

Informed Consent for Lung and Heart/Lung Transplant Patients

This document is an informed consent of the transplant evaluation process, surgical procedure, alternative treatments (if applicable), potential medical and psychosocial risks, and finally, national and transplant center specific outcomes from the most recent United Network for Organ Sharing (UNOS) reports for one year survivals. The purpose of this consent is to help protect and promote patient's rights by education.

Evaluation Process

You will be evaluated for lung or heart/lung transplantation by consultations, lab tests and various procedures that will determine the medical appropriateness of your candidacy for transplant. You will meet with members of the transplant team who may 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 lung transplant process.
- A **Pulmonologist** is a physician who specializes in lung disease. The pulmonologist will assist in the medical management of your lung disease and work with the transplant team to determine if you are medically suitable for a transplant.
- A **Cardiologist** is a physician who specializes in heart disease. The cardiologist will assist in the medical management of those patients with heart/lung disease and work with the transplant team to determine if you are medically suitable for a transplant, and whether heart and lung is necessary.
- 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 lung or heart/lung transplant, the various types of surgical options available, 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. The social worker will also help to identify your support network.
- 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** will conduct a more in-depth evaluation and assessment, should that be necessary. 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 cardiologist (heart doctor), nephrologist (kidney doctor), or a hepatologist (liver doctor) to assess for other medical conditions.

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 will 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 chest x-ray helps your physician confirm your diagnosis, and identify any new problems with your lungs.
- A urine test is used to screen for the presence of urinary tract diseases as well as drugs and alcohol in your system.
- An EKG, echocardiogram, stress test, or cardiac catheterization will show how well your heart is beating and the function of your heart valves. This will help your physicians decide if your heart function is strong enough for transplant surgery, or if you need combined heart/lung transplantation.
- A CT scan or MRI determines the extent of your heart and lung disease, the presence of any tumors, and shows any potential anatomical risks for surgery.
- An ultrasound of your abdomen helps assess the size, shape, and circulation of your liver, kidneys and pancreas.
- Pulmonary function tests are required to assess the extent of your lung disease. This is a breathing test to analyze your lung capacity.

Surgical Procedure

Lung and Heart/Lung 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 lung or heart/lung transplant. It is never fully known how some potential conditions that cause underlying lung disease such as sarcoidosis or scleroderma will affect your transplanted lung. The operation is complex and the risks are high. The overall success rate, roughly defined as the patient surviving with the transplant lung for at least one year, is about 80-85%, and for heart/lung is about 69%. In other words, the chance of dying following a lung transplant is about 15-20% , and for heart/lung transplant is about 30%, in the first year. 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.

Lungs and Heart/lungs are allocated according to the policy of United Network for Organ Sharing (UNOS). The organs are primarily allocated according to how sick a patient is. Being put on the waiting list for a lung or heart/lung transplant does not guarantee the availability of a donor or receiving a transplant.

Heart/lung candidates will need both organs from the same donor and because of this, may experience longer waiting times. The following description of the operation, care, recovery and potential risks applies to both lung **and** heart/lung recipients.

The Transplant Operation

When a donor organ becomes available, you will be called and you must come to the hospital right away. If the organ is considered an extended criteria organ your surgeon will review this with you and assist you in making your decision. It is at this point that the surgeon has a clear picture of the risks associated with this particular organ versus the risk of waiting for the next available donor and can base the specific recommendations on this information. 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 before surgery. The

transplant surgeon will make an incision in your chest. Through this incision your heart/lung, lung or lungs will be removed and a donated heart/lung, lung or lungs will be placed into your chest.

During the surgery you may be placed on a heart/lung machine for lung candidates and definitely placed on the heart/lung machine for heart/lung recipients. This can be done by placing tubes to drain blood from your body, circulating it through the heart/lung machine, and then returning it to you. An incision in the groin may be required to access your blood vessels to accomplish this procedure. The transplant surgeons will decide if this machine will be used based upon your condition.

