KIDNEY TRANSPLANT PROGRAM
INFORMED CONSENT FOR EVALUATION AS A LIVING KIDNEY DONOR

This document is to help inform you of the living donor process and ensure that you have full knowledge and understanding of the purpose, possible risks, and benefits of organ donation and the alternative options available to the recipient. It is part of a process known as “informed consent”. In order to decide whether or not you should agree to donation, you should have enough information to make an informed decision. This consent form gives detailed information about the living donor phases of evaluation, some of which the transplant team has already discussed with you or will discuss during your evaluation.

Once you have had all aspects of this consent reviewed and have been given the opportunity to ask questions, you will be asked to sign the consent form if you wish to proceed. You will be given a copy for your records. Please be aware, you cannot be considered a suitable candidate for donation until the evaluation process described below is complete. Your candidacy will be determined based on existing hospital-specific guidelines or practices and clinical judgement.

PURPOSE
The purpose of kidney transplantation is to give a healthy kidney to a person who has chronic kidney disease (CKD) or end stage renal disease (ESRD). A successful kidney transplant may allow someone with kidney disease to avoid dialysis and live a healthier life. Kidney transplant may be performed using deceased donor kidneys or living donor kidneys. Statistics shows that kidneys from living donors have a greater overall success rate than kidneys from deceased donors.

SELECTION CRITERIA
Inclusion Criteria: The potential living donor must:
• Be 18 years of age or older
• Have made initial contact with the transplant center expressing an interest in donation
• Be ABO compatible with potential recipient and have a negative crossmatch (or if ABO incompatible, be willing to donate in a paired or chain donation)
• Have an Estimated Glomerular Filtration Rate (eGFR) \( \geq 80 \text{ mL/min/1.73m}^2 \), calculated by CKD-EPI formula, or creatinine clearance \( \geq 80 \text{ mL/min} \)
• Be able to adhere to a therapeutic regimen & follow up for a minimum of two years
• Have clearance by living donor advocate

Absolute Contraindications: The potential living donor is excluded if they meet any of the following criteria:
• Is both less than 18 years old and mentally incapable of making an informed decision
• HIV
• Hepatitis B and C
• Active malignancy, or incompletely treated malignancy (except for non-melanoma skin cancer)
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- Evidence of acute symptomatic infection (until resolved)
- Uncontrollable hypertension or history of hypertension with evidence of end organ damage
- Diabetes
- BMI ≥ 35
- Reno-vascular disease or significant renal or urologic abnormalities
- Coronary artery disease or valvular heart disease associated with increased risk for surgery
- Kidney disease including autosomal dominant PKD
- Untreated tuberculosis
- History of thrombosis, thromboembolism, or coagulation disorders
- Disorders requiring anti-coagulation
- Excessive use of alcohol
- Use of illegal/non-prescribed substances
- Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality
- High suspicion of donor coercion and/or illegal financial exchange between donor and recipient
- Current pregnancy or less than one-year post-partum

Relative Contraindications: The potential living donor will be carefully assessed for degree of risk if any of the following are present:
- Over 70 years of age
- Proteinuria AEB>300mg protein in 24-hour urine collection
- Drug treated hypertension
- Family history of diabetes
- History of kidney stones
- Family history of Polycystic Kidney Disease (PKD)
- Evidence that donation would cause substantial financial hardship
- Other medical conditions that in the opinion the donor team, places the donor at an unacceptable risk for medical problems either during surgery or post-donation

EVALUATION PROCESS
The living donor evaluation typically involves many phases including the referral or screening process, the evaluation process, and the team decision process. A team of health care professionals experienced in living donation is involved in the entire process. Part of the evaluation includes assessing your personal support system, as well as providing you with information about your financial obligations.

The evaluation may reveal certain conditions which would make donating your kidney a poor choice. No information about you, including results of doctor visits and tests, will be discussed with...
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the intended transplant recipient unless you desire this and give your written permission. It is up to you to discuss your donor information and results – or not - with the potential recipient, except under unique circumstances such as Anonymous living donors. The donor and recipient medical teams are two separate teams. The living donor team advocates on your behalf without any consideration for the potential recipient.

You will meet with many members of the living donor team that will include:

- The **Transplant Nurse Coordinator** will provide education regarding the donor evaluation process and coordinate your evaluation tests, procedures and surgery. He/she will keep you informed about the results of your tests and procedures along the way.

- The **Nephrologist** is a doctor who specializes in kidney disease. The nephrologist will assess the function of your kidneys and determine the safety of donation so that you are not knowingly at any additional risk for kidney disease or other medical conditions.

