

CONSENT FOR LUNG TRANSPLANTATION

INTEGRIS Baptist Medical Center, Inc.
Nazih Zuhdi Transplantation Institute
Lung Transplant Division

NOTICE: This is a legal document. Read it carefully before signing and make sure that all the blanks are completed. You will be legally bound by this document.

A lung transplant is a surgical procedure to remove severely diseased lungs and replace them with healthy lungs from a human donor. One or both lungs may be transplanted. In some cases, a heart transplant is done simultaneously, in which case the procedure is called a heart-lung transplant. This consent form will cover only lung transplants. The majority of lungs that are transplanted come from deceased organ donors. It is important that you fully understand the risks, benefits and alternatives to lung transplantation. The purpose of this document is to provide written information to you concerning the risks, benefits and alternatives to lung transplantation. The information provided here is a supplement to the discussions you have had with your physicians and surgeons in preparation for the procedure. You should read this consent form and ask your physicians any questions before giving your consent.

1. By signing below, you acknowledge that you have been informed in general terms and understand the following about the Procedure described above:
 - a. **Nature and purpose of procedure** (*Describe in laymen's terms*):

A lung transplant may be recommended for persons who have serious lung dysfunction that cannot be improved with maximal medical therapy and whose life expectancy without a transplant is 12 to 24 months. Lung transplants may be performed on all ages from newborn to adult, generally up to age 65. A lung transplant is done to treat irreversible, life-threatening lung disease, including but not limited to:

- End-stage [chronic obstructive pulmonary disease \(COPD\)](#) (includes [chronic bronchitis](#) and [emphysema](#));
- [Cystic fibrosis](#) (an inherited disease characterized by an abnormality in the glands that produce sweat and mucus. It is chronic, progressive, and is usually fatal);
- Pulmonary hypertension (PPH) (increased pressure in the arteries of the lungs), including PPH caused by heart defects;
- Alpha-1 antitrypsin deficiency;
- [Sarcoidosis](#)
- Pulmonary fibrosis, severe scarring or inflammation of the lung, from any number of causes
- Other hereditary conditions affecting the lungs

However, not all cases of these conditions require lung transplantation. A lung transplant is not recommended as a treatment for lung cancer. There may be other reasons for your physician to recommend a lung transplant.

A lung transplant is a complex surgical procedure performed to replace a diseased lung with a healthy lung from another person. The transplant procedure typically takes 6 to 12 hours for a double lung transplant and 4 to 8 hours for a single lung transplant; however, the operation might take substantially longer if any difficulties are encountered. Most people who have this procedure will need to stay in the Hospital between 7 – 14 days.

b. Before the procedure:

Once you have been accepted as a transplant candidate, you will be placed on the United Network for Organ Sharing (UNOS) list. Lung recipients are selected based on blood type, geographic location (distance between donor and recipient), and lung allocation score. When an appropriately matched lung is available, you will be contacted by telephone. You will be asked to report to the Hospital without delay. You will then wait for the new lung to arrive at the Hospital before you are prepared and taken to the operating room for the procedure. Very occasionally, the new lung may be found to be unsuitable for you just prior to the planned procedure. Your procedure will then be cancelled. If this should happen, it will not affect your place or priority on the waiting list for another lung.

Lung transplantation from a living donor is not performed at NZTI.

c. During the procedure:

Generally, a lung transplant follows this process:

1. You will be asked to remove any jewelry and other objects that may interfere with the procedure.
2. You will be asked to remove clothing and will be given a gown to wear.
3. An intravenous (IV) line will be started in your arm or hand. Additional catheters will be inserted in your neck and wrist to monitor the status of your heart and blood pressure, as well as for obtaining blood samples. Alternate sites for the additional catheters include the subclavian (under the collarbone) area and the groin.
4. You will be taken to the operating room and positioned on a table. Your position will depend on the type of procedure to be performed. For a single lung transplant, you will be positioned on the side opposite the side of the transplant. For a bilateral sequential lung transplant, you will be lying on your back with your arms above your head.
5. A catheter will be inserted into your bladder to drain urine.
6. Lung transplant surgery will be performed while you are asleep under general anesthesia. A tube will be inserted through your mouth into your lungs. You will be put on a ventilator to maintain your breathing.
7. The anesthesiologist will continuously monitor your heart rate, blood pressure, and blood oxygen level during the surgery.
8. The skin over the surgical site will be cleansed with an antiseptic solution.
9. The surgeon will make an incision in the chest. For a single lung transplant, the incision will be made on the side of the lung to be transplanted. For a bilateral sequential transplant, the incision will be made horizontally across the chest below the breasts. A small section of rib is permanently removed to allow access to your lung.
10. The diseased lung(s) will be carefully removed and replaced by the donor lung(s). Depending on your underlying lung condition and the type of transplant being

performed, you may be placed on a cardiopulmonary bypass machine (heart-lung machine) to maintain circulation and provide oxygen to the body during the procedure.

