

## **Guidance for the Informed Consent of Living Donors**

### **Purpose**

The Living Donor Committee developed this resource to help transplant professionals develop consent processes for 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. Most living donors give their organ to a family member or acquaintance. However, some living donors are nondirected and do not influence the placement of their donated organ. This resource contains some recommendations that only apply to nondirected donors. Above all else, the potential donor must understand that he or she may 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:

- a. The 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. The disclosure that the donor will receive a thorough medical and psychosocial evaluation.

The medical evaluation will be conducted by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post donation, which will include a screen for any evidence of occult renal and infectious disease and medical co-morbidities which may cause renal disease.

The psychosocial evaluation will be conducted by a psychiatrist, psychologist, or social worker with experience in transplantation to determine decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion.

- c. A disclosure that living donor transplant programs must provide an Independent Donor Advocate (IDA) whose responsibilities include but are not limited to the following.
  - to promote the best interests of the potential living donor
  - advocates for the rights of the potential donor
  - assist the potential donor in obtaining and understanding information regarding the:
    - i) consent process
    - ii) evaluation process
    - iii) surgical procedure, and

iv) benefit and need for follow-up

- 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. The provision of 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. The provision of education that discusses what remaining organ function will be left after the donation and what the impact on the donor might be.
- g. The provision of sufficient time for the potential donor to reflect after consenting to donate.
- h. Disclosure of alternate procedure or course of treatment 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.
- i. Explain that a decision by the potential donor not to proceed with the donation will not be disclosed without the prior consent of the potential donor.
- j. A determination that the potential donor understands that he or she will undertake risk and will receive no medical benefit from the operative procedure of donation.
- k. 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.
- l. An explanation that medical information on the potential donor may not be revealed to a potential recipient unless authorized by the potential donor. If the potential donor has a condition that might harm a recipient the medical team in charge of his or her evaluation will not allow the donation to occur.
- m. A specification of the medical, psychological, and financial risks associated with being a living donor. These risks may be transient or permanent and include, but are not limited to the following:
  - i. Potential Medical Risks
    - potential for surgical complications including risk of donor death
    - potential for decreased kidney function in kidney donors. Every kidney donor will experience a decrease in the kidney function compared to pre-donation. The amount will depend upon the potential donor's age and history. The anticipated change in their individual kidney function is to be discussed with each donor
    - 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 depression, anxiety, or emotional distress
  - 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
- n. Disclose that transplant centers are required to report living donor follow-up information for at least two years, so the donor should expect to be contacted by the transplant program regarding the current health status.
- o. Disclose that living donor follow-up is the best method for the collection of information on the health implications of living donation.
- p. Disclose that centers will specify who is responsible for the cost of follow-up care.
- q. The agreement of the potential donor to commit to post-operative follow-up testing coordinated by the recipient transplant center for a minimum of two years.
- r. Disclosure that it is unlawful for any person to knowingly acquire, obtain or otherwise transfer any human organ for valuable consideration. In certain cases, donors may be reimbursed for limited travel expenses and may receive subsistence assistance.
- s. Disclosure that living donor follow-up is the only method for the collection of available for the collection of short-term health implications of living donation.
- t. 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.

- u. Disclose to all potential non-directed donors the following:
  - i) the transplant program will determine who will receive the donated organ;
  - ii) the transplant center will take all reasonable precautions to provide anonymity for the donor and recipient;
  - iii) the transplant center should obtain a separate consent to allocate your organ to a paired donation system; and
  - iv) the transplant center should disclose there is an increased risk associated with the transport of nondirected living donor organs and obtain additional consent to transplant the organ if it will not be transplanted at the recovery center.