Drains, also called chest tubes, will be put into your body at the end of your operation to monitor blood loss and to allow fluids 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 will experience pain. This will be carefully monitored and controlled. Most transplant recipients have a significant reduction in the pain two to three weeks after surgery.

When your medical condition has stabilized you will be transferred to the 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 one to two weeks. The hospitalization time can vary depending on the severity of your illness prior to transplant or complications after surgery. During your stay you will participate in daily pulmonary rehabilitation. This therapy will help speed your recovery and is an essential part of both pre and post lung transplant regime.

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 scans of your chest to see how well your transplanted heart/lungs or lungs are working. Bronchoscopies with biopsies will be done routinely and as needed to diagnose possible complications including rejection or infection. Echocardiograms and cardiac catheterization will be done to monitor heart function for those patients who undergo heart/lung transplants.

The transplant team will see you frequently for the first year, and periodically thereafter for life after transplant. Every effort is made to transition your routine medical care to your primary care physician after the first year. You will be followed in the transplant clinic for life. For most patients this involves frequent lab work and a bi-annual clinic visit with pulmonary function studies and chest x-ray. Heart/lung recipients will also undergo cardiac catheterization to assess heart function and development of coronary artery disease yearly. Heart/lung recipients will also be co-managed by their transplant cardiologist. 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

There are inherent risks in all surgeries, especially surgeries conducted under general anesthesia. 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.

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 lung(s) or heart/lungs. Such a delay may increase the length of your hospital stay and increase the risk of death and other complications. There is a possibility that the transplanted lung(s) or heart/lungs will not function. When this occurs a second transplant is needed. You will be placed on the UNOS waitlist in the highest priority category allowed. However, while waiting your body may develop failure of other organs. As a result, you may become unsuitable for re-transplantation. If a second organ does not become available death may occur.

Occasionally, bypass machine may be necessary. This is a life support machine that helps circulate blood and oxygen to the body while surgery is performed on the heart or lungs. The use of this machine has inherent 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 the 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.

Airway dehiscence occurs in a small percentage of lung transplants. This is a separation of the connection between the donor and the recipient's wind pipes. Airway dehiscence can cause respiratory failure and can require return to the operating room for repair. This can increase the risk of later development of bronchial stenosis, an obstruction of the large airway that can impair respiratory airway clearance, leading to infection. Bronchial stenosis sometimes requires a stent- a metal object that is placed into the narrowed area to open it back up and maintain the airway patency.

There are other risks associated with heart/lungs and lung transplants. Infections from bacteria, viruses, or fungi, acute rejection, and 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 repeated lung bronchoscopies, surgeries, and other procedures, or a prolonged intensive care unit or hospital stay after a heart/lung or lung 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:

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. Also, infection is more frequent in heart/lung and lung transplant recipients as the lung itself is predisposed to pneumonia. The chest incision for the lung transplant or heart/lung transplant and any incision needed for the heart/lung bypass machine 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 contact within the chest or from pressure or positioning of the arms, legs or back during the surgery. Nerve damage can cause numbness, weakness, paralysis and/or pain. Injury or trauma to the phrenic nerve, which allows the diaphragm to function properly, may occur. 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, heart attack, stroke, and permanent scarring at the site of the chest 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, 82% of lung transplant recipients are alive. The donated lung (the “graft”) is functioning 83% of the time at 1 year after transplant. These statistics also show that 69.3% of heart/lung recipients are alive after one year. The results at Miller School of Medicine/Jackson Health Systems do not significantly differ from the national 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 Health Systems meets all requirements for transplant centers.

Organ Donor Risk Factors

Certain conditions in the donor may affect the success of your heart/lung or lung 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.

Right to refuse transplant

You have the choice not to undergo transplantation. If you choose not to have a transplant, treatment for your heart or lung 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/lung or lung 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.

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.

I have provided this information to the prospective lung transplant patient.

Nurse Coordinator: _____ Date: _____

Patient: _____ Date: _____

Family Member: _____ Date: _____

Surgeon: _____ Date: _____

Pulmonologist: _____ Date: _____