

**CONSENT TO PARTICIPATE IN THE  
KIDNEY TRANSPLANT PROGRAM****02.16.2021**

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**Transplant Program Information**

➔ Please read this form carefully. If there is anything that you do not understand or if you have questions, please ask any member of the Transplant Team for help.

**INTRODUCTION**

You have been diagnosed with advanced kidney disease and your nephrologist believes that you may benefit from a kidney transplant. Before the team can decide if a kidney transplant is the right choice for you, a detailed evaluation needs to be completed. It is important that you understand the risks and benefits of the evaluation process, need for general anesthesia, surgery and immunosuppression, alternative treatment options, our program's transplant outcomes, donor risk factors as well as financial and insurance considerations before you decide to be evaluated.

This consent form and the Transplant Team will provide you with detailed information about the evaluation process at our Kidney Transplant Program. If you decide that you want to be evaluated and participate in our Kidney Transplant Program, you will need to sign this form. Even if you decide to participate, you may change your mind at any time before you undergo the kidney transplant surgery. If you are unsure whether you are healthy enough for transplantation, we can arrange for you to meet with one of our physicians or surgeons for a preliminary discussion before any testing is performed. Please let any member of the Transplant Team know if you do not want to continue your participation in the Kidney Transplant Program.

You will receive a copy of this consent form. Please keep it where you can find it easily. This consent form will help you to remember the information that has been discussed with you.

**THE EVALUATION PROCESS**

The transplant evaluation process begins at the time you are identified as a potential transplant candidate and continues until you are either placed on the waiting list or determined not to be an appropriate candidate. During this process, you will receive a detailed evaluation that includes a medical history review and a physical examination by a transplant physician. In addition, you will need to undergo some, or all, of the following tests to determine if you are healthy enough for transplantation.

- **Blood Tests** to determine your blood type and compatibility with potential organ donors. You also will be tested to see if you have been exposed to certain viruses such as hepatitis and HIV.
- **Lung Testing** to include a chest x-ray to check for lung problems. A skin test is required to see if you have been exposed to tuberculosis. Lung function testing also is sometimes required. Smokers may need to have a chest CT for lung cancer screening purposes.
- **Heart Testing** to include an EKG, echocardiogram and other testing to determine the strength of your heart and evaluate whether any other cardiac abnormalities exist.
- **Blood Vessel Ultrasound Imaging** to determine if your circulation is adequate for transplantation.
- **Cancer Screening** appropriate to your age and gender must be current and includes colonoscopy, PAP smear, mammography or PSA testing.
- **Dental Evaluation** and treatment as necessary.
- **Urine Testing** may be used to screen for drugs and alcohol in your system.

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- **Other Tests** may be required based on your medical history and/or the results of the tests outlined above.

In addition to your medical screening, you are required to participate in evaluations by the Transplant Team that includes our Social Worker, Nutritionist and Pharmacist. These evaluations are important in determining your readiness for transplant, and also your need for additional support following transplant to maintain your health and treatment regimen. Patients with a history of depression or other mood disturbances may be required to undergo a psychiatric evaluation.

You will meet with members of the Transplant Team in the Transplant Clinic as part of the education, informed consent, and kidney transplant evaluation process. Your family also may be asked to participate in interviews or consultations with Transplant Team members to discuss how a transplant will affect them and to answer their questions. Team members you will meet include:

