 <p>Dartmouth Health</p>	<p>Dartmouth Hitchcock Medical Center Section of Transplant Surgery</p>	<p>MRN: NAME: DOB:</p>
<p>Patient to be Evaluated as a Living Donor</p>		

CONSENT STATEMENT:

By signing this document, you are agreeing to undergo testing to determine your suitability as a living kidney donor. Please fully read this document and call your transplant coordinator if you have any questions about the testing or the evaluation process.

BACKGROUND:

For patients with kidney failure, transplantation of a kidney from a living or deceased donor is the preferred treatment. In medically acceptable recipients, kidney transplantation offers them a longer life and a better quality of life. It is important to understand that transplantation is not the only option for treating kidney disease. Patients can also be treated with either hemodialysis (blood dialysis) or peritoneal dialysis (via a stomach tube). Your potential recipient has been evaluated by the multidisciplinary team at Dartmouth Hitchcock and has been determined to be medically acceptable to receive a transplant.

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

1. Shorter wait times to transplant. The recipient does not have to be put on a list for transplant. Patients can be transplanted before starting dialysis in certain situations.
2. In general, 10% more of living donor kidneys are likely to be functioning at 1 year when compared to those from deceased donors. More importantly, the expected life span of a living donor kidney is 50% greater than that of a deceased donor kidney.
3. Living donor transplants can be scheduled at a time which is convenient to both donor and recipient.
4. The kidney is healthier because the donor is extensively evaluated. The kidney does not experience the trauma of brain or cardiac death, and the kidney is not kept cold for long periods of time.
5. Almost all living donor kidneys (98%) function right away and frees the recipient from dialysis. Deceased donor kidneys may take longer to "wake up", and the recipient may have to continue dialysis temporarily.
6. Prior living kidney donors who develop kidney failure and become kidney transplant candidates themselves, are currently given priority on the transplant list.

Although most living kidney donors are related by blood, over 30% of transplants now utilize living unrelated donors, for example, spouses or close friends. Because of the effectiveness of modern medicines in preventing rejection, essentially all living donor organs have equal transplant survival times.

Despite these advantages, transplantation using a deceased donor kidney is still highly effective and life-saving. Your potential recipient can receive a kidney transplant from the waiting list and live a long life after transplant.

A deceased donor organ may become available for the candidate before the hospital completes the living donor's evaluation or the living donor transplant surgery occurs. The decision to accept the deceased donor kidney is made between the recipient and their physicians.


Transplant candidates are determined to be good potential recipients based on our hospital's specific protocols and clinical judgement.

The recipient of a transplanted kidney (deceased or living) may have increased likelihood of adverse outcomes, including, but not limited to: graft failure, complications, and mortality. These outcomes may exceed our hospital or national averages, but do not necessarily prohibit transplantation. This information cannot specifically be disclosed to the donor. However, the transplant program has social services available should they be needed to assist with any issues of depression or loss.

The recovery hospital can disclose to the donor certain information about the recipient, only with the recipient's permission, including the reasons for a transplant candidate's increased likelihood of adverse outcomes, personal health information collected during the transplant candidate's evaluation.

If you agree to be a non-directed donor (not directing your kidney to a known recipient) or are involved in an exchange kidney program, you will not be able to decide who receives your kidney. This decision is made according to the by-laws of the Organ Procurement Transplantation Network (OPTN). Your medical health information is provided to the recipient's transplant program and that program will evaluate you as a potential donor based on their medical criteria.

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, vacations, or anything of value. The penalty of breaking this law is a fine of \$50,000 or up to five years in prison, or both. This law does contain an exception permitting a person to acquire, receive, or otherwise transfer a human organ for reasonable payments associated with the organ removal such as travel, housing and lost wages incurred by a living donor.

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RISK AND BENEFITS OF LIVING KIDNEY DONATION:

You have expressed the desire to donate a kidney to a waiting recipient. It is important that you fully understand the risks, benefits, and alternatives to the procedure of donor nephrectomy (removal of the kidney for transplant). This document provides important information to you that supplements your discussions with your physicians and transplant team members about the donation. You need to read this information thoroughly and be sure you fully understand before you sign your consent. We encourage you to ask any questions you may have.

