

# **Ethical Guidelines for the Evaluation of Living Organ Donors**

**University Health Network  
Bioethics Program**

**Updated December 2008**



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Accepted by MOT Management Committee  
13<sup>th</sup> January 2003 & April 2008

Approved by UHN Medical Advisory Committee  
6<sup>th</sup> February 2003 & 4<sup>th</sup> December 2008

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## INTRODUCTION

Considerations around the ethical evaluation of living organ donors are complex and continually evolving. Accordingly, the guidelines set out in this document are regularly updated.

A high quality ethical living donor transplant program can be described and evaluated on the basis of three elements: structure, process and outcome [1]. Structural elements are the overall qualities of the program that we must attend to such as philosophy of care and issues of confidentiality. Process elements describe the encounters between staff, potential donors and recipients, including, for example, the selection process and procedures for valid informed consent. Outcome elements relate primarily to evaluation and subsequent health status of donors and recipients including follow up and bereavement.

## 1. STRUCTURE

### Ethical Principles

The Multi Organ Transplant Program (henceforth “the program”) is based on the following ethical principles:

- Autonomy
- Non-maleficence
- Beneficence
- Justice

#### *Autonomy*

The principle of autonomy recognizes that the choice to donate rests in donors’ hands. To make autonomous decisions, donors must be fully informed about, and capable of understanding, the benefits and risks of donations, as well as the alternative courses of action available to them. They must also be free of pressure or coercion in making a decision whether or not to donate.

#### *Non-Maleficence*

The principle of non-maleficence is a contemporary restatement of the imperative to do no harm. It is a *prima facie* rather than an absolute requirement. Non-maleficence requires providers to ensure that procedures offered to patients result in the least possible degree of harm.

## ***Beneficence***

The principle of beneficence requires health care providers to act in the best interests of their patients. It may require providers to refrain from offering or recommending treatments to patients for which the potential risks may significantly outweigh the potential benefits.

### **Balancing Non-Maleficence and Beneficence**

In transplantation, the benefit to the recipient is greater than the benefit to the living donor. It is acknowledged that the benefit to the donor is primarily psychological, i.e. increased self-esteem and sense of well-being resulting from helping another individual. In balancing beneficence and non-maleficence, the program strives to minimize risks, maximize benefits, and facilitate autonomous decision-making by maintaining a high standard in the process of obtaining informed consent.

## ***Justice***

Considerations about justice are used to help make decisions about the equitable allocation of scarce resources among patients. Justice based decisions ensure that patients are treated equally unless such patients have morally relevant differences that warrant treating them differently.

The program recognizes that the above principles may be in conflict in particular cases and thus there may be difficulty in balancing decisions. The members of the health care team are active participants and act as moral agents. The program aims to listen carefully to potential donors, family members and health care providers in an attempt to make optimal decisions. Where there is a lack of agreement or serious reservations, consultation may be sought from the Bioethics Program or other relevant resources within and outside the University Health Network.

## **2. PROCESS**

### **Confidentiality**

The donor is notified that all information pertaining to his or her workup will be strictly confidential and will not be divulged to anyone else including the recipient.

### **Voluntarism**

It is essential that potential donors offer to donate voluntarily rather than in response to undue pressure. This is assessed in detail in the psychiatric and social work interviews by examining the following:

1. Potential donor's psycho-social situation
2. Potential donor's financial condition
3. Potential donor's relationship with the recipient
4. Potential donor's rationale for donation
5. Information on whether the potential donor was asked to donate, by whom and under what circumstances
6. Potential donor's appearance of comfort to decline the request
7. Potential donor's comfort level in the presence of other family members or people involved in the donation
8. Evidence or suggestion of material reward for donation
9. Potential donor's willingness and motivation to donate
10. Power imbalances between potential donor and recipient

### **Payment/Financial considerations**

In accordance with the law the program prohibits profit in any form in exchange for the donation of an organ. However, the program allows the genuine reimbursement for costs incurred in the process of donation such as loss of income, travel, meals, accommodation, and parking near the hospital. Potential and actual living donors may apply for reimbursement of eligible expenses up to a maximum of \$5,500 through Trillium Gift of Life Network's (TGLN) Program for Reimbursing Expenses of Living Organ Donors (PRELOAD) [2].