- The **Transplant Nephrologist** is a physician who specializes in kidney disease. The nephrologist works with the Transplant Team to determine if you are medically suitable for transplantation and, if so, also manage immunosuppression and the medical aspects of your kidney disease afterwards to ensure you do well long term.
- The **Transplant Surgeon** will discuss the benefits and risks of having a kidney transplant based on the information obtained during your evaluation. The surgeon also will explain the nature and benefits of the surgery as well as potential risks and complications of transplantation and what it is like to live with a kidney transplant.
- An **Infectious Disease Specialist** may interview you and review your health history to see if you have been exposed to or are likely to get certain infections. The Infectious Disease Specialist may order tests to see if you have any active infections. If you have an active infection, you will need to be treated before transplant surgery. Additionally, the Infectious Disease Specialist may recommend that you have certain vaccines.
- A **Nurse Coordinator** will provide information about the transplant evaluation process, placing your name on the transplant waiting list and your responsibilities before and after transplant. The Nurse Coordinator will provide you with additional education about the transplant and informed consent process.
- A **Financial Counselor** will discuss the costs associated with your transplant and the cost of the medications you will require after transplant surgery. The Financial Counselor will work with you to understand your insurance coverage and what expenses may be your financial responsibility.
- A **Transplant Pharmacist** will give you an understanding of the medications needed as part of your transplant, and assess your ability to understand and follow a medication regimen following transplant.
- A **Registered Dietician** will perform a nutritional assessment and talk to you and your family about the importance of proper nutrition following transplant.
- A **Clinical Social Worker** will evaluate your mental health status, psychosocial needs, support system and needs for ongoing support following transplant.

At any time during the transplant process, you can ask any Transplant Team member if you have questions. If the Transplant Team member does not know the answer to your questions, s/he will find out which Transplant Team member can help you.

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Completion of testing and meetings with Transplant Team members do not guarantee that you will be selected as a transplant candidate. After collecting information about you, the Transplant Team will meet to decide if a kidney transplant is a medically appropriate choice for you. After the Transplant Team makes a decision, a Transplant Team member will discuss your options with you.

**Benefits of Participating in the Evaluation Process**

The primary benefit of participating in the kidney transplant evaluation process is that you may be able to receive a kidney transplant. The evaluation is an important and required piece of the transplant process. Additionally, during the evaluation process, you will undergo tests and examinations that may show that you need care for medical problems of which you are unaware. . During this process, you will learn the results of your physical examination and laboratory tests, be provided with information regarding factors or conditions that would make you suitable or not suitable for transplant, understand the importance of psychosocial factors in your ability to care for yourself following transplant, your financial responsibilities, and the need to follow a strict medical regimen after transplant.

**Risks of Participating in the Evaluation Process**

Some of the risks of participating in the evaluation process are listed below. Other risks relating to invasive medical testing procedures, (for example the risks related to cardiac catheterization), will be discussed with you in detail before the test is performed.

- **Risk of Blood Drawing:** As with all blood drawing, there is a risk of bruising, bleeding, pain, swelling or infection at the site of the blood draw.
- **Radiation Risks from Imaging Studies:** Some tests involve exposure to radiation. The amount of radiation exposure you may receive from these standard diagnostic tests is considered small, and is not likely to cause any serious problems for you.
- **IV Contrast:** Contrast dye may be used during a CT scan or for angiography (blood vessel imaging). The major risks include allergic reactions and deterioration of kidney function, which may be a significant problem if you are not yet on dialysis.
- **Reportable Illnesses:** The Transplant Team will keep your medical records private. However, state laws require that certain illnesses be reported to the public health department. If the evaluation shows that you have such an illness, the Transplant Team will discuss this with you and report this information to the public health department.
- **Unexpected Information:** The testing that occurs during the evaluation process, such as blood and tissue typing, may reveal unexpected information about you or your family (for example, persons in your family may not be genetically related) and occasionally, undiagnosed serious conditions may be uncovered.
- **Risk of being unable to proceed with transplantation:** Some patients who complete all of the testing are found to have serious medical conditions that prevent them from undergoing a kidney transplant.

**Alternatives to Participating in the Evaluation Process**

You have the choice NOT to go through the evaluation process or have a kidney transplant. If you choose not to complete the evaluation process, you cannot have a kidney transplant, but treatment for your kidney

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disease will continue. If you do not undergo the transplant surgery, your condition may worsen and limit your life expectancy.

