

## **INFORMED CONSENT FOR EVALUATION TO KIDNEY TRANSPLANTATION**

This document is to help you be informed of the process of having a kidney transplant. It is part of a process we call 'informed consent process'. This evaluation has two purposes. The first is to determine whether you are physically able to undergo transplant surgery. The second is to determine if you have adequate medical insurance to cover the cost of the transplant and the cost of immunosuppressive medications you must take after the transplant.

It is important that you read and understand this document before you sign it. You should ask questions about any of the information that you do not understand.

### **PURPOSE**

The purpose of the kidney transplant program is to provide an alternate treatment for patients with chronic kidney disease (CKD). Because your kidneys are not working properly, you are faced with an important decision. The decision to begin (or continue) lifelong dialysis or to have a kidney transplant. Kidney transplant is an option for patients that may give them a lifestyle free from dialysis. Kidney transplant may also restore a more meaningful quality of life. There are two types of possible kidney transplant procedures, deceased donor kidney transplant, and living donor kidney transplant. Your transplant coordinator and physician will discuss these procedure options with you to determine which is right for you.

### **ADULT KIDNEY SELECTION CRITERIA**

#### **Indications:**

- Irreversible kidney failure
- Chronic kidney disease Stage IV or V (Pre-emptive)

#### **Absolute Contraindications to Kidney Transplant:**

- Current untreated malignancy
- Active infection
- Life expectancy < 3 years (Adult), < 2 years (Pediatric)
- Uncorrected severe vascular disease: Coronary, Cerebral, or Peripheral
- Significant valvular heart disease
- Chronic severe lung disease and / or required use of continuous oxygen
- Decompensated Cirrhosis
- End stage organ disease
- Sickle cell disease
- Active substance abuse
- Uncontrolled psychiatric disease
- Anatomy that makes transplantation technically impossible

**Relative Contraindications to Kidney Transplant:**

- Moderate cardiac disease (i.e. LVEF <35% (Adult), <40% (Pediatric))
- Moderate pulmonary disease; PA pressure > 50 mmHg
- Medical disease that could result in graft loss
- Moderately reduced functional capacity and / or moderate frailty
- Morbid obesity (BMI > 40) or cachexia (BMI < 18)
- Pediatric age < 2 years or weight < 10kg
- Psycho-social and financial barriers which may increase the risk of transplant and require ongoing surveillance / intervention, in the opinion of the psychosocial team
- Proven habitual medical non-adherence
- Multiple medical comorbidities that will place the patient at high risk for graft loss and/or mortality
- Inability to travel back to transplant center

**EVALUATION PROCESS**

You will be evaluated with consultations, lab tests and various procedures to determine the medical appropriateness of kidney transplant. You will meet with many members of the transplant team who will include:

- The **Transplant Coordinator** provides education regarding the transplant evaluation process, listing for transplant and patient responsibilities before and after transplant.
- The **Nephrologist** is a physician who specializes in kidney disease. The nephrologist will assess the function of your kidneys and the safety of your transplant. He or she will follow up with you throughout your transplant course. The results of your physical examination will be discussed with you. The nephrologist will also discuss alternative treatments to transplant with you.
- The **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 kidney transplant, the various types of kidney available, and the risks of the surgery and the possible complications after your transplant. He/she will also discuss how the surgery is expected to improve your health, about how long you will be in the hospital, how long it will take you to recover from the surgery, and when you may go back to normal activities.
- The **Social Worker** will evaluate your ability to cope with the stress of transplant. The social worker will also help to identify your support network. Any psychosocial concerns that could affect the success of the transplant will be discussed with you.

- The **Financial Coordinator** will discuss any possible costs associated with your transplant. The financial coordinator will work with you to help you understand your insurance coverage and financial responsibilities related to the transplant.
- The **Pharmacist** will perform medication reconciliation, provide brief overview of post-transplant medications, and evaluate any potential drug interactions prior to and after the transplantation.
- The **Registered Dietitian** will perform a nutritional assessment and provide nutrition education.
- **Additional consultations** - some patients may be referred to another service for consultation. For example, some patients need to be seen by a hepatologist (liver doctor) or a cardiologist (heart doctor) to assess for other medical conditions.

The evaluation may take several weeks or even months. You will be required to complete diagnostic and laboratory testing to determine if you are a suitable transplant candidate. The results of tests, procedures, and consults will be discussed with you. The following tests may be included in your evaluation process, with additional testing if warranted.

- Blood tests to help determine the extent and/or cause of your kidney disease. Other tests performed include determining your blood type for organ matching and screening tests for 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 identify any 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 echocardiogram and/or stress test 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.
- A CT scan or MRI determines the extent of your kidney disease, the presence of any tumors, and verifies the circulation to your kidney. It also allows the surgeon to determine whether he or she can sew in a new kidney.
- A kidney biopsy may be requested by your transplant team. During a kidney biopsy, a needle will be used to remove a tiny portion of your kidney. This is an outpatient

procedure. A microscopic examination of the tissue will provide information to your physicians regarding the cause and severity of your kidney disease.

