

LIVING KIDNEY DONOR CONSENT FOR EVALUATION

You have expressed the desire to be a donor. It is important that you understand the risks, benefits, and alternatives to the procedure of donor nephrectomy. This document provides written information to you to supplement your discussions with your transplant team about donation.

I understand that I will need to sign this consent form if I wish to proceed with medical evaluation for living kidney donation. I also understand that it is a federal crime if I receive any payment in exchange for being a donor. I understand that going through the medical work-up for donor surgery does not guarantee that I will be able to donate my organ. I understand that I may choose to stop the donation process at any time. I understand my donor evaluation and post surgical follow-up care will be conducted at Medstar Georgetown University Hospital and my surgery will be performed at Medstar Georgetown University Hospital. I understand that all potential donors will be provided with the services of an independent donor advocate to offer assistance throughout the entire process.

GENERAL INFORMATION

In a living donor kidney transplant, a person volunteers to have one kidney removed and placed in another person whose kidneys have failed. This is the preferred kidney replacement method for most patients if they are medically suitable. It is not the only treatment for patients with kidney (renal) failure. For many patients, dialysis, either hemodialysis or peritoneal dialysis is an alternative treatment and the treatment needed while waiting for transplant.

A kidney recipient may receive a kidney from either a living or a deceased donor from the national list. There are advantages to receiving a living donor kidney and they include:

1. Recipients are already on a national waiting list for a deceased donor transplant. Those who receive a living donor kidney transplant often spend significantly less time on the list than deceased donor kidney recipients. Patients can even be transplanted before starting dialysis in certain situations.
2. Transplants from living donors are commonly more successful, especially in the modern era of anti-rejection therapy and have one-year graft survival rates 10 % higher than deceased donors. In certain types of patients, including infants, living donation is the best option. A copy of the SRTR center-specific report for MedStar Georgetown Hospital's living kidney donor program will be provided to you. This contains the most recent transplant outcomes.
3. Living donor transplants can be scheduled ahead of time at both donor's and recipient's convenience.
4. Because of modern medication for preventing rejection, a donor does not have to share a

match of transplant genes for a successful outcome.

5. The great majority of living donor kidneys (>90%) work right away and free the recipient from dialysis. Although most living donors are related to their recipient, over 30% are now unrelated, for example, spouses, friends, and coworkers.

Despite these advantages, your recipient can receive a quality deceased donor kidney if a living donation is available and still receive the benefits of transplantation.

EVALUATION PROCESS

An initial work-up will be done to find out if you can donate. This will involve a health assessment and blood and urine tests. If the initial screening shows that you can possibly be a donor, you will then complete the second phase of evaluation. This is a more thorough phase that involves a variety of tests and consultations. All information that we obtain will be confidential. At no time is your information shared with the potential recipient. If you wish to discontinue your consent or evaluation process, this information is also protected and confidential.

These tests may include, but are not limited to:

1. Blood tests and urine tests to determine your renal function and assure that you do not have any transmissible diseases (such as HIV or hepatitis) that can be transferred to the recipient with the kidney.
2. Blood tests to determine your blood type. Donors do not have to necessarily have to have the same blood type, but should be compatible with their recipient. For example, an O blood type can donate to anyone and an AB blood type can receive from anyone.
3. Blood tests called “Tissue Typing” and “Crossmatching evaluate the possibility of your recipient rejecting the kidney.
4. A chest x-ray, electrocardiogram, and abdominal x-ray will be performed to look for lung or heart disease and assure there are no kidney stones.
5. An MRI of the abdomen is completed to assess the anatomy of the kidneys.
6. Other tests may be required to help the team evaluate you and will be discussed with you as indicated.

Each test will be explained to you before it is done. Some tests may have risks. These risks will be discussed at the time the test is planned and you will be asked to sign a separate consent form.

A psychosocial work-up will be performed. There are three main reasons for this work-up:

1. To decide if I am capable of giving an informed consent.
2. To discuss my reasons why I want to be a donor.
3. To ensure your understanding of the medical, social, and financial risks of undergoing this elective surgery.

After these tests are completed the results are reviewed by the entire team. In addition to the review of your other medical records, including PAP, mammogram, and colonoscopy results, the team will decide your candidacy for donation.

SURGERY

Procedure

Removal of a kidney is called a nephrectomy. Your surgeons commonly use a technique called laparoscopic donor nephrectomy. In this procedure, small incisions are made in various parts of the abdomen to place a camera and other working instruments to perform the procedure. The kidney is then removed through a small abdominal incision approximately 3 inches long. The procedure takes about 3-4 hours. The alternative technique to remove the kidney is called an open nephrectomy that is performed through an incision on the side of the abdomen and may require the removal of a rib. This is not our standard, but in less than 1% of the laparoscopic cases, may be necessary to allow safe removal of the organ.