**PICKING A TRANSPLANT CENTER**

Before you decide to participate in our Transplant Program, it is important for you to know how we compare to others. We will provide you with information on where to find our most current transplant outcomes, and explain what they mean. This information also is available on the Scientific Registry for Transplant Recipients (SRTR) website, [www.srtr.org](http://www.srtr.org). If you have questions or need assistance with this, please contact a member of the Transplant Team.

You may wish to register at more than one transplant center. However, each center determines who it accepts as candidates and reserves the right to decline patients who are listed at other centers. Any patient planning to list at multiple centers must notify the Transplant Team of this plan. If you would like to discuss becoming listed at multiple centers, please contact a member of the Transplant Team. Additionally, please be aware that if you have Medicare, and you do not receive your transplant at a Medicare-approved transplant center, Medicare may not pay for the medications you need after the transplant. Our Transplant Program is Medicare-approved.

**THE UNOS WAITING LIST AND KIDNEY TRANSPLANT OPTIONS**

If you decide to participate in our Transplant Program and complete the evaluation process, and the Transplant Team members decide that a kidney transplant may be a good option for you, you will be added to a national kidney transplant waiting list. You also may be declined or deferred for placement on the waiting list if the Transplant Team decides that transplant is not an appropriate medical option for you following your evaluation. There are more people waiting for kidney transplants than there are available kidneys. All patients accepted by a transplant program are registered on the national organ transplant waiting list managed by the United Network for Organ Sharing (UNOS). UNOS is a non-profit, charitable organization which operates the Organ Procurement and Transplantation Network (OPTN) under federal contract. UNOS maintains a centralized computer network and the UNOS organ placement specialists operate the network 24 hours a day, seven days a week. Additional information about the waiting list and UNOS can be obtained by logging on to [www.unos.org](http://www.unos.org).

Once you have been added to the waiting list, there are two options for receiving a donated kidney: a living donor, or a deceased donor. A living donor may be a family member, friend, coworker, or even a complete stranger who is willing to donate, and is a suitable medical match for you. A kidney transplant from a living donor will mean less time on the waiting list for you, and will generally last longer than a kidney from a deceased donor. If you have a living donor who does not match with you, paired donation may be an option. In paired donation, you are both entered into our local and/or national registry to be matched with a compatible donor or recipient.

A kidney from a deceased donor would require you to wait for a suitable match to become available for you. Kidneys from deceased donors are allocated nationally based on a number of factors including blood and tissue type, how long the candidate has needed a kidney, and how long the donor kidney is likely to function. Kidneys that are likely to function for the longest amount of time are considered first for candidates who are likely to need them the longest.

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You will be asked if you will agree to accept a kidney from a deceased donor that has a shorter expected longevity. Your willingness to accept a kidney from such a donor may increase your likelihood of receiving a kidney sooner.

Being placed on the organ transplant waiting list does not guarantee that you will remain on the waiting list, or that you will receive an organ. During the course of your, care unforeseen circumstances can arise which may negatively affect your suitability as a transplant candidate and the Transplant Team might decide to remove you from the waiting list on a temporary or permanent basis. For example, certain medical conditions, lack of adherence to prescribed treatment, or inability to contact you may result in a change to your listing status or your removal from the waiting list. You will be notified regarding any changes to your listing status and why changes need to be made.

**WAITING PERIOD**

Once you are placed on the waiting list, you will begin the waiting period. Your medicines may be changed as needed to keep you in the best possible medical condition for a transplant. It is critically important that you continue to work with your local nephrologist to control your kidney failure parameters during the waiting period. For example, blood pressure, blood sugar, phosphorus and fluid control all affect outcomes before and after kidney transplantation. During this time, periodic tests may be required. Your physicians may wish to repeat one or more of the tests that were performed during the evaluation process or order other tests for you. You may need to be seen by the Transplant Clinic every 12-18 months to maintain your place on the waiting list. **You MUST keep all your scheduled appointments with the Transplant Clinic and undergo requested testing from time to time. Failure to do so may affect your ability to remain on the waiting list.**

It also is very important that you contact our office with any changes such as your telephone number, address and insurance coverage. If you are hospitalized or your disease worsens you must contact your coordinator. Any medical changes may alter your position on the waiting list and may place your transplant on hold.

