

Informed Consent for Adult Heart Transplant Candidates

The following information is provided in order to help inform you of the heart transplant evaluation procedure surgical procedure, treatment course, and potential risks and benefits. If you have any questions, please do not hesitate to ask. You are ready to be evaluated to see if you are a candidate for heart transplantation. In order to decide whether or not you should agree to this treatment plan, you should understand enough about its risks and benefits to make an informed decision. This consent form gives detailed information some of which the transplant team has already discussed with you or will be discussed during your evaluation. Please be aware that you have the right to review with your transplant team any part of this consent that you do not understand. Once you have read this consent and have had all your questions answered, you will be asked to sign this form at the time of the evaluation if you wish to proceed. You will be given a signed copy of this consent form for your records.

PURPOSE

Because you have been diagnosed as having end stage cardiac disease, a heart transplant evaluation has been recommended to see if heart transplantation is the best treatment option for you. The purpose of heart transplantation is to restore a meaningful quality of life to you, as well as extend your life.

SELECTION CRITERIA:

The following criteria are used to determine if you are a candidate:

Inclusion criteria include:

- End stage cardiac disease defined by New York Heart Association Class III/IV with limited expected survival of less than one year.
- Age generally less than or equal to 70 years of age
- Absence of systemic disease or infection
- Psychosocial stability and supportive family /social structure as defined by social assessments.
- No expectation of improvement with alternative medical or surgical treatment.

Exclusion criteria (relative risks and absolute) include:

- Sepsis or active infection
- Significant systemic disease with presence of end organ damage not explained by heart failure or deemed reversible.
- Severe pulmonary hypertension as evidenced by by fixed pulmonary vascular resistance of greater than 6 wood units, or transpulmonary gradient greater than 15mmHg.
- Malignancy within the past three (3) years
- History of chronic non-compliance
- Extensive peripheral vascular disease
- Significant psychiatric history or psychosocial instability
- Evidence of drug, tobacco or alcohol abuse currently or within the past six (6) months
- Obesity (Body mass index greater 35)
- Severe Chronic obstructive pulmonary disease
- Significant cachexia related to end-stage cardiac disease

Evaluation Process

You will be evaluated with consultations, lab tests and various procedures to determine the medical appropriateness of heart transplant. These are conducted to determine that you are otherwise healthy and free of other serious problems which would limit the success of a transplant.

The evaluation may reveal certain conditions which need to be corrected before transplant surgery. It could also reveal conditions which would make the transplant surgery a poor choice for you. We understand that you will be undergoing many tests which may become frustrating. We are looking for you to commit to an active role in your health care.

Most evaluations will be done on an out-patient basis. During the evaluation, you will see many different people who all function as part of the heart transplant team. These people include:

- The **Transplant Coordinator** provides education regarding the transplant evaluation process, listing for transplant and patient responsibilities before and after transplant. This meeting is intended to provide you with an opportunity to ask questions and to become fully informed about the heart transplant process. Along with your physicians they will keep you informed regards tot the progress and outcomes of your testing.
- A **Transplant Cardiologist** is a physician who specializes in heart disease. The cardiologist will oversee your care. They will assist in the medical management of your heart disease and work with the transplant team to determine if you are medically suitable for a transplant.
- A **Transplant Surgeon** will meet with you and discuss the appropriateness of a transplant based on the information obtained during your evaluation. The surgeon will also discuss the significance of undertaking a heart transplant, and the risks of the surgery and the possible complications after your transplant.
- A **Social Worker** will meet with you to evaluate your ability to cope with the stress of transplantation and your ability to follow a rigorous treatment plan, both before and after transplantation. They will assist you in your social and financial concerns of living with a new heart. The social worker will also help to identify your support network, home health needs, insurance concerns, financial obligations and needs.
- A **Financial Coordinator** will discuss the costs associated with your transplant and with the medications you will require after transplant. They will work with you to help you understand your insurance coverage. It is important that you understand the costs that may not be covered by insurance.
- A **Psychiatrist/Psychologist** may conduct a more in-depth evaluation and assessment. Some patients with a history of drug or alcohol abuse may be required to participate in a rehabilitation program as well to meet abstinence requirements prior to and after transplant listing.
- A **Registered Dietitian** may perform a nutritional assessment and provides nutrition education to patients.

- Some patients may be referred to another service for consultation. For example, many patients need to be seen by a nephrologist (kidney doctor), pulmonologist (lung doctor), or a hepatologist (liver doctor) to assess for other medical conditions. You may also need to be seen by an anesthesiologist to determine the need for any additional workup to determine your risk from anesthesia.