11. The new lung's blood vessels and airways will be attached. For a bilateral sequential transplant, the lungs will be attached one at a time.
12. The incision will be closed with sutures or surgical staples.
13. A sterile bandage/dressing will be applied to the incision.
14. One or more chest tubes will be placed in the chest to remove air, fluid, and blood from the surgical site and to allow the new lung(s) to expand fully.
15. An epidural catheter to infuse pain medication into your back or other devices for pain control may be inserted before you leave the operating room.
16. The surgeon will notify your family when the procedure is completed.

d. **After the procedure:**

After the surgery you may be taken to the recovery room before being taken to the intensive care unit (ICU) to be closely monitored for several days. Alternately, you may be taken directly to the ICU from the operating room. You will be connected to monitors that will constantly display your electrocardiogram (ECG or EKG) tracing, blood pressure, other pressure readings, breathing rate, and your oxygen level. Lung transplant surgery requires an in-hospital stay of seven to 14 days, or longer.

You will have a tube in your throat so that your breathing can be assisted with a ventilator until you are stable enough to breathe on your own. The breathing tube may remain in place for a few hours up to several days, depending on your situation. You may have a thin, plastic tube inserted through your nose into your stomach to remove air that you swallow. The tube will be removed when your bowels resume normal function. You will not be able to eat or drink until the tube is removed. Blood samples will be taken frequently to monitor the status of the new lung(s), as well as other body functions, such as the kidneys, liver, and blood system. You may be on special IV drips to help your blood pressure and your heart, and to control any problems with bleeding. As your condition stabilizes, these drips will be gradually weaned down and turned off as tolerated. You may receive pain medication as needed, either by a nurse, through an epidural catheter, or by administering it yourself through a device connected to your intravenous line. Once the breathing and stomach tubes have been removed and your condition has stabilized, you may start liquids to drink. Your diet may be gradually advanced to more solid foods as tolerated.

Your immunosuppression (anti-rejection) medications will be closely monitored to make sure you are receiving the optimum dose and the best combination of medications. Nurses, respiratory therapists, and physical therapists will work with you as you begin physical therapy and breathing exercises. When your physician feels you are ready, you will be moved from the ICU to a private room on a regular transplant unit. Your recovery will continue to progress here. Your activity will be gradually increased as you get out of bed and walk around for longer periods of time. Your diet will be advanced to solid foods as tolerated.

Nurses, pharmacists, dietitians, physical therapists, and other members of the transplant team will teach you how to take care of yourself once you are discharged from the hospital.

e. **Benefits of the Procedure:**

If your lung transplant is successful, you might receive the following benefits after recovering from your lung transplant. We cannot guarantee that you will receive any of these benefits. We also cannot guarantee that you will live longer than if you had not had a transplant. Only you can decide if the potential benefits are worth the risks:

1. Lung transplantation is considered to be a life-saving procedure.
2. Most people who have had a lung transplant consider that they have more energy and a better quality of life after the transplant.
3. You may no longer have the common symptoms of your underlying lung disease (COPD, pulmonary fibrosis, pulmonary hypertension, cystic fibrosis etc.)

f. **Material Risks of the Procedure:**

The following risks are well-recognized, but there may be other risks not included in this list that are unforeseen by your physicians. As with any surgery, complications may occur from lung transplantation, which include, but are not limited to, the following:

- bleeding
- infection (both usual - for example, bacterial and community acquired pneumonias - and unusual - viral infections (viral hepatitis, CMV, herpes, etc.), fungal infections, tuberculosis and TB like bacteria.)
- blockage of the blood vessels to the new lung(s)
- blockage of the airways
- severe pulmonary edema (fluid in the lung)
- primary graft dysfunction
- blood clots
- bronchiolitis obliterans with deteriorating lung function (inflammation and scarring occur in the airways of the lung, resulting in severe shortness of breath and dry cough)
- respiratory failure
- renal impairment or renal failure requiring dialysis
- cancer, including but not limited to skin cancers and an increased risk of post transplant lymphoma (a blood cancer which is often/usually associated with death or graft failure)
- severe osteoporosis (at times resulting in pain, the need for joint e.g. hip or knee, replacements)
- cataracts
- skin thinning and easy bruisability
- stomach ulcers
- diabetes mellitus (requiring insulin or pills)
- elevated blood cholesterol and triglyceride levels (resulting in premature hardening of the arteries, cardiac disease, high blood pressure, pancreatitis)
- anemia
- low platelets with a tendency to bleeding or bruising
- low blood white cell count which might temporarily or permanently affect your ability to fight infection
- high blood pressure
- rare neurological conditions

