

LIVING KIDNEY DONOR INFORMED CONSENT

Before you decide to donate one of your kidneys to another person it is very important that you understand the process for kidney donation. There are four phases of the living donation process, which includes consent, medical and psychosocial evaluations, pre and post-operative care and required post-operative follow-up. Please read the following information and ask any questions you may have before you decide whether or not to donate.

Purpose of a Kidney Transplant

The purpose of a kidney transplant is to give a healthy kidney to a person with chronic kidney disease. A successful kidney transplant may allow someone with chronic or end stage kidney disease the chance to avoid dialysis and live a healthier life. The Christ Hospital did its first kidney transplant in 1972. The wait list for a deceased donor can be very long and many patients die waiting for a deceased donor kidney to become available. Statistics show that kidneys from living donors have a greater overall success rate than a kidney from a deceased donor.

Alternative Treatment Options for the Recipient

There are other treatment options available to the potential recipient other than transplantation. In most cases people with end stage renal disease can be treated with dialysis. Also, if a living kidney donor is not available the recipient can be placed on a national waiting list for a deceased donor transplant. The transplant team is available to discuss these other treatment options with you.

Regulatory Requirements

The Christ Hospital is required to provide information about all organ transplants to UNOS (The United Network for Organ Sharing). This includes name, birth date, sex, social security number and blood type of the donor, the donor's relationship to the recipient, and some blood test results. UNOS then assigns a case number to the transplant recipient and the living donor. The identifying information is not accessible to the public or other researchers. This information is then monitored in order to determine how many live donor kidney transplants are performed. UNOS also tracks success rates, complications, and education to assure donors receive appropriate care and attention. UNOS requires that we re-evaluate donors at 6 months, 1 year and 2 years after the donation was made.

Our transplant center will take all reasonable precautions to provide confidentiality for the living donor and recipient. Information about your medical evaluation, psychosocial evaluation, and diagnostic testing will **not** be discussed or shared with the kidney transplant recipient unless you desire this or give written permission to do so. It is up to you to discuss this information with the recipient unless you are an anonymous donor. The donor and recipient will have different social workers assigned to avoid any potential conflict of interest that may exist between team members.

There is a possibility that donor's name may appear on a matched recipient's insurance estimation of benefits EOB statement.

Transplant hospitals determine candidacy for transplantation based on existing hospital specific guidelines (Living Donor Selection Criteria) or practices and clinical judgement.

The recovery hospital can disclose to the living donor certain information about candidates (recipient) only with permission of the candidate (recipient), including:

- The reasons for a transplant candidate's (recipient's) increased likelihood of adverse outcomes.
- Personal health information collected during the transplant candidate's (recipient's) evaluation, which is confidential and protected under privacy law.

Any health information obtained during the living donor evaluation is subject to the same regulations as all medical records and could reveal conditions that our transplant center must report to local, state and federal public health authorities.

National and Transplant Center Specific Outcomes

All transplant centers are required to report data on outcomes, specifically National and Hospital one year recipient and kidney survival rates and living donor follow-up rates. These results are published by The Scientific Registry for Transplant Recipients (SRTR). See attached form for specific information. SRTR updates outcome data results every six months.

Additional data can be obtained from the SRTR web site at www.srtr.org or UNOS website at www.unos.org.

Transplant Team

During the evaluation process you will meet with several clinical members of the team that will include:

A Transplant Coordinator: Your transplant coordinator is a registered nurse who does the initial screening and education about the donation process. Your coordinator will facilitate all aspects of the donation process through transplantation. The coordinator will be your liaison with the hospital staff during your inpatient stay and post donation as you desire.

A Nephrologist: A nephrologist is a kidney specialist. This physician will do a complete history and physical to determine if it is safe for you to donate a kidney. You will visit the nephrologist office for this assessment. You may see a nurse practitioner in the office rather than the nephrologist. The nurse practitioner will review his / her assessment with the nephrologist. Your coordinator will arrange this visit. Risk factors will be assessed to determine if there could be potential future risk to you. Any potential risks will be shared with you and recommendations made based on their assessment and findings.

A Transplant Surgeon will meet with you to discuss the surgical procedure, potential risks and benefits for you and the recipient. The surgeon may also examine your abdomen if you have had previous abdominal surgeries.

