I. DESCRIPTION, PURPOSE AND BENEFITS OF PROCEDURE

Prior to being added to the national United Network for Organ Sharing (UNOS) kidney transplant waiting list, I understand that patients are asked to indicate their interest in accepting a non-standard criteria donor kidney. The transplant physician or designee has explained that acceptance of a kidney in this category may reduce time on the UNOS waiting list, and may offer similar transplant survival rates when compared to standard criteria donor kidneys.

I understand that my consent to accept any of these types of kidneys offered is entirely voluntary and the consent may be withdrawn at any time, including at the time the kidney offer is made and prior to surgery, I further understand that a separate Surgical Consent will be required to proceed with the transplant surgery.

I further understand that if I agree to accept a non-standard criteria donor kidney prior to being added to the deceased donor waiting list, then I will be considered for both standard criteria and non-standard criteria donor kidneys when they become available. The transplant physician or designee has explained that I may be offered a kidney from an increased risk donor, and that I can decline receiving this particular kidney without losing time accumulated on the UNOS kidney transplant waiting list.

II. RISKS ASSOCIATED WITH THE PROCEDURE

The transplant physician or designee has explained to me that the usual and most frequent risks involved with accepting a kidney from an increased risk donor include the following.

I understand 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 using the currently available tests to decrease the chance of transmission of infections to kidney recipients. **Kidneys from donors with negative testing are offered to patients on the UNOS kidney transplant waiting 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 comprehensively reliable method to screen deceased and living donors for all transmissible diseases. 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 by the transplant team 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 following criteria to be at increased risk of transmitting HIV, Hepatitis C and Hepatitis B:

- 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;
men who have had sex with men within the previous 12 months;
• women who have had sex with a man with a history of having sex with men within the previous 12 months;
• people who have had sex for money or drugs within the previous 12 months;
• people who have had sex with a person who had sex in exchange for money or drugs within the previous 12 months;
• people who have injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons within the previous 12 months;
• 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;
• people who have been in lockup, jail, prison or juvenile correctional facility for more than 72 consecutive hours in the preceding 12 months;
• persons who have been newly diagnosed with, or have been treated for syphilis, gonorrhea, chlamydia, or genital ulcers in the preceding 12 months;
• persons whose medical/behavioral history cannot be obtained;
• persons whose blood specimen is hemodiluted.
• a child who is ≤ 18 months of age and born to a mother known to be infected with, or at increased risk for HIV, HBV, or HCV infection;
• 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 further understand that if my donor falls into the category listed above, then I 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 my blood. If my post-transplant testing is positive, then 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.

C. Alternative Courses of Treatment

The transplant physician or designee has explained to me that the alternative courses of treatment include being placed on the UNOS transplant waiting list for only a standard criteria kidney donor and then undergoing kidney transplantation surgery. I further understand that other management options include dialysis or no treatment.

I understand the risks of accepting a kidney from an increased risk donor as described above, and I acknowledge that I have had the opportunity to ask questions which were answered to my satisfaction. I hereby consent to be placed on the UNOS transplant waiting list for a kidney from an increased risk donor.

X

Signature of ☐ Patient ☐ Parent ☐ Guardian ☐ Authorized Representative Date Time AM | PM ☐ Witness Signature

Printed name of person signing on behalf of the patient: ___________________________ Patient is a ☐ Minor or ___________________________

Consent given by telephone ☐ Patient ☐ Other ___________________________ Telephone # ___________________________

Printed name of interpreter ___________________________ Reason ☐ Sign ☐ Language ☐ Other ___________________________

X

Signature of Physician or Designee Date Time 24 Hour Printed Name