

**Iowa Methodist Medical Center
Transplant Center
Informed Consent for Kidney Transplant Recipient**

This document is to help you be informed of the process of kidney transplant evaluation. It is part of a process we call 'informed consent process'. It is important that you read this document. You should ask questions about any of the information that you do not understand. You will be given a copy of this consent and the Transplant Center will keep the original copy in your transplant record.

Evaluation Process

An evaluation for a kidney transplant involves many tests, procedures, and visits with other doctors. It also includes meeting with many members of the transplant team. All these consultations, tests, and procedures will help us to know if a kidney transplant is the right treatment for you. It will also help us to know if there is any other treatment besides a kidney transplant that can help you.

Transplant Team Members

- 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 kidney transplant process.
- 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 risks of the surgery, and the possible complications after your transplant.
- The **Nephrologist** is a physician who specializes in kidney disease. The nephrologist will assist in the medical management of your kidney disease and work with the transplant team to determine if you are medically suitable for a transplant.
- The **Social worker** 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.
- The **Clinical Psychologist** will conduct a more in-depth psychological evaluation and assessment. Some patients with a history of drug or alcohol abuse may be required to

participate in a rehabilitation program as well to meet abstinence requirements prior to and after transplant listing.

- The **Registered Dietician** performs a nutritional assessment and provides nutrition education to patients. The dietician will meet with you pre and post- transplant to help with dietary needs.
- The **Pharmacist** provides education to pre and post-transplant patients about immunosuppression medication, as well as medications the patient is currently taking. The transplant pharmacist is also a resource to the entire transplant team by providing drug information and education about complex drug interactions.
- Some patients may be referred to another service for consultation. For example, many patients need to be seen by a cardiologist (heart doctor), pulmonologist (lung doctor) or hepatologist (liver 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 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.
- An EKG, echocardiogram, stress test and/or cardiac angiogram will show how well your heart is beating and the function of your heart valves. This will assist your physicians in deciding if your heart function is strong enough for transplant surgery.
- An ultrasound of your abdomen helps assess if you have the presence of gallstones.
- 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.

Surgical Procedure

Kidney transplantation is a life-saving therapy; however, the potential benefits cannot result from surgery alone and are dependent upon you following the rigorous treatment plan prescribed by your physicians. You must be aware of the potential risks and complications outlined by your physician. Your physicians cannot predict exactly how your body will respond to kidney transplant. It is never fully known how the condition that caused your underlying kidney disease will affect your transplant kidney. The operation is complex and the risks are high. The overall success rate, roughly defined as the patient surviving with the transplant kidney for at least one year is about 98%. In other words, the chance of dying following a kidney transplant is about 2%

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in the first year. The success rate varies according to how sick the patient is prior to the transplant surgery, with the sicker patients having a lower chance of a successful outcome.

Kidneys are allocated according to the policy of United Network for Organ Sharing (UNOS). Being put on the waiting list for a kidney transplant does not guarantee the availability of a kidney 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. Every kidney offered for transplant will have a Kidney Donor Profile Index (KDPI) score, the score is from 0 to 100%. The score is associated with how long the kidney is likely to function compared to other kidneys. Deceased donor kidneys with a KDPI of 0-20% are expected to function, on average, nearly 11.5 years. Deceased donor kidneys with a KDPI of 21-85% (the majority of deceased donor kidneys) are expected to function on average, about 9 years. Donors with a KDPI over 85% are expected to function more than 5.5 years. If the organ is considered a KDPI over 85%, you will sign a consent to accept. At the time an organ is offered the surgeon has a clear picture of the risks associated with this particular organ versus the risk of waiting for the next available donor organ to become available to you. You always have the option to decline an organ without penalty.

During the transplant surgery you will be put under general anesthesia, which means you will be given medication 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.

Post-Surgical Care and Recovery

When your medical condition has stabilized, you will be transferred to the transplant floor where you will be closely monitored. Intermittent pressure 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 pain two to three weeks after surgery.

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 five to six days. The hospitalization time can vary depending on the severity of your illness prior to transplant or complication 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. 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 kidney is working. Biopsies may be done to diagnose possible complications including rejection or recurrent kidney disease.

The transplant team will see you regularly for twelve months post-transplant. Every effort is made to transition your routine medical care to your primary nephrologist. 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.

Right to refuse transplant

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 is likely to worsen and limit your life expectancy.

Alternative Therapy

Alternative treatment therapies may be available for your medical condition. Please discuss your condition and any possible alternative treatments with your health care team; alternative therapies can be hemodialysis, peritoneal dialysis, or you may choose no further treatment.

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 or 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 kidney. 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 kidney will not function. When this occurs a second transplant may be needed. You will be placed on the UNOS waitlist and return to dialysis.

There are other risks associated with kidney transplants. Infections from bacteria, viruses, or fungi, acute 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 hospital stay after a kidney transplant.

There is a slight increase in the risk of certain kinds of cancer (including skin cancer and post-transplant lymph proliferative diseases or lymphoma) because of the immune suppressing medications.

Psychosocial Risks

Transplant recipients are at increased risk for depression, anxiety, dependence on others, emotional trauma, feelings of guilt, possible future health and mental health problems from the impact of receiving a transplant. Scarring or other aspects of the transplant surgery could possibly contribute to problems with body image. There may be an impact on future medical, disability and life insurance and there may be a negative financial impact from the burden of life long medication and medical follow-up.

Miscellaneous risks:

Despite the use of leg sleeves, 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. Also, kidney disease itself decreases the body's ability to fight infection. The abdominal incision for the kidney transplant is potential sites for infection.

Damage to nerves may occur. This can happen 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.

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 incision.

National and Transplant Center-Specific Outcomes

Statistics are from the Scientific Registry of Transplant Recipients (SRTR) www.ustransplant.org. You will be given the most recent center specific data at the time of the evaluation. The results at Iowa Methodist Medical Center Transplant Center meet these standards and do not significantly differ from the expected survival rates. We will show you the most recent results from the statistics.

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. Currently, Iowa Methodist Medical Center meets all requirements for transplant centers.

Organ Donor Risk Factors

Certain conditions in the donor may affect the success of your kidney transplant such as the donor's history and condition or age of the organ when it is received in the operating room for your surgery. Additionally, there is potential risk that you may contract HIV and other infectious diseases if they cannot be detected in the donor.

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 by Medicare and Medicare Part B could be affected.

After you have a kidney 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 premium may increase and remain higher. In the future, insurance companies could refuse to insure you.

Concerns or Grievances

The United Network for Organ Sharing (UNOS) 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 any problems you may be experiencing with your transplant center or the transplantation system in general. The toll-free patient services line number is included in the attached UNOS patient information letter.



Iowa Methodist Transplant Center

Kidney Transplant - Informed Consent for Evaluation

I understand that I need to sign this consent form if I wish to proceed with the medical evaluation for kidney transplant. I understand my signature does not commit me to kidney transplant. I may remove myself from the evaluation process at any time prior to transplant. A surgical informed consent will occur prior to surgery.

Patient

Date

Legally Authorized Representative

Date

Transplant Coordinator

Date

Transplant Surgeon

Date

Date Created/Revised: 10/09; 01//10; 06//11; 07//11; 12//11; 03//13; 2//15; 04//11/2018

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Page 7 of 7