Many different tests are done to determine if you are a suitable transplant recipient. Some of the following tests may be included in your evaluation process. Remember, other tests may need to be done based on the results of these tests.

- Blood tests help to determine your blood type for organ matching and screen for your immunity to or the presence of specific viruses, including HIV. Additional blood tests may be used to determine how well other organs are functioning.
- A Metabolic Stress test may be done. This will reveal the functional capacity of your heart during exercise. In other words, it determines the ability of your heart to do work.
- A urine test is used to screen for the presence of urinary tract diseases as well as drugs, nicotine and alcohol in your system.
- An echocardiogram will show how well your heart is beating, size of your heart and the overall function of your heart.
- A CAT scan of the chest gives the transplant team a more detailed picture of your lungs and inside of your chest. It also helps to determine the extent of your cardiac disease, and the presence of any tumors or anatomical risks for surgery.
- Skin Tests are done to establish past or present exposure to certain diseases such as tuberculosis.
- A right heart catheterization measures the pressures in your lungs and the right side of your heart. If the pressures are very high, medication may be used to lower them. These pressures are important and often will need to be reassessed during your evaluation and waiting for transplant phase.
- An ultrasound of your abdomen helps assess the size, shape, and possible abnormalities of your kidneys, gallbladder and liver.
- Pulmonary function tests help evaluate how well your lungs and airways work. Tests include different breathing tests such as: breathing deeply and rapidly, taking a deep breath in and breathing out rapidly and completely, and other breathing maneuvers. A sample of blood may be taken from an artery at your wrist to measure oxygen and carbon dioxide levels.
- A colonoscopy will be required if you are over age 50. This is to rule out the presence of polyps or pre-cancerous lesions.

- You will need to see your dentist or oral surgeon. Oral hygiene is important since infections in the teeth and gums can travel to the heart. If you have dental problems which cannot be repaired, it may be suggested that your teeth be pulled. This would need to be completed before transplantation.
- Some patients may require individualized additional testing such as mammogram, Gynecological exam and pap test, ultrasound of carotid arteries and doppler studies of the extremities

CANDIDATE SELECTION

After all tests, procedures and consults are completed; all results are gathered and presented to our transplant team. Each case is examined individually and many factors are weighed before a final decision is made. The nurse coordinator will notify you once a final decision is made.

WAITING PERIOD

You will receive written confirmation and orientation of your listing for transplant from your nurse coordinator. There is no way to know when a donor heart will become available. There is a system in place through United Network for Organ Sharing (UNOS) to ensure that all patients in need of a heart transplant are given fair and equitable access to available donor organs. UNOS coordinates efforts among donor hospitals and transplant centers throughout the country to allocate donated organs for transplantation. After the donor heart is matched for compatible blood type and body size, it is allocated to the sickest patient with the longest waiting time who is closest to the donor heart. From the time you are placed on the waiting list, you need to be ready to receive a transplant. At some point during the waiting period, you may become too sick to receive a transplant. This could be a temporary condition in which you can get better and go back on the list, or it could become a permanent condition where you will no longer be eligible to receive a donor heart. If either of these happens, they will be discussed with you at that time. If your listing status is changed at any time during the waiting period, you will be notified of this change and the reasoning for it will be discussed with you. You will also receive a written notice within 10 days of your status change. All reasonable efforts will be made to accept a suitable donor organ for you.

You could also clinically deteriorate to the point where IV medications cannot keep you alive to wait for a heart. At this point you may need one or more of the following three mechanical means of keeping you suitable for a transplant:

- Intra-Aortic Balloon Pump (IABP) – This is a special catheter placed in the main artery leading to the heart. The end of the wire remaining outside of your body is attached to a machine which will help push blood through the heart and body each time the machine pumps. It is a temporary means of stabilizing your condition. You have the right to refuse to have the IABP placed, at which point you will likely die.
- Ventilator (Vent) – This is a device that breathes for you when you are unable to breathe on your own. It is also used immediately after surgery until you are awake and able to breath on your own. You have the right to refuse to be placed on the ventilator, at which point you will likely die.
- Ventricular Assist Device (VAD) – This is a device or devices that may be used to support right heart function, left heart function, or both at the same time. Implantation of ventricular assist devices requires major cardiac surgery with having your breastbone opened and being placed on the heart-lung machine. Tubes for these devices go into the aorta and ventricle(s) of the heart – the pumps attached to the tubes may be either implanted into your chest or left outside your chest. Rarely can these pumps be removed for any reason other than transplant. Once you have a VAD, it will remain implanted until you are either transplanted or die. Possible complications include but are not limited to bleeding, need for blood transfusions, infection, stroke, any major organ system failure, and death. After insertion of this device(s), you may not be eligible to be placed on the list for a transplant for several to many months, and may experience complications that will prevent you from ever being eligible to being placed on the list. You will be able to get up and around once you have recovered from