Typically, the left kidney is removed due to having longer blood vessels. After reviewing the results of your diagnostic testing, a final determination will be made as to which kidney will be removed. In certain situations, removal of the right kidney may be preferable due to differences in function or anatomy of your two kidneys.

Living donor recipients generally do extremely well, but there is no guarantee of success for you or your recipient. Despite improvements in your speed of recovery noted in the medical literature for laparoscopic nephrectomy, all patients have some pain and we do everything possible to make your recovery easier. Laparoscopic procedure has improved recovery times over the open technique. Your hospital stay is usually 1-2 days. Most patients can return to full activity within 3 weeks and work within 6 weeks of donation and sometimes sooner depending on their type of employment.

Risks

Evaluation

The following are inherit risks associated with the living donation evaluation:

- Allergic reactions to contrast
- Discovery of reportable infections
- Discovery of serious medical conditions
- Discovery of adverse genetic findings unknown to the donor
- Discovery of certain abnormalities that will require more testing at your expense or create the need for unexpected decisions on the part of the transplant team

Surgical

There are risks for operative procedures, especially those done under general anesthesia. The risk of having some type of complication (either minor or major) from a living donor kidney transplant surgery is low. Most complications are minor and resolve on their own. Scars, pain, fatigue, and other consequences typical of any surgical procedure are possible. In rare cases, the complications are serious enough to require another surgery or medical procedure.

Early operative risks include but are not limited to wound or urinary tract infections and pneumonia. Abdominal or bowel symptoms such as bloating or nausea may occur. There may be some increased risks with the use of some over the counter medications and supplements. On

average, donors will have 25-35% permanent loss of kidney function after donation. The baseline risk of end-stage renal disease does not exceed that of members of the general population with the same demographic profile. More serious problems including bowel injury or obstruction, blood clots in the legs and pulmonary embolus, injury to the spleen, nerve injury, development of a hernia, or need for reoperation have been reported in the literature. The risk of death from this procedure in the United States is between 3 to 6 out of 10,000. This is most commonly caused from a blood clot migrating to the lung. All efforts are made to avoid these issues postoperatively. Early mobilization, breathing exercises, and the use of special leg devices while you are in bed are techniques utilized to decrease your risk of developing these complications.

Late risks of this surgery are primary related to the outcome of only having one kidney. These risks rarely develop in donors. Donors may be at higher risk for chronic kidney disease if they sustain damage to the remaining kidney. Development of chronic kidney disease and progression to end-stage renal disease may be more rapid with only one kidney. Dialysis is required when reaching end-stage renal disease.

In the general population, if a person were to develop chronic kidney disease (CKD), it would usually develop in midlife (40-50 years old); end-stage renal disease (ESRD) usually develops after age 60. There are slightly increased risks of hypertension, protein in the urine, and renal disease in some studies, but for the majority of donors the loss of the kidney is of no consequence long term. Additionally, morbidity and mortality of the donor may be impacted by obesity, hypertension, or other specific pre-existing conditions.

Some patients have developed renal failure and have actually received a kidney transplant themselves. In these rare cases, living kidney donors who become kidney transplant candidates receive prioritization in the current organ allocation system.

Despite these limited risks, it is important that persons who have donated a kidney maintain a healthy lifestyle and obtain yearly physicals to monitor their health. The medical evaluation of a young living donor cannot predict lifetime risk of CDK or ESRD.

Psychosocial

- Problems with body image
- Post-surgery depression or anxiety
- Feelings of emotional distress or bereavement if the recipient experiences any recurrent disease or in the event of the recipient's death
- Impact of donation on the donor's lifestyle

Post Surgery

Your incision will heal with a scar. The visibility of the scar will vary. Additionally, your mood may be influenced by the outcome of the recipient. Although most donors have a positive feeling about their donation and ability to help their recipient, up to 10% of patients in the literature have been prescribed antidepressants to help cope with the process. These issues are recognized and should be addressed with your donation team.

Blood Transfusions

Somewhere between 1% to 2% of patients will require a blood transfusion. Because of your good health, however, most donors can tolerate a lower blood count.

Follow-up

I understand and agree that a team of doctors at MedStar Georgetown Transplant Institute will follow my post-surgical care. I will be given an appointment at MedStar Georgetown Transplant Institute to see my doctors and have blood work and urine tests to assure my kidney is functioning properly. Donors are required to have follow-up appointments at 1 week, 6 months, 1 year, and 2 years after donation. If you live out of the area, these appointments can take place over the phone and a visit to your primary care provider.

