

JOHNS HOPKINS COMPREHENSIVE TRANSPLANT CENTER CLINICAL POLICY AND PROCEDURES

Johns Hopkins Hospital Comprehensive Transplant Center Informed Consent Form for Thoracic Organ Recipient Evaluation

The decision to undergo transplantation can be extremely difficult and often confusing. The transplantation process may be complex and may include a large amount of testing and frequent visits to the transplant center or your primary physicians. Our goal is to provide you with as much information as possible to describe and explain the transplant process from initial inquiry to long-term follow-up.

This initial consent provides the basic information you should know about transplantation. This document will provide you with the nature, risks and benefits of transplantation; a comprehensive picture of all the requirements leading up to the procedure; and your rights as a patient being evaluated for transplantation.

What is transplantation?

Transplantation is the operation/procedure in which the patient's own diseased or non-functioning organ/tissue is replaced with healthy, functioning organ/ tissue from a deceased donor.

Who can participate?

Transplantation is open to individuals meeting specific criteria that are established by the Organ Procurement and Transplant Network (OPTN) and the transplant center. Inclusion criteria are organ dependent; and based on scientific findings and continually collected statistics. Specific inclusion criteria are available by request.

How and what is involved in the evaluation process?

Transplantation in general is divided into two steps. The first step is a comprehensive evaluation to decide if you are an appropriate candidate for transplantation. If it is decided that you are a potential candidate, you will be added to the national wait list to await a deceased donor organ. The second step of transplantation is the surgery. The surgery will involve the removal of your diseased organ(s) and the placement of the new organ. The surgery is followed by a stay in the hospital and a life-long course of medication. Going through the evaluation process does not guarantee that you will be eligible for transplantation. Additionally, you have the right to withdraw from the evaluation or wait list at any time.

Evaluation Process

The transplant evaluation process is comprehensive. In order to make the very best decision about transplant candidacy, our team must complete a thorough evaluation. Organs for donation from a deceased donor are a scarce resource. As an advocate for the transplant process, we must provide assurance that the use of an organ for transplant is done appropriately, ethically, and fairly based on need. Further, the governing body for transplant the Organ Procurement and Transplant Network (OPTN) requires that all candidates meet strict criteria for transplant consideration.

The evaluation process involves a medical, psychological/social, and financial component. A determination will be made following medical and surgical consultation and testing; a consult with our staff psychologist and/or social worker; and financial clearance.

The medical and surgical consultation and testing will involve a health assessment along with blood and urine tests. You will also have a series of diagnostic tests. Each will focus on

JOHNS HOPKINS COMPREHENSIVE TRANSPLANT CENTER CLINICAL POLICY AND PROCEDURES

identifying any problems that could cause issues with receiving a transplant or proving that no problems exist. A standard list of tests is usually adhered to but individual health concerns may require additional testing. The following list of tests are common but the final list is dependent on the type of organ to be transplanted:

Tests may include but are not limited to:

- Chest X-ray
- 3-Dimensional CT or standard CT or organ or organ location
- Ultrasound of affected organ
- Biopsy- A test in which a needle is used to remove a small piece of tissue. The tissue is then examined under the microscope.
- Cardiology testing and/or consultation (EKG, Stress test, echocardiogram, ex)
- Cardiac catheterization
- 6 Minute walk
- Pulmonary testing and/or consultation
- Mammogram; Pap test (females of age)
- Cancer screening
- Colonoscopy (recipients of age) or with concern
- Vascular testing
- Vaccinations
- Swallowing study
- Gastroenterology tests

Each test required will be explained to you before it is done. Some of these tests have risks (CT scan with dye, biopsy, and stress test). These risks will be discussed with you at the time of the test. You will be asked to sign a separate consent form for some of these procedures.

