

## TRANSPLANTATION

### **RISKS AND BENEFITS/INFORMED CONSENT**

#### **KIDNEY DONOR (LIVING RELATED AND LIVING UNRELATED)**

Becoming a living donor is your choice. The best thing for you to do is learn all you can about the kidney donation process. The importance of education is to make sure you understand all aspects of the donation-before **and** after. During the donation process your donor team is devoted to confidentiality. All information will be shared with only you.

Some donors choose to donate instantly. Others wait longer to make the choice. It is important that you take time to make the best decision for you. The transplant team will respect your decision. Should you decide not to donate; the recipient will be informed that you are not an acceptable candidate without providing specific reasons for the Transplant Team's decision.

Below is a description of the donor evaluation process:

Phase I: Blood type confirmation

Phase II: Donor-Recipient crossmatch

Phase III: Blood and urine testing

Phase IV: Medical, psychosocial, and surgical evaluations, tissue typing and diagnostic tests

Phase V: Presentation at Selection Committee

Phase VI: Pre-op appointments, anesthesia clinic

Phase VII: Surgery at Carolinas Medical Center

Phase VIII. Required post-op follow up at approximately 2 weeks & 8 weeks.

And Long-term follow up at 6months, 1 year, & 2 years.

#### Informed Consent of Living Kidney donors: **Evaluation phase**

- Donating a kidney to someone is a very rewarding experience however it involves some "risk" both generally and center specific - it is not designed to benefit the donor- in fact, there is no medical benefit from removing a kidney. It is designed to help the recipient.
- Transplant hospitals determine candidacy for transplantation based on existing hospital specific guidelines or practices and clinical judgement. Personal health information collected during the transplant candidate's evaluation is confidential and protected under privacy law.

- The recovery hospital will take all the reasonable precautions to provide confidentiality for the living donor and recipient.
- **You**, the donor will receive a thorough medical and psychosocial evaluation to assess **your** overall general health.
- African Americans could have more risks with donating. They may develop high blood pressure, diabetes or kidney failure. A study of living donors who donated between 1993 and 2005 showed that kidney failure might be higher for African American donors. This study stated the risk of African American donors for having kidney failure after donation as 44/8,889 or 0.49%. The same study showed the risk of kidney failure for Caucasian donors to be 0.13%. Among African American population who are not donors, the risk of having kidney failure is 48/10,000 or 0.48%.

**Gibney, E.M., et.al. Living Kidney Donors Requiring Transplantation: Focus on African American.** Transplantation. 84(5): 647-649, September 15, 2007

- Age, obesity, hypertension, pre-existing conditions as well as other specific medical conditions of a potential donor may have an impact on the long-term health, and potentially a shortened life span and thus you may be declined for living donation.
- Other potential risks associated with the evaluation testing include:
  - Allergic reactions to contrast dye.
  - Discovery of reportable infections.
  - Discovery of serious medical conditions.
  - Discovery of adverse genetic findings unknown to the donor and discovery of certain abnormalities that will require more testing at the donor's expense or create the need for unexpected decisions on the part of the transplant team.
- Health information obtained during the evaluation will follow the same regulations as all records and could reveal conditions that the transplant center must report to local, state or federal public health authorities.
- The donor may choose not to donate as well as discontinue their evaluation at any time, the team will protect and respect your decision and take all precautions to maintain confidentiality.
- An independent living donor advocate functions independently from the transplant team and is available to assist you during this process and will meet with you as part of your evaluation.
- The transplant center may refuse the potential donor. In this case, you will be informed of your right to be evaluated at another center that may have different selection criteria.

- It is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for valuable consideration (for example: Anything of value such as cash, property, vacations)
- The recipient will have other treatment options available to them, including dialysis and deceased donor transplantation.
- At times a deceased donor kidney may become available for the recipient before the donor evaluation is completed or the living donor transplant occurs.
- The transplant candidate may have other medical problems such as diabetes, obesity, and heart disease, and other potential complications along with their kidney failure which may increase the risks of transplant failure or even death. These may exceed local or national average, however, may not necessarily prohibit transplantation. These can not necessarily be disclosed to a potential donor, without permission of the candidate.
- In some instances, there is a risk that the recipient's kidney disease may affect the new kidney.