A Social Worker will meet with you to assess your personal, psychosocial situation, life stressors, and support systems in your life. Specific questions will be asked regarding why you wish to donate. The social worker will also discuss and assess any potential psychosocial or emotional impact the donation process may have as well as plans for recovery after donation.

An Independent Living Donor Advocate (ILDA) will be provided to assist you through the process and provide instruction about all phases of the living donation process. This includes the consent, medical and psychosocial evaluation, pre and post operative care and required post operative follow-up. The ILDA is not involved with the recipient evaluation or treatment decisions and is independent of the decision to transplant the potential recipient. The ILDA serves as a knowledgeable advocate for the rights of the living donor.

A Dietician will be involved in the multidisciplinary team meetings and will determine if a dietary consult will be needed prior to donation. This may or may not be required depending on your current state of health, weight, or lab values. While in the hospital, after donation, the dietician will visit you and assess your dietary intake and tolerance as your diet is advanced. The dietician will provide education at discharge regarding your diet after donation.

A Pharmacy Representative will be involved in the multidisciplinary team meetings and will determine if a pharmacy consult will be required prior to donation. The pharmacist will review any medications and herbal remedies that you may be taking. She will offer recommendations based on that list. The pharmacist will visit with you post donation and provide education on new medications and discuss your discharge plan.

The evaluation includes a complete and thorough medical and psychosocial evaluation.

Medical Evaluation

This evaluation includes a history for the presence of behaviors that may increase risk of disease transmission. You will be asked to complete a questionnaire related to high risk behaviors. The medical evaluation also includes questions about your family history and your social history.

There are many different tests that need to be done to determine if you are suitable for donation. Listed below are some of the common tests included in the evaluation process. Additional tests may be ordered based on the results of these tests.

Blood tests – Multiple blood tests are required to determine if your blood type matches the recipient. Other blood tests are done to assess how your kidneys are functioning and status of your overall health. Blood will also be screened for immunity to certain viruses. We also screen for transmissible, endemic and pandemic diseases. Living donor blood specimens will need to be obtained within 24 hours of organ donation, stored for 10 years, and can only be used for investigation of potential donor-derived disease.

Urine tests – Your urine is tested to assess your kidney function and any signs of infection.

Stool Tests – age 45-49 or if requested by transplant MD or surgeon.

CXR - A chest x-ray helps us identify any problems with your lungs.

EKG – An EKG will check for any abnormality of your heart rhythm.

CT Angiogram – This CT scan of your kidneys will be done to determine if there are any abnormalities in your kidneys or with major blood vessels.

ECHO or Stress Test – If you are 60 years or older or as requested by transplant MD or surgeon this test will be ordered to evaluate your heart.

If you see any physicians for any medical or psychological conditions the transplant team may ask that you sign a release of information to obtain records and clearances from those physicians.

Routine donor tests are paid for by recipients' insurance. In the event other medical issues are discovered during the work-up process that is unrelated to donation, we will refer you back to your primary care physician or recommend a specialist to consult. Payment for any testing or consults that you receive that is not related to the kidney donation process will be your responsibility or your insurance provider's responsibility.

For Example: if your CXR comes back abnormal and the transplant team feels that additional testing is required to determine if you are a candidate for donation, they will refer you back to your PCP for follow-up. We may ask you to do further testing. An abnormal CXR may disqualify you as a donor but additional testing (like a CT scan) may reveal that it is a benign finding and allows

you to still be considered for donation. The cost associated with this additional testing would be your responsibility or that of your insurance.

It is important to note that while you are completing the donor work-up and evaluation a deceased donor kidney may become available for the recipient before your donor evaluation is complete. The recipient may be transplanted with a deceased donor kidney instead of your kidney.

Cancer Screening for Donors

It is also expected and required that all kidney donors are up to date on the general cancer screenings that are part of their general wellness. If the donor is not up to date on the screenings, they will be expected to do that prior to being considered as a donor.