the operation and may even be able to go home with the pump, depending on which one you have. Prior to insertion of this device, the surgeon will discuss any additional potential risks or complications with you or your family. You have the right to refuse having a VAD or VADs implanted, at which point you will likely die.

Organ Donor Risk Factors

Certain conditions in the donor may affect the success of your heart transplant such as the donor's history and the condition of the organ when it is received in the operating room for your surgery. Additionally, there is a potential risk that you may contract HIV and other infectious diseases if they cannot be detected in the donor.

Surgical Procedure

Heart transplantation is a life-saving therapy; however, the potential benefits cannot result from surgery alone and are dependent upon your following the rigorous treatment plan prescribed by your physicians. You must be aware of the potential risks and complications outlined in this document that can result in serious injury, and death. Your physicians cannot predict exactly how your body will respond to a heart transplant. It is never fully known how the condition that caused your heart disease will affect your transplanted heart. The operation is complex and the risks are high. Life expectancy after heart transplantation has improved dramatically over the years. While patients with advanced heart failure have lives that are severely shortened by their heart disease, patients who undergo heart transplantation may have as much as a 87% 1-year survival with excellent quality of life. The success rate varies according to how sick the patient is prior to the transplant surgery with sicker patients having a lower chance of a successful outcome.

The Transplant Operation

When a donor organ becomes available, you will be called and you must come to the hospital right away. You always have the option to decline an organ.

During the transplant surgery you will be put under general anesthesia, which means you will be given medications to put you to sleep, block pain and paralyze parts of your body. You will also be placed on a machine to help you breathe. The anesthesiologist will talk with you in more detail about the risks of anesthesia. The transplant surgeon will make an incision through your breastbone (sternum). You will be placed on a special machine called a heart-lung bypass machine to maintain oxygenation and blood supply to your body while your heart is prepared to be removed. The use of this machine has its own possible risks that include stroke (blood clot to the brain or bleeding in the brain), myocardial infarction (heart attack), and bleeding. If the bypass machine is used, access may be obtained within the heart and aorta (blood vessel arising from the heart) or by using blood vessels in your groin. There is a specific risk of developing poor circulation and deep vein thrombosis if your groin vessels are used. When the heart arrives your surgeon will remove your old heart, and sew in your new heart.

Drains, also called chest tubes will be put into your body to allow fluids to be removed and to help you heal. Special mechanical boots or sleeves around your legs will be used to keep blood flowing through your legs to try to prevent dangerous blood clots. You will be in the operating room approximately 6-12 hours.

Post-Surgical Care and Recovery

After the surgery you will be taken to the intensive care unit where you will be closely monitored. You will be on a machine to help you breathe and you will have many tubes and drains in place. Intermittent pressure boots or sleeves around your legs will be used to prevent blood clots.

Immediately following the surgery, you may experience pain. This will be carefully monitored and controlled. Most transplant recipients have a significant reduction in the pain one to two weeks after surgery.

When your medical condition has stabilized you will be transferred to the surgical transplant floor. Your length of stay in the hospital will depend on the rate of your recovery. You will remain in the hospital as long as your physicians feel hospitalization is necessary. Most patients stay in the hospital for approximately seven to ten days. The hospitalization time can vary depending on the severity of your illness prior to transplant or complications after surgery.

After you leave the hospital you will still be recovering. For the first 4-6 weeks you will have some restrictions on your daily activities. If you experience any post-operative complications your recovery time may be longer. During the recovery period the transplant team will follow your progress. You will need to be monitored on a long-term basis and you must make yourself available for examinations, laboratory tests and cardiac biopsies to see how well your transplanted heart is working. Biopsies will be done routinely and as needed to diagnose possible complications including rejection or recurrent heart disease.

The transplant team will see you frequently the first year, and periodically thereafter for the life of your transplant. Every effort is made to transition your routine medical care to your primary care physician. You will be followed in the transplant clinic for life. For most patients this involves frequent lab work and a yearly clinic visit. Patients who develop complications may need to be seen more often by the transplant team.

