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 the course of 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 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 am aware that the practice of medicine and surgery is not an exact science and I acknowledge that MEDICAL SCIENCE CANNOT 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 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.  

- **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**

**II. Pre-Operative Consent to Accept a Kidney From a Public Health Service Increased Risk Donor (Optional)**

This Section is required to be completed for patients who previously consented to be listed for an increased risk donor kidney and who now are being offered an increased risk donor kidney.

Additional Risks Associated with Acceptance of a Kidney From an Increased Risk Donor

The physician responsible for this surgery or designee has explained to me that organ transplantation carries a small risk of infection transmitted by the donor kidney. These infections include HIV, Hepatitis B and Hepatitis C and others despite negative blood testing. All organ donors are screened by the currently available tests to decrease the chance of transmission of infections to kidney recipients. Only kidneys from donors with negative testing are offered to patients on the national kidney UNOS wait list. The reason that the risk is not zero is that current testing methods are not perfect in detecting infection in donors with extremely early infections (i.e., within a few days between infection and organ donation). The small risk of infection when accepting a kidney from one of these donors needs to be compared with the increased risk of complications and death from dialysis. There is no comprehensive way to screen deceased and living donors for all transmissible diseases and malignancies may be identified and transmitted after transplantation. Donor evaluation and screening results may affect post-transplant evaluation, screening, and management. Recipients of increased risk donor organs will be monitored closely for any potential post-transplant health issues; this monitoring may include additional testing and reporting requirements in accordance with Organ Procurement and Transplantation Network (OPTN) policies. In accordance with OPTN Policy 2.3: Evaluating and Screening Potential Deceased Donors, deceased donors are evaluated and screened using the donor’s medical and behavioral history as provided by one or more individuals familiar with the donor, medical record review, physical examination of the donor including vital signs, and documentation if any of this information is not available and why it is not available. In accordance with OPTN Policy 14.4: Medical Evaluation Requirements for Living Donors, living donors are required to undergo screening for transmissible diseases including CMV,
EBV, HIV antibody, Hepatitis B surface antigen, Hepatitis B core antibody, Hepatitis C antibody, HCV (NAT), syphilis, and tuberculosis.

The United States Public Health Service defines donors meeting the criteria to be at increased risk of transmitting HIV, Hepatitis C and Hepatitis B: (i) people who have had sex with a person known or suspected to have HIV, Hepatitis B or Hepatitis C infection within the previous 12 months; (ii) men who have had sex with men within the previous 12 months; (iii) women who have had sex with a man with a history of having sex with men within the previous 12 months; (iv) people who have had sex for money or drugs within the previous 12 months; (v) people who have had sex with a person who had sex in exchange for money or drugs within the previous 12 months; (vi) people who have injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons within the previous 12 months; (vii) people who have had sex with a person who has injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons in the previous 12 months; (viii) people who have been in lockup, jail, prison or juvenile correctional facility for more than 72 consecutive hours in the preceding 12 months; (ix) persons who have been newly diagnosed with, or have been treated for syphilis, gonorrhea, chlamydia, or genital ulcers in the preceding 12 months; (x) persons whose medical/behavioral history cannot be obtained; (xi) persons whose blood specimen is hemodiluted. (xii) a child who is < or equal to 18 months of age and born to a mother known to be infected with, or at increased risk for HIV, HBV, or HCV infection; (xiii) a child who has been breastfed within the previous 12 months and the mother is known to be infected with or at increased risk for HIV infection.

I understand that I am being offered a kidney from an increased risk donor, and that I can decline receiving this particular kidney without losing time accumulated on the national kidney UNOS wait list.

Your donor falls into increased risk situation(s) above: ______. You will be tested before and at 4, 12, and 52 weeks post transplantation to assess the presence of HIV, Hepatitis B, or Hepatitis C in your blood. If your post-transplant testing is positive, 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.

I hereby consent to receive a kidney from an Increased Risk 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.

☐ III. 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%.

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 receiving this particular kidney without losing time accumulated on the national kidney UNOS wait list.

I hereby consent to receiving 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.

IV. Pre-Operative Consent to Accept a Kidney From a Hepatitis C+ Donor (Optional)

This Section is required to be completed for patients who previously consented to be listed for HCV+ donor kidney 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 wait list 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 receiving this particular kidney without losing time accumulated on the national kidney UNOS wait list.
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.

<table>
<thead>
<tr>
<th>Patient or Authorized Representative Signature</th>
<th>AM</th>
<th>PM</th>
<th>Date</th>
<th>Time</th>
<th>Witness Signature</th>
</tr>
</thead>
</table>

Interpreter Printed Name

Interpreter Signature (if available)

Date | Time

☐ V. 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 being 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 2, 4, 12, and 52 weeks 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.

<table>
<thead>
<tr>
<th>Patient or Authorized Representative Signature</th>
<th>AM</th>
<th>PM</th>
<th>Date</th>
<th>Time</th>
<th>Witness Signature</th>
</tr>
</thead>
</table>

Interpreter Printed Name

Interpreter Signature (if available)

Date | Time