



Living Kidney Donor Education — Evaluation

Living donors and their recipients



RWJ ROBERT WOOD JOHNSON
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Overview

1. The Gift of Kidney Donation

Your decision to donate your kidney to a loved one or person in need should be considered a life-enhancing “gift” based on a desire to dramatically improve the quality of that person’s life.

2. Motivation

The desire to donate your kidney should be purely of your own free will and should be free from undue pressure or monetary compensation. You will meet privately with a registered nurse; social worker, physician, and living donor advocate who will each discuss this decision with you. Your participation is completely voluntary and you are free to withdraw your decision to donate at any time. The transplant team will help you to discontinue the donor evaluation in a way that is protected and confidential.

3. Alternatives

You should not think of this decision as a matter of life and death, because persons with kidney failure have other alternatives, including dialysis and waiting for a deceased donor organ. You should also know that it is possible that a deceased donor organ could become available to your potential recipient during the evaluation process.

4. Recipient Benefits

Recipients usually experience an enhanced quality of life immediately after receiving a live donor transplant. A live donor transplant lasts about twice as long, on average, as a deceased donor kidney. A live donor transplant also indirectly makes a deceased donor kidney available for someone else awaiting transplant who has no living donor available to them.

5. Donor Benefits

Generally, a willing donor receives tremendous emotional benefit by fulfilling their wish to donate. There is no medical benefit to you having this surgery. However, a possible medical benefit of the evaluation is finding out about health problems that you did not know that you have. Discovering these health problems may allow you to seek treatment.

6. Risks and Benefits

The risks to both the donor and recipient will be discussed and outlined in detail during the evaluation process by the Transplant Team. After the Transplant Physician reviews with you the medical and surgical risks of live donation, you will be asked to sign the Informed Consent for Living Kidney Donation. At that time, you will be given a copy of this document, which also reviews the risks.

7. Payment

Under the National Organ Transplant Act (NOTA), the sale or purchase of organs is a federal crime, subject to \$50,000 fine or up to five years in prison. Donors should understand that it is illegal to receive money or any other material benefit such as property, vacations etc. (also called valuable consideration) for agreeing to be a donor. In certain circumstances, donors may be reimbursed for limited travel expenses and/or may receive subsistence assistance if financially qualified.

8. Medical Record

A separate medical record is established for each potential donor. The health information obtained during the course of your evaluation becomes part of your medical record and is subject to the same regulations as any regular medical record and is not additionally protected. Also, you should know that your evaluation could reveal conditions that the transplant center must report to local, state, or federal public health authorities. An example of a reportable diagnosis would be Hepatitis or HIV.



Additional Information

The following web pages provide general information, resources and frequently asked questions and patient testimonials about living donor transplants:

- ▶ United Network for Organ Sharing (UNOS): www.unos.org
- ▶ UNOS-Transplant Living: www.transplantliving.org
- ▶ National Kidney Foundation: www.livingdonors.org
- ▶ American Society of Transplantation: www.myast.org
- ▶ Coalition on Donation: www.donatelife.net
- ▶ National Living Donor Assistance Center www.livingdonorassistance.org
- ▶ Living Donor Financial Toolkit: www.myast.org/patient-information/live-donor-toolkit

Living Donation Options

1. Living-Related Donor Transplantation

Living donors who have a genetic relationship with the recipient are called living-related donors. Donor/recipient pairs that share a close genetic relationship tend to have improved compatibility upon testing. Identifying a donor who has a strong genetic relationship with the recipient can lessen the chance of rejection of the new kidney.

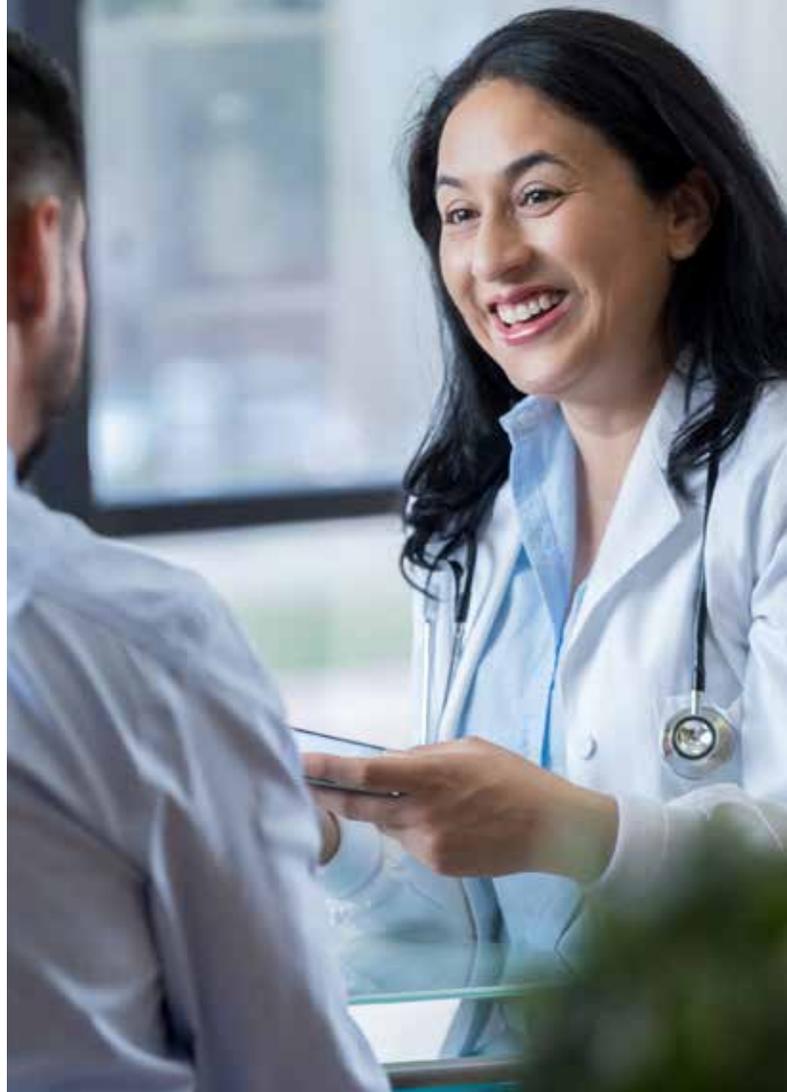
2. Emotionally-Related Donor Transplantation

If immediate family members are unable to donate, kidneys for transplant can also come from living unrelated or emotionally-related donors. Examples of common emotionally-related donors are a spouse or close friend.

3. Altruistic Living Donation

The two types of altruistic living donors are directed altruistic donors and non-directed altruistic donors.

- ▶ The directed altruistic donor is a person who has some knowledge of the recipient, such as through house of worship or mutual acquaintance. The directed altruistic donor is thus directing their donated kidney to this recipient.



- ▶ The non-directed altruistic donor is a person who wishes to donate to a person they do not know, either through donation to a recipient on the waiting list or through a Kidney Exchange.

While all donors are considered “altruistic” by nature of their gift of life, the two types of donors described above have no genetic or emotional relationship with their recipient. Their evaluation typically requires a slower pace that allows them more time to reflect upon their decision to donate.