Current National and Program-specific transplant recipient outcomes: #

Most kidney transplants from living donors are successful. But there is no 100% guarantee in any transplant. Below are statistics of the kidneys donated by living donors at CMC compared to all other Transplant centers in the US.

**See attached report for January 2023, as reported on 01/05/2023.**

This data is updated every six months at [www.SRTR.org](http://www.SRTR.org) .  
If you have questions about this data, please discuss with your coordinator.

- Our living donor -patient survival rate is 100%
- After surgery donation complication rate was 5% in 2022.

Informed Consent of Living kidney donors: Psychosocial (reinforced by Medical Social worker)

- There is a potential impact on the donor's life after surgery. The possibilities of recipient death, rejection, re-transplant, or disease in the new kidney, are all things to consider.
- Problems with body image, after-surgery depression or anxiety, feelings of emotional distress or grief if the transplant does not work or the recipient

dies.

- Personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed; however, resources may be available to defray some donation related costs.
- Need for life-long follow-up at the donor's expense.
- Potential loss of employment or income
- Potential negative impact on the ability to obtain future employment
- Potential negative impact on the ability to obtain, maintain, or afford health, disability and life insurance.
- Future health problems experienced by living donors following donation may not be covered by the recipient's insurance
- Possible changes to the donor's lifestyle after donation

### Informed Consent of Living kidney donors: Surgical phase

There can be risks/complications with any surgical procedure both transient and permanent. Our Transplant team has many steps in place to prevent these from occurring. Below is a list of potential problems, meant to inform not alarm you. There may also be additional risks (unforeseen) not listed below. Review the list and discuss any questions you may have with your transplant team.

- Reaction to anesthesia (The doctor will immediately correct this.)
- The kidneys are close to the lung. If this space is opened, the lung may collapse.
- Cardiac arrhythmias, cardiac collapse or other cardiac related issues may occur.
- Blood clots (A risk of any major surgery). Getting out of bed as soon as you can is encouraged to help prevent this possible complication.
- Pneumonia (You will be asked to cough and take deep breaths to prevent this.)
- Bleeding (Potentially requiring a blood transfusion or re-operation.)
- Pain at incision (Pain relief medication will be given as needed); nerve injury
- Wound infection (approximately 2% may develop), scarring
- Incisional hernia at wound site (early or late)
- Bowel obstruction requiring a Nasogastric (NG) tube placement
- Acute kidney failure and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period.
- Death (3 per 10,000) – 0.03%
- Minor physical symptoms such as nausea, vomiting, gas pain, bloating, fever, fatigue, and anxiety are fairly common.

The donor's average length of stay is 2.5 days with a 0-1% rate for donor re-admission. This is typically due to physical symptoms such as nausea, poor appetite, and dehydration. These symptoms are typically short lived and able to be handled as an outpatient.

### Informed Consent of living kidney donors: Postop/Long-term phases

- Decreased kidney function: On average, donors will have a 25-35% permanent loss of kidney function at donation.
- Although risk for ESRD (end stage renal disease) for living donors does not exceed that of members 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 risk must be interpreted in light of what is known for both Chronic Kidney Disease (CKD) and End Stage Renal Disease (ESRD)—CKD generally develops in mid-life (40-50 years old) and ESRD generally after the age of 60. The medical evaluation of a young potential donor cannot predict lifetime risk of CKD or ESRD.
- Donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD is more rapid with one kidney.
- If your remaining kidney fails and you develop ESRD, dialysis is required for the donor.
- Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to OPTN policy 8.3: *Points*
- "A recent retrospective study of female living kidney donors were compared to non-donors, looking specifically at the risk of gestational hypertension or pre-eclampsia during pregnancy after kidney donation. This study found that of kidney donors who became pregnant after donation, 11% reported either gestational hypertension or pre-eclampsia, compared to 5% of non-donors, which was statistically significant. There was no statistically significant difference between rates of pre-term birth (8% in donors, 7% in non-donors) or in low birth weight (6% in donors, compared to 4% in non-donors)." Garg AX, New England Journal of Medicine, 372: 122.