The amount of time you must wait for a kidney varies depending upon organ availability. You will need to be available by telephone with the contact information that you have provided to us, at all times so that if an organ becomes available you can be reached by your Transplant Coordinator. If an organ becomes available and you are called, you must come to the hospital immediately to prepare for surgery.

**KIDNEY TRANSPLANT SURGERY OVERVIEW****Description, Purpose and Benefits of the Procedure**

The physician responsible for this surgery or his designee has explained to me that kidney transplant surgery may involve the removal of my 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. The physician responsible for my care has explained to me that kidney transplantation likely will increase the quality of my life by providing freedom from kidney dialysis, or artificial organ assist device, overall better health, and return to involvement in normal societal activities.

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**Risks Associated with the Procedure**

The physician performing the procedure or designee has explained to me that **kidney transplant surgery** is a major operation and carries the same potential for complications as any other operation. The usual and most frequent risks and hazards include but not limited to the following: death, heart attack or heart failure, infection, difficulty breathing, hernia, nerve injury, anesthesia risk, bleeding allergic reaction, blood clots, temporary artificial ventilation and other unforeseen complications. I understand that failure or rejection of the donated kidney also is a risk of this procedure.

In order for a kidney to function normally, two **vascular anastomoses** need to be performed. This involves joining the artery and vein of the kidney to an artery and vein of the recipient. Specific risks and complications associated with this procedure include bleeding, clotting, infection narrowing of the artery or vein supplying the kidney, non-function of the kidney, and the need for additional surgery.

In addition to the vascular anastomoses listed above, the **ureter** of the transplant kidney needs to be joined to the bladder of the recipient. Specific risks and complications associated with this procedure include urine infection, bladder pain, blood in the urine, blockage of the kidney, leakage from the bladder, and prolonged catheter drainage.

In order to prevent transplant rejection, you will be required to undergo a regimen of **immunosuppressive drugs**. Specific risks and complications associated with this regimen include rejection of the transplanted kidney, cardiovascular disease including hypertension, high cholesterol levels and heart attack, damage to the transplanted kidney, diabetes, infection, increased risk of developing certain cancers, and death.

I understand that the potential psychosocial risks associated with kidney transplant surgery include depression, post-traumatic stress disorder (PTSD), generalized anxiety, anxiety regarding dependence on others, and feelings of guilt.

**Alternative Courses of Treatment**

Kidney transplantation surgery is a treatment option that may be offered to patients with irreversible kidney failure. Other management options include no treatment or dialysis.

I understand that some medical care will be provided by physicians and others employed by MMC; some care may be provided by physicians in their own private practice. Anesthesiology, radiology, and pathology services and many other medical specialty services are provided by physicians and other clinicians who are not employed by MMC but are authorized to provide care at the hospital as members of their own private practices. My primary care physician and my treating physicians can explain on request my options for selecting treating physicians at MMC or at another facility. I understand that MMC is a teaching hospital and authorized physicians and trainees may observe or assist in diagnosis and treatment. Images may be made to share with consulting physicians or for research and teaching, while using reasonable efforts to avoid identifying me.