- An ultrasound of your kidney and abdomen helps assess the size, shape, and circulation to your kidney.

## **WAIT LIST**

After your evaluation by the transplant team members and upon receipt and review of your test results, a Multidisciplinary Selection Committee will meet to review and discuss your case to determine your eligibility for transplantation. Eligibility is determined by a set of program criteria and clinical judgement. In order to be placed on the United Network for Organ Sharing (UNOS) waitlist for an organ, the Committee members must unanimously agree that you are eligible. You will be notified of the decision within 10 days of the Committee's decision in a letter from your transplant coordinator.

If you are accepted as a kidney transplant candidate and are placed on the waiting list, you should also be aware that the United Network for Organ Sharing (UNOS) allows patients to be listed at two or more transplant centers. Not all transplant centers accept multiple listed patients. This is because waiting time priority is allocated to all candidates within the local donation area, not for each hospital individually. If you want to end your listing at one transplant center and transfer to another, you can transfer your waiting time as long as you inform both programs. In order to be listed at another center, you must meet their acceptance criteria and it must be approved by your insurance carrier. We have provided you with further information regarding multiple listing and wait time transfer in your folder. Please refer to the brochure entitled "*Questions and Answers for Transplant Candidates and Families about Multiple Listing and Waiting Time Transfer.*"

During the time that you are on the waitlist, your health status will be periodically evaluated by members of the Transplant Team. If, at any time, you are deemed ineligible by the Committee to remain on the active list due to a change in your health status, you will be notified within 10 days by letter of the decision to change your status to "Waitlist Inactive" or "Waitlist Removed".

Deceased donor kidneys are allocated according to the policy of United Network for Organ Sharing (UNOS). The kidneys are primarily allocated according to waiting time, quality of match with donor and your antibody level. Being put on the waiting list for a kidney transplant does not guarantee the availability of a kidney or receiving a transplant. There is no way to know when a deceased donor kidney will become available. The longer you are on the waitlist, the better your chance of receiving the next suitable kidney. If you have a living donor, your wait time will be much shorter.

## **SURGICAL PROCEDURE**

Prior to your transplant, your surgeon will discuss the actual procedure being performed and possible risks of the surgery with you in detail. You will sign a separate consent for the kidney transplant surgery at the time of transplantation. Kidney transplantation typically takes 3-4 hours. It is hard to predict how long the operation will take, but your family will be updated while the surgery is in progress. Removing your nonfunctioning kidneys is usually not necessary unless there is a reason to do so. While you are under anesthesia, the surgeon connects the artery and vein of the new kidney to your artery and vein. This creates the blood flow through the kidney so that it may function and make urine. The ureter, or the tube coming from the kidney, is sewn into your bladder. Sometimes the new kidney will start working right away or it may take several days to weeks. There is a small chance that the kidney may never work.

## **SURGICAL RECOVERY**

After the surgery you will be taken to the post anesthesia care unit or recovery room where you will be closely monitored. You may be on a machine to help you breathe and you will have some 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 days after surgery.

When your medical condition has stabilized, usually within 24 hours, you will be transferred to the transplant unit. Your length of stay in the hospital will depend on the rate of your recovery. Early ambulation will help speed 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 5 days. The hospitalization time can vary depending on the severity of your illness prior to transplant or complications after surgery. An important part of your hospital stay is learning your medications and when to take them.

After you leave the hospital you will still be recovering. For the first 4 to 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 for life and you must make yourself available for examinations, laboratory tests and scans of your abdomen to see how well your transplanted kidney is working. Biopsies may be done routinely and as needed to diagnose possible complications including rejection or recurrent kidney disease.

The transplant team will see you frequently for three to six months post-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 monthly to quarterly clinic visit, Patients who develop complications may need to be seen more often by the transplant team.

## RISKS

- Surgery/Anesthesia: 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. Additional possible complications include, but are not limited to injury to structures in the abdomen, pressure sores on the skin due to positioning, burns caused by the use of electrical equipment during surgery, damage to arteries and veins, and permanent scarring at the site of the abdominal incision.

Organ Donor Risk Factors: Potential donors go through a rigorous screening process to ensure that the organs are appropriate to be transplanted. Despite this process, donors are representative of the general public and may have risk factors that potentially could affect your long-term health, including but not limited to the donor's history, age, or their potential risk of contracting HIV or other infectious diseases that cannot yet be detected. The risk for undetected HIV, HBV, or HCV infection is very low but not zero. Recipients will be tested for HIV, HBV, and HCV infections after transplantation and should transmission occur, effective therapies are available.

