



# INFORMED CONSENT FOR KIDNEY DONOR EVALUATION / DONATION

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PATIENT IDENTIFICATION LABEL  
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## 1. Materials and Information Provided

- I am being provided materials containing information about the items below so I will understand the general and transplant center specific risk of being a donor.
- I am being provided information about the phases of the living donation process:
  - Informed Consent
  - Evaluations: Medical/Surgical and Psychosocial
  - Operative Care: Pre and Post Surgery
  - Follow up Care related to the donation

## 2. Written Assurances

- I am donating my kidney free from inducement and coercion. I understand that I may decline to donate my kidney at any time. I understand that I may discontinue the living donor consent or evaluation process in a way that is protected and confidential.
- I understand I am being provided with an Independent Living Donor Advocate (ILDA), whose job it is to advocate for me and protect my interests and to assist me during this process. The ILDA's involvement is completely separate from the potential recipient, his/her evaluation and the decision to transplant him/her.
- I understand that I may not receive valuable consideration (including without limitation monetary or material gain) for agreeing to be a donor. I understand it is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for anything of value including, but not limited, to cash, property, and vacations.

## 3. Confidentiality

- Information regarding my evaluation will remain confidential and will not be discussed with the potential kidney transplant recipient.
- Health information obtained during the living donor evaluation is subject to the same regulations as all records and could reveal conditions that must be reported to local, state, or federal health authorities. All reasonable precautions will be used to provide confidentiality for the donor and recipient.

PATIENT / AUTHORIZED REPRESENTATIVE INITIAL: \_\_\_\_\_

WITNESS INITIAL: \_\_\_\_\_

PHYSICIAN INITIAL: \_\_\_\_\_

**4. Medical Evaluation**

- The medical evaluation will be conducted by a physician and /or surgeon experienced in living donation. The goal of the evaluation process is to assess and minimize risks post donation. The medical testing will include a screen for any evidence of kidney or infectious disease and medical problems which may lead to kidney disease. The following tests are included in the living donor evaluation process. Other tests may be added based on these results and/or living donor medical/family history:
  - Blood tests are done to determine living donor blood type and to look at matching between living donor and potential recipient. There are blood tests to screen for immunity to or presence of specific viruses, including HIV. If HIV or certain venereal diseases (sexually transmitted diseases) are revealed the transplant center is mandated to notify local, state, or federal public health authorities.
  - Urine test or nuclear renal scan will be tested to see how well the living donor's kidneys function and to see if there is any evidence of infection or other identifiable problems.
  - A chest x-ray will help identify any problems with the lungs.
  - An EKG will check for any abnormalities of heart rhythm. Additional heart testing may be added depending on living donor medical and social history.
  - A CT angiogram (a special x-ray) of the kidneys will be performed to determine if there are any problems with the kidneys or major blood vessels.
  - Cancer screenings (i.e. mammogram, Pap smear, colonoscopy) dependent on age.

**5. Declined or Disqualified as a donor**

- I understand that I may be declined as a donor at Charleston Area Medical Center Transplant Center, and if I am turned down as a donor at this facility I have the option of being evaluated by another transplant program with different criteria.
- The exact criteria for acceptance will be shared with me if I so desire and I understand that this criteria may vary significantly among transplant hospitals.

**6. Other Treatment Options Available to Someone Considering a Transplant**

- I understand that alternate treatment exists for the potential recipient of my kidney including:
  - Kidney transplantation from a deceased donor
  - Dialysis: Peritoneal dialysis or Hemodialysis

**7. Potential Future Insurance Implications / Financial Risks**

- I have been informed that if my potential recipient undergoes renal transplantation at a non-Medicare approved facility their immunosuppressive drugs will not be paid for under Medicare Part B.
- My personal expenses of travel, housing, childcare, and lost wages related to kidney donation might not be reimbursed. I have been informed of resources that may be available to defray some donation-related costs.
- Possible loss of employment (if not covered by FMLA or prolonged recovery) and income.
- Potential negative impact on my ability to obtain future employment (depending on requirements for different types of employment)
- Potential negative impacts on my ability to obtain, afford, or maintain health, disability, and life insurance.
- Health problems experienced by kidney donors following donation may not be covered by the recipient's insurance resulting in life-long medical follow-up at the donor's expense.
- I will need life-long follow-up at my expense.

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**8. Risks**

- I understand that I am undertaking risk and will receive no medical benefit from the donation surgery. These risks may be temporary or permanent.
- Potential Risks Associated with Evaluation for Donation
  - Allergic reactions to contrast.
  - Detection of infections reportable to health authorities.
  - Detection of serious medical conditions.
  - Detection of adverse genetic finding unknown to the living donor, detection of certain abnormalities that will require more testing at the living donor's expense or create the need for unexpected decisions on the part of the transplant team.
- Potential Psychological Risks
  - Potential for problems with body image
  - Potential for post-surgery depression or anxiety
  - Feelings of emotional distress or grief if the transplant recipient experiences any recurrence of disease or death
  - Possibility of transplant recipient rejection and need for re-transplantation
  - Potential impact of donation on living donor's lifestyle – psychological recovery from loss of an organ.
- Potential Medical / Surgical Risk of Kidney Donation- Surgical Risks may be temporary or permanent and include but are not limited to:
  - Potential for surgical complications including the risk of living donor death
  - Acute kidney failure and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period
  - Potential for organ failure and the need for a future organ transplant for living donor
  - Potential for other medical complications including long-term complications currently unforeseen
  - Scars, Wound infection, Blood Clots, Pneumonia, Pain, Fatigue, Nerve Injury, Hernia, Urinary Tract Infection, Non-function of the kidney
  - Abdominal or bowel symptoms such as bloating, nausea, and bowel obstruction
  - Increased risk of kidney problems with the use of over the counter medications and supplements
  - Risk of preeclampsia or gestational hypertension are increased in pregnancies after donation.