Laboratory tests will be focused according to the required organ, your age and health status, and present or past risks. Each potential recipient should expect to have screened:

- Basic blood chemistry
- Hematological tests (WBC, Hematocrit; Bleeding times, etc)
- Serology (Tests for hepatitis, childhood viruses, and acquired/transmitted diseases)
- HIV screening
- Microbiology (Blood, urine, and sputum cultures)
- Cancer markers (for example PSA for males to screen for prostate cancer)
- 24 hr urine collection for creatinine and protein clearance

A psychosocial consultation will be performed. There are three main reasons for this:

1. to determine if you are capable of giving informed consent.
2. to discuss your understanding of transplantation and the risks and benefits that may occur.
3. to determine if you and your family will be able to hold up under the emotional, financial and physical stress of this type of surgery.

A financial screen and/or consultation will be performed. There are two main reasons for this:

1. to determine transplant insurance benefits
2. to discuss financial concerns and identify problems that may occur as a result of transplant

You need to know that future health, disability and life insurance premiums may be higher as a result of transplantation. There is a risk that you may not be able to get health, disability and life insurance in the future if you lose your current insurance or become uninsured.

JOHNS HOPKINS COMPREHENSIVE TRANSPLANT CENTER CLINICAL POLICY AND PROCEDURES

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. The Johns Hopkins Hospital **is** an approved facility.

At any time during the evaluation process, or prior to surgery, you are free to decide, for any reason, that you no longer wish to be considered for transplant. Additionally, if something changes we may decide that you are no longer a candidate.

How and what is involved in the transplant surgery process?

Transplant in the United States occurs via two mechanisms:

1. Deceased donor donation and transplantation
2. Live donor donation and transplantation

Heart and/ or lung transplantation at the Johns Hopkins Hospital, at this time, is conducted using deceased donor organs.

Candidates found acceptable to undergo deceased donor transplantation will be placed on a national wait list. Distribution of organs will depend on the severity of illness, blood type of the donor, and organ availability. Wait times will vary on blood type and organ required. Extensive information on organ donation, national wait lists, allocation processes, and transplantation statistics are publicly available via the UNOS website at www.unos.org.

Benefits - Overall

The most obvious benefit to transplant is the potential to extend your life. It is firmly believed that transplantation will increase a person's quality of life. This may include freedom from oxygen, artificial organ assist device; overall better health; and return to involvement in normal societal activities.

Risks – Surgery and after

Complications do happen secondary to transplantation including death. Additionally, the transplanted graft may fail immediately or after transplant. Each center is required to report all patient deaths and graft issues to UNOS. This data is analyzed on a regular basis and publicly available at www.ustransplant.org. Center specific reports are updated and published every 6 months. The most recent information is provided to you as a supplement to this document. Please consult one of the medical care providers for help in interpretation.

Other risks and alternatives follow:

Interrupted Surgery

The evaluation process of the potential donor and recipient does not stop when the surgery begins. It continues throughout the surgery. If at any point the surgical team believes that you are at risk or that the organ is not right for transplantation, the surgery may be stopped.

Surgery

There are always risks with any surgery. Pain, bleeding, infection and/or injury to other organs are potential risks. Other risks include post-operative fever, pneumonia, nausea and urinary tract infections. Patients who have surgery are also at risk to form blood clots in their legs. These blood clots can break free and move through the heart to the

JOHNS HOPKINS COMPREHENSIVE TRANSPLANT CENTER CLINICAL POLICY AND PROCEDURES

lungs. In the lungs, the blood clot may cause a serious problem called pulmonary embolism. Pulmonary embolism is usually treated with blood thinners. In some cases these clots can cause death. There are special devices (plastic boots), used to keep blood flowing in the veins of the legs during surgery to try to prevent clots from forming.

General Anesthesia

This surgery will be done under general anesthesia. There are a number of known possible risks with any surgery done with general anesthesia. These risks will be discussed with you. A separate consent form will need to be signed for anesthesia.

Blood Transfusions

You may need blood during this surgery, although transfusions are not always necessary during the surgery. In these cases you will be given blood from the blood bank. This blood is carefully screened for HIV, Hepatitis and other diseases. There is still a small risk of getting an infection from this blood.