2020 U.S. Public Health Service (PHS) has identified the following as risk criteria for acute transmission of HIV, HBV, or HCV:

1. People who have had sex with a person known or suspected to have HIV, HBV, or HCV infection in the preceding 30 days
2. Men who have had sex with men (MSM) in the preceding 30 days
3. People who have had sex in exchange for money or drugs in the preceding 30 days
4. People who have had sex with a person who had sex in exchange for money or drugs in the preceding 30 days
5. People who have had sex with a person who injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons in the preceding 30 days
6. People who have injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons in the preceding 30 days
7. People who have been in lockup, jail, prison, or a juvenile correctional facility for more than 72 consecutive hours in the preceding 30 days

8. A child who is  $\leq 18$  months of age and born to a mother known to be infected with HIV, HBV, or HCV infection
9. A child who has been breastfed within the preceding 30 days and the mother is known to be infected with HIV infection

Transplant candidates might have a higher chance of survival by accepting organs from donors with risk factors for HIV, HBV, and HCV infections compared with waiting for an organ from a donor without recognized risk factors. If you refuse the organ, it will not affect your status on the UNOS waitlist.

- Risk of Bleeding: Bleeding during or after surgery can occur. Treatment 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).
- Risk of Infection: The abdominal incision is a potential site 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. Because your immune system is suppressed after surgery, these infections can become life threatening.
- Risk of Rejection: Rejection occurs when the body tries to destroy a transplanted organ or tissue because it is a foreign object. Immunosuppressive (anti-rejection) medications help prevent rejection, however, rejection is always a possibility with a transplanted kidney. If you do NOT take your immunosuppressive medications as prescribed, you will experience rejection of your transplanted kidney.
- Delayed Graft Function or Non-Function: Delay in the function of your transplanted kidney may increase the length of your hospital stay and increase the risk of other complications. There is a possibility that the transplanted kidney will not function. When this occurs, the kidney may be removed and you will be kept on dialysis. If you wish to consider another transplant, your waiting time will not be lost.
- Cancer: Certain cancers, such as basal cell carcinoma, Kaposi sarcoma, carcinoma of the vulva and perineum, non-Hodgkin lymphoma, squamous cell carcinoma, renal cell carcinoma, and carcinoma in situ of the uterine cervix, occur more frequently in people who have undergone kidney transplantation.

- Urinary Complications: Some patients experience urinary complications such as leaks, fluid collection, and strictures (narrowing). Most leaks get better without the need for surgery. Occasionally, tubes or stents need to be placed to aid in the healing process. In some cases, surgery is necessary to correct the urinary leak.
- Risk of Blood Clots: 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. Renal artery thrombosis, or clots that develop in one of the major blood vessels going to your kidney, occurs in a small percentage of kidney transplants. Renal artery thrombosis can cause kidney failure, kidney abscesses and strictures. Most patients who develop renal artery thrombosis will require a second operation; some will require removal of the transplanted kidney.
- Nerve Damage During Surgery: Damage to nerves may occur from direct contact within the abdomen or from 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.
- Risk to the Unborn: Because of the immunosuppressive and other medications taken after transplant, it is important that women who wish to become pregnant have a discussion with their transplant team PRIOR to becoming pregnant. It is recommended to wait a minimum of 2 years after the operation. While many women have taken their pregnancies to term after transplantation, there is an increased risk of kidney rejection and fetal complications.
- Psychosocial Risks: There are mental health risks such as depression, post-traumatic stress disorder, generalized anxiety, anxiety regarding dependence on others, and feelings of guilt that you may experience after your transplant.
- Other Complications: Cardiac complications such as rhythm changes or heart attack could occur. You could have a stroke. Any medical complications have the potential for multi-organ failure and death.
- Future Insurance Coverage: Future health problems related to transplantation may not be covered by your insurance carrier.



- **Obtaining Insurance in Future:** It may be difficult to obtain medical, disability and life insurance in the future and denial of coverage is a possibility.
- **Immunosuppressive Therapy:** The following medications (listed with their potential side effects) will or may be used to treat or to prevent rejection. You will remain on one or more of these medications for the remainder of your life.
  - Tacrolimus – This medication will cause immune suppression with increased risk of infection. It may also cause kidney and liver damage, headaches, tremors in hands, diabetes, an imbalance of sodium, potassium, magnesium (electrolytes), high blood pressure and hair loss.
  - Mycophenolate – This medication will cause immune suppression with increased risk of infection and may also cause low white blood cell counts, stomach upset, and diarrhea. For women of child-bearing age, this medication may cause increased risks of first trimester pregnancy loss and birth defects.
  - Prednisone/Methylprednisolone – These medications will cause immune suppression with increased risk of infection and may cause fluid retention, weight gain, high blood pressure, high blood sugar, increased appetite, mood changes, loss of calcium from bone (osteoporosis) with increased risk of broken bones, erosion of the bone (bone damage), and impaired wound healing. Vision abnormalities (cataracts) are rare but may occur.
  - Thymoglobulin – This drug will cause immune suppression with increased risk of infection, allergic reactions, fever, muscle pain, joint pain, and rash. It may be used at the time of transplant and/or for rejection episodes.
  - Simulect – this drug will cause immune suppression with increased risk of infection, high blood pressure, and swelling in legs.