*Recommended Reading:* [3]

### **Adequate Time**

The entire process of living donation can be time consuming. Adequate time must be allowed so that appropriate decision-making can occur between the potential donor, recipient and the transplant team. It is desirable to have a "cooling off period" between donor consent being given and the scheduled donor operation, to provide the potential donor time to reconsider his or her decision to donate. In emergency cases it is imperative that every possible step be taken to ensure that potential donors feel supported in choosing or declining to donate and that coercion is not an influence.

### **Selection**

#### ***Separate Health Care Teams***

In order to avoid conflict of interest, it is optimal for the potential donor and recipient to be assessed by separate health care teams. The potential donor is interviewed by a physician who is not involved in the care of the recipient and

who acts as an independent donor advocate. The potential donor is interviewed without the recipient present. Other consultations such as psychiatry and social work are also done by separate professionals when possible.

### ***Information for Donors, Recipients and Families***

The potential donor is informed about the process of assessment at the outset, i.e. how the program is run and the exact steps that will be taken. This information is also shared with the recipient. It explains clearly that initial screening is carried out on up to four potential donors. The program does not inform each potential donor of how many people are undergoing initial testing for a particular recipient or who they are. Each candidate is independently informed of the results of the initial testing. When it is clear which potential donor will proceed with testing, the full workup is initiated for that person. The potential donor is informed of which tests will or may be carried out. Potential donors and recipients are informed that the program interprets failure of the donor to keep appointments for tests as a possible indication of reluctance to proceed with donation, and the donor will be informed of how the program addresses this situation (see “Failure to Complete Testing”). The above information is provided verbally by the nurse coordinator and should also be available in written form.

### ***Medical/Surgical Suitability***

To be medically suitable, the risk to the potential donor’s health must be deemed within acceptable limits, as assessed by the donor’s physician who acts as an independent donor advocate. Where there are special surgical considerations, the donor is also seen by an independent surgeon, acting as an additional donor advocate. In general, potential donors at added risk are not accepted unless there is an overriding reason to accept them, e.g. a parent donating to a child who is doing poorly.

### ***Psychosocial Suitability***

Psychosocial suitability is assessed by the social worker and the psychiatrist, in two separate interviews, or more if needed, thus providing at least two independent assessments of the potential donor’s social stability and suitability to donate. It is optimal for these interviews to be conducted on separate days because the potential donor may present differently at different times and to different people.

The goal of the assessment is to establish that the potential donor is competent, understands the nature of donation and the likely psychosocial consequences to the donor family and the recipient. The level of motivation for donation is examined to determine that the potential donor has sufficiently resolved any ambivalence regarding donation. The donor's expectations of donation are examined to establish that they are realistic. The donor’s ability to cope with donation including the possibility of a poor outcome and the adequacy of social

support are evaluated. It must be established that there is no psychiatric illness that would prevent the donor from donating.

The attitudes of the potential donor's family about donation are explored in order to ascertain if there is conflict and, if so, counseling is offered to resolve such conflict. How donation has been or will be presented to children is addressed. The economic impact of donation is explored and the donor is informed of any insurance or financial assistance programs that may be available. Timing of the surgery is discussed in terms of reducing economic or social hardship. The plan for surgery is discussed in terms of the donor's need for accommodation near the hospital, accompaniment of family, and care of children or elderly relatives at the time of donation.

*Recommended Reading:* [4]

### ***Failure to Complete Testing***

If a donor does not attend for a required test, the test will be re-booked and the donor informed by telephone. This may be done twice. If the donor fails to attend for the same test a third time without notifying the transplant centre, a letter will be sent stating that unless the transplant team hears from the donor within two weeks of receipt of the letter (date to be clearly indicated) the transplant centre will view the lack of contact as an indication that the donor does not wish to proceed with the workup. The recipient will then be informed that the donor is not suitable at this time and workup may commence on another donor. The recipient is not given information about the reason for the unsuitability to protect the confidentiality of the donor.