- rare blood disorders (multifocal leukoencephalopathy, hemolytic uremic syndrome) related to the immunosuppressive drugs and some viral infections
- death

In addition if you are hepatitis C antibody **positive/negative**. The risks associated with accepting a hepatitis C positive donor (without evidence of active liver inflammation) include: acquisition of the hepatitis C virus (in those previously negative) or possible superinfection with a different strain of hepatitis C in those already positive. There is a small but real risk of the development of active hepatitis and cirrhosis with the possibility of death due to liver failure in 1-5 years.

If there is a Hepatitis B core antibody positive donor, there is a very small chance of acquiring hepatitis B infection through lung transplantation from a donor with Hepatitis B core antibody positivity. The chance decreases if you, the recipient, receive vaccination or has surface antibodies prior to transplantation.

The new lung may be rejected. Rejection is a normal reaction of the body to a foreign object or tissue. When a new lung is transplanted into a recipient's body, the immune system reacts to what it perceives as a threat and attacks the new organ, not realizing that the transplanted lung is beneficial. To allow the transplanted organ to survive in a new body, medications must be taken to trick the immune system into accepting the transplant and not attacking it as a foreign object.

The medications used to prevent or treat rejection have side effects. The exact side effects will depend on the specific medications that are taken.

Contraindications for lung transplantation include, but are not limited to, the following:

- current or recurring infection that cannot be treated effectively
- metastatic cancer - cancer that has spread from its primary location to one or more additional locations in the body
- severe cardiac or other medical problems preventing the ability to tolerate the surgical procedure
- serious conditions other than lung disease that would not improve after transplantation
- noncompliance with treatment regimen

There may be other risks depending upon your specific medical condition. Be sure to discuss any concerns with your physician prior to the procedure.

g. What is done to prevent rejection?

The following are some of the most common symptoms of rejection. However, each individual may experience symptoms differently. Symptoms may include:

- fever
- fluid collection in the lung
- decreased oxygen level in the blood
- shortness of breath

The symptoms of rejection may resemble other medical conditions or problems. Consult your transplant team with any concerns you have. Frequent visits to and contact with the transplant team are essential.

To allow the transplanted lung(s) to survive in your body, you will be given medications for the rest of your life to fight rejection. Each person may react differently to medications, and each transplant team has preferences for different medications. The anti-rejection medications most commonly used include:

- cyclosporine
- tacrolimus
- azathioprine
- mycophenolate mofetil
- prednisone
- sirolimus

New anti-rejection medications are continually being approved. Physicians tailor medication regimes to meet the needs of each individual patient.

Usually several anti-rejection medications are given initially. The doses of these medications may change frequently, depending upon your response. Because anti-rejection medications affect the immune system, persons who receive a transplant will be at higher risk for infections. A balance must be maintained between preventing rejection and making you very susceptible to infection.

Some of the infections you will be especially susceptible to include oral yeast infection (thrush), herpes, and respiratory viruses. You should avoid contact with crowds and anyone who has an infection for the first few months after your surgery.

h. **Alternative Treatments:**

Lung transplantation is the only successful form of treatment for irreversible, life-threatening lung disease.

i. **If applicable, DNR Order or DNI/Special Code status suspended unless indicated otherwise:** _____

2. The Scientific Registry of Transplant Recipients (SRTR) is a national database of statistics related to all solid organ transplants. It covers the full range of transplant activity, from organ donation and waiting list candidates to survival statistics. The information is updated every six months. Information specific to all transplant centers is available at www.ustransplant.org. If you do not have access to the Internet and wish to review any or all of the data available from SRTR, our transplant coordinators will be happy to provide you with a copy at your request.

3. **Unable to Guarantee Outcome:** Notwithstanding the foregoing, you understand that there is no guarantee of success for the lung transplantation procedure and the possibility exists that your body may reject the lung or the procedure otherwise may not be successful. If so, you may or may not be placed on the waiting list to receive a lung from another donor depending on your medical condition and predicted success of such a transplant. In the event transplantation is not successful for any

reason, you understand and agree that the donated lung or any tissue, organ, specimen, member or implant, removed or severed in the procedure may be retained, preserved, used for medical education and training purposes or disposed of by Hospital.