Any infectious disease or malignancy pertinent to acute recipient care that is discovered during the first two years of your follow-up care:

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

ECONOMIC CONSIDERATIONS

Your evaluation, hospitalization, and follow-up care are paid for by Kidney Acquisition and your recipient's insurance. If you receive a bill related to these expenses in error, please contact our department immediately. However, future health problems experienced by living donors following donation may not be covered by the recipient's insurance. Personal expenses of travel, housing, child care, and lost wages related to donation might not be reimbursed; however, resources may be available to defray some donation-related expenses. I understand the need for life-long follow-up care which may be at my expense. I further understand that donation may lead to loss of employment or income and/or negatively impact my ability to obtain future employment.

I understand and agree that my future health, disability, and/or life insurance premiums may be higher due to this donation. I understand and agree that I also may not be able to obtain health, disability, and/or life insurance in the future if I lose my current insurance or if I am not currently insured. Future health problems your experience following donation may not be covered by the recipient's insurance.

ALTERNATIVES

The alternative to living kidney donation is deceased (cadaveric) kidney donation (using a kidney from a donor who has been declared deceased) or to remain or start dialysis. Should you decide not to donate a kidney; the potential recipient will continue to receive care by the transplant team at MedStar Georgetown University Hospital or MedStar Washington Hospital Center. His or her name will remain on the (UNOS) transplant waitlist and he or she will wait for a cadaveric organ or another living kidney donor to become available. The details of this process will be described upon your request. Medstar Georgetown Transplant Institute reserves

the right to decline an individual to donate his/her kidney. It is your right to be evaluated at another transplant center which may use different selection criteria at any time during your evaluation.

RECIPIENT BENEFITS

I understand that, by my donation, the recipient will receive a benefit. For the most part, this benefit includes a decrease in waiting time on the list, which may have an effect on his/her recovery. A deceased donor organ may become available for the candidate before your evaluation is complete or transplant occurs. Any transplant candidate may have risk factors for increased morbidity or mortality that are not disclosed to the potential donor. Graft failure in the recipient will lead to a return to dialysis and may lead to a repeat transplant.

DONOR BENEFITS

I understand that there is no medical benefit to me by having this surgery. A possible medical benefit of the evaluation is finding out about health problems that were unknown to me so that I may seek treatment. The 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 public health authorities.

PAIRED KIDNEY EXCHANGES

- What if a donor and recipient are not the same blood type?
- What happens if I have a positive crossmatch with my recipient?
- If we are compatible should we still consider an exchange?

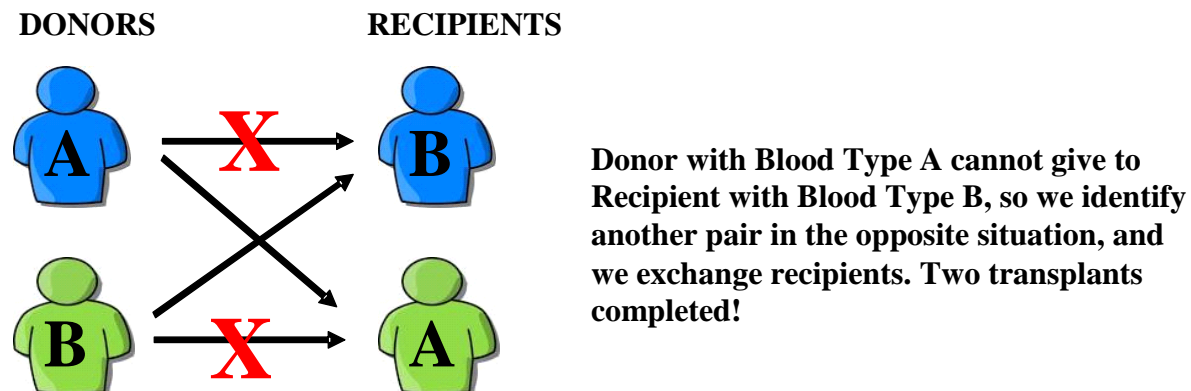
There are three options for donor/recipient pairs who are not compatible:

1. Desensitization – sometimes it may be possible for the recipient to undergo procedures that make it possible to still receive a kidney from their donor.
2. Paired Kidney Exchange (PKE) – donors and recipients exchange partners so that everyone receives a Living Donor transplant.
3. Sometimes Desensitization and a Paired Kidney Exchange can be combined.

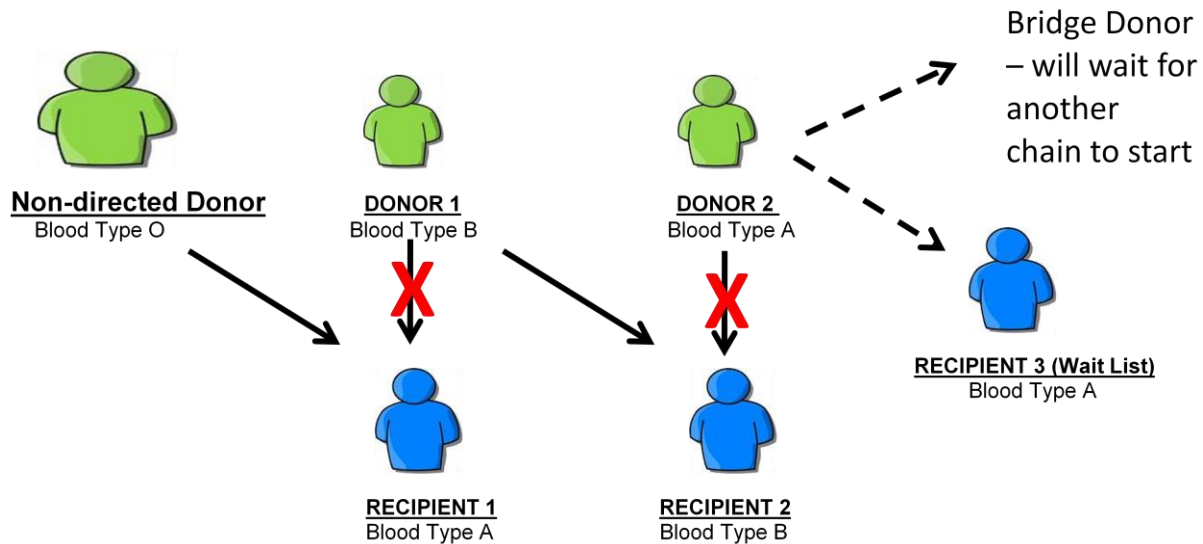
How Does a Paired Kidney Exchange Work?

A paired kidney exchange (or swap) takes incompatible and compatible pairs and re-assigns donors and recipients to allow everyone to find a compatible match.

For example, if we have two pairs with donors and recipients of different blood types, we can plan the following:



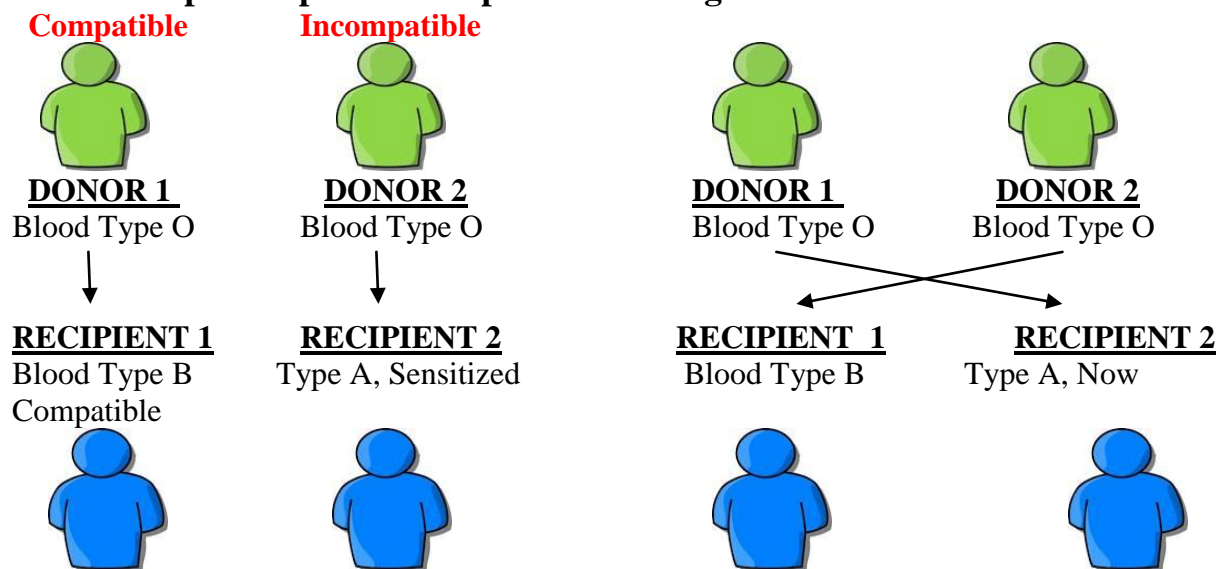
We can also complete exchanges with many more pairs. Frequently, these multi-pair exchanges or ‘chains’ begin with a **non-directed donor** (someone who wishes to donate without a particular recipient in mind). Some chains will involve 3 or 4 pairs and may occur over a few days. The last donor may either donate to the deceased donor waiting list or act as a ‘bridge donor’ to soon continue the chain when more pairs have been identified.



I am compatible with my donor – should I be in an exchange?

Even if you are compatible with your donor, you may still wish to consider participating in an exchange. Your recipient may be paired with a better matched kidney which potentially could have fewer long-term problems with rejection. Equally important, your gift may allow several other transplants to occur. Many recipients are very difficult to match and might never receive a life-sustaining transplant. It is quite possible that you represent their “needle in a haystack.” Be assured, your recipient will receive a comparable kidney for transplantation at the same time.

How a compatible pair can help in an exchange:



In this example, the second pair could not move forward due to a positive crossmatch (although the blood types are compatible). However, once donors are exchanged, Recipient 2 receives a kidney he/she may not have otherwise been able to due to be incompatible with the original donor.

We need your permission to include you in any type of exchange planning. Please sign below if you would consider participating in an exchange. We will be happy to answer any questions regarding our exchange program. This is NOT a consent to move forward with surgery. This consent allows us to input your name into our computer system to see if any matches are possible for you or others.

If you cannot directly donate to your intended recipient, the only way your recipient can participate in an exchange is with a willing donor. You may not be giving a kidney directly to your recipient, but you are still the sole reason that he/she will be eligible for a living donor!

1. If I am incompatible with my recipient (NOT a match), I am willing to participate in exchange.

_____ YES _____ NO

2. Even if I am compatible with my recipient, I am willing to consider a kidney exchange.

_____ YES _____ NO

Signature

Date of Birth

Printed Name

Date

CONSENTS

- I consent to the release of my protected health information to Organ Procurement and Transplantation Network.
- I consent to the release of my protected health information to my primary care provider as indicated on the Living Kidney Donor Candidate Questionnaire.
- I understand that MedStar Georgetown University Hospital is a teaching facility and part of my care, under the guidance of my physicians, may be conducted by Fellows, Residents and students.
- I understand that my medical information, specimens and procedures, without revealing my identity, may be used for teaching and research activity.
- I consent to taking photographs. The photographs may be taken only with the consent of my physician or surgeon and under such conditions as may be approved by him/her. The photographs shall be taken by my physician or by a competent photographer approved by my physician. These photographs shall be used for medical records only, unless in the judgment of my physician, medical research, education or science will benefit from their use. In that event, I agree that they may be used for such purposes, provided that my identity is not revealed by the photographs or by descriptive text accompanying them.
- I understand that lab testing includes HIV, Hepatitis C, and Hepatitis B. Positive results from these tests are required to be reported to the Department of Health. I consent to undergoing these tests.

CONFIDENTIALITY

Hospital personnel who are involved in the course of my care may review my medical record. Per applicable laws and hospital policies, they are required to maintain my confidentiality and privacy. If I do become a donor, data about my case, which will include my identity, will be sent to the Organ Procurement and Transplantation Network (OPTN) and may be sent to other places involved in the transplant process as permitted by law. I understand that if I do become a donor, that the hospital that I donate at is required to report living donor follow-up information at 6 months, 1 year, and 2 years.

ADDITIONAL INFORMATION

I understand that I may obtain more information about living kidney donor transplants from the www.unos.org web page. MedStar Georgetown Transplant Institute may contact me from time to time after the surgery to learn about concerns I might have about my health, insurance, employment and overall well being.

SIGNATURES

I, certify by my signature below that:

1. I have read, or had read to me, this informed consent form.
2. I understand that I may withdraw my consent at any time prior to the surgery.
3. I agree that I am proceeding with evaluation free of inducement and coercion.
4. I would like to proceed with the donor evaluation.

Printed Name of Potential Donor

Date of Birth

Signature

Date



STATE GRIEVANCE ORGANIZATIONS

The following agencies are also available to you. If you file a grievance with either agency, you may contact them during any phase of the Grievance Process.

Grievance and Appeals Coordinator
District of Columbia Department of Health
825 North Capital Street, NE
Room 4119
Phone: 202-442-5979
Fax: 202-442-4797
Email: charlita.brown@dc.gov

The United Network for Organ Sharing provides a toll-free patient services line to help transplant candidates, recipients, and family members understand organ allocation practices and transplantation data. The toll-free patient services line number is 1-888-894-6361. You may also call this number to discuss a problem you may be experiencing with your transplant center or the transplantation system in general.