

JOHNS HOPKINS COMPREHENSIVE TRANSPLANT CENTER CLINICAL POLICY AND PROCEDURES

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

The decision to undergo transplantation can be extremely difficult and often confusing. The transplantation process is complex and may include a large amount of testing and frequent visits to the transplant center and/or your primary physicians. Our goal is to assess your individual needs related to transplantation and provide information to help you understand the transplant process from initial referral to long-term follow-up.

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

What is transplantation?

Transplantation is the operation/procedure in which a healthy, functioning organ(s) from a living or deceased donor is placed within your body to replace the function of that same organ which is not properly working in you.

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. Who is considered for transplantation depends upon the type of organ being transplanted, the results of the medical testing performed, and continually collected information about other people who have already been transplanted. Examples of these guidelines are available by request.

How and what is involved in the transplantation process?

Transplantation, in general, is divided into three phases. The first phase is a complete evaluation to decide if it is safe and medically advisable for you to undergo transplantation. If it is decided that you are potential candidate, there are two possible options; receiving a living donor transplant from a relative; or friend or being placed on the national waiting list to await a deceased donor transplant. Those who decide to wait for a deceased donor organ will enter the second phase, waiting on the national waiting list for a deceased donor. The third phase of transplantation is the surgery. The surgery may involve the removal of your diseased organ(s) (failed kidneys are rarely removed) and the placement of the new organ. The surgery is followed by a stay in the hospital and a life-long course of medication to prevent rejection of the organ. **Going through the evaluation process does not guarantee that you will be eligible for transplantation.** You may withdraw from the evaluation or wait list at any time.

Evaluation Process

In order to make the very best decision about you as a possible transplant candidate, our team must complete a thorough evaluation. Organs for donation whether from a deceased or live donor are a scarce resource. In order to fulfill our responsibility to patients, donors, donor families and the national organ transplantation system, we must provide assurance that 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 guidelines for transplant consideration.

The evaluation process involves a medical, psychological/social, and financial component. You will be evaluated by our medical and surgical teams. You will be seen by our social worker and/or

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psychologist. A financial review will be done by our business office coordinators. In select cases, a consult by our substance abuse counselor will be necessary.

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 identifying any potential problems that could increase the risk of receiving a transplant or the difficulty of the procedure. Individual health concerns may require additional testing.

Tests may include but are not limited to:

- Chest X-ray
- 3-Dimensional CT or standard CT
- Ultrasound
- 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, etc.)
- Pulmonary testing and/or consultation
- Mammogram
- Cancer screening (Pap test –females; PSA-males)
- Colonoscopy (recipients of age) or with concern
- Urodynamics/VCUG
- Vascular testing
- Vaccinations

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 chemistries
- Hematological tests (WBC, Hematocrit; Bleeding times, etc)
- Serology testing (Tests for hepatitis, childhood viruses, and acquired/transmitted diseases)
- HIV screening
- Microbiologies (Blood and/or urine cultures)
- Cancer markers

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

1. to determine if you are capable of understanding the procedure and 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 have adequate coping mechanisms to withstand 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 resources to meet the long term costs associated with transplant

Your 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.

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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.

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

Due to patient confidentiality we are unable to share any of the donor's test results, findings or the decisions made without written consent from the donor.

Coercion by recipients and/or suggestion of payment, or other promises are taken very seriously and will prevent the donation evaluation from proceeding. You will be asked to sign a separate agreement acknowledging this concern.

Live donor transplantation will occur when both donor and recipient are physically and mentally prepared.

Candidates found acceptable to undergo deceased donor transplantation will be placed on a national wait list. Allocation of organs will depend on the severity of illness, blood type of the donor, and organ availability. Wait times will vary based upon 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 extension of life that may result. It is firmly believed that transplantation will increase a person's quality of life. This may include freedom from kidney dialysis, or artificial organ assist device; overall better health; and return to involvement in normal societal activities.

Risks – Surgery and after

Complications do happen during transplantation including occasionally death. Additionally, the transplanted graft may fail immediately or at some point after transplant. Each center is required to report all patient deaths and graft issues to UNOS. This information is analyzed on a regular basis and is 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 is ongoing. It does not stop when the surgery begins. It continues throughout the surgery. If at any point the surgical team

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believes that you are at risk or that the organ is not right for transplantation, the surgery will 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 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 usually necessary during the surgery. If needed, you will be given blood from the blood bank. This blood is carefully screened for HIV, Hepatitis and other diseases. There is still a very small risk of getting an infection from this blood.

Post Surgical Course/Discomfort

After the surgery, you will have many drains, intravenous lines, and tubes placed throughout your body. These are temporary devices. You will go to an intensive care bed where you will be closely monitored. There is a chance that you will still be on the ventilator (breathing machine) after surgery. You will have some discomfort (incisional pain, gas pains, sore throat, soreness, back aches, etc.) after the surgery. As you get better, you will be moved to a general Transplant Unit bed to continue your recovery. 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 being rejected.