Post Surgical Course/Discomfort

After the surgery, you will have many drains, intravenous catheters, and tubes placed throughout your body. These are temporary devices. You will go to the Cardiac Surgical Intensive Care Unit where you will be closely monitored. You will still be on the ventilator (breathing machine) after surgery. You will have some discomfort (gas pains, sore throat, soreness, back aches, etc.) after the surgery. As you get better, you will be moved to the Step-down Unit to continue your recovery. While most patients require a hospital stay of around 14 days, you should plan to be in the hospital for as few as 5 days and potentially for a longer stay. This is dependent on how your body reacts to the new organ and medications needed to prevent that organ from rejecting.

You will be followed on a regular basis by the Transplant Center after your discharge. This includes routine lab work, biopsies, clinic visits and other diagnostic testing as needed.

Infection

Following transplant you will be on a number of medications that prevent your body from rejecting the organ. These medications lower your immune system and make you susceptible to infections by viruses, bacteria and fungi. The transplant team will do everything possible to protect you while in the hospital and offer suggestions for prevention at home.

Recipient Organ Failure/Recurrence of Disease

It is possible that the donor organ may fail or be rejected for a variety of reasons. This may require re-listing for another transplant. During the waiting time, death may occur if a suitable organ is not found.

It is also important to understand that a transplant does not cure some diseases. In the cases of Hepatitis B and C, these recur after surgery. Additionally, some diseases might recur in the transplanted organ(s). This should be discussed with the health team.

Risks – Donor Risk Factors

JOHNS HOPKINS COMPREHENSIVE TRANSPLANT CENTER CLINICAL POLICY AND PROCEDURES

Deceased donors are carefully screened. Donor scarcity and/or need may require use of what is referred to a “High Risk Donor”. This label is applied, but not limited to: donors of advanced age; those with a history of substance abuse; cigarette smoking of more than 20 pack years (example 1 packs per day for 20 years); prison inmates; homosexual males; an extensive medical history; or trauma to the organ or any combination of these factors. You will be asked at listing regarding your interest in higher risk donors. Your decision to not consider these organs will not jeopardize your placement on the wait list but may result in another candidate being transplanted before you. There is a low risk for spread of infectious disease such as hepatitis or HIV. These diseases are screened in the evaluation process. You will be informed at the time of organ offer of any of these findings.

Alternatives

The alternative to transplantation is continued chronic medical care. There is no way of predicting success or failure with transplant nor is there for life without transplantation. Your decision to refuse transplant will not change the relationship you have with your primary or specialty physician(s). Consideration of transplantation may also occur later should you not be ready at this time.

Confidentiality

Hospital personnel who are involved in the course of your care will have access to your medical records. They are required to maintain confidentiality as per law and the policies of this hospital. If you do become a potential recipient, data about your case, which will include your identity, will be sent to UNOS. It may also be sent to other places involved in the transplant process as permitted by law. Your medical history and results **will not** be discussed with anyone not associated with the transplant process or your care.

Additional Information

The Johns Hopkins Hospital Patient Bill of Rights will be provided to you on clinic check in and admission to the hospital. The Bill of Rights clearly defines the rights of the patient and the grievance policy should the need arise. It is also available per request.

Once listed on the United Network for Organ Sharing wait list, you will have the option to be listed at other centers. Each center does have there own inclusion and exclusion criteria for listing, which you will want to explore if this option is right for you. Additionally, you'll have the option to transfer your care and wait time without a loss of accrued time. You can obtain more information about transplantation, donation, organ allocation, and center statistics from the UNOS web page at www.unos.org

You can obtain detailed center statistics from the Scientific Registry for Transplant Recipients (SRTR) at www.ustransplant.org

UNOS has also an established toll-free patient services phone line to help transplant candidates, recipients, and family members understand organ allocation practices and transplant data. This number may also be called to discuss a problem you may be experiencing with the transplant center or the transplantation system in general. The toll-free patient services line number is 1-888-894-6361.

For any questions about the information in this document, please call the Thoracic Transplant Offices at the Johns Hopkins Hospital. The Heart Office number is (410) 955-7935 and the Lung Office is (410) 614-4898.