- The **Transplant Surgeon** is the doctor who will perform the operation. The surgeon will meet with you to discuss whether or not you are a surgical candidate for donation and the potential risks and benefits of the operation as well as possible complications after donation.

- The **Transplant Social Worker** will meet with you to assess your psychosocial situation and possible stressors related to donation, while discussing your reasons for donating. The social worker will also help you identify your support network, financial resources, the potential psychological or emotional impact of donation and your plans for recovery after donation. Any concerns that could affect the outcome of donation will be discussed with you.

- The **Financial Coordinator** will make sure that we have all of the information necessary to ensure that the costs of the kidney donation are paid by the insurance of the recipient. The Financial Coordinator will also discuss with you the possibility that future health problems related to the donation may not be covered by your insurance or the recipient’s health insurance.

- The **Independent Living Donor Advocate (ILDA)** is a healthcare professional not involved with the potential recipient evaluation or recipient team. The ILDA will discuss any questions you have at any time. This person makes sure your rights are promoted, protected, and all decisions are in the best interest of the potential the living donor. The Advocate will talk with you in person or by telephone at several points along the way. At ANY point you wish to stop the evaluation or donation process, all you have to do is tell the Advocate. There will be no questions asked and the potential recipient will not be told why you are no longer a potential living donor.

- The **Dietician** – will perform a nutritional assessment and education as appropriate.
Additional consultations - Based on our evaluation, some potential donors may also be referred to other services for consultation. Examples include: Psychologist (mental health), Pulmonologist (lung doctor), or Cardiologist (heart doctor).

EVALUATION TESTS AND PROCEDURES
A series of examinations and tests are done to determine that you are otherwise healthy and free of other serious problems which would limit your ability to be a living donor. The initial phase of the donor evaluation process consists of medical screening, blood typing, crossmatching and human leukocyte antigen (HLA) typing to assess how well your kidney will match the recipient immune system. Some additional tests included in your evaluation are (but not limited to):

- **Blood tests** will be done to determine blood type and identify any possible reason that might prevent you from donating one of your kidneys. These tests will screen for immunity to or the presence of specific viruses, including HIV.
- A **chest x-ray** will help identify any problems with your lungs.
- A **urine test** – will screen for the presence of urinary tract diseases as well as drugs in your system.
- An **Electrocardiogram (ECG)** will check for any abnormality of your heart rhythm or determine if you need additional cardiac testing.
- A **CT or MRI Scan** of your kidneys will be done to identify the blood flow to and from the kidneys and if there are any abnormalities.
- A **24-hour Urine collection** will be completed to make sure you have adequate kidney function.
- A **colonoscopy** will be completed on all candidates age 50 or greater.
- A current **Pap smear** is necessary for female patients.
- A current **mammogram** is necessary for all females age 40 and older or with a family history of breast cancer.
- A **prostate exam** and/or a PSA will be completed on all males age 40 and greater.

While these tests and procedures are in progress, the nurse coordinator will communicate with you regularly to keep you informed of the results. Once all the tests and procedures are completed, a decision about your suitability for living kidney donation is made by the transplant team. Each case is examined individually and many factors are weighed before a final decision is made. The nurse coordinator will notify you after a decision is made. If SUNY Downstate denies you as a living donor, you may seek an evaluation at another transplant center which may have different selection criteria.

SURGICAL PROCEDURE
Prior to the surgery, your surgeon will discuss the actual procedure being performed and possible risks of the surgery with you in detail. You will sign a separate consent for the removal of your kidney.
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at the time of the operation. Surgery for donating your kidney generally takes 2-3 hours, under general anesthesia. It is difficult to predict how long the operation will take, but your family will be updated while the surgery is in progress. The standard surgical approach is called “Laparoscopic Donor Nephrectomy”, although it can very occasionally require an open nephrectomy. For a laparoscopic approach, the surgeon will place a few small holes in your abdomen used for a camera and surgical instruments. In addition, you will have an incision that is approximately 2-3 inches long, to remove your kidney. Your abdomen will then be stitched closed. When the incision site heals, this will leave a small scar. If your kidney cannot be removed using the laparoscopic approach, the surgeon will do an open nephrectomy which requires a larger incision and longer recovery time. Additional vessels may be removed at the time of your surgical procedure. These vessels can only be used for the transplant surgery or a surgical modification in the original intended recipient of your donated kidney.

SURGICAL RECOVERY
After the surgery, you will be taken to the post anesthesia care unit or recovery room where you will be closely monitored until you are fully awake. You may have some tubes and drains in place, including a small IV for at least a day or so after surgery. Intermittent pressure boots or sleeves around your legs will be used to prevent blood clots.

