for transplant and the post-transplant phase; (8) dietary evaluation; (9) social worker evaluation; (10) the potential psychosocial effects of transplantation and need for additional psychosocial assessment/evaluation as determined by the transplant team; and (11) the role of the financial coordinator and information about insurance and financial issues associated with the transplant process.

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

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 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; and (10) the reasonably foreseeable risks and consequences of the transplant surgery, including the fact that the transplant surgery may not achieve the desired objective. I have been informed specifically that the risks of the transplant surgery may include: early graft failure requiring mechanical circulatory support, anesthesia risks, pneumonia, blood clot in lungs or legs, kidney failure, wound infection, bleeding, fluid collection, re-operations or re-transplantation, rejection, stroke and death.

I have been informed of other possible complications related to the transplant surgery that are 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 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. Immunosuppression (caused by medications which are taken to prevent organ rejection) – I may experience infection, organ rejection, organ failure, malignancy, death, heart attack, hypertension, increased cholesterol, diabetes, weight gain, depression, insomnia, anxiety, osteoporosis, kidney failure, and other side effects.

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, or abnormal laboratory values.

3. Cigarette smoking and alcohol consumption will increase my risk of additional complications including cancer, lung, heart disease, organ transplant injury and early death.

4. The need for a Trans Esophageal Echocardiogram. If this procedure is necessary, the physician will discuss the risks with me and I will be asked to sign a specific informed consent form relating to this procedure.

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. Alternatives to heart biopsy such as ALLOMAP testing have been reviewed.

I have been informed of 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. 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 undetected infectious disease (bacterial and fungal infections, human immunodeficiency virus (HIV), TB or other) or cancers or any other previously undetected disease that may affect the success of my transplant or my health. I understand that other factors related to the organ donor, such as the donor’s history and the condition or age of the organs used may also affect the success of my transplant or my health.

Patient Initials ________
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 if I lose my current insurance.

Patient Initials______

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 by me post-transplant.

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

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 am active on the OPTN/UNOS waitlist.
b. I am not an acceptable candidate for transplantation at the Hartford Hospital Transplant Program.

I understand that the Hartford Hospital Transplant Program may remove candidates for transplantation from its waitlist if future developments (i.e. 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 policy as long as my organ is functioning. I agree to return for follow-up visits as necessary, even though this may require additional time and expense.

I have the right to notify the Organ Procurement and Transplantation Network 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. I wish to proceed with the transplant evaluation process to find out if I can be accepted as a candidate for transplantation at the Hartford Hospital Transplant Program.

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INFORMED CONSENT FOR TRANSPLANT PROCESS

_________________________________________    Date:________Time:_________
Signature (Patient or legally authorized representative)

_________________________________________
Signature (MD, APRN, PA)

Interpreter responsible for explaining procedures and special treatment:

_________________________________________________  (Interpreter)

PATIENT UNABLE TO SIGN  [ ]  BECAUSE:

_________________________________________________

_____________________________________ M.D., PA, APRN
_____________________________________ Witness     Date:________Time:_________