



Hartford Hospital Kidney Transplant Program Informed Consent for Kidney Transplant Evaluation Process

The evaluation process begins when you are first identified as a potential transplant candidate in the Hartford Hospital Kidney Transplant Program and continues until a decision is made and you are deemed suitable or declined for living and/or deceased donor kidney transplant.

This document is to help you be informed of the steps in a kidney transplant evaluation. It is part of what we call the "informed consent process". It is important that you read and understand this document before you sign it. You should ask questions about any information that you do not understand. In fact, we expect and encourage questions throughout your transplant experience.

Evaluation Process

An evaluation for a kidney transplant involves having many tests, procedures and meeting with members of the Multidisciplinary Transplant Team. You may also have visits with other health care providers. All these consultations, tests and procedures will help us decide if a kidney transplant is the right treatment for you. It will also help us to know if you are well enough to have a kidney transplant which is considered major abdominal surgery.

Transplant Team Members

The professionals who make up the Multidisciplinary Transplant Team come from different specialties to ensure the many issues experienced by a patient requiring a kidney transplant are addressed (hereafter referred to as the Transplant Team). The members of this team include:

- The **Transplant Nephrologist** is a medical doctor with expertise in nephrology who specializes in transplantation medicine. The transplant nephrologists will assist in the medical management of your kidney disease and post-transplant care. They are part of the multidisciplinary team that will determine if you are medically suitable for a transplant.
- The **Transplant Coordinator** is often an individual with a nursing background who provides education regarding the transplant evaluation process, listing and waiting for transplant and required follow up care. They will explain your responsibilities before and after transplant. The coordinator is your **advocate**



throughout the transplant process. You are encourage to bring family members and significant others to this meeting.

- The **Transplant Surgeon** is a surgeon with special training and expertise in kidney transplantation and 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 kidneys available, the risks of the surgery and the possible complications associated with the transplant surgery.
- The **Transplant Nurse Practitioner (APRN)** is a registered nurse who has advanced education and clinical training. The transplant nurse practitioner has extensive experience in kidney disease and transplantation. They are part of the multi-disciplinary team that will determine if you are medically suitable to undergo a transplant, and care for you after you have received one.
- The **Transplant Social Worker** is a licensed social worker with special training in transplant issues and 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 and coping strategies. If you need assistance in these areas, they will work with you to try and find what is available to you.
- The **Financial Coordinator** has special training in the financial issues associated with transplant and will discuss the costs associated with your transplant and with the medications you will require after transplant. They will be sure you understand your insurance coverage. It is important that you understand the costs that may not be covered by insurance. It is also very important that any changes in insurance coverage is reported to them immediately so that you do not risk being placed on a financial hold for transplant.
- A **Psychiatrist** is a physician who will conduct a more in-depth psychiatric evaluation and assessment if our social worker or other physician members of the Team feels this would be appropriate. Some patients with a history of drug or alcohol abuse may be required to participate in a formal rehabilitation program. Patients with recent substance abuse must meet abstinence requirements prior to and after transplant listing.

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- The **Transplant Dietitian** has special expertise in the nutritional issues associated with kidney disease and will perform a detailed nutritional assessment and provides nutrition education to patients. Most people with end stage kidney disease have problems meeting their nutritional needs and maintaining muscle mass while avoiding high potassium, phosphorous and sodium containing foods.
- The **Transplant Pharmacist** has knowledge of the multiple medication requirements of transplant patients and will review all of your medications throughout the transplant process. They look for medication interactions and may suggest changes to maximize results or minimize side effects. They are also available to both patients and staff as a resource.
- Some patients may be referred to another specialty physician for consultation. For example, a urologist (genito-urinary tract surgeon), pulmonologist (lung doctor) or cardiologist (heart doctor). If you are already seeing a local specialist in your community, we will contact them to help with the evaluation process. It may be necessary to refer you to a specialist on staff at Hartford Hospital, to care for you during your admission, or if specific testing is needed but not available through your current provider. Be assured we will work with your community nephrologist and other physicians to provide you with the best care possible.