## **Informed Consent**

Informed consent may be viewed as a process of information disclosure, and patient understanding and acceptance, which occurs during the process of assessment. Time is needed to ensure adequate disclosure and understanding of donation, and its risks and benefits. In the case of lung and liver living donors, where risk is higher than in kidney donors, a two-step or multi-step process of consent is recommended.

### ***Capacity***

The donor's capacity to understand the nature of donation, and its risks and benefits, is assessed by all team members and in particular by the psychiatrist, physician and social worker. When the donor is found to lack capacity, he/she will be disqualified as a donor. In circumstances where there are compelling reasons to consider a potential donor who does not have capacity, the program will undertake a special review to consider the use of a legally authorized substitute decision maker. In such cases, the Bioethicist will be consulted.

### ***Disclosure***

The team members must give each donor full programme specific information regarding the risks and benefits to both himself or herself and the recipient during the evaluation process. The authors for the Live Organ Donor Consensus Group outline the contents of the disclosure for the potential living donor [5]:

- 1 Description of the evaluation, the surgical procedure, and the recovery period.
- 2 The plan for both short and long term follow-up care.
- 3 Alternative donation procedures, e.g. laparoscopic donor nephrectomy or open flank, including those available at other transplant centers.
- 4 Possible medical, surgical and psychological complications for donor, including reports of donor deaths and the specific experience with complications in the local program.
- 5 The medical uncertainties, including estimates of risk and the potential for long term donor complications.
- 6 Any financial costs that may be borne by the donor.
- 7 The potential impact of donation on the ability of the donor to obtain health and life insurance in the future.
- 8 The potential impact of donation on the lifestyle of the donor, and the ability to obtain future employment.
- 9 Information regarding specific risks and benefits to the potential recipient.
- 10 Expected outcome of transplantation for the recipient, i.e. results of second and third transplants, effects of co-morbidities, diabetes, arthritis, etc.
- 11 Alternative treatments available to the recipient.
- 12 Programme specific statistics of donor and recipient outcomes for this transplant centre.

### ***Understanding***

Information regarding the risks and benefits to both the donor and recipient needs to be presented in a way that is easy for the donor to comprehend, taking into account their language and educational level. Family members should not be used as interpreters as they may not be impartial toward the information being discussed. Instead, professional interpreters should be used.

### ***Voluntariness***

The donor's motivation for donation is evaluated throughout the assessment process, specifically during the interviews with the coordinator, social worker, psychiatrist and independent donor physician. Any concerns regarding the donor's

lack of voluntariness are noted in the professional's report, discussed with the team at large and, when there is a lack of consensus, with the Bioethics Program.

The donor should be told by the coordinator at the outset of the assessment process that if he or she decides at any point in the process NOT to proceed with donation, help will be offered to address his or her decision with other people. The health care team will assist the donor in coaching and planning, as well as offer ways to express his or her decision. The team may accompany the donor for moral support or announce the donor's decision if he or she so wishes. Counseling may be offered to help the donor cope with his or her decision. If the donor appears to be unsure of the decision to donate, counseling will be offered by the psychiatrist or social worker to help the donor to come to a decision.

### **Procedure for Decision Making on Donor Suitability**

Where there is a lack of consensus among team members, the concerns are shared with the potential donor and recipient as appropriate, and the following process is followed:

1. Donor is approved to donate from a medical standpoint.
2. Donor is approved to donate from a psychosocial standpoint.
3. Consultations pertaining to the assessment are completed by written report.
4. Donor Team Discussion.
5. If there is a lack of consensus about acceptability of a donor, the team consults the following:
  - Other professional members of staff when medical or psychosocial aspects of the case need clarification.
  - Bioethicist (UHN) of the Multi Organ Transplant Program when ethical issues are in question.
  - Legal Counsel when legal aspects require clarification.
  - Hospital Administration when there are organizational or public relations concerns.
  - Outside resources and consultation, i.e. ethicist or legal counsel independent of UHN / University of Toronto when it would appear that complete impartiality of involved staff may be questioned.
6. Plan for Donation accepted or refused by Team.
7. Donor informed of decision by donor physician, alone or with another team member. When a donor is not accepted, the reasons for the decision are shared with the donor and opportunities for addressing the issue(s) are explored. He/she will be offered a referral for a second opinion at this or another institution.
8. Plan for informing recipient discussed with donor.