You will be followed on a regular basis by the Transplant Center after your discharge. This includes routine lab work to monitor your organ function, clinic visits and possible diagnostic testing.

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, fungi, and bacteria. You will receive antibiotics to prevent the most common forms of infection seen in transplant patients. The transplant team will do everything possible to protect you while you are in the hospital and offer suggestions for prevention at home.

Recipient Organ Failure/Recurrence of Disease

There is a small possibility that the donor organ may fail or be rejected for some reason. This may require re-listing for another transplant. During the waiting time for a second transplant, death may occur if a suitable organ is not found.

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It is also important to understand that a transplant does not cure disease. In some cases, the causative disease of organ failure may return in many recipients. Viral diseases such as Hepatitis B and C usually recur after surgery. This should be discussed with the healthcare team.

Malignancy

It is important to understand that after a transplant you will be at an increased risk of developing certain cancers due to the anti-rejection medications you will be taking. In addition to the risk of developing common cancers (skin, colon, lung, prostate, breast, cervical, etc), transplant recipients are at risk of developing a cancer of the lymph nodes called post-transplant lymphoproliferative disorder (PTLD). Of note, PTLN occurs at a higher rate in transplant recipients that have not had an Epstein-Barr virus (EBV) infection in the past.

Potential Psychosocial Risks

It is important to understand that the recipient may experience problems with post-traumatic stress disorder (PTSD), general anxiety, depression, dependence on others and/ or feelings of guilt.

Risks – Donor Risk Factors

In the case of live donation, donors are carefully screened for any potential problems that may occur to themselves and/or you as the recipient of their organ. However, even the most careful of screens may miss something that may harm you. *Currently, the risk of infection with HIV in the United States through receiving a blood transfusion or blood products is extremely low and has become progressively lower, even in geographic areas with high HIV prevalence rates. www.cdc.gov (2007).* Transmittable diseases are screened in the evaluation process and prior to donation. Donor age and medical health can also affect the organ quality.

Donors are carefully screened. However, there is no way to screen donors for every possible infection that can be transmitted to a recipient. While current testing is very reliable, it is not 100% accurate. Donor scarcity and/or need may require use of what is referred to an "Increased Risk Donor". This label is applied to: People who have used a needle to inject drugs into their body for non-medical use; People who have engaged in sex for money or drugs in the last year; Men who have had sex with one or more men in the last year; People who have had sex in the last year with someone with HIV, HBV and/or HCV; People who have had sex in the past year with any person described above; Inmates of a jail, lockup, or detention facility for more than three days in the past year; People with certain blood diseases who have received blood and/or blood product transfusion; People who have been newly diagnosed with any sexually transmitted disease in the past year; Children born to mothers at risk for being infected with HIV, Hepatitis B (HBV), or Hepatitis C (HCV); People who have been on hemodialysis. You will be asked at listing regarding your interest in increased 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 of contracting an 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 quality and extent of 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.

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Confidentiality

Hospital personnel who are involved in the course of your care will have access to your medical records. Federal law and hospital policy require employees to maintain confidentiality. Each employee is required to have signed user agreements and have met hospital HIPAA requirements. 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. Your medical history and results **will not** be discussed with potential donors unless requested with a signed authorization.

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 their 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.

Kidney patients with unresolved complaints have also the right to contact the Maryland Department of Health & Hygiene, Office of Health Care Quality, Hospital Compliant Unit, Spring Grove Hospital Center, 55 Wade Avenue, Bland Bryant Building, Catonsville, MD 21228, 410-402-8016 or toll-free 1-877-402-8218. You may also contact the Joint Commission Office of Quality Monitoring, One Renaissance Boulevard, Oakbrook Terrace, IL 60181, toll free 1-800-994-6610 or compliant@jointcommission.org.

For any questions about the information in this document, please call the Abdominal Transplant Offices at the Johns Hopkins Hospital. The Kidney/Pancreas Office number is (410) 502-0703 and the Liver Office is (410) 614-2989.

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**The Johns Hopkins Comprehensive Transplant Center
Informed Consent Form**

I have read the Informed Consent Form. I understand the nature, risks, benefits and alternatives to transplantation. I understand I may withdraw from the evaluation process or refuse transplant at any time. I wish to proceed with the evaluation to find out if I can become a transplant recipient.

I understand that in the United States it is against the law to buy, or to compensate in any way, a potential donor for his or her organ (e.g. kidney, liver). I understand that compensation to the donor does not include the reasonable payments associated with the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ. I agree to abide by this and not enter into any illegal financial arrangement with potential living donor(s).

Printed Name

Date of Birth

Date

Signature

Please return this page to the Transplant Office by either mail or fax.
Kidney/Pancreas office (fax) (410) 614-6906
Liver office (fax) (410) 614-8741

Mail to:

Kidney/Pancreas Transplant Office
The Johns Hopkins Hospital
600 N. Wolfe Street – Osler 625
Baltimore, MD 21287

Liver Transplant Office
The Johns Hopkins Hospital
600 N. Wolfe Street – Blalock 242
Baltimore, MD 21287

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Date received at JHH _____

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