4. **Consent to Other Necessary Procedures:** You realize that, during the procedure, the physician/surgeon may become aware of conditions which were not apparent before the start of the procedure, or may determine that additional or different operations or procedures are necessary or appropriate. You therefore, consent to and authorize the above named physician/surgeon and/or any assistants who may be present to perform additional or different operations or procedures the physician/surgeon deems necessary or advisable, including those procedures that may be unforeseen or not known to be needed at the time this consent is obtained; so long as these additional procedures do not conflict with your stated DNR or DNR/Special Code preferences as indicated herein.
5. **Observations/Photographs Related to Treatment and/or Operations:** If acceptable to the physician/surgeon, you understand that observers may be present during the procedure for purposes related to your care, treatment and/or for purposes related to medical education and training only. You further authorize the physician/surgeon, or his/her designee, to photograph/videotape you before, during, or after the Procedure for purposes related to your care, treatment and/or for purposes related to medical education and training. You understand that photographs taken during the procedure may be used professionally, as long as your health information has been de-identified in accordance with federal regulations.

6. **Special Considerations:** Please circle the following as applicable:

Based on the information provided above I , _____ **am / am not** willing to accept a hepatitis C positive donor.

Based on the information provided I, _____ **am / am not** willing to accept a hepatitis B core antibody positive donor.

7. **CMS INFORMATION**

Specific outcome requirements need to be met by transplant centers and we are required to notify you if we do not meet those requirement. Currently, Nazih Zuhdi Transplant Institute (NZTI) at INTEGRIS Baptist Medical Center meets all Center of Medicare & Medicaid Services (CMS) requirements and is an approved Medicare lung transplant center. If at some point during the time you are waiting for a lung transplant, the hospital does not meet CMS transplant criteria, we will notify you in writing. If you receive a transplant at a non-Medicare-approved transplant center, it could affect your ability to have your immunosuppressive drugs paid for under Medicare Part B.

8. **Voluntary Consent for Treatment:** Your consent to this procedure is voluntary and free from coercion. You acknowledge that no financial inducement has been offered or accepted. You understand your consent may be withdrawn at any time prior to the procedure, with the acknowledgement that such withdrawal of consent will not affect present or future care. You acknowledge that you are at least 18 years of age, competent and able to consent on your own behalf. You have read this Consent Form and understand that some of the language in the Consent Form may be technical. You have been given an opportunity to ask any questions regarding the Consent Form and the informed consent process, and all questions and inquiries have been answered to your satisfaction. You also have been informed that you may contact the Hospital Transplant Program at (405) 949-3349 regarding further questions about this procedure.

You acknowledge that no guarantees have been made concerning the outcome of the surgery or transplant, and you realize that the practice of medicine and surgery is not an exact science. As evidenced by your signature below, you voluntarily consent to undergo this procedure at Hospital. You authorize Dr. _____ and/or any other agents or employees of Hospital or NZTI Clinic, and any such assistants as may be selected by any of them to perform the procedure. You have been fully informed and have carefully considered the risks of this procedure and have had an ample opportunity to discuss your decision with members of your family and friends. You have also had ample opportunity to meet with and to fully discuss with Dr. _____ the details about the procedure and any related procedures and follow up care.

By signing below, you acknowledge that consent is given freely, with no pressure or coercion, by choice and without the influence of any other party.

THE UNDERSIGNED HEREBY STATES THAT I HAVE READ THIS CONSENT FOR LUNG TRANSPLANTATION AND THAT ALL OF MY QUESTIONS ABOUT THE PROCEDURE, ALTERNATIVE PROCEDURE(S), AND RISKS OF EACH HAVE BEEN ANSWERED IN A LANGUAGE THAT I UNDERSTAND AND THAT ALL BLANKS WERE FILLED IN PRIOR TO MY SIGNATURE.

Patient's Name (print)

Signature of Patient

_____/_____
Date/Time

WHEN PATIENT IS INCOMPETENT TO GIVE CONSENT, I HEREBY CONSENT FOR THE PATIENT:

Authorized Person Name (print)

Signature of Person Authorized to Consent for Patient

Power of Attorney Guardian Substitute Decision Maker*

_____/_____
Date/Time

Witness Name (print)

Hospital Witness to Signature

_____/_____
Date/Time

*Substitute Decision Maker as per SYS-ETH-112