The Transplant Institute
METHODIST DALLAS

Informed Consent for Kidney and Pancreas Transplant Patients

Evaluation Process

You will be evaluated with consultations, lab tests, and various procedures to determine the appropriateness of transplant. You will meet with many 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 transplant process.

- A **Transplant Nephrologist** is a physician who specializes in kidney disease. The Transplant Nephrologist assesses medical suitability for transplantation, discusses the significance of transplantation (including alternatives and potential medical complications), manages transplant-related medical needs before and after transplant, participates in care during the transplant hospital admission, and follows transplant recipients during clinic appointments at specific time periods post-discharge.

- A **Transplant Surgeon** will meet with you during the evaluation and/or prior to surgery to discuss the appropriateness of a transplant based on the information obtained during your evaluation. The Transplant Surgeon evaluates surgical suitability for transplant, discusses the significance of transplantation with the patient (including the risks, benefits, and surgical complications), discusses the various types of organs available, performs the operation, and provides post-operative care for a defined period of time following surgery.

- An **Anesthesiologist** may meet with you and review your medical records to determine the need for any additional workup to determine your risk from anesthesia.

- A **Social Worker/Business Coordinator** 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. They will discuss psychological risks, the costs associated with your transplant, and the costs associated with the medications you will require after transplant. They will also 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** may conduct a more in-depth evaluation and assessment. Some patients with a history of drug or alcohol abuse may be required to participate in a rehabilitation program and meet abstinence requirements prior to and after transplant listing.

- A **Registered Dietitian** will perform a nutritional assessment and provide nutrition education.

- Some patients may be referred to another service for consultation. For example, many patients need to be seen by a pulmonologist (lung doctor) or a cardiologist (heart 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 help to determine the extent and/or cause of your kidney and/or pancreas disease. Other 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 identify any problems with your lungs.

- An EKG, 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.

- An ultrasound of your kidneys and abdomen helps assess the size, shape, and circulation of your kidneys and/or pancreas.

- Pulmonary function tests may be required, especially if you have a history of smoking or a history of lung disease. This is a breathing test to analyze your lung capacity.

Overview of Kidney/Pancreas Transplant

A successful kidney transplant eliminates the need for dialysis. Many patients who had a successful kidney transplant report an improvement in their quality of life. There is evidence to support that compared to patients who undergo dialysis, a functioning transplanted kidney extends the life-expectancy of patients with end-stage kidney disease. A successful kidney transplant may improve your blood counts and energy levels. The strength of your bones, your growth, and appetite may also improve. You may enjoy a less restricted diet. A pancreas transplant can restore normal insulin production and improve blood sugar control in people with diabetes

The potential benefits of transplantation 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 transplant. It is never fully known how the condition that caused your underlying kidney and/or pancreas disease will affect your transplant. The operation is complex and the risks are high. The overall success rate, roughly defined as the patient surviving with the transplanted organ for at least one year, is about 96-97%. In other words, the chance of dying following a kidney and/or pancreas transplant is about 3-4% 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.

Donated organs are allocated according to the policy of United Network for Organ Sharing (UNOS). The Kidney Allocation System was revised in December 2014 and uses a point system to calculate longevity of the kidney and the compatibility of the donor organ with the recipient. This system will be discussed with you by the transplant coordinator. Being placed on the transplant waiting list does not guarantee the availability of a kidney and/or pancreas or receiving a transplant.

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 has a Kidney Donor Profile Index (KDPI) greater than 85% our 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. The transplant surgeon will make an incision in your abdomen. Through this incision a donated kidney and/or pancreas will be placed into your abdomen.

Drains may be put into your body to allow fluids to 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 4-6 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 5-7 days, but hospitalization time can vary depending on the severity of your illness prior to transplant or complications after surgery.

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. Most patients can return to all normal activity after 12 weeks (including heavy lifting). 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 abdomen to see how well your transplanted organ is working. Biopsies may be done as needed to diagnose possible complications including rejection or recurrent disease.

The transplant team will see you regularly for three to six months post-transplant. You will be followed in the transplant clinic for life. For most patients this involves frequent lab work and a yearly clinic visit. 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, including initiating or remaining on dialysis and continuing current treatment regimens for your diabetes. Additional alternatives will be discussed with you by the Transplant Nephrologist.

Potential Medical 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 organ. Such a delay may increase the length of your hospital stay and increase the risk of other complications. There is a possibility that the transplanted organ will not function. When this occurs a second transplant is needed.

There are other risks associated with 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 biopsies, surgeries, and other procedures, or a prolonged intensive care unit or hospital stay after a 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.

Potential Psychosocial Risks

Emotional and psychosocial issues before and after transplant vary. In general, the first year after transplant is best characterized as a period of readjustment and rehabilitation, with gradual improvement in physical, emotional, and social aspects of your life.

Some of the psychosocial challenges you may face include (but not limited to):

- The stress of coping with physical changes in your body and complications from transplant
- Enduring the psychological highs and lows that sometimes occur as side-effects of drugs that suppress the immune system.
- Adhering to a complex post-transplant regimen (taking your medications, monitoring your vital signs, follow-up visits, diet, exercise, etc.)
- Anxiety regarding dependence on others
- Feelings of guilt and anger
- Psychological acceptance of the transplant
- Depression
- Post-Traumatic Stress Disorder (PTSD)

It is therefore important that you stay in close contact with the transplant team. Should you experience these issues, please notify your Transplant Nephrologist, Transplant Surgeon, Transplant Coordinator, or Transplant Social Worker.

Miscellaneous risks

Despite the use of compression boots, 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.

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. The abdominal incision for the transplant and any incision needed for the kidney bypass machine (neck, underarm, and groin) 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 abdomen or from pressure or positioning of the arms, lets 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.

Other possible complications include: 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, pneumonia, heart attack, stroke, and permanent scarring at the site of the abdominal incision.

National and Transplant Center-Specific Outcomes

The most current data available from the Scientific Registry of Transplant Recipients (SRTR) describing patient and graft survival one year after transplant is represented in the attached document and do not significantly differ compared to national data.

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, Methodist Dallas Medical Center meets all requirements for transplant centers.

Organ Donor Risk Factors

Certain conditions in the donor may affect the success of your 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. You have the right to withdraw consent for transplant at any time. If you choose not to have a transplant, treatment for your kidney and/or pancreas disease will continue. If you do not undergo the transplant surgery, your condition is likely to worsen. If you have kidney disease, dialysis will need to be initiated or continued with a decrease in 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 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 1-866-678-6411.