- All females must have an updated and negative pap smear.
- All females 40 years or greater must have a mammogram.
- Females less than 40 years of age must have a documented breast exam by a physician.
- All men and women 50 years or greater must have a colonoscopy.
- All men 50 years or greater must have a prostate check (PSA blood level and digital rectal exam).
- Any African American male and other males over 45 years old with a family history of prostate cancer will need to have a digital rectal exam and a PSA level.
- Lung cancer screening per ACS guidelines (55-74 w/ h/o 30 pack year smoking)

These cancer screenings are required for consideration of donation but not part of the routine testing. These appointments will need to be set up by the donor and will be billed to the donor's insurance.

Psychosocial Evaluation

The living donor social worker will evaluate the living donor for any psychosocial issues, including mental health issues that might complicate the living donor's recovery and could be identified as potential risks for poor psychosocial outcomes. This evaluation includes:

- An assessment of risk criteria for acute HIV, HBV, and HCV infection according to the *U.S. Public Health Service (PHS) Guideline 2020*
- A review of the living donor's history of smoking, alcohol, and drug use, abuse, and dependency
- The identification of factors that warrant educational or therapeutic intervention prior to the final donation decision
- The determination that the living donor understands the short and long-term medical and psychosocial risks for both the living donor and recipient associated with living donation
- An assessment of whether the decision to donate is free of inducement, coercion, and other undue pressure by exploring the reasons for donating and the nature of the relationship, if any, to the transplant candidate
- An assessment of the living donor's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes evaluating whether the donor has a realistic plan for donation and recovery, with social, emotional and financial support available as recommended
- A review of the living donor's occupation, employment status, health insurance status, living arrangements, and social support

Preparing for Surgery and Post Donation

Pre-Operative Care-

Approximately 7-14 days prior to the scheduled surgery you will come to the hospital for Pre- Admission Testing. During this visit you will have blood drawn, urine samples obtained, Chest X-ray and an EKG performed. You will also meet with your Transplant Coordinator, Surgeon, Social Work and Independent Living Donor Advocate. A pharmacist and dietician might meet with you as well, depending on your current needs at the time of your surgery. The results of your Pre- Admission Testing will be reviewed by the transplant team. If approved, you will proceed with the scheduled donation surgery.

On the morning of surgery, you will come to the Same Day Surgery Department. You will be prepared for surgery in this department. You will have an IV placed and medication given to you to help you relax until you are taken to the operating room.

Surgical Procedure / Post Operative Care

During surgery you will receive general anesthesia. The Christ Hospital has been doing laparoscopic kidney donation since 2000. You will have an incision that is approximately 2-3 inches long. In addition, you will have several smaller cuts used for surgical instruments. If the surgeon feels that your kidney can't be removed laparoscopically, he will discuss it with you before surgery is scheduled.

After surgery you will have an IV and a catheter in your bladder for a day. You will have pain after surgery. You will have pain medication to help with the pain. You should expect and plan to go home in 1-2 days after surgery. You should not lift more than 10 lbs. for at least 6 weeks after surgery. You will not be permitted to drive until you see the surgeon at your 2-week visit. The surgeon will then discuss with you any further restrictions.

Potential Risks to Donor Surgical Medical, Psychosocial and Financial

There are potential risks with any surgery especially when those surgeries are done under general anesthesia, including risk of death. The morbidity and mortality of the living donor may be impacted by age, obesity, high blood pressure or other donor- specific pre-existing condition. Should complications occur, they are usually minor and improve on their own. In rare cases, the complications may require additional surgery or medical procedures. These risks may be temporary, transient, or permanent and include, but are not limited to, all of the following:

The following are inherent risks to the potential living donor associated with evaluation for living donation:

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

Potential Medical / Surgical Risks:

Bleeding – Bleeding can occur during or after surgery. The bleeding may require blood transfusions or blood products. These blood products can contain bacteria and viruses that can cause infection. Although rare, these infections include: HIV, Hepatitis B, and Hepatitis C.

Blood clots – After any operation a blood clot may develop. The blood clot can break free and travel to the heart or lungs. In the lungs it can cause serious breathing problems and can lead to death. Blood clots are treated with blood thinning medications that may need to be taken for an extended period of time.

Infection – Infections can occur when bacteria enter your body at the surgical incision sites or where tubes were placed in your body. Infection can be at a specific site such as your incision or wound, in your lungs (pneumonia), urinary tract, or bloodstream.

Other – Other possible complications include but are not limited to: Hernia, decreased kidney function, fatigue, pain, bloating, nausea, bowel obstruction, injury to structures in the abdomen, pressure sores on the skin due to positioning, nerve damage, burns caused by the use of electrical equipment during surgery, damage to the arteries and veins, pneumonia, heart attack, stroke, scarring at the site of the abdominal incision, and other consequences typical of any surgical procedure. Risk for preeclampsia or gestational hypertension may be increased in pregnancies after donation.

Usually, healthy people who donate a kidney recover and lead normal lives. However, in rare circumstances, a small number of donors have lost the function of their remaining kidney resulting in acute kidney failure and the need for dialysis or kidney transplant. This could occur in the immediate post-operative period or at a later time in life. Possible situations in which this could occur include: kidney cancer, trauma, kidney stones with infection, or development of kidney disease that was not evident at the time of donor evaluation.

Expected post- donation kidney function and how chronic kidney disease and end stage renal failure might potentially impact the donor in the future include:

- On average, living donors will have 25-35% permanent loss of kidney function after donation.
- Although risk of End Stage Renal Disease (ESRD) for living kidney donors does not exceed that of the general population with the same demographic profile, risk of ESRD for living kidney donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors.
- For those people that do develop Chronic Kidney Disease (CKD), it generally develops in mid life (40 – 50 years old).
- For those people with End Stage Renal Disease it generally develops after age 60.
- Medical evaluation of young living donors cannot predict lifetime risk for CKD or ESRD. The medical evaluation that is done as part of the donor evaluation tells us about your current state of health.
- Living donors may be at higher risk for Chronic Kidney Disease if they sustain damage to the remaining kidney.
- Development of Chronic Kidney Disease and subsequent progression to End Stage Renal Disease may

- be faster with only one kidney.
- Dialysis is required if the living donor develops End Stage Renal Disease.
 - Current practice is to prioritize prior living kidney donors who became kidney transplant candidates.

Psychosocial / Financial Risks

The majority of our living donors state that they receive a great psychological benefit from donation, yet there is also the possibility that donation may create, or increase stresses related to your emotional, family, social, employment, or financial situation. Living donors may have feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or death.

Potential Psychosocial Risks

- Problems with body image
- Post- surgery depression or anxiety
- Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies
- Changes in living donor lifestyle from donation

Potential Financial Impacts

- Personal expenses of travel, housing, childcare costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation-related costs
- Need for lifelong follow-up at the living 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

Expectations about your donation and the transplant outcome might not be met. It is for this reason that such issues are discussed with the living donor team in advance so that you can realistically prepare as best as possible. The living donor team is available to provide ongoing support before and after donation and it is important to share any of these concerns with appropriate staff.

Living Donor Follow-up

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 wellbeing after donation and are available to discuss any of your health concerns, yet it is the living donor's responsibility to inform us of any problems related to the donation so we can properly intervene or give you additional recommendations. United Network for Organ Sharing (UNOS) requires our center to report living donor follow-up in a timely manner. Currently UNOS policy requires follow-up at 6 months, 1 year, and 2 years after donation. This will require you to come to our Transplant Clinic on 2-S of the Main Campus on Auburn for a follow-up visit with a nurse. At that time, we will check your blood pressure and weight as well as take a blood and urine sample from you. This allows us to monitor your kidney function after donation. All of these results are given to our medical director to review. If a problem is discovered, the medical director will offer recommendations for treatment and follow-up care. We also suggest regularly scheduled visits with your primary care physician for routine health maintenance and that any healthy lifestyle changes you make in order to become a living donor be maintained (i.e. weight

loss, diet, exercise). It is expected that an out of town donor follow-up in Cincinnati at our transplant center at the abovementioned visits. There will be no charge to you for the routine labs and follow-up visits that are completed in our transplant clinic.

If there is any discovery of infectious disease or malignancy that is pertinent to the care of the recipient during this 2 year post operative follow-up period, it:

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

Potential Risks to the Recipient

Our goal for the recipient is to benefit from the transplant, yet any transplant candidate may have increased likelihood of adverse outcomes including but not limited to graft failure, complications and mortality that exceeds local and national averages, do not necessarily prohibit the transplantation and are not disclosed to the living donor. Transplant recipients must also take their transplant medications for the rest of their lives or they will reject the organ. We screen all transplant candidates before allowing them to proceed; yet success relies on multiple factors.