Alternative Treatments

Alternative treatments or therapies may be available for your medical condition. Please discuss your condition and any possible alternative therapies with your health care team.

Potential Medical/Psychosocial Risks

Despite the use of high standards, there are inherent risks in all surgeries, especially surgeries conducted under general anesthesia. Sometimes, despite all the best efforts by both you and the heart transplant team, unexpected complications or outcomes occur. Many complications are minor and get better on their own. In some cases, the complications are serious enough to require another surgery or medical procedure.

Post transplant bleeding, when it occurs, is usually slow but persistent. Bleeding to some degree occurs in most patients and post operative transfusion may be required. Blood is evacuated through the drains left in place at the time of the transplant, but blood and blood clots can occlude the drains and possibly interfere with function of the transplanted heart. A return to the operating room may be required to assess bleeding or to remove these clots

Bleeding during or after surgery may require blood transfusions or blood products that can contain bacteria and viruses that can cause infection. Although rare, these infections include, but are not limited to, the Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

There may be a delay in the function of your transplanted heart. Such a delay may increase the length of your hospital stay and increase the risk of other complications. There is a possibility that the transplanted heart will not function. When this occurs a second transplant may be needed. If it is believed that you can only survive with a second transplant, you will be placed on the UNOS waitlist in the highest priority category allowed. If a second heart does not become available death may occur.

The chance of primary non-function (heart not working right after surgery) is about 3%. Re-transplantation is required emergently for cases of primary non-function.

Rejection and infection are common after heart transplantation. Acute rejection is a very common type of rejection. Patients can experience at least one acute rejection episode in the first year after surgery. Understanding the process of acute rejection involves understanding the immune system. The immune system includes white blood cells in the body that recognize what is part of the body and what is not. These cells protect the body from foreign invaders. When the donor heart is transplanted into the patient, the white blood cells recognize that the donor heart is foreign and will attempt to attack and destroy it. That is called acute rejection. Patients take anti-rejection medication for the rest of their lives to help prevent acute rejection, and they take additional medication to treat acute rejection.

Most of the time, patients do not have any symptoms to let them know that they are experiencing an episode of acute rejection. Therefore, it is necessary to monitor whether a patient is having acute rejection through heart biopsies. Heart biopsies are routinely performed (as an outpatient procedure) in a cardiac catheterization lab. The specific treatment of rejection depends on the biopsy results.

Patients may also experience chronic rejection (also called vasculopathy or arteriopathy) after a heart transplant. Chronic rejection is fairly common and usually occurs more than one year after surgery. Chronic rejection involves the coronary arteries of the donor heart. Chronic rejection causes the coronary artery vessel walls to become thicker, and therefore, blood flow through the narrow coronary arteries decreases. Although most patients do not experience chest pain (angina) with chronic rejection, it is possible. Being on a low fat diet, exercising, and taking anti-rejection medicines, aspirin, and other medicines, may help reduce the risk of developing severe chronic rejection. Chronic rejection is monitored with [cardiac catheterization testing](#).

Heart transplant patients are at an increased risk for infection because of the anti-rejection medicines they are taking. Anti-rejection medicines decrease the response of the immune system's ability to fight an infection. Therefore, patients learn about symptoms of an infection so that they can notify their doctor early and receive appropriate treatment.

There are other risks associated with heart transplants. Infections from bacteria, viruses, or fungi, acute rejection, side-effects from drugs that suppress the immune system are all possible complications. Side-effects from immune-suppressing drugs include kidney problems, gastrointestinal complaints, blood count abnormalities, nerve damage, high blood pressure, weight gain, diabetes, and others. There may be a need for other procedures, or a prolonged intensive care unit or hospital stay after a heart transplant.

There is a slight increase in the risk of certain kinds of cancer (including skin cancer and post-transplant lymphoproliferative diseases or lymphoma) because of the immunity-suppressing medications.

Miscellaneous risks:

Despite the use of compression boots, blood clots may occasionally develop in the legs and can break free and occasionally move through the heart to the lungs. In the lungs, they can cause serious interference with breathing, which can lead to death. Blood clots are treated with blood-thinning drugs that may need to be taken for an extended period of time.