Additionally, you should be aware that at any point you may stop the process without consequence. The recipient will not be notified of the reason for withdrawal from the program and will simply be informed that you do not meet our center's criteria for kidney donation.

CONFIDENTIALITY:

We take all reasonable precautions to provide confidentiality for both the donor and recipient. As with any hospital patient, medical personnel involved in your care may have to view sections of your medical record. They are required to maintain confidentiality as per Federal law (HIPPA, 1996) and the policy of this hospital. If you do become a donor information about your case, which will include your identity, will be sent to the Organ Procurement Transplant Network (OPTN) and may be sent to other places involved in the transplant process as required by law by law. Health information obtained during your evaluation is subject to the same regulations as all medical records and could reveal conditions that must be reported to local, state, or federal public health authorities.

If you are involved in a kidney exchange or are a non-directed donor, your identity will be anonymous to the potential recipient. However, there is a slight possibility that your identity may be disclosed on a recipient's insurance Explanation of Benefits form.

EVALUATION:

The kidney's function is to remove waste products from the blood and excrete them into the urine. Most people have two kidneys. If a person is healthy, it is generally safe to remove one kidney and donate it to another person. The kidney has great reserve capacity and a single kidney can provide adequate function to take care of your body's needs.

As a potential living donor, you must have a primary care physician (PCP) and must have had a full physical exam within the past year of the living donor evaluation. You must also have age-appropriate cancer screenings completed prior to donation.

We will perform a number of tests and have various specialists evaluate you in order to give us the best information regarding your ability to successfully and safely donate.


The medical evaluation includes:

1. Blood tests and urine tests to determine your kidney function.
2. Blood and urine tests to assure that you do not have certain infections including HIV or Hepatitis that can be transferred to the recipient with the kidney. If certain infectious disease testing comes back positive it may have to be reported to local state, federal, public health authorities.
3. Blood tests to determine your blood type. Donors do not have to necessarily have to the same blood type as the recipient but they should be compatible. For example, a 0-blood type can donate to anyone of any blood type.
4. Blood tests called tissue typing or cross-matching assures that you and your recipient are not at high risk for rejection. This test combines your cells and your recipient's blood and tells us if the recipient's immune system responses to certain genetic markers in your body. A positive response indicates that there is a response and you would not be able to directly donate to your intended recipient as they would reject the kidney.
5. A chest x-ray and electrocardiogram (EKG) will be performed to look for lung or heart disease.
6. A special x-ray called a CT scan will be performed to look at the blood vessels that go into your kidney and determines the blood supply to your kidney.
7. Possible testing, based on your personal history, for substance use disorders such as smoking, alcohol, and drug use.
8. Other tests may be required to help the team evaluate you and will be discussed with you as needed

OTHER COMPONENTS OF THE EVALUATION:

You will meet with your surgeon, a medical kidney specialist called a nephrologist, a social worker, a dietician, a financial coordinator, a transplant coordinator (nurse) and an independent living donor advocate. The sole responsibility of both physicians is to make sure that kidney donation is safe for you.

Transplant Coordinator: A transplant coordinator is a specialist nurse with knowledge of living donation and transplantation. The nurse is your guide through the transplant process. They will assist you in scheduling all of your required testing and will keep you updated with test

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results and team decisions. They will help plan for your surgery if you are approved as a living donor. They will be able to answer most of your questions and will be a resource for you throughout the evaluation, surgery and follow-up care.

Psychosocial Evaluation: You will meet with the social worker whose evaluation will focus on your state of mind and feelings regarding the donation. The social worker will discuss why you want to donate a kidney. They will also want to be sure that you and your family will be able to hold up under the emotional and physical stresses of this type of surgery.

Financial Evaluation: The financial coordinator will review your current financial situation and help you make a plan for the evaluation and surgery. The hospital cannot refund expenses for travel, lodging or time out of work. There are other programs that may be able to help with these expenses if appropriate. The financial coordinator and social worker will work together to assist you in this area.

Nutritional Evaluation: The dietician will be checking to see if you have good eating habits so you can be as healthy as possible for the surgery. They will also provide dietary guidelines for maintaining your health in the future.

A **transplant pharmacist** will review your medical record to be sure you are not on any medications that may interfere with your kidney function and may keep you from being able to donate.

