

LIVING DONOR CONSENT FOR EVALUATION (1 OF 4)

The purpose of the Consent for Evaluation is to ensure that all donors know what to expect and have had an opportunity to have their questions answered before agreeing to be a donor. Please review the following information and discuss any questions you have with your Transplant Team. When you are satisfied, please sign and return this form to Virginia Mason before proceeding with your medical assessment. Your questions are encouraged.

There are medical, psychological, and financial risks associated with being evaluated to be a living donor and donation, including, but not limited to the following:

Potential Medical Risks (Transient or Permanent)

- Infection, hernia, blood clots, pneumonia, nerve injury, scars from the surgery
- Pain, fatigue and any other surgical complications including risk of donor death
- Acute urinary retention
- Abdominal or bowel symptoms such as bloating, nausea, and developing a bowel obstruction
- Certain medical conditions such as obesity, hypertension, or other donor-specific medical condition may impact morbidity and mortality of the donor
- Acute kidney failure and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period.
- Increased risk with the use of certain over the counter medications and supplements
- Potential allergic reaction to contrast
- Potential discovery of reportable infections
- Potential discovery of serious medical condition
- Potential decreased kidney function
- On average, living donors may have a 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 profiles, risk of ESRD for living kidney donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors.
- Living donor risks must be interpreted in light of the known epidemiology of both chronic kidney disease (CKD) and ESRD. When CKD or ESRD occurs, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60
- The living donor medical evaluation cannot predict lifetime risk of CKD or ESRD.
- Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD may be faster with only one kidney.
- Dialysis is required if the living donor develops ESRD.
- Potential for other medical complications including long-term complications currently unforeseen
- Current practice is to prioritize prior living donors who become kidney transplant candidates.
- Specific to female living donors is the increased risks of preeclampsia or gestational hypertension in pregnancies after donation.

Potential Psychosocial Risks (Transient or Permanent)

- Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or dies
- Potential for problems with body image

Patient Initials

Date (month/day/year)

PATIENT NAME & ID #

VIRGINIA MASON MEDICAL CENTER – Seattle WA

Consent to Evaluate and List for Transplantation



LIVING DONOR CONSENT FOR EVALUATION (2 OF 4)

Potential Psychosocial Risks (Transient or Permanent) (continued)

- Possibility of post-surgery adjustment problems
- Possibility of transplant recipient death, recurrence of disease, and rejection and need for re-transplantation
- Potential impact of donation on the donor's lifestyle
- Potential post-surgery depression or anxiety

Potential Financial Risks

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

Potential Benefits from Donation

- Satisfaction in knowing you have helped improve another's quality of life
- Sense of well-being from helping others
- Possibility of early identification of an unknown medical condition during the medical evaluation

I understand I will be provided the opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential.

I understand the recovery hospital must provide an Independent Living Donor Advocate (ILDA). The ILDA at Virginia Mason Medical Center is _____.
The ILDA is available to assist me during the consent process.

I have been provided printed materials that explain all phases of the living donation process. The phases are consent, medical and psychosocial evaluation, pre- and post- operative care, and required post-operative follow up. Independent interpreters have been provided as needed to make sure I understand all phases of living donation and its associated risks and benefits.

I understand that as a donor I must be willing to donate without pressure and I understand that I may decline to donate at any time.

I understand that the intended recipient will not die if I do not donate and they have the following treatment options: dialysis, choosing not to dialyze, and listing for deceased donor transplant, living donor transplant from myself or someone else.

I understand that a deceased donor kidney might become available for the recipient before the donor evaluation is completed or the living donor transplant occurs.

I understand the recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient.

I understand that information I share with the Transplant Team is protected and will not be shared with the recipient unless authorized by me.

Patient Initials

Date (month/day/year)

PATIENT NAME & ID #

VIRGINIA MASON MEDICAL CENTER – Seattle WA

Consent to Evaluate and List for Transplantation

LIVING DONOR CONSENT FOR EVALUATION (3 OF 4)

I understand that medical information of both the potential donor and potential recipient may need to be revealed in order for both parties to determine whether they should donate or receive the organ. This would only be done with my express permission and I have the right to choose not to donate rather than have this revealed.

I understand that transplant hospitals determine candidacy for transplantation based on existing hospital specific guidelines or practices and clinical judgement.

I understand that the intended recipient may have an increased likelihood of adverse outcomes (including but not limited to graft failure, complications and mortality) that exceed local or national averages, do not necessarily prohibit transplantation, and are not disclosed to me.

I understand the recovery hospital can disclose to me certain information about candidates only with permission of the candidate including the reason for the candidate's likelihood of adverse outcomes and personal health information collected during the transplant candidates' evaluation, which is confidential and protected under privacy law.

I understand I will receive a thorough medical and psychosocial evaluation. The psychosocial evaluation will be completed by someone with mental health training which could include, for example, a licensed clinical social worker, psychologist, or psychiatrist.

I understand that disclosure of health information obtained during my evaluation is subject to the same regulations as all records and could reveal conditions that must be reported to local, state, or federal public health authorities.

I understand that sometimes unanticipated genetic information can be uncovered when HLA typing is done, such as unknown sibling or parental relationships. In this event, I would ____ would not ____ want that information provided to me.

I understand my evaluation may lead to the discovery of adverse genetic findings unknown to the donor, and discovery of certain abnormalities that will require more testing at my expense or create the need for unexpected decisions on the part of the transplant team.

I understand that as part of my medical and psychosocial evaluation, I will be screened for the presence of behaviors that may increase risk for disease transmission as defined by the 2013 U.S. Public Health Services Guideline. If I fall into a category that is determined to be increased risk, I have two options. I can stop the donor process, and my information will be kept confidential. Or I can proceed with the donor evaluation, and the transplant hospital will need to disclose to the recipient the increased risk of disease transmission with my clear consent.

I understand that as a potential donor I undertake risks and receive no medical benefit from the operative procedure of donation.

I understand the transplant hospital may refuse me as a donor. In such cases, I understand I can be evaluated by another transplant program that may have different selection criteria.

I understand that I may be reimbursed by the recipient for limited travel expenses and may receive subsistence assistance and that there may be other resources available to assist with these expenses.

I understand Virginia Mason is required by UNOS (United Network of Organ Sharing) to report living donor follow-up information for at least two years. Current reporting requirements are at 6 months, 1 year and 2 years post transplant. The specific information to be gathered is dictated by UNOS and will be sent to me approximately one month before it is due. Virginia Mason transplant program will cover the cost of these laboratory test.

I agree to commit to postoperative follow-up testing for a minimum of two years and to report it back to Virginia Mason. I understand that living donor follow-up is the only method for the collection of information on the long-term health implications of living donation and is required by UNOS.

Patient Initials

Date (month/day/year)

PATIENT NAME & ID #

VIRGINIA MASON MEDICAL CENTER – Seattle WA

Consent to Evaluate and List for Transplantation

DISTRIBUTION: WHITE: Medical Record

YELLOW: Patient

VMMC Form 901968 (07-18)

LIVING DONOR CONSENT FOR EVALUATION (4 OF 4)

I understand that any infectious disease or malignancy pertinent to acute recipient care discovered during the potential living donor's first two years of post-operative follow-up care: will be disclosed to the donor; may need to be reported to local, state or federal public health authorities; will be disclosed to their recipient's transplant center; and will be reported through the OPTN Improving Patient Safety Portal.

I understand that medical expenses due to complications as a result of my donation will be covered by the recipient's insurance or the Transplant Program and must be preauthorized by Virginia Mason. The determination of donor-related complications is solely at the discretion of the donor surgeon. I will contact the Transplant Team first if I have any concerns. If there are complications, they are most likely to occur within the first three months post donation.

I was provided a copy of the recovery hospital national and program-specific transplant recipient outcomes from the most recent SRTR center-specific reports, release date of: _____. It includes national 1 year patient graft survival and 1 year patient and graft survival. I understand that recovery hospital must notify me if the CMS outcome requirements are not being met.

I understand national as well as center-specific outcomes are available on-line at the Scientific Registry of Transplant Recipients (SRTR) at www.srtr.org

I understand that Virginia Mason Transplant Center is a Medicare certified transplant program. If Virginia Mason Medical Center were to lose its Medicare certification, the recipient would not be able to be transplanted at that program, and if a transplant is not provided in a Medicare-approved transplant center it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid for under Medicare Part B. All donors would be notified of any outcome requirements not being met by the transplant center and if Virginia Mason Medical Center were to lose its Medicare certification.

I understand it is a federal crime for any person to knowingly acquire, obtain or transfer any human organ for valuable consideration (i.e., for anything of value such as cash, property, vacations).

My decision to be evaluated to be a living donor is free from pressure, inducement, and coercion. I am willing to donate and understand I can back out of the process at any time up to the point of surgery.

I certify that I have read this form and understand its contents.

Signature of Patient Date (month/day/year) Time

Patient's Printed Name

Signature of Witness Date (month/day/year) Time

Printed Name of Witness

Signature of Transplant Educator Date (month/day/year) Time

Printed Name of Transplant Educator

Responsible Physician's Attestation: I have explained the procedures or treatments stated on this form including possible risks, complications, alternative treatments, and anticipated results, to the patient/legal representative. To the best of my knowledge, this patient has been adequately informed and has consented.

Signature of Responsible Physician Date (month/day/year) Time

PATIENT NAME & ID #

VIRGINIA MASON MEDICAL CENTER – Seattle WA

Consent to Evaluate and List for Transplantation