The risk of infection is higher for transplant recipients than other surgical patients because the treatments needed to prevent organ rejection make the body less capable of fighting infection. The chest incision for the heart transplant and any incision needed for the bypass machine (neck, underarm, and groin) are potential sites for infection. Infections in the sites where tubes are placed in your body (tubes to help you breathe, tubes in your veins to provide fluids, nutrition and to monitor important body functions) can cause pneumonia, blood infections and local infections.

Damage to nerves may occur. This can happen from direct pressure or positioning of the arms, legs or back during the surgery. Nerve damage can cause numbness, weakness, paralysis and/or pain. In most cases these symptoms are temporary, but in rare cases they can last for extended periods or even become permanent.

Other possible complications include: injury to structures in the chest, pressure sores on the skin due to positioning, burns caused by the use of electrical equipment during surgery, damage to arteries and veins, pneumonia, stroke, and permanent scarring at the site of the surgical incision.

National and Transplant Center-Specific Outcomes

Statistics from the Scientific Registry of Transplant Recipients (SRTR) (www.ustransplant.org) show that one year after transplantation 88% of heart transplant recipients are alive and 79% are alive 3 years after transplant. The donated heart (the “graft”) is functioning 87% of the time at 1 year after transplant and 73% of the time at 3 years after transplant. The results at Jackson Memorial Hospital / University of Miami Medical Center meet or exceed these standards and do not significantly differ from the expected survival rates.

Notification of Medicare Outcome Requirements not Being Met by Center

Specific outcome requirements need to be met by transplant centers and we are required to notify you if we do not meet those requirements. Currently, Miller School of medicine / Jackson Memorial Hospital Health Systems meets all requirements for transplant centers. If at some point during the time you are waiting for a heart transplant, the hospital does not meet CMS transplant criteria, we will notify you in writing.

Right to refuse transplant

You have the choice not to undergo transplantation. If you choose not to have a transplant, treatment for your heart disease will continue. If you do not undergo the transplant surgery, your condition is likely to worsen and limit your life expectancy.

Transplantation by a Transplant Center Not Approved by Medicare

If you have your transplant at a facility that is not approved by Medicare for transplantation, your ability to have your immunosuppressive drugs paid for under Medicare Part B could be affected.

After you have a heart transplant, health insurance companies may consider you to have a pre-existing condition and refuse payment for medical care, treatments or procedures. After the surgery, your health insurance and life insurance premiums may increase and remain higher. In the future, insurance companies could refuse to insure you.

Confidentiality

We are required by law to maintain the privacy/confidentiality of your health information. All information that is obtained in connection with this procedure, which can be linked to you, will remain as confidential as possible within the requirements of state and federal law. The results of this procedure will be reviewed and may be published in a scientific journal or book without identifying you by name. If the data is used for publication in the medical literature or for teaching purposes, your name will not be used. Records will be kept regarding this procedure and will be made available for required reviews/audit by representatives of the Food and Drug Administration (FDA), members of the Jackson Memorial Hospital Heart Transplant program, members of the Cardiac Transplant Research Database (CTRD) and INTERMACS (Ventricular assist device Database), and representatives of United Network for Organ Sharing (UNOS) under the guidelines established by the Federal Privacy Act. Federal and State reviewers/auditors may also have access to your medical records, which contain your identity however they are required to maintain confidentiality. Your insurance company may also review your record.

Waiting Time Transfer and Multiple Listing

If listed for transplant, you have the option of being listed for transplant at multiple transplant centers and the ability to transfer your waiting time to a different transplant center without loss of the accrued waiting time.

Concerns or Grievances

The United Network for Organ Sharing provides a toll-free patient services line to help transplant candidates, recipients, living donors, and family members understand organ allocation practices and transplantation data. You may also call this number to discuss a problem you may be experiencing with your transplant center or the transplantation system in general. The toll-free patient services line number is 1-888-894-6361.

Voluntary Participation

Your participation is voluntary, and you may choose to withdraw from evaluation; be taken off the list at your request at any time without adversely affecting your relationship with your doctors and nurses. The treatment plan you receive from your doctors and nurses is based upon their experience plus ongoing review of the scientific literature related to care of heart transplant patients.

Authorization

Your signature certifies that you have decided to proceed, having read the information contained in the consent form, having received and read the patient educational manual provided to you at the time of your evaluation, and having had the risks and benefits explained to you, either today or previously. Upon signing this form, you will receive a copy.

Patient Signature

Date

Transplant Team Physician / Surgeon Signature

Date

Transplant Coordinator or Nurse Practitioner Signature

Date

Translation

Date