9. Recipient informed of decision by donor or donor team members as agreed to by the donor.

### **Emergency Situations**

Transplantation from a deceased donor remains the standard of care for the lung and liver transplant programs. In emergency cases, every attempt is made to balance a living donor's autonomy, i.e. the right to consider a procedure that may save the life of someone who is important to them, with the need to ensure that the donor is acting voluntarily and is giving informed consent. It is recognized that a donor will inevitably experience internal pressure in such a situation. In order to minimize external pressure, the usual process is followed with extreme caution:

1. The family is informed by a member of the medical team of the urgent need of an organ and the option of living donation.
2. If someone offers to donate, a physician explains the risks and benefits of the procedure and an outline of the workup process. The donor is informed that if he/she wishes to withdraw, complete confidentiality will be maintained around this decision. The donor will be officially classified as an "unsuitable donor".
3. If the donor indicates that he/she wishes to proceed and consents to further testing, he or she is assessed by a member of the psychosocial team to verify voluntariness. The donor's motivation for donation is carefully examined to ensure that perception and expectations of donation are realistic. This includes assessment of both current and past family dynamics, the donor family's attitude about donation, the possible repercussions of donation or non-donation, and the donor's need for help in handling this.
4. Testing process is then carried out in full.
5. The donor is seen without other family members by the donor physician, acting as an independent donor advocate. The donor is asked again if he or she wishes to withdraw, and informed again that complete confidentiality will be maintained related to the reasons for this decision and he/she will be officially classified as an "unsuitable donor".
6. If the donor wishes to proceed and has been approved by the transplant team, i.e. team members confirm that the donor appears to be acting voluntarily and to be adequately informed, the second and final consent is taken by a physician from the transplant team.

### **Final Decision for Organ Donation from a Living Donor**

For living organ donation to proceed, there must be agreement among the donor, recipient and the medical team. Since the physicians and members of the transplant team also act as moral agents, the final decision to perform the living donor transplant rests with the transplant physician. There is no obligation on the transplant team to perform a transplant where they believe that the potential risks may significantly outweigh the potential benefits.

## **Procedures to Follow when Donation does not Proceed**

When a donor is deemed unsuitable on medical grounds, arrangements will be made for the appropriate care of the donor to address the medical issue if indicated. Potential donors who decide not to proceed with donation or who are ruled out as donors on medical grounds will be offered counseling by a social worker, psychiatrist or psychiatric nurse from the transplant team.

The goals of the intervention are:

1. To enable the potential donor to work through any feelings or conflicts which he or she may have around the decision not to donate.
2. To help the potential donor decide how he or she wants to inform the recipient of the decision not to donate. Staff will help the potential donor to make a plan and to carry it out, if the donor so chooses.
3. To help the potential donor deal with the discovery of a serious problem, where this applies.

## **Incidental Discovery of Misattributed Paternity**

The program conducts HLA testing routinely on kidney donors and recipient candidates to determine their tissue compatibility. When such testing is conducted on a donor and recipient, who believe they are genetically related (i.e., on a parent and child), the results may suggest that there is no genetic link between them. Therefore, during the evaluation, the team informs the potential donor and recipient that HLA testing may yield results that suggest non-paternity. The donor and recipient are told that further testing in a qualified laboratory through a family doctor would confirm such results. The donor and recipient are each given the opportunity to register his or her wish to have or not to have such information disclosed to him or her by the team. The donor and recipient are also informed that psychosocial support and follow up will be provided to help them deal with such information [6].

## **Communication between a Potential Donor and Recipient**

To achieve confidentiality, recipients will be told in advance that they will not be provided with an explanation if a potential donor does not meet the criteria for safe donation or elects to withdraw as a donor. They will be told that this donation was not suitable. It is acknowledged that this may cause the recipient, or others, anxiety around the potential donor's health. The team is available to help the potential donor plan how to impart this information. They will also provide counseling, if needed, to the recipient and the potential donor, as well as their families, to help cope with the outcome.

While in hospital, staff will aim to maintain confidentiality surrounding donor and recipient information. The issue of providing the donor with information about the recipient or *vice versa* may best be addressed prior to the admission to the hospