

KIDNEY TRANSPLANT SURGERY CONSENT

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Patient Name: _____

MRN: _____ DOB: _____

Treatment Location: _____

I. CONSENT TO KIDNEY TRANSPLANT SURGERY (Required)*This Section is required to be completed by all patients who undergo kidney transplant surgery.*

I hereby consent to and authorize Dr. _____ and his/her assistant(s), including supervised physicians in residency or fellowship training, to perform kidney transplant surgery and such additional procedures or treatment as are considered advisable on the basis of findings during this procedure on me or on my _____, (indicate relationship) or other procedures and related tasks, tests and treatment on me, including dissecting tissue, removing tissue, and retaining for research and teaching purposes tissue and specimens that would be otherwise discarded, harvesting grafts, blood transfusion and related medical treatment.

A. 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.

B. 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 are 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. I understand that the physician performing the procedure has also informed me of any donor risk criteria for acute HIV, HBV, or HCV infection according to the 2020 U.S. Public Health Service Guideline.

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 transplanted 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, heart attack, damage to the transplanted kidney, diabetes, infection, increased risk of developing certain cancers, and death.

I am aware that the practice of medicine and surgery is not an exact science and I acknowledge that MEDICAL SCIENCE CAN NOT PRODUCE GUARANTEED RESULTS AND NO GUARANTEES HAVE BEEN MADE TO ME CONCERNING THE RESULTS OF MY KIDNEY TRANSPLANTATION SURGERY OR POST SURGICAL CARE. I have been counseled about the long term risks and benefits of the procedure as discussed with the transplant team.

C. 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

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provided by physicians in their own private practice. Anesthesiology, radiology, 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 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.

DO NOT make images of me for teaching or research.

Blood Products. I understand that the transfusion of blood components (red cells, plasma, platelets, cryoprecipitate) may be necessary or appropriate as part of my care, or to treat conditions arising during this hospital stay. Mild reactions such as fever and hives are quite common. Despite testing, the risk of an extremely rare but serious reaction or infection exists, including HIV, Hepatitis, lung injury, and death. Under some clinical situations and with appropriate planning, alternatives to transfusion may be considered. Additional discussion of the risks and alternatives has been offered. I hereby consent to surgery, treatment, **AND Blood Products UNLESS** the “DECLINE Blood Products” box is checked below.

DECLINE Blood Products

Company Representative. I have been informed that a company representative may observe the procedure to provide technical information or gain knowledge useful in the development of medical devices. The representative will not “scrub” or use devices but will have minimal information about me. I hereby consent to the presence of the representative UNLESS the “Decline Representative presence” box is checked below.

DECLINE Representative presence

X

_____ Date	_____ Time AM PM	_____ Signature <input type="checkbox"/> Patient <input type="checkbox"/> Parent <input type="checkbox"/> Guardian <input type="checkbox"/> Authorized Representative	_____ Printed Name
If by telephone consent given by: <input type="checkbox"/> Patient <input type="checkbox"/> 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: <input type="checkbox"/> Sign Language <input type="checkbox"/> Foreign Language <input type="checkbox"/> Other		_____	Print Name or identifying information _____

X

_____ Date	_____ Time 24 Hour	_____ Signature of Physician or Designee	_____ Printed Name
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II. KDPI>85%/Expanded Criteria Donor Informed Consent (Optional)

This Section is required for a patient who previously consented to be listed for a KDPI>85%/Expanded criteria donor kidney who is now being offered a KDPI>85%/Expanded criteria donor kidney.

Additional Risks Associated with Acceptance of a Kidney from an Expanded Criteria Donor

The physician responsible for this surgery or designee has explained to me that the quality of deceased donor kidneys is variable, with some lasting longer than others after transplantation. You may be interested in receiving a kidney that is expected to be less durable in order to reduce your waiting time for transplantation. The national kidney UNOS waiting list increases by several thousand each year and many individuals will die waiting for a kidney transplant. The waiting time for a deceased donor kidney is over 4 years in many areas of the country.

I understand that there are many factors that contribute to the performance of a transplanted kidney. Each deceased donor kidney receives a Kidney Donor Profile Index (KDPI) score between 0-100%. KDPI predicts how long a kidney will work after transplantation. The lower the score, the longer the kidney is expected to last while a higher score means the kidney is expected not to last as long. The score depends upon many donor factors including the donor’s height, weight, history of high blood pressure, diabetes, Hepatitis B or C, cause of death, race, and donor creatinine, which is a measure of how well the kidney works. Current data indicate that the biggest change in outcomes for patients undergoing transplantation occurs when the KDPI exceeds 85%.