Once you are fully awake, you will be transferred to the transplant unit where you will remain until discharge. The typical hospital stay is about 2-3 days. Immediately following the surgery, you will experience some pain. You will be given pain medication to help relieve your discomfort.

You will probably feel more tired than usual for one to two months after the surgery. The complete healing period may be approximately six weeks. During this time, you will have some restrictions of your daily activities:

- You cannot lift more than 10 pounds for at least 6 weeks following surgery.
- You should not drive for one week following surgery or while you continue to use pain medication.
- Do not use pain relievers known as NSAIDs (Ibuprofen, Advil, Motrin, Naproxen, Aleve, etc.). They are toxic to your remaining kidney. You may use plain Tylenol (Acetaminophen) if needed unless otherwise directed by your doctor.

FOLLOW-UP CARE
Medical follow-up recommendations after your donation will be given to you upon discharge. It is your responsibility to follow those recommendations to assure your ongoing future health. We are concerned for your well-being after donation and are available to discuss any of your health concerns,
yet it is your responsibility to inform us of any problems related to the donation so we can properly intervene or give you additional recommendations.

We are required to report follow-up of living donors to United Network for Organ Sharing (UNOS) at 6 months, 12 months and 24 months post-donation. At each of these intervals, a member of the living donor team will contact you to schedule an appointment here at the transplant center. It is important that you keep these appointments to monitor your health. In some cases, we may be able to obtain this information from your primary care physician. This testing includes but is not limited to blood pressure readings, urine tests, blood tests and a history and physical. Health information obtained during your evaluation will be subjected to the same regulations as all records and could reveal conditions that the transplant program must report to local state or federal public health authorities. Any infectious disease or malignancy pertinent to acute recipient care discovered during the donor’s first two years of follow up care will be disclosed to the donor, recipient, and may be reported to local, state or federal public health authorities, the recipient’s transplant center and will be reported through the OPTN Improving Patient Safety Portal.

The transplant center cannot require you to pay for post-donation testing or examination for follow-up purposes.

RISKS
Living donation is not without risk, despite careful selection of suitable candidates. Therefore, risks should be carefully considered and weighed when making your decision to donate. The risk/complications listed below include the most common, but not all the possible complications that could occur.

- **Evaluation:** The following are possible inherent risks associated with evaluation for living donation:
  - Allergic reaction to contrast
  - Discovery of reportable infections
  - Discovery of serious medical conditions
  - Discovery of adverse genetic findings unknown to the potential donor
  - Discovery of certain abnormalities that may require more testing at the potential living donor’s expense or may create the need for unexpected decisions on the part of the transplant team
- **Surgery/Anesthesia:** There are inherent risks in all surgeries, especially surgeries conducted under general anesthesia. Many complications are minor and get better on their own. In some cases, the complications are serious enough to require another surgery or medical procedure.
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Additional possible complications include, but are not limited to injury to structures in the abdomen, pressure sores on the skin due to positioning, burns caused by the use of electrical equipment during surgery, damage to arteries and veins, and permanent scarring at the site of the incisions and death.

- **Risk of Bleeding:** Bleeding during or after surgery and may require blood transfusions or blood products that can contain bacteria and viruses that can cause infection. Although very rare, these infections include, but are not limited to HIV, Hepatitis B Virus, and Hepatitis C Virus.

- **Risk of Infection:** The incisions are potential sites for infection. Infection in the sites where tubes are placed in veins to provide fluids or in other sites to monitor body functions can cause blood infections and local infections.

- **Risk of Blood Clots:** Blood clots may occasionally develop in the legs and can break free and occasionally move through the heart to the lungs. In the lungs, they can cause serious interference with breathing, which can lead to death. Blood clots are treated with blood-thinning drugs that may need to be taken for an extended period of time.

- **Acute kidney failure** and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period. Current practice is to prioritize prior living kidney donors who become kidney transplant candidates.

- **Short Term Complications:** Should complications occur they are usually minor and improve on their own prior to discharge from the hospital. Most of these complications are reversible by the time of hospital discharge:
  - Atelectasis – lungs not expanding as well as they should be
  - Pneumonia – infection in the lungs – can be treated with antibiotics
  - Cardiac events - arrhythmias, heart attack or cardiovascular collapse
  - Pneumothorax – collapsed lung – can be re-expanded by placing a chest tube
  - Hypotension – low blood pressure – can occur with loss of blood
  - Urinary retention – unable to pass urine
  - Urinary tract infection – infection in the bladder
  - Hernia development – bulge at incision site
  - Bowel dysfunction – such as bloating, nausea, and developing bowel obstruction

- **Potential Long-Term Complications:**
  - Low-grade proteinuria – protein in the urine

- **Potential Psychosocial Risks:** There are mental health risks such as disappointment, feelings of guilt, anxiety about dependence on others, generalized anxiety, depression, problems with body image, feelings of emotional distress or grief if the transplant recipient experiences any
recurrent disease or if the transplant recipient dies, changes to the donor’s lifestyle from
donation, or change in relationship with the recipient.