4. Compatible Share Program

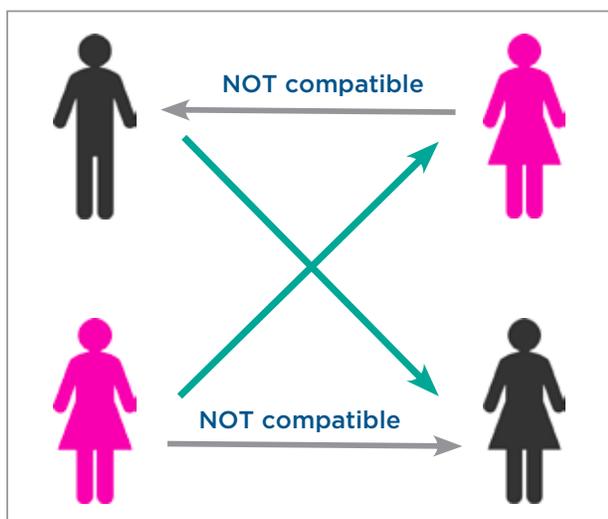
In this program, a compatible donor/recipient pair may be offered the opportunity to participate in a kidney exchange. A compatible donor and recipient may choose this option because it provides one or more of the following:

- ▶ A chance to improve the recipient’s long term outcome, i.e., younger donor kidney, improved compatibility.

- ▶ An altruistic opportunity for the compatible pair because their participation in a kidney exchange would allow one or more incompatible recipient/donor pairs the opportunity to be transplanted.

5. Kidney Paired Donation

- ▶ If the recipient from one pair is compatible with the donor from the other pair, and vice versa, the transplant center may arrange for two (or more) simultaneous transplants to take place. This allows two transplant candidates to receive organs and two donors to give organs even though the original recipient/donor pairs were unable to do so with each other.
- ▶ In paired exchange, an incompatible donor/recipient pair (such as a mother and son that don't have compatible blood types) are matched with another incompatible donor/recipient pair for a match.



6. Program for Incompatible Transplants

Many patients have living kidney donors who are not a match to them either because of blood type or because of immunological factors. These donors may be otherwise able and willing to donate. Depending on the type and degree of incompatibility, this program offers some potential recipients the option to receive a living donor kidney from their incompatible donor.

The Evaluation Process

1. Eligibility/Ineligibility

The potential donor undergoes a thorough medical and psychosocial evaluation. The evaluation process is designed to determine if you are eligible to be a donor. If a health problem is found during the evaluation process you will be referred to your private physician for further evaluation and/or treatment. If a serious health problem is found it is possible that you may not be able to donate. The medical evaluation of a living donor ensures that you have good kidney function and no major risk factors for future kidney disease. However, if you are young, this medical evaluation cannot perfectly predict whether you will develop kidney disease in the distant future. People who develop chronic kidney disease usually develop kidney problems in mid-life (after age 40 or 50) or later in life (after age 60).

After careful evaluation, the transplant team makes a decision regarding your suitability for donation following established selection criteria based on your current medical and psychosocial status as well as the results of required testing.

The following criteria guide the transplant team in their decision making.

2. Selection Criteria for Living Donors

Absolute Exclusions:

1. Evidence of NOTA violation (illegal financial exchange between donor and recipient)
2. Evidence of donor coercion
3. Untreated or active substance abuse
4. Untreated psychiatric condition(s), including suicide risk
5. Mentally incapable of making an informed consent
6. Age <18 or > 75
7. On 2 BP medications
8. Diabetes Mellitus
9. Obesity if a BMI is > 40 kg/m²
10. Kidney stones with a high likelihood of recurrence with metabolic conditions that predisposes to stone formation or history of recurrent stones
11. Persistent infection

12. Active malignancy or incompletely treated malignancy
13. Severe lung disease
14. Protein in the urine >300mg/24h
15. Reduced kidney function (Creatinine clearance < 80 mls/min)
16. Clinical, radiographic or laboratory evidence of inheritable kidney disease
17. Sickle cell disease
18. Sickle cell trait with loss of kidney ability to concentrate urine (urine osmolality of 500 mOsm or greater following an overnight fast)
19. Donor who is unwilling to accept a blood transfusion

Relative Exclusion Criteria:

1. Suspicion of NOTA violation (illegal financial exchange between donor and recipient)
2. Lack of or insufficient family, caregiver, social, and/or economic support
3. Strained donor/recipient relationship
4. Inability to complete the donor evaluation process (i.e. unmotivated, persistent lack of communication and/or lost to follow-up)
5. Likelihood of obtaining adequate health insurance in the future is uncertain
6. Significant psychiatric history including but not limited to history of clinical depression, bi-polar disorder, post-traumatic stress disorder (PTSD) and suicidal ideation.
7. Systolic blood pressure > 135/85 on one BP medication.

8. Protein in urine >150 mg per 24h unless this is orthostatic proteinuria or that associated with recent vigorous exercise.
9. History of malignancy, especially if metastatic or likely to recur
10. History of bleeding or coagulation disorder
11. Significant cardiovascular disease
12. Reduced Kidney Function (Creatinine clearance < 90 mls/min)
13. Risk of future diabetes as determined by an impaired fasting blood sugar
14. Blood in the urine (sometimes not visible to the naked eye)
15. Kidney stones
16. Presence of large renal cyst > 5cm
17. Family history of genetic renal disease

The transplant team makes decisions regarding the patient's suitability for donation based on established selection criteria and the patient's current medical and psychosocial risk factors as well as the results of required testing and Living Donor Advocate assessment. You need to understand that the decision of the transplant team is final. However you can choose to be evaluated by another transplant program that may have different criteria, specifically in accepting or declining donors who may be at increased medical risk.

3. Screening for High Risk Behaviors

Your transplant coordinator will review behaviors with you which may indicate that the donation would be considered high risk for transmission of infectious disease to your recipient, per the United States Public Health Service (US PHS). Your transplant coordinator will also educate you about the importance of abstaining from high risk behaviors during the evaluation and donation process. If any risk factors are identified, you will be referred to the transplant physician for further discussion and decision-making. If the donation is considered to be high risk, the recipient must be informed accordingly but this can only be done with your permission. If you do not wish to disclose this information, the transplant team will assist you to halting the evaluation in a way that is protected and confidential.



4. Compatibility Testing

Blood tests will be completed in order to find out if your blood type and tissues are compatible with your recipient. The following tests will be performed as part of the initial workup:

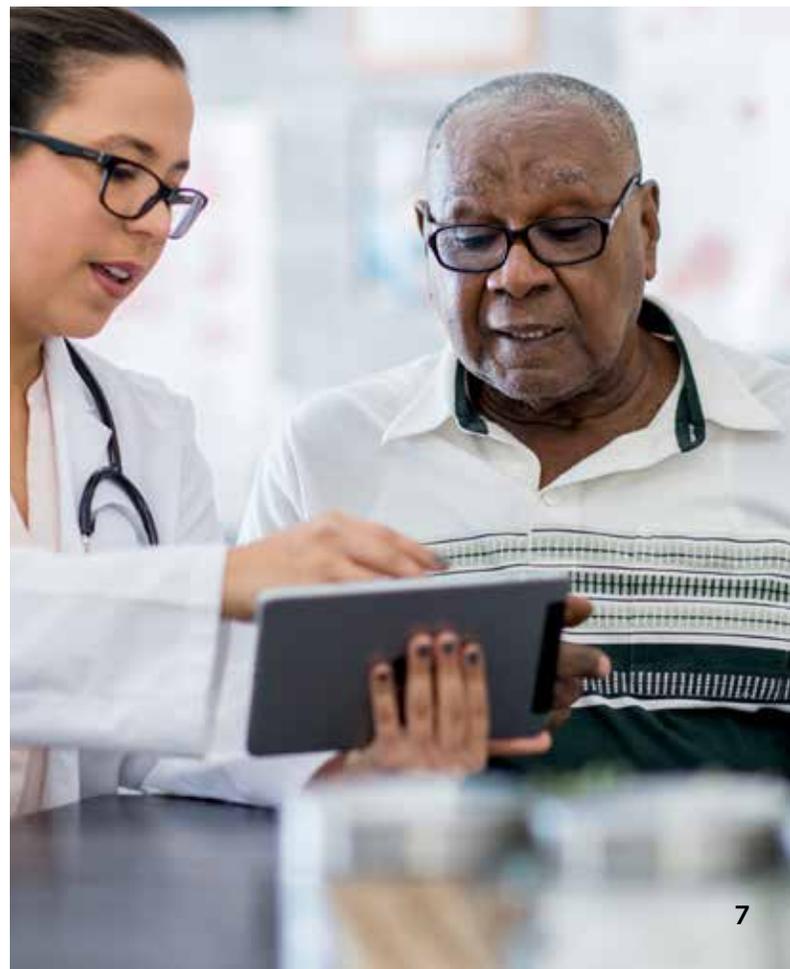
- a. Blood Type Compatibility
 - b. Tissue Typing and Crossmatching
- ▶ Tissue typing is done to determine the genetic markers (antigens that you possess). Everyone inherits six different antigens, three from your mother and three from your father. Therefore, children and parents are a three out of six match. Siblings can match six, three, or none at all. Other living donors, such as spouses or friends, may or may not have any antigens matching.
 - ▶ Crossmatching is the most important test to determine compatibility. Blood is mixed from the potential recipient and the potential donor.
 - ▶ A positive crossmatch means there was a reaction between the recipient's antibodies and the donor's protein markers. The donor therefore cannot donate directly, to the recipient. In the event that this occurs, and there are no other willing donors, the patient and donor may be referred to the alternative programs for living donation.
 - ▶ A negative crossmatch means there was no reaction and the recipient and donor are compatible. This will only change if:
 - ▶ The recipient becomes pregnant.
 - ▶ The recipient has a blood transfusion
 - ▶ Or the recipient receives a transplant.

5. Education and Evaluation/ Consultation Sessions

In addition to completing compatibility testing, you will also undergo the following education and evaluations:

- a. Transplant Coordinator
 - ▶ Nursing assessment
 - ▶ Education/discussion including:
 - ▶ Living donation options
 - ▶ Selection criteria
 - ▶ Testing/Consultation requirements

- ▶ Long term donor follow up
 - ▶ Confidentiality
 - ▶ Initial screening labs or diagnostic testing if indicated
- b. Physician Evaluation
 - ▶ History and Physical
 - ▶ Education/discussion including:
 - ▶ Donation surgical procedure
 - ▶ Potential risks and complications
 - ▶ Post operative course and medical follow up
 - ▶ Donor and recipient outcome data.
 - c. Social Work interview, which will include:
 - ▶ A thorough discussion of your psychological and social history
 - ▶ An evaluation to determine if you are capable of giving an informed consent
 - ▶ A discussion of your reasons for wanting to be a donor
 - ▶ A discussion of the possible psychosocial and financial risk factors that donation may pose to you and your family



6. Laboratory and Diagnostic Testing

If initial testing and consultations show that you can possibly be a donor then you will enter a second phase of the workup.

- a. Laboratory and diagnostic testing
 - ▶ Laboratory blood and urine testing
 - ▶ EKG
 - ▶ Chest X Ray
 - ▶ Pap Smear according to the American Cancer Society recommended screening schedule.
 - ▶ Depending on your medical history and age, more tests may be needed. Some common additional tests may include a mammogram, cardiac stress test and/or colonoscopy.
- b. CT Scan

A CT scan takes detailed pictures of your kidneys and other abdominal organs. A dye is given intravenously to perform this test. The details of this test will be discussed with you at the time the test is planned and you will be asked to sign a separate consent form.

7. Independent Living Donor Advocate

Independent Living Donor Advocate (ILDA) is an individual who functions independently from the transplant team as an advocate for the rights of the donor. The ILDA is trained to:

- ▶ Represent and advise the donor
- ▶ Protect and promote the interests of the donor
- ▶ Ensure the donor's decision is informed and free from pressure or coercion.

You will be provided with written education materials on donor advocacy, including contact information for your assigned ILDA. He/she will contact you early in the evaluation process to make an introduction and explain the role of the ILDA. You will be scheduled to meet with the ILDA after your education and evaluation with the living donor team has been completed. However, you may contact the ILDA at any time during the evaluation process should you

have any concerns or feel the need to speak to someone independently of your transplant team. Your transplant coordinator can help you with this.

8. Unforeseen Risks:

Your evaluation process for living donation is extensive. However, it still may not reveal unforeseen risks or medical problems that lead to health problems in the future. There are psychosocial and financial risks associated with living donation. These risks may be temporary or permanent and include, but are not limited to, the following:

Potential Psychosocial and Financial Risks

1. Potential Psychosocial Risks

- ▶ Problems with body image
- ▶ Post surgery depression or anxiety
- ▶ Feelings of emotional distress or bereavement if the recipient experiences an unexpected or poor outcome, such as recurrent disease or death of the recipient.
- ▶ Impact on current lifestyle
- ▶ Short or long term loss of employment or income
- ▶ Ability to obtain future employment, such as employment by military, law enforcement, aviation, or fire services

2. Insurance Coverage for Donation

The evaluation and hospitalization costs for living donation are covered by the recipient's insurance. Your insurance will not be billed directly. During your evaluation, only tests ordered by the transplant team for the purposes of determining your suitability for donation will be covered. If tests are performed for the purposes of routine medical care, treatment or are not ordered by the transplant team, you or your insurance company will be billed.

Should you experience any donation-related medical problems immediately post donation, the evaluation and treatment for those medical problems should be covered by your recipient's insurance. If you are experiencing any problem that you feel might be donation related,

you must notify the transplant team prior to receiving treatment, so that we can authorize and provide proper billing information to the provider. Future health problems experienced by living donors following donation may not be covered by the recipient's insurance.

3. Donor Non-Medical Expenses

The recipient's insurance generally does not reimburse the donor for personal expenses related to donation. Donors may receive assistance to pay for donation costs from the recipient. Allowed costs for the donor and up to two donor caregivers include (but not limited to) travel, housing, lost wages, childcare, food, and medicine. Grants are available for those recipient/donor pairs that financially qualify. The social worker can provide you with more information.

4. Insurance Coverage for Future Medical Costs Related to Donation

Your existing health and disability insurance may not cover the potential long term costs of medical and psychological consequences of donation. At any time in the future, if you feel you have a problem related to donation, you must contact your transplant coordinator. If these problems are not related to the surgery and not covered by your own personal insurance, you will be responsible for all costs.

5. Future Insurability Issues

- a. If a health problem is found during the evaluation, it is possible that this may affect your ability to obtain, maintain, or afford health insurance, disability insurance, or life insurance in the future. If you have a known risk factor for a health problem, this will be discussed with you when possible.
- b. There have been rare reports of living donors experiencing problems with their health and life insurance after donation. This could involve denial of coverage by insurers who might consider having only one kidney as a preexisting condition. In this situation, the denial could be appealed, but there is no guarantee that coverage would be granted.

6. Transplant Services Received at a Non-Medicare Certified Facility

The Renal and Pancreas Transplant Division of Robert Wood Johnson University Hospital

is a Medicare approved facility. However, you should know that if your transplant recipient were to receive his/her transplant at a non-Medicare approved transplant center it could affect the recipient's ability to have immunosuppressive drugs paid for under their Medicare Part B.

Required Donor Follow Up

1. Importance of Donor Follow-up

It is well documented in scientific literature that transplantation with a living donor kidney offers transplant recipients the best chance for long-term graft survival. As the number of living donors continues to grow, there is a need to gather more information about long-term outcomes for donors.

The long term health of living donors is an important focus of the Living Donor Institute. Following the medical condition of donors at certain times will allow the transplant team to gather valuable information about your health. Additionally, this information will help improve guidelines for living donation and advance the field of living donation.

It is extremely important to remember that all patients who proceed to donation must be committed to a lifetime of healthy living





and routine medical care with their primary care provider. After the immediate post-operative period, barring any donation related complications; your healthcare is your financial responsibility.

After donation, all live donors are required follow up as outlined here. You will have a surgical follow-up visit scheduled for 10 days to 2 weeks post donation. Under the requirements of the United Network for Organ Sharing (UNOS), the Transplant Center will coordinate and follow your progress at three pre-determined intervals after donation:

- ▶ Six months
- ▶ One year
- ▶ Two years

2. Data Collection and Results

A member of the transplant team will contact you prior to each pre-determined interval as a reminder to schedule an appointment with your physician or at our Transplant Center for the following:

- ▶ basic blood tests
- ▶ urine test
- ▶ blood pressure reading

The costs for this post-donation follow-up care will be submitted to your own insurance policy. If your insurance coverage requires a pre-authorization, a referral, or has an arrangement with an outside laboratory for these services, you must obtain the appropriate approvals from your primary care physician prior to having this testing done.

If an abnormality is found, we will discuss it with you at that time, but it is your responsibility to follow up with your medical doctor to evaluate the situation further. Remember, the cost of this follow up is not covered by your recipient's insurance.

For donors who live out of state or prefer to visit their primary physician, the transplant team will forward you the necessary prescriptions for the required tests. Once you have the results, we ask that you mail or fax them to your Transplant Coordinator in a timely manner.

Those who choose to come to the Transplant Center for these tests are asked to bring their current insurance information. If you do not have insurance coverage, please contact the Transplant Team and they will assist you in making alternate arrangements. You will be responsible for contacting the Transplant Center to update your contact information in the event that you move or change you phone number following donation.

3. Annual Primary Physician Visits

Although the Transplant Team is required to collect information for two years after donation, we strongly recommend that you continue to schedule yearly visits with your primary care physician in order to promote a healthy lifestyle.

4. Pregnancy

There is no impact on an individual in becoming pregnant or carrying a pregnancy successfully after donation. Nonetheless, we advise patients to maintain a close follow-up with their obstetrician during the entire pregnancy. Monitoring for high blood pressure, high blood sugar, kidney function or any fetal distress will be important.

There is no clear evidence to guide the timing of pregnancy following donation. Planning to delay pregnancy for at least a year is advisable.

Confidentiality

All communication between donors and Robert Wood Johnson University Hospital (RWJUH) is confidential. Likewise, communication between the recipient and RWJUH is confidential. This means that your recipient may have risk-factors for increased morbidity and mortality that are not disclosed to you. All reasonable precautions will be taken to provide confidentiality for the donor and recipient.

Hospital personnel who are involved in the course of your care may review your medical record. They are required to maintain confidentiality as per law and the policy of this hospital. If you do become a donor, appropriate medical information which will include your identity, will be sent to the UNOS (United Network for Organ Sharing) and may be sent to other places involved in the transplant process as permitted by law.

You should know that a separate medical record is maintained for each donor and for each recipient. In living donor transplantation, when the donation is not anonymous, tissue compatibility reports are filed in each chart for patient safety and continual reference by the transplant team. These and other documents that reference the living donor pair and their compatibility may contain identifying information of both the donor and the recipient on the same report and thus would be found in each medical record. This identifying information would be restricted to name, SSN#, date of birth, relationship and HLA compatibility. In the circumstance where the donation is anonymous, this identifying information is blinded.

During the two year period following your donation, if either you or your recipient is diagnosed with any infectious disease or cancerous malignancy, this will be disclosed to you or to the recipient's transplant center, as applicable, since further evaluation to determine the need for treatment would be warranted. The condition may also be reportable to local, state or federal public health authorities, for example as would be the case for Hepatitis or HIV and to the Organ Procurement and Transplant Network (OPTN) for patient safety.

If you do not meet the selection criteria for donation or you decide not to proceed with donation this will only be told to the recipient with your approval. You will be encouraged to speak with the recipient directly about your decision.

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