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I further understand that I am being informed about KDPI>85% kidney transplants and being offered one of this type of kidneys because I have kidney failure, do not have a potential living kidney donor, and, given my age and overall health condition, I might receive significant benefit from a KDPI>85% kidney since it will shorten the wait time for a kidney transplant. Recent transplant study data indicate that the longer a patient receives dialysis, the poorer the transplant outcome.

If I accept a KDPI>85% kidney, I understand that I will receive the standard post-transplant care. However, I understand that I may require additional post-transplant biopsies to assess my kidney function and that long term kidney function may be less than that from a KDPI<85% kidney.

I understand that I am being offered a KDPI>85% kidney and that I can decline to receive this particular kidney without losing time accumulated on the national kidney UNOS waitlist.

I hereby consent to receive a kidney transplant with a KDPI>85%. I understand the risk of receiving this type of kidney and I acknowledge that I have had the opportunity to ask questions which were answered to my satisfaction.

_____	_____	_____
Patient or Authorized Representative Signature	AM PM Date Time	Witness Signature
_____	_____	_____
Interpreter Printed Name	Interpreter Signature (if available)	AM PM Date Time

III. Pre-Operative Consent to Accept a Kidney from a Hepatitis C Positive Donor as a Hepatitis C Positive Recipient (Optional)

This Section is required to be completed for patients who previously consented to be listed for HCV+ donor kidney and are HCV+, and who are now being offered a HCV+ kidney.

Additional Risks Associated with Acceptance of a Kidney from a Hepatitis C+ Donor

The physician responsible for this surgery or designee has explained to me that approximately 5% (1 in 20) of deceased kidney donors are Hepatitis C virus (HCV) positive. The majority of patients on the national kidney UNOS waitlist for a kidney are not HCV positive. Kidneys from HCV positive donors will be only offered to HCV positive recipients. Therefore, these patients may experience significantly lower waiting times for transplantation.

I understand that the usual and most frequent risks and hazards of accepting one of these kidneys from HCV positive donors include the possibility of receiving a different strain (genotype) of the Hepatitis C virus than that which I already have since the genotype of an HCV positive donor will not be known until after transplantation. I further understand that this may influence the choice of antiviral therapy needed after kidney transplantation. I also have been informed that 5 and 10-year patient and kidney transplant survival is slightly lower in patients who receive kidney transplants from HCV positive donors; however, kidney transplant recipients from HCV positive donors live significantly longer than patients remaining on dialysis.

If I accept a HCV positive kidney, I understand that my post-transplant care will include a referral to Hepatology within the first year post-transplant for consideration of treatment once my kidney function has stabilized and my immunosuppression has been minimized.

I understand that I am being offered a HCV positive kidney, and that I can decline to receive this particular kidney without losing time accumulated on the national kidney UNOS waitlist.

I hereby consent to receive a kidney from a HCV positive donor and understand the risk of receiving a different genotype of Hepatitis C virus than that which I already have. I acknowledge that I have had the opportunity to ask questions which were answered to my satisfaction.

_____	_____	_____
Patient or Authorized Representative Signature	AM PM Date Time	Witness Signature

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Interpreter Printed Name	Interpreter Signature (if available)	Date Time
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IV. Pre-Operative Consent to Accept a Kidney from a Hepatitis B Core Antibody Donor (Optional)

This Section is required to be completed for patients who previously consented to be listed for a HBV+ donor kidney and who now are being offered a HBV+ kidney.

Additional Risks Associated with Acceptance of a Kidney from a Hepatitis B+ Donor

The physician responsible for this surgery or designee has explained to me that the kidney is offered to me has tested positive for this virus (Hepatitis B core antibody+). I understand that my healthcare providers previously have confirmed that I have the antibody to Hepatitis B (surface antibody). The risk of contracting Hepatitis B under these circumstances has been studied and is reported to be minimal in the medical literature.

If I accept a Hepatitis B positive kidney, I understand that my post-transplant care will include laboratory testing at regular intervals post-transplantation to assess the presence of Hepatitis B in my blood. If my post-transplant Hepatitis B virus testing becomes positive, then I understand that I will be counseled and assessed by a transplant infectious disease specialist, treatment will be initiated as deemed appropriate, and the UNOS Disease Transmission Advisory Committee (DTAC) committee will be informed of my status.

I hereby consent to receive a kidney from a Hepatitis B Positive Donor. I understand the risk of receiving this type of kidney and I acknowledge that I have had the opportunity to ask questions which were answered to my satisfaction.

Patient or Authorized Representative Signature	AM PM Date Time	Witness Signature
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Interpreter Printed Name	Interpreter Signature (if available)	AM PM Date Time
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V. Pre-Operative Consent to Accept a Kidney from a Hepatitis C Virus NAT* Positive Donor as a Hepatitis C Virus Negative Recipient (Optional)

This Section is required to be completed for patients who previously consented to be listed for HCV+ donor kidney and are HCV-, and who are now being offered a HCV+ kidney.

I have been previously informed about and consented to be listed for a Hepatitis C virus nucleic acid testing (NAT) positive donor kidney on the kidney transplant list. NAT testing is a highly sensitive method of testing blood for the presence of this virus. I am now being offered a kidney from a deceased donor that has tested NAT positive for the Hepatitis C virus (HCV).

Additional Risks Associated with Acceptance of a Kidney from a Hepatitis C positive Donor.

- I understand that if I accept an organ from a donor who tests positive for HCV, I will become infected with the HCV. Additionally, after my transplant, I will undergo sequential blood testing to detect the HCV infection. Once confirmed, I will be prescribed treatment/medications to treat the HCV infection initially for 8 weeks.
- It has been explained to me that current treatments for HCV are very effective, curing over 95% of patients.
- I am aware that there is an approximate 5% probability that I may not be cured by the treatment and the HCV can permanently damage my liver. When damage occurs, it usually takes several years to affect the liver and may cause cirrhosis. However, in rare circumstances, this damage can happen earlier and be severe enough to cause jaundice, loss of liver function leading to liver failure and possibly death.

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In addition to the above I am aware of the following risks:

- If my insurance provider does not pay for the HCV treatment after transplant, I will be responsible for payment.
- I have been informed about the length of the HCV treatment and side effects of the medications including the following:
 - As part of HCV treatment, I will need to take anti-Hepatitis C pill(s) initially for eight (8) weeks and potentially longer based on the initial response to therapy. These pills will be in addition to my usual immunosuppression medications.
 - Side effects of HCV treatment range from mild (tiredness, headache, and nausea) to severe (very rare, acute liver inflammation leading to failure and or death) among others.
 - If I have ever had Hepatitis B, my transplant team will do additional blood tests to monitor Hepatitis B activation during and after my HCV treatment. If Hepatitis B becomes active as a result of treatment for HCV, I may need additional medication.
 - HCV treatment medication may interact with some of my other medications. My transplant team will review my medication list and adjust them to avoid potential interactions.
 - As part of HCV treatment, I will have additional blood tests that are required to monitor treatment response, and to determine if I have been cured from the HCV.

Benefits Associated with Acceptance of a Kidney from a Hepatitis C positive Donor

I am aware that the main benefit from participating in this program is to potentially decrease my waiting time for a deceased donor kidney transplant which translates to less years on dialysis which will help me to live longer.

Alternatives to accepting an organ from a donor who is infected with Hepatitis C Virus (HCV) infection.

- It has been explained to me that I have other treatment alternatives including to wait for a kidney donor who tests negative for Hepatitis C Virus (HCV) infection or search for a living kidney donor.

I have been fully informed and counseled about the potential benefits, risks and alternatives of receiving an organ from a donor who tests positive for Hepatitis C virus (HCV) infection. My questions have been answered to my satisfaction. I understand that unexplained and unpredictable events can occur and that I will become infected with Hepatitis C virus (HCV) after transplantation with an organ from a donor infected with Hepatitis C virus (HCV). However, I know that receiving a transplant may help me live longer. I understand I can refuse any offer from any potential donor without affecting my chances or changing my position on the waiting list for kidney transplant.

By signing this consent form, I authorize my transplant surgeon to accept and implant an organ donated by a person who tests positive for Hepatitis C virus (HCV) into me even though I currently do not have the Hepatitis C (HCV) infection.

Patient or Authorized Representative Signature

AM|PM
Date|Time

Witness Signature

Interpreter Printed Name

Interpreter Signature (if available)

AM|PM
Date|Time