- **Potential Financial Impacts:** personal expenses of travel, housing, child care costs, and lost
wages related to donation might not be reimbursed (resources may be available to assist some
donation related costs), need for lifelong follow up at the donor’s expense, loss of employment
or income, negative impact on the ability to obtain future employment, negative impact on the
ability to obtain, maintain, or afford health insurance, disability insurance, and life insurance,
future health problems experienced by living donors following donation may not be covered by
the recipient’s insurance.

- **Considerations for women of childbearing age:**
  - Pregnancy should be postponed for at least 1-year post donation surgery
  - You should consult with your primary care physician prior to becoming pregnant as
    pregnancy may stress the remaining kidney
  - Preeclampsia or gestational hypertension may be increased in pregnancies after
    donation

Expected post-donation kidney function and how chronic kidney disease (CKD) and end-stage-renal-
disease (ESRD) might potentially impact your future may include:

- On average, donors will have a 25-35% permanent loss of kidney function after donation
- Baseline risk of end stage renal disease does not exceed that of members of the general
  population with the same demographic profile. Donor risk must be interpreted in light of the
  known epidemiology of both chronic kidney disease (CKD) and end stage renal disease
  (ESRD). When CKD or ESRD occur, CKD generally develops in mid-life (40-50 years old) and
  ESRD generally develops after age 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 developing CKD or ESRD than healthy non-donors with
  similar medical characteristics.
- The development of CKD or ESRD may be more rapid with only one kidney.
- Dialysis is required when reaching ESRD. Current practice is to prioritize prior living donors
  who become kidney transplant candidates.

Overall healthy people who donate a kidney recover and lead normal lives. However, part of the
evaluation process is intended to discover the possibility of present and future kidney and other
medical illnesses. Despite this evaluation, you may develop disease or other illness within your
lifetime that could affect your remaining kidney; requiring dialysis or a kidney transplant. Possible
situations where this could occur include; kidney cancer, trauma, kidney stones with infection.
Morbidity and mortality of the living donor may be impacted by age, obesity, hypertension, or other donor specific pre-existing conditions.

RECIPIENT ORGAN FAILURE
It is possible that the donated kidney may not work or may be rejected by the recipient’s immune system. The donated kidney could also be damaged if the kidney disease of the recipient recurs in the transplanted kidney. Failure of the transplanted kidney may happen immediately, days, weeks or years later.

ALTERNATIVES
There are alternative treatments available to the potential recipient if a living donor kidney transplant is not performed. In most cases, a person who reaches end stage kidney disease can be treated with dialysis. Additionally, when a living kidney donor is not available for transplantation a potential recipient can be placed on the OPTN/UNOS national wait list for a deceased donor kidney. It is possible for a deceased donor kidney to become available for the recipient before the donor evaluation is completed or the living donor transplant occurs. The health care team is available to discuss these alternatives with you. Kidney transplant for the recipient is an elective treatment and not a cure for kidney disease.

ADVERSE OUTCOMES
The transplant candidate may have an increased likelihood of adverse outcomes (including but not limited to graft failure, complications and mortality) that:

- exceed local and national averages
- do not necessarily prohibit transplantation
- are not disclosed to the living donor

Certain information can be disclosed to the living donor about the recipient only with the permission of the recipient that includes the reason for a transplant candidate increased likelihood of adverse outcomes and personal health information collected during the candidate’s evaluation, which is confidential and protected under privacy law.

BENEFITS
There is no physical benefit to you from donating a kidney, but most donors report an emotional benefit from donation with similar or better quality of life than before donor surgery.

RIGHT TO WITHDRAW
You have the right to withdraw your participation as a potential donor at any time during the process. You should not feel pressured or obligated to undergo such a serious procedure and should discuss
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any concerns with your donor team so they can further assist you. If you wish, the transplant team can inform the recipient that you are no longer a donor candidate. None of your health or evaluation information will be shared with the potential recipient.