Federal Law Regarding Donation of Human Organs

The sale or purchase of human organs is a federal crime and it is unlawful for any person to knowingly acquire, obtain or otherwise transfer any human organ for anything of value, including, but not limited, to cash, property, and vacations.

It is illegal in the U.S. to financially benefit from donation; yet financial support without profiting is permissible in order to offset potential costs that may be associated with donation (i.e. lodging, travel).

Donor Benefit

There is no medical 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 or discontinue your participation as a living donor at any time during the process. You should not feel pressured or obligated to undergo such a serious procedure and should discuss any concerns with your living donor team so they can further assist you. If you wish, the transplant team can inform the recipient that you are no longer a living donor candidate. None of your health or evaluation information will be shared with the potential recipient and will be kept protected and confidential. The Independent Living Donor Advocate (ILDA) is available to assist the living donor through this process.

NOTE: If a high risk behavior is discovered during the evaluation period that could result in possible transmission of a potential virus to the recipient, and you are still approved to donate, the information is

required to be shared with the recipient. Before we inform the recipient, we will discuss this with you. You can then decide to move ahead with the donation and allow us to inform the recipient of this increased risk or withdraw as a donor. If you choose to withdraw from being a living donor that high risk behavior information will remain confidential.

In the event The Christ Hospital Transplant Team declines to use you as a living kidney donor you are welcome to go to a different transplant center for evaluation and consideration using different selection criteria.

Concerns and Grievances

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

The Ohio Department of Health (ODH) is also available to help transplant candidates, recipients, living donors and family members to discuss a problem you may be having. If you have an unresolved issue with your transplant center or the donation process in general you can contact the Ohio Department of Health 246 N. High Street Columbus, OH 43215 Phone: 1-614-466-3543 www.odh.ohio.gov.

Notification about all Centers for Medicare and Medicaid Services (CMS) Outcome Requirements Not Being Met By Center

Specific outcome requirements need to be met by transplant centers and we are required to notify you if we do not meet those requirements. Currently, The Christ Hospital meets all of the requirements as a transplant center under CMS (Medicare).

Transplantation by a Transplant Center Not Approved by CMS (Medicare)

If you donate your kidney to a recipient having a transplant at a facility that is not approved by CMS (Medicare) for transplantation, the recipient's ability to have immunosuppressive drugs paid for under Medicare part B could be affected. Currently, The Christ Hospital meets all of the requirements as a transplant center under CMS (Medicare).

CONFIDENTIALITY

We are required by law to maintain the privacy/confidentiality of your health information. All information that is obtained in connection with this procedure, which can be linked to you, will remain as confidential as possible within the requirements of state and federal law. The results of this procedure will be reviewed and may be published in a scientific journal or book without identifying you by name. If the data is used for publication in the medical literature or for teaching purposes, your name will not be used. Records will be kept regarding this procedure and will be made available for required reviews/audit by representatives of the Food and Drug Administration (FDA), members of The Christ Hospital's kidney transplant program, members of the Kidney Transplant Research Database, and members of the United Network for Organ Sharing (UNOS) under the guidelines established by the Federal Privacy Act. The reviewers/auditors may also have access to your medical records, which contain your identity however they are required to maintain confidentiality. Your insurance company may also review your record.

By signing this consent:

I acknowledge that the kidney donation process has been reviewed with me.

I understand the process and my rights as a donor.

I understand I have the right to decline to donate at any time in the process.

I am free from inducement and coercion.

I understand the risks and am willing to undertake the risks.

I understand that I will receive no medical benefit by donating my kidney.

I wish to continue with the donation process and am willing to donate my kidney.

I commit to the UNOS follow-up requirements for 6 months, 1 year and 2 years post donation.

I understand blood specimens will need to be obtained, stored for 10 years, and can only be used for investigation of potential donor-derived disease.

Signature of Donor

Date

Witness

Date

Initiated 3/1/08/Revised 3/18/10, 8/8/10, 1/27/11, 7/19/11, 01/26/12, 7/24/12, 3/25/13, 4/7/14, 5/14/14, 12/16/14, 2/1/15, 6/23/16, 1/23/17, 6/1/17, 5/29/18, 5/21/20, 6/30/20, 2/17/21, 5/18/21