### Other Things You Should Consider:

- The evaluation process is not a pledge to donation. (you may opt out at any time)
- Almost all donors fully recover and return to their normal life.
- Although donors have been followed for several decades now and shown to do well, long term medical implications of organ donation have not been fully identified.
- **Continual** follow-up with a doctor each year is strongly recommended to ensure any issues are identified early in order to maintain long term health.

- All donor surgeries are done laparoscopically.
  - Exercise before surgery can make recovery easier.
  - Have a positive attitude. Have someone to talk to. If you are interested in a mentor, please discuss with your coordinator.
  - The “United Network for Organ Sharing” provides a toll-free patient services line (888-894-6361) Staff is available to discuss any issues, concerns, or grievances.
- If the recipient is transplanted at a non-Medicare hospital, you may not be allowed any Medicare benefits related to donation.

**Carolinas Medical Center is an approved Medicare facility. If the Transplant Center ever fails to meet Medicare approval, you will be notified in writing.**

**This is a personal decision and a big commitment. We are here to help you any way we can.**

MANDATORY POST OP CARE OF LIVING DONORS

**The Organ Procurement and Transplantation Network requires Transplant Centers to collect blood on all living donors at the time of surgery. This blood will be stored for 10 years and will be used for investigating a potential donor derived infectious disease should that be needed for a recipient after transplant.**

Once discharged from the hospital, your surgeon will want to see you at approximately 2 weeks and again at 8 weeks after surgery to be sure you are recovering as expected. Labs will be done at these visits to check kidney function.

The Transplant Center is also **required** to report accurate, complete, and timely living donor follow up information by submitting a “Living Donor Follow-up” form about your health status. This is **extremely** important and must be done at 6 months, 1 year and 2 years **after** donation. Living Donor follow up is the best method for collecting data about your health and reporting it to the United Network for Organ Sharing. This will be coordinated by our Transplant Center or with your local physician and requires a physical exam and lab work.

**I agree to comply with this requirement. \_\_\_\_\_ (patient initials)**

Any infectious disease or malignancy pertinent to acute recipient care discovered during the donor’s first 2 years of post-operative follow-up care:

- Will be disclosed to the donor
- May need to be reported to local, state or federal health authorities
- Will be disclosed to their recipient’s transplant center/MD
- Will be reported through the OPTN Improving Patient Safety Portal.

**I HAVE RECEIVED THE RISK AND BENEFITS FOR LIVE DONATION AND**

LAPAROSCOPIC DONOR NEPHRECTOMY. I HAVE READ THE ABOVE LIST OF POTENTIAL COMPLICATIONS AND PROBLEMS RELATED TO LIVE DONATION. I HAVE BEEN GIVEN THE OPPORTUNITY TO DISCUSS MY CONCERNS/ QUESTIONS.

**Reviewed prior to donation:**

Patient Signature:

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Date/Time

Nurse/Transplant Coordinator:

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Date/Time

Transplant Physician:

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Date/Time

Transplant Surgeon:

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Date/Time

Revised February 11, 2019, Revised March 5, 2019, Revised July 3, 2019, Revised January 2020, Revised August 2020, Revised January 2021, March 2021, Revised July 2021, Revised January 2022, Revised March 2022, Revised July 2022, Revised January 2023

Scientific Registry of Transplant Recipients  
**January 2023** Report of Living Donor Comparison

**and June 13, 2020- December 31, 2021.** Follow-up ends on 3/21/2020 for recipients transplanted prior to 3/13/2020. This information is updated every six months and can be found at their website [www.srtr.org](http://www.srtr.org). If you have questions about this data, contact your coordinator.