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- Potential Medical / Surgical Risk of Kidney Donation- Surgical Risks may be temporary or permanent and include but are not limited to: *(Continued)*
  - The morbidity and mortality of living donors may be impacted by age, obesity (overweight), hypertension, or other donor specific pre-existing condition:
    - On average kidney donors lose 25-35% of kidney function after donation.
    - Although risk of End Stage Renal Disease (ESRD) for living kidney donors does not exceed that of the general population with the same demographic profile, risk of ESRD for living kidney donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors.
    - Donor risks must be interpreted in light of known epidemiology (information and statistics) regarding both Chronic Kidney Disease (CKD) and ESRD. CKD generally develops in mid-life (40-50 years old) ESRD generally develops after age 60. The medical evaluation of a young living donor cannot predict lifetime risk of CKD or ESRD.
    - Donor may also be at a higher risk for kidney disease if sustain damage to remaining kidney. Dialysis is required when reaching ESRD. The current practice is to prioritize living donors who become transplant candidates.

**9. Disclosure**

- The medical condition of the potential recipient of my kidney has been reviewed with me. I am aware of the following conditions: \_\_\_\_\_
- Transplant hospitals determine candidacy for transplantation based on existing hospital specific guidelines or practices and clinical judgement.
- Any transplant candidate may have an increased likelihood of adverse outcomes (including but not limited to graft (transplant kidney) failure, complications, and mortality) that:
  - Exceed local or national averages
  - Do not necessarily prohibit transplantation
  - Are not disclosed with the potential donor
- Information regarding my evaluation will remain confidential and will not be discussed with the potential kidney transplant recipient however health information obtained during the evaluation is subject to the same regulations as all records and could reveal conditions that must be reported to local, state, or federal health authorities. All reasonable precautions will be used to provide confidentiality for the donor and recipient.
- The recovery hospital can disclose to the living donor certain information about candidates only with permission of the candidate, including:
  - The reasons for a transplant candidate have increased likelihood of adverse outcomes.
  - Personal health information collected during the transplant candidate's evaluation, which is confidential and protected under privacy law.
- I have been informed of my potential recipient's status on the transplant waiting list and if there is the potential that a deceased donor kidney could become available for the recipient before donor evaluation is complete or transplant occurs.
- I understand any infectious disease or malignancy that is pertinent to acute recipient care discovered during the first two years of follow up care:

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**Continued-**

- Will be disclosed to the donor
- Will be disclosed to the recipient's transplant center
- May need to be reported to local, state, or federal public health authorities
- Will be reported through the OPTN Improving Patient Safety Portal

**10. Post-Donation Follow-Up**

- The transplant center will assume the financial responsibility of laboratory testing ordered for me by the transplant center for the first six months following donation.
- I understand that the transplant center is required to report living kidney donor follow-up information to the federal regulatory agency, currently the United Network for Organ Sharing, at 6months, one year and two years post donation.
- I commit to maintain a relationship with CAMC transplant by a clinic visit at 2 weeks, then via clinic, mail, or telephone communication at 3 months, 6 months, 1 year and 2 years.

**11. Concerns or Grievances**

- I have received a copy of the United Network for Organ Sharing (UNOS) patient letter. It describes the services and information offered to patients by UNOS and the Organ Procurement and Transplantation Network. It provides a toll-free patient service line to help transplant candidates, recipients, living donors, and family members understand organ allocation practices and transplantation data. I may also call this number to discuss a problem I may be experiencing with a transplant center or the transplantation system in general.

**12. Outcomes Data**

- I have received both the national and center-specific outcomes from the most recent Scientific Registry of Transplant Recipients center-specific report (Release date : \_\_\_\_\_). The information included the 1-year patient and graft survival and national 1-yr patient and graft survival. I also received available center specific donor outcomes compared to national outcomes and was told I would be notified about any Medicare outcome requirements not being met by the transplant center. Currently, CAMC meets all Medicare outcome requirements.

**I CERTIFY: I HAVE READ (OR HAD READ TO ME) THE CONTENTS OF THIS FORM: I UNDERSTAND THE RISKS AND ALTERNATIVES INVOLVED IN LIVING DONOR EVALUATION/DONATION (sign before Returning)**

DATE: \_\_\_\_\_ Time: \_\_\_\_\_ SIGNATURE :( Required) \_\_\_\_\_  
(Required) (Required) (Signed by patient)

**TO BE COMPLETED AT TIME OF VISIT**

**TRANSPLANT STAFF STATEMENT:** I have reviewed that the living donor has received information on informed consent, evaluation process, surgical procedure, medical risk, psychosocial risks and follow-up requirements. I have answered all questions from the potential donor.

DATE: \_\_\_\_\_ Time: \_\_\_\_\_ PHYSICIAN SIGNATURE: \_\_\_\_\_  
(Required) (Required) (Required)

DATE: \_\_\_\_\_ Time: \_\_\_\_\_ WITNESS SIGNATURE: \_\_\_\_\_  
(Required) (Required) (Required)

**DONOR ACKNOWLEDGEMENT**

I UNDERSTAND THE RISKS AND ALTERNATIVES INVOLVED IN LIVING DONOR EVALUATION/DONATION . I have had an opportunity to ask questions and have them answered to my satisfaction.

DATE: \_\_\_\_\_ Time: \_\_\_\_\_ SIGNATURE: \_\_\_\_\_  
(Required) (Required) (Signed by patient or person legally authorized to consent for patient with relationship)