Your original disease such as high blood pressure, diabetes, glomerulonephritis and weakening of the bones may continue after transplant. There are other risks associated with kidney transplants. Infections from bacteria, viruses, or fungi, acute/chronic 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 repeated kidney biopsies, surgeries, and other procedures, or a prolonged intensive care unit or hospital stay.

## **SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS**

The SRTR (Scientific Registry of Transplant Recipients) is a national database of transplantation statistics related to solid organ transplantation - kidney, liver, pancreas, intestine, heart, and lung. It can be found at [www.srtr.org](http://www.srtr.org). Transplant outcomes can vary from center to center. Many factors make up these differences. These factors range from the recipient's medical condition to the donor organ transplanted. The outcome for kidney transplants continues to improve with advances in immunosuppressive medications.

The information on the SRTR website allows you to look at every transplant center in the United States. It may be useful to you when choosing a transplant program. Contact your coordinator if you have additional questions or for assistance with use of the website.

## **NOTIFICATION TO PATIENTS**

In the event that SUNY DS transplant program only has one surgeon or physician, all potential candidates and candidates on the waitlist will be sent a letter within 10 business days. At this time SUNY DS has multiple surgeons and multiple physicians.

In the event that SUNY DS transplant program is unable to accept donor organ offers, all active patients on the waitlist will be sent a notification within 10 business days of when the information becomes available.

In the event that SUNY DS transplant program's Medicare approval is terminated, either voluntarily or involuntarily, at least 30 days prior to the termination, all potential candidates and candidates on the waitlist will be sent a notification letter. The program would then help potential candidates and candidates on the waitlist to find another Medicare-approved transplant center. You would not lose time accrued on the waiting list.

## **RIGHT TO REFUSE**

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

## **RIGHT TO WITHDRAW**

You have the right to withdraw consent for transplantation at any time during the evaluation or waitlist period, up to the time of going into the operating room.

**TRANSPLANT BY A TRANSPLANT CENTER THAT IS NOT APPROVED BY MEDICARE**

If you have your kidney 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. Currently, SUNY DS meets all of the requirements as a transplant center under Medicare.

**CONCERNS OR GREVIANCES**

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. The toll-free patient services line number is 1-888-894-6361.

In order to help you understand the transplant process, we have prepared several informational booklets for you to read in addition to the information session with the Transplant Coordinator and discussions with other clinical staff.

The following information is included in your packet:

- General Consent to Treatment Form/HIPAA Privacy Package
- Health Care Proxy Form
- Authorization for release of health information pursuant to HIPAA
- NYCHHC HIPAA Authorization to Disclose Health Information
- UNOS Frequently Asked Questions about Multiple Listing & Waiting Time Transfer
- Before and After Kidney Transplant: A Step-by-step Guide
- Medications Commonly Used after Transplantation
- Additional information from UNOS

**Acknowledgment and Consent**

I have reviewed this document and its attachments completely and I have discussed their contents with a member of the transplant team. I have been given the opportunity to ask questions, have them answered, and to discuss the transplantation evaluation process, surgical procedure, and post-transplant care process in detail.

I understand that organ transplantation is a serious medical treatment and that the outcome is not guaranteed. I further understand that the success of my transplant is directly dependent on taking my medications exactly as prescribed by the doctor and my kidney function may be harmed by failure to take my medications.

I have been informed of my financial responsibility. I understand that I am fully responsible for the cost of all my medications prior to and following kidney transplant surgery and that Downstate Medical Center is in no way responsible for providing me with out-patient medications, regardless of my insurance status. I understand that the Downstate Transplant staff will help me resolve any insurance matters, however, it is my own responsibility to maintain my insurance coverage. It is also my responsibility to call the Financial Coordinator PRIOR to making any insurance changes.

I, \_\_\_\_\_, want to proceed with evaluation of my candidacy for organ transplantation.

If I am accepted as a kidney transplant candidate, I hereby list my name on the transplant waiting list at the SUNY Downstate Medical Center, University Hospital of Brooklyn.

I hereby give permission to release my medical records to the Transplant Division, State University Hospital of Brooklyn.

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

Witness Signature: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_