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 on an as-needed basis depending on 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 help us determine how well your other organs are functioning.
- A chest x-ray and pulmonary function tests will allow your physician to analyze lung capacity and function.
- A urine test is used to screen for the presence of urinary tract diseases as well as drugs and alcohol in your system.

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- An EKG, echocardiogram and nuclear stress test will show how well your heart muscle works, if you have high pressure in the lungs that can cause heart failure and if you have any abnormalities with your heart valves. This will assist your physicians in deciding if your heart is strong enough for transplant surgery.
- A MRI, CT scan or ultrasound can help determine the extent of your kidney disease, the presence of any tumors, and define the blood supply to your 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.
- After completing the evaluation process the members of the Transplant Team will meet to present your results and determine if you meet the Hartford Hospital selection criteria for placement on the United Network for Organ Sharing (UNOS) Kidney Wait List or are suitable for living donor transplant. You will be notified of this decision in writing. Our inclusion and exclusion criteria are available in writing to all patients. At Hartford Hospital we review each person as an individual. A few general criteria for placement on our list include:
 - Chronic kidney disease stages five or six.
 - An estimated glomerular filtration rate (eGFR) of less than or equal to 20 milliliters per minute.
 - Mental competency and the ability to participate in post-transplant care.
 - Desire to undergo kidney transplant evaluation, surgery and follow-up care.
 - An individual usually between the ages of 1 and 80.

In addition, the candidate must have the ability to pay for the transplant and post transplant medications, no evidence of significant, untreatable heart or lung disease, must be free of systemic infection, and must show that there is sufficient social support to maintain the often difficult post transplant follow up.

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Risks of Surgical Procedure and Allocation

The potential benefits of kidney transplant 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 complications and death. Your physicians cannot predict exactly how your body will respond to a kidney transplant. Sometimes the condition that caused your underlying kidney disease will affect your transplanted kidney. The operation is complex and the risks are high. 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.

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 is considered a non-standard criteria organ your surgeon will review the details of this particular organ with you at this time and assist you in making your decision. At this point your surgeon has a clear picture of the cumulative risks associated with this particular organ versus the risk of waiting for the next available donor and can base their specific recommendations on this information. You always have the option to decline a specific non-standard criteria organ even if you have consented to consider them.

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 graft will be placed into your abdomen or pelvis.

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 2-4 hours.

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Post-Surgical Care and Recovery

After the surgery you will be taken to post-anesthesia care unit where you will be closely monitored. 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. The goal of pain control is to keep you as comfortable as possible so you can move, take deep breaths and begin the recovery process.

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 a period of 4 to 7 days. The hospitalization time varies 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. During the recovery period the transplant team will closely monitor your progress. You will require life-long follow up and 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 regularly for three to six months post transplant. Every effort is made to transition your routine medical care to your primary care physician or nephrologist. However, you will be followed in the Transplant Clinic for life. For most patients this involves frequent lab work (usually quarterly for life) and a yearly clinic visit. Patients who develop complications may need to be seen more often by the Transplant Team.

Alternative Treatments

Alternative treatment therapies include dialysis. Please feel free to discuss your condition and any possible alternative therapies with your Transplant Team.

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Potential Medical and Surgical Risks and Complications

There are inherent risks in all surgeries, especially surgeries conducted under general anesthesia. Many complications are minor and do not require additional treatment. In some cases, the complications are serious enough to require additional surgery or medical procedure but severe complications can result in prolonged coma or even death.

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 or diminished function of your transplanted kidney. Such a delay may increase the length of your hospital stay and increase the risk of other complications. When this occurs your kidney function will be monitored with lab work and if necessary dialysis will be performed. Explantation (removal of the transplanted kidney) may be required for cases of primary non-function.

Renal artery or vein thrombosis occurs in a small percentage of kidney transplants. This is a clot that develops in one of the major blood vessels going to or from your kidney. Renal artery or vein thrombosis can cause kidney failure. Most patients that develop renal artery or vein thrombosis will require a second operation; some will require explantation.

Some patients experience ureteral complications such as leaks and strictures (narrowing). Occasionally, a drain called a nephrostomy tube is placed through the skin and into the kidney to allow urine to drain and aid in the healing process. Most urine leaks get better without the need for surgery. In some cases surgery is necessary to correct the urine leak. Kidney transplant patients can have both short and long term problems with ureteral strictures. A ureteral stricture is a narrowing of the vessel carrying urine from the kidney to the bladder. Some of the strictures can be repaired by non-surgical means such as dilation and insertion of a stent that is changed on a regular basis until the problem resolves. Occasionally, the surgeon will have to do a surgical procedure to correct the stricture.

Some kidney diseases can return after transplant. Diseases that may recur include primary focal and segmental glomerulosclerosis, primary membranous nephropathy,

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IgA nephropathy/ Henoch-Schonlein Purpura, hemolytic uremic syndrome (related to factor H mutations), primary hyperoxaluria and diabetic nephropathy. In the event of kidney transplant failure, patients can return to dialysis or initiate a work-up for another transplant. Unfortunately repeat transplants have a lower chance for success and not all patients are appropriate candidates for additional transplants.

There are other risks associated with transplantation. Infections from bacteria, viruses, or fungi, acute rejection, side-effects from drugs that suppress the immune system are all possible complications. In certain cases, we may recommend that you consider a donor who had a history of hepatitis B or C. We offer hepatitis C kidneys to recipients who already have a diagnosis of C and we will offer hepatitis B kidneys to patients who are immunized.

Side-effects from immune-suppressing drugs include, but are not limited to: kidney problems, gastrointestinal complaints, blood count abnormalities, neurologic toxicity, high blood pressure, weight gain, higher risk of infection, diabetes, and others. There may be a need for repeated kidney biopsies, surgeries, and other procedures, or a intensive care unit or hospital stay after a kidney transplant.

Transplant recipients have a slight increase in the risk of certain kinds of cancer (including skin cancer and post-transplant lymphoproliferative diseases or lymphoma) because of the immune suppressing medications you will take to prevent rejection.

Rejection can occur following kidney transplantation. It occurs when your body sees your new kidney as foreign (not a part of your body) and tries to attack it. Your body will then try to attack and destroy the new kidney. You will take medication for the rest of your life to prevent rejection from happening. Although you are taking anti-rejection medication, it can still occur. There are two types of rejection. They are acute rejection and chronic rejection. Acute rejection usually happens in the first 3 to 6 months after your transplant but can occur at any time. It is usually is diagnosed by a kidney biopsy and treated with strong immune suppressing therapies and increased doses of your anti-rejection medicines. If acute rejection responds to treatment it usually does not do permanent damage or scarring in the transplanted kidney. Chronic rejection occurs over time. It causes scarring of the kidney that is not reversible. The causes of acute and chronic rejection are not totally understood but it may be caused by not taking the correct doses of your anti-rejection medicines or from missing doses over time. It is very important that you take your anti-rejection medicine as directed. If you have difficulty affording your medications-you should discuss this with the Transplant Team right away.

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Psychosocial risks

This can be a very stressful time for you and your family. Possible psychosocial risks may include, but are not limited to, depression, generalized anxiety, post traumatic stress disorder, feelings of guilt and anxiety related to loss of control, dependence on others and suicidal thoughts. Our social workers and others will be available for support should you or your family need help with any of these feelings.

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 or a filter may need to be placed in a large blood vessel leading to your lungs.

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 kidney transplant 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.

In rare cases, nerve damage 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 related to any abdominal surgery 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, irregular heart beat, stroke, permanent scarring at the site of the abdominal incision, multiple organ failure and even death.