The **Independent Living Donor Advocate** is a special role provided for living kidney donors only. This person is your advocate. They help you decide if donation is the right choice for you. Their role is to protect the donor's rights and as such they are not directly part of the transplant team. This is an excellent opportunity to discuss any concerns you may have regarding the donation without inducing any potential feelings about guilt if you choose not to proceed.

We will proceed with transplant only if the following things occur:

1. You decide that you want to proceed with transplantation.
2. All your evaluation testing is complete and you have been determined to be in good health and medically and psychosocially stable to donate a kidney.

If the evaluation determines that you are not an acceptable donor for your recipient, we will proceed with your recipient's other options which may include evaluating another donor. Our responsibility is to ensure that there is no harm to you. You and your intended recipient also have the right to seek another option from a different transplant program.

SURGICAL PROCEDURE:

The removal of a kidney for transplantation is called a donor nephrectomy. At Dartmouth Hitchcock Medical Center, we perform the nephrectomy through very small incisions and the use of camera equipment. This is known as a laparoscopic technique. You will have a very small (about one inch) incision for the camera port. The kidney is about the size of your fist and is removed through a larger incision (about 4 inches) in your lower abdomen. In most cases, we insert a device known as a hand port that allows the surgeon to insert his/her hand inside your body to grasp the kidney and remove it through this larger incision. This modification of the procedure is known as hand assisted laparoscopic donor nephrectomy.


On very rare occasions it is necessary to convert to a larger incision during the operation in order to improve exposure to the surgical field. This is known as an open donor nephrectomy. This would occur in circumstances such as bleeding complications that cannot be stabilized through small incisions and allow the surgeon to safely extract the kidney. This conversion to an open procedure is necessary in less than 2% of cases.

The average operation time is 3 to 4 hours and most patients spend approximately two nights in the hospital following their nephrectomy surgery.

The CT scan obtained during your evaluation will help the surgeon to determine which kidney is used. If any difference in size or function of the kidneys is noticed, we will remove the less good kidney for donation and leave the "better" kidney for you.

Despite improvements in speed of recovery noted in the medical literature for laparoscopic nephrectomy, all patients have some pain and we will do all that is possible to make your recovery easier.

The laparoscopic procedure has improved recovery times for living donors. Most patients can return to full activity in two to three weeks and return to work within four to six weeks of donation. These times are essentially doubled with the open technique. Restrictions typically include no driving for about one week, or until you are completely off narcotic pain medication. Also, you will be restricted to lifting no more than 10 lbs. for at least 6 weeks.

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RISKS:

This is a major operation and cannot be done without the risk of complications.

The following are inherent risks associated with evaluations for living donation:

1. Allergic reactions to contrast
2. Discovery of reportable infections, such as Hepatitis, Syphilis or HIV
3. Discovery of serious medical conditions
4. Discovery of adverse genetic findings unknown to the donor
5. 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.

Potential complications of the surgery will be reviewed by your surgeon. Risks of surgery maybe temporary or permanent. These complications may include, but are not limited to:

1. Death
2. Bleeding sufficient to require a blood transfusion
3. Wound infection
4. Damage to adjacent tissues and organs
5. The need for an open operation
6. Blood clots
7. Stroke, heart attack, or death
8. Acute (sudden) kidney failure and the need for dialysis or kidney transplant or a kidney transplant in the immediate post-surgery period.
9. Pain
10. Scars from the surgery
11. Post-surgery pneumonia
12. Nerve injury
13. Fatigue
14. Abdominal symptoms such as nausea, vomiting, bloating, constipation and bowel obstruction
15. Late complications can include, but are not limited to, an incisional hernia (bulge), incisional pain, and bowel obstruction due to adhesions (tissue that grows together).
16. Decreased kidney function over time
17. Risk of pre-eclampsia or gestational hypertension are increased in pregnancies after living donation for women of child-bearing age.
18. The morbidity and/or mortality of any living donor may be impacted by age, obesity, hypertension, or other donor-specific pre-existing conditions.

Potential psychosocial risks can include but are not limited to:


1. Problems with body image
2. Post-surgery depression or anxiety
3. Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient should die
4. Changes to the donor's lifestyle from donation

Potential financial impacts:

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

OTHER ECONOMIC CONSIDERATIONS:

Your evaluation and hospitalization are paid by your recipient's Medicare or personal insurance.

