

Guidance for the Informed Consent of Living Donors

Purpose

The OPTN/UNOS Living Donor Committee developed this resource document to help transplant professionals obtain the informed consent of all living donors.

Introduction

Education is important in the consent process for any potential living donor. The potential donor must understand all aspects of the donation process and understand the risk and benefit associated with being a living donor as well as center-specific risk factors. Above all else, the potential donor must understand that the donor can stop the evaluation or donation process at any time.

Living Donor Consent

The consent process for any potential living donor should include, but is not limited to, the following:

- a. An assurance that the potential donor is willing to donate, free from inducement and coercion, and understands that he or she may decline to donate at any time.
- b. A psychosocial evaluation of the potential donor completed by someone with mental health training which could include, for example, a licensed clinical social worker, nurse specialist, psychologist, or psychiatrist.
- c. A disclosure of alternate procedures or courses of treatment for the potential donor and recipient, including deceased donation. All potential donors should be informed if the intended recipient has or has not been listed for deceased donation. Pre-existing, life threatening conditions of the potential recipient should be disclosed to the potential donor prior to obtaining consent.
- d. An evaluation of the potential donor's ability to comprehend the donation process, including procedures employed for both donor and recipient and possible outcomes.
- e. Printed materials that explain all phases of the living donation process. Materials should be written at an appropriate reading level and provided in the potential donor's native language. When necessary, independent interpreters should be provided to make certain the potential donor comprehends all phases of living donation and its associated risks and benefits.
- f. Sufficient time for the potential donor to reflect after consenting to donate.
- g. An offer for any potential donor of a general, nonspecific statement of unsuitability for donation should they wish not to proceed with donation.
- h. An explanation that a potential donor's decision not to proceed with the donation can only be disclosed if authorized by the potential donor.

- i. An understanding that the donor undertakes risk and receives no medical benefit from the operative procedure of donation.
- j. A disclosure that the potential donor's medical evaluation could reveal conditions that the transplant center must report to governmental authorities such as HIV or certain venereal diseases
- k. An explanation that medical information on 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
- l. A specification of the medical, psychological, and financial risks associated with being a living donor, to include, but not be limited to the following:
 - i. Potential Medical Risks
 - potential for surgical complications including risk of donor death
 - potential for organ failure and the need for a future organ transplant for the donor
 - potential for other medical complications including long- term complications currently unforeseen
 - scars
 - pain
 - fatigue
 - abdominal or bowel symptoms such as bloating and nausea
 - increased risk with the use of over the counter medications and supplements
 - ii. Potential Psychosocial Risks
 - potential for problems with body image
 - possibility of post surgery adjustment problems
 - possibility of transplant recipient rejection and need for re-transplantation
 - possibility that the transplant recipient will have a recurrence of disease
 - possibility of transplant recipient death
 - potential impact of donation on the donor's lifestyle

iii. Potential Financial Risks

- personal expenses of travel, housing, and lost wages related to live donation might not be reimbursed; however, the potential donor should be informed that resources may be available to defray some donation-related costs
 - child care costs
 - possible loss of employment
 - potential impact on the ability to obtain future employment
 - potential impact on the ability to obtain or afford health, disability, and life insurance
 - health problems experienced by living donors following donation may not be covered by the recipient's insurance
- m. A disclosure that transplant centers must report living donor follow-up information for at least two years
- n. A statement from centers that specifies who is responsible for the cost of follow-up care
- o. The agreement of the potential donor to commit to postoperative follow-up testing coordinated by the recipient transplant center for a minimum of two years
- p. A disclosure that donors may not receive valuable consideration (including without limitation monetary or material gain) for agreeing to be a donor. In certain cases, donors may be reimbursed for limited travel expenses and may receive subsistence assistance.
- q. A disclosure that living donor follow-up is the only method for the collections of information on the long-term health implications of living donation.
- r. The stipulation that transplant centers will provide potential donors with both national and their center-specific outcomes from the most recent SRTR center-specific report. This information should include, but not be limited to, 1-year patient and graft survival, National 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center.