**If I am determined to be a suitable candidate to undergo kidney transplant surgery, then I understand that I will be asked to sign a separate Consent to Kidney Transplant Surgery and separate Consent to Anesthesia which will include a description of the nature and benefits of the procedures, the usual and most frequent risks, and the alternative courses of treatment.**

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**Risks Related to the Donated Organ**

The condition of the donor and the donor organ may affect how well the kidney works after it is transplanted, or your health following transplantation. Before an organ is made available for transplant, the organ donor is carefully screened. Blood is taken from the potential donor and tested to see if the donor has an infectious disease, such as hepatitis or the human immunodeficiency virus (HIV). However, if the donor has an infectious disease or malignancy but the disease or malignancy is not detected during the donor testing, it is possible that the disease could be transmitted after the organ transplant. Other factors, such as the donor's age, cause of death, medical and social history, condition, or behaviors may also affect how well the organ works after transplant. If a donor kidney that is being offered for you has any risk criteria for acute HIV, Hepatitis B Virus (HBV) or Hepatitis C Virus (HCV) according to the U.S. Public Health Service (PHS) Guideline, the surgeon will discuss this with you prior to surgery. The risks related to the transplant of donated organs are discussed in further detail in the Consent to Kidney Transplant Surgery. All transplant recipients are tested post-transplant for HIV, HBV, and HCV.

**POST-SURGICAL CARE AND RECOVERY**

The hospitalization time varies greatly depending on severity of your illness prior to transplant and/or complications after kidney transplant surgery. After you are discharged from the hospital, you will still be recovering. For the first four (4) to six (6) weeks, you will have some restrictions on your daily activities. If you experience any complications after surgery, your recovery time could be longer. During the recovery period, the Transplant Team will follow your progress.

The Transplant Team will evaluate you on a frequent basis after your transplant and you will be expected to come to the Transplant Clinic for these appointments. If you anticipate that you will have any problems attending these appointments at the Clinic please let the Transplant Team know right away. The Transplant Team will make every effort to transition your routine medical care to your primary care physician after transplant surgery. However, **you will need to be monitored for the rest of your life and you must agree to make yourself available for examinations and laboratory tests to evaluate the functioning of your transplanted kidney.** For most patients, this involves at least monthly lab work and being evaluated by a kidney specialist every three (3) months. Patients who develop complications may need to be evaluated more often by the Transplant Team.

**If you move to an area where distance prevents you from keeping regularly scheduled appointments or undergoing requested diagnostic tests at the hospital, the Transplant Team may refer you to a Transplant Center closer to your location for your follow-up care.**

**MEDICATIONS REQUIRED AFTER TRANSPLANT**

After transplantation, you will be required to take medications for the rest of your life to prevent your body from rejecting the transplanted kidney. Other medications may be required for the rest of your life to treat or prevent various infections. The types and doses of medications will be determined and adjusted by your physicians and Transplant Pharmacist based on your medical condition and health. Following transplantation, you will receive further instructions and education regarding the medications specifically ordered for you. It is important to note that all anti-rejection medications can increase your risk for infections and malignancies (the growth of cancerous cells). The Transplant Nephrologist and Transplant Pharmacist will discuss side effects, risks and benefits with you for the specific medications that you are

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taking. It is important for you to work closely with the Transplant Team on your medication management, and to alert your Transplant Coordinator IMMEDIATELY with any problems related to your medications or inability to afford or retrieve your medications.

**MEDICAL COSTS AND INSURANCE**

You are responsible for arranging for payment of medical costs that are not covered by your insurance. If you have not made such arrangements, you may not be able to undergo transplant surgery or your surgery may be delayed. A Transplant Financial Counselor will meet with you to help you understand your insurance benefits and need for any additional insurance or resources.

After you have a kidney transplant, health insurance companies may consider you to have a preexisting condition and refuse pay for medical care, treatments or procedures. Following the surgery, your health insurance and life insurance premiums could be raised and remain higher. In the future, you could have difficulty obtaining medical, disability, and life insurance and denial of coverage is a possibility. If you develop future health problems related to transplantation, they may not be covered by your insurance.

Please be aware that if you have Medicare, and do not receive your transplant in a Medicare approved transplant center, Medicare may not pay for the medications you need after the transplant. Maine Medical Center's Transplant Program is Medicare-approved program.

**CONFIDENTIALITY**

Federal and state laws require that information about you and your condition be kept private. All Transplant Team members will protect your private information as required by law. However, if you do become a transplant candidate, federal regulations require that some personal health information about you be sent to the United Network of Organ Sharing (UNOS) national transplant registry when you are listed as a transplant candidate, and additional information will be sent to the registry on an ongoing basis as part of your follow up care.

**TEACHING FACILITY**

Your physicians and other members of your medical team may be associated with Tufts University School of Medicine or other educational institutions. This means that residents, fellows, students and others may assist with parts of procedures or other medical appointments as deemed appropriate by, and under the supervision of, your physicians and in accordance with Maine Medical Center institutional policies as well as Medical Staff Bylaws and Rules and Regulations.

**SUMMARY**

This document describes the kidney transplant evaluation process along with its benefits, risks and alternatives. This information has been discussed with you by members of the Transplant Team. You should carefully read and consider this information, and discuss it with individuals who are important to you, before you make a decision on whether to participate in the Transplant Program. If you understand this information and decide to participate in the Transplant Program, please sign this consent form.



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I hereby agree with the statements below and consent to participate in the kidney transplant evaluation process:

- I have read (or had read to me) and understand the information contained in this Kidney Transplantation - Transplant Program Information and Consent to Participate form and other additional information provided to me by the Transplant Team.
- I have had an opportunity to ask questions and my questions have been answered to my satisfaction.
- I understand and consent to the various screening tests, labs and consultations required as part of the evaluation process.
- I understand that transplantation is one treatment option for my kidney disease and there are other alternative treatments available.
- I understand that I can change my mind at any time before I receive a kidney transplant and I can withdraw my consent at any time.
- I understand that some of my protected health information (PHI) will be released to UNOS (United Network for Organ Sharing) in order to be placed on the waiting list for a donor organ.
- I understand that once I am placed on the UNOS waiting list, periodic tests may be required and my medications may be changed to keep me in the best possible condition for transplant.
- I understand that I must keep all of my scheduled appointments with the Transplant Clinic and undergo requested lab testing from time to time. If I fail to keep my appointments or I fail to undergo required lab testing, then I further understand that my listing status may be affected.
- I understand the medical, psychosocial and financial risks, benefits, and alternatives to kidney transplant evaluation that has been explained to me. I understand that the evaluation process and transplant surgery have risks, including the possibility of serious injury or death, and agree to participate in the Transplant Program.
- I understand that I am responsible for arranging for payment of costs that are not covered by my insurance. If I do not arrange for payment of these costs, my kidney transplant procedure may be delayed.
- I understand that if I receive a kidney transplant, I must make myself available for examinations and laboratory tests, and I will be required to take certain medications for the rest of my life.
- I promptly will contact the Transplant Program if there are any changes to my telephone number, address, and/or insurance coverage.
- I understand that there are no guarantees of a successful kidney transplant.
- I have been provided with information on the selection criteria used for kidney transplant candidacy and where to find current outcome information from the Scientific Registry for Transplant Recipients for the Maine Transplant Program, as well as any Medicare outcome requirements that are not being met.
- I understand that I will be signing separate consent forms for both the kidney transplant surgery and anesthesia at the time of my surgery.

\_\_\_\_\_ **X** \_\_\_\_\_  
 Date Time AM|PM Signature  Patient  Parent  Guardian  Authorized Representative Printed Name

If by telephone consent given by:  Patient  Other \_\_\_\_\_ Phone number \_\_\_\_\_

\_\_\_\_\_ **X** \_\_\_\_\_  
 Date Time AM|PM Witness Signature (For phone consent or when patient is physically unable to sign) Printed Name

Interpreter for:  Sign Language  Foreign Language  Other \_\_\_\_\_ Print Name or identifying information \_\_\_\_\_

\_\_\_\_\_ **X** \_\_\_\_\_  
 Date Time 24 Hour Signature of Physician or Designee Printed Name