If you are a woman of childbearing age, it is important to understand that pregnancy after a kidney transplant can endanger both your life and health as well as that of your fetus. Although pregnancy after kidney transplant has been successful, it is not recommended during the first year after transplant. **Patient Initials** _____



Pregnancy may injure your new kidney and even cause it to fail. Prior to becoming pregnant, you should inform the Transplant Team of your plans and discuss the risks and benefits.

National and Transplant Center-Specific Outcomes for Adult Kidney Transplantation:

National statistics from the Scientific Registry of Transplant Recipients (SRTR) provides statistics for all transplant centers in the United States. Review the included data sheet detailing one year patient and transplanted organ survival for the Hartford Hospital Transplant Program. Feel free to ask any questions you may have about this data and then initial on the line below.

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 met those requirements. Currently, the Hartford Hospital Kidney Transplant Program:

- meets all requirements for transplant centers
- does not meet the following requirements- one year patient survival is statistically lower than expected.

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.

Organ Donor Risk Factors

You should be aware that all donors are screened for communicable diseases or problems, such as cancer, that may affect the kidney and your health. There is no guarantee that all contagious diseases or problems have been detected. There may be unforeseen factors including undetected cancer or undetectable infectious disease that may affect the success of your transplant or your health. These include; HIV, Hepatitis B virus, Hepatitis C virus, malaria or other bacterial, viral or fungal infections. There are other factors related to the specific organ donor, such as the donor's history, the

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donor's age and condition of the donated organ that can affect the success of the transplant and your health. The surgeon will discuss the specific donor risk factors with you in detail as part of your decision to consent to the transplant surgery.

Right to refuse transplant

You always have the option not to undergo transplantation and can choose to be removed from the list. If you choose not to have a transplant, your option is to continue with dialysis and medical management. Keep in mind there is no guarantee that another organ will become available to you. If you do not undergo the transplant surgery, your condition may worsen and limit your life expectancy. If the Transplant Team is concerned about the reason you declined a particular organ, you will need to come in and meet with them to discuss this.

Life and Health Insurance

It is very important that you notify the Transplant Team immediately of any insurance changes so that the Financial Coordinators can verify your benefits and coverage. Failure to do this can result in lack of payment for your transplant and/or medications.

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 premiums may increase and remain higher. In the future, insurance companies could refuse to insure you.

Patient Relations

The patient relations department provides information to patients and their families about services at Hartford Hospital. They help patients and their families interpret hospital policies and procedures, provide a formal mechanism for the investigation, resolution and recording of patient complaints and assure the observation of patient's rights, and handle certain special requests. You can reach the Patient Relations office at Hartford Hospital at (860) 545-1400.

You also have the right to notify the Organ Procurement and Transplantation Network at 1-888-874-6361, if you have any concern or grievance about the Hartford Hospital Transplant Program. **Patient Initials** _____



General

In addition to the information provided in this document, I have been informed and have received information about wait time transfer and multiple listing.

I will receive a letter of notification concerning my status at the end of this evaluation process indicating that either:

- a. I have been accepted and I am active on the UNOS waitlist.*
- b. I have been conditionally accepted and placed on hold status on the UNOS waitlist, pending completion of evaluation or treatment.*
- c. I am not an acceptable candidate for transplantation and the reason(s) for this decision.*

I understand that the Hartford Hospital Kidney Transplant Program may remove a candidate from the waitlist for changes in their medical condition or inability to comply with medical care.

I have received this information from the Transplant Team. I have been provided an opportunity to read the information and ask questions. I understand the information that has being provided to me. I also consent to have my photograph taken and scanned into my electronic chart in the Kidney Transplant Office.

_____	_____	_____
Patient	Date	Time
_____	_____	_____
Nurse Coordinator	Date	Time
_____	_____	_____
Transplant Surgeon/Nephrologist	Date	Time