FINANCIAL RESPONSIBILITY
There is no cost to you as a potential living donor for medical testing and doctors’ visits required for the evaluation or surgery. These costs are paid by the recipient’s insurance or Medicare through the transplant center. However, should medical problems unrelated to donation be revealed during the process, we will refer you back to your primary physician for additional attention. Payment for any care you receive that is not specifically related to the kidney donation will be the responsibility of you and your insurance provider. For this reason, it is strongly recommended that you establish care with a primary care physician for lifelong monitoring and maintain health insurance as a living donor.

HEALTH AND LIFE INSURANCE
Your current or future ability to obtain health, life or disability insurance should not be affected by kidney donation; however, several studies have shown that in rare instances, a few donors have reported an increase in premiums, or being denied for future insurance. Our staff is available to assist donors in appealing such decisions. Any post-operative problems related to the donor procedure are covered by the transplant program, as appropriate.

SALE OF HUMAN ORGANS
It is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organs for anything of value including, but not limited, to cash, property, and vacations. By agreeing to be a living donor you are stating that you understand it is against the law to be paid to donate an organ, and that if any money is or will be given in exchange for your kidney, you may be subject to criminal prosecution. Any insurance coverage may no longer apply and you will become personally responsible for all the health care costs associated with the donation, and your private health information will be made available to law enforcement agencies.

U.S. PUBLIC HEALTH SERVICE (PHS) GUIDELINE FOR RISK CRITERIA
The Organ Procurement and Transplant Network (OPTN) regulations require that transplant centers determine potential living donors risk criteria for acute HIV, Hepatitis B virus, and Hepatitis C virus infection according to the US Public Health Service (PHS) Guideline. You will be required to complete a risk criteria assessment questionnaire as part of your evaluation. The intended recipient will be informed if risk criteria are present in the donor. If you choose not to complete the questionnaire in its entirety, you cannot be considered a candidate for kidney donation.
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POST-DONATION LIVING DONOR SPECIMEN COLLECTION AND STORAGE
By agreeing to be a living donor, you are stating that you understand the requirement for collection and storage of your blood specimen for ten years, **ONLY** to be used for investigation of potential donor-derived disease.

REQUIRED REPORTING TO UNOS
SUNY Downstate Health Sciences University is required to provide information about all organ transplants to the United Network for Organ Sharing (UNOS). This includes the name, birth date, gender, social security number, and blood type of the donor, the donor’s relationship to the recipient and some blood test results. UNOS keeps this information confidential. It is used to assigns a case number to the transplant recipient and donor, and later to determine how many living donor kidney transplants are performed, how many are successful, whether complications occurred and to assure that donors receive appropriate attention. This national data is also used to educate prospective donors and recipients considering future transplants.

SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS
The Scientific Registry of Transplant Recipients (SRTR) ([www.srtr.org](http://www.srtr.org)) keeps statistics about the success of living donor transplants. Center specific data about SUNY Downstate Hospital Kidney Transplant Program outcomes can be obtained by visiting the website listed above. You should contact your coordinator if you have additional questions or need assistance with navigating the website.

TRANSPLANT BY A TRANSPLANT CENTER THAT IS NOT APPROVED BY MEDICARE
If you donate your kidney to a recipient having a transplant at a facility that is not approved by CMS (Medicare) for transplantation, Medicare may not pay for immunosuppressive drugs needed by the recipient post-transplant. Currently, SUNY Downstate Kidney Transplant Program meets all of the requirements as a transplant center under Medicare.

CONCERNS AND GRIEVANCES
The United Network for Organ Sharing (UNOS) website [www.unos.org](http://www.unos.org) or the Organ Procurement and Transplantation Program (OPTN) toll-free patient service line (1-888-894-6361) helps transplant candidates, recipients, living donors and family members with general organ-transplant related information. You may also call this number to discuss a problem you may be experiencing with your transplant center or the transplantation system in general. You may also obtain additional information about living kidney donor transplants from members of the transplant team at SUNY Downstate (718-270-3169).
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CONSENT
Your signature certifies that you have decided to proceed with the living donor evaluation process, having read (or having interpreted for you) the information contained in this document and your understanding of the purpose, benefits, risks, and alternatives to live kidney donation and recipient transplantation. You have been given the opportunity to ask questions and have your questions answered. Upon signing this consent form, you will receive a copy.

Your signature confirms that:
• I am willing to donate
• I am free from inducement and coercion
• I am not being compensated in any way to donate
• I am aware that I may withdraw my evaluation or decline to donate at any time

Patient/Donor Signature: __________________________ Date: ________ Time: ________

Patient/Donor Printed Name: __________________________

Living Donor Coordinator Signature: __________________________ Date: ________ Time: ________

Living Donor Coordinator Printed Name: __________________________