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It is important to note, that although the risk is limited, medical issues that might develop relative to the donation may not be covered by your recipient's insurance. Donation should not impact your personal coverage and the ability to obtain health and life insurance after your donation is not restricted by most insurance companies. However, some donors have had difficulty changing insurance carriers after the donation due to higher premiums or a preexisting waiting period. We have experienced social work and financial counseling to help you decide how these issues may impact your health or life insurance coverage.

FOLLOW-UP AFTER DONATION:

It is a federal requirement that all transplant hospitals report follow-up information on donors for a minimum of two years after kidney donation. By consenting to donate, you also agree and consent to return for a follow-up evaluation at six months, one year and two years after your surgery. Any infectious disease or malignancy in donors during the first two years of follow up (1) may be reported to local, state, and federal public's health authorities (2) will be disclosed to their recipients transplanting center, and (3) will be reported through the OPTN (Organ Procurement Transplant Network) safety portal. As a medical community, we are still researching the long-term health impact of kidney donation, and follow-up visits are the only method for collecting this information. During your evaluation we will provide you with the most recent information on outcomes in kidney donors and kidney recipients, both at our center and nationally. They include:

1. National and our hospital's one year patient survival
2. National and our hospital's one-year transplanted kidney survival.
3. Our hospital living donor 6-month, one-year and two-year follow-up rates
4. Notification of any Centers for Medicare and Medicaid Services (CMS) outcome requirements not being met by our transplant hospital.

Education about expected post-donation kidney function, as well as how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the living donor in the future will be provided during the evaluation. Information includes the following:

1. On average, living donors should expect to have a 25-35% permanent loss of kidney function after donation.
2. The risk of end-stage renal (kidney) disease (ESRD) for living kidney donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors.
3. Living donor risks are based on the current knowledge of the normal patterns of developing CKD (chronic kidney disease and ESRD. When CKD occurs, it generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The development of CKD and subsequent progression to ESRD may be faster with only one kidney.
4. Dialysis is required if the donor develops ESRD
5. The medical evaluation of a young living donor cannot truly predict the lifetime risk of CKD or ESRD.
6. Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney.
7. The morbidity and mortality of the donor may be impacted by obesity, hypertension, or other donor-specific pre-existing conditions
8. Current practice is to prioritize prior living kidney donors who become kidney transplant candidates on the OPTN waitlist according to OPTN Policy 8.3.


TRANSPLANTS AT UNAPPROVED CENTERS:

Medicare has official requirements for certification of transplant centers. If a transplant is performed at a facility that is not Medicare-approved, the transplant recipient may not receive coverage for transplant medications under Medicare part B. **Dartmouth Hitchcock Medical Center is a Medicare-approved transplant hospital.**

CONCLUSION:

The living kidney donation process is usually a very positive experience for both donor and recipient. However, as risk is involved, this document is our attempt, to the best of our ability, to help you understand the process so that you can make an informed decision. You should feel free to ask questions at any time from any transplant team member.

Signing this document indicates your agreement and consent to be considered for donation at this time. However, you may choose to stop the process at any time and we will support that decision. Again, this decision will be confidential and will not be discussed with anyone including your potential recipient.

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SIGNATURE:

By signing this consent prior to meeting with the transplant team, I am attesting that I have read this document in its entirety. I understand I can contact the living donor coordinator or other members of the living donor team with any questions or concerns. I understand I am agreeing to start the living donor evaluation testing. I am consenting to having my blood drawn to test for genetic matching with my intended recipient if I am a directed donor or multiple recipients if I am a non-directed donor. I am also consenting to having blood and urine testing done to determine my current degree of kidney function.

Patient Name Printed	Date	Time
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Signature of Patient or Person Authorized to Consent on Patient's Behalf	Relationship
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Optional Witness

INTERPRETER

If the interpreter is necessary and physically present, please request a signature below:

Signature of person interpreting information for patient

If interpreting is done using a commercially available language line, identify the name of the interpreter and the commercial service:

Name of individual interpreting information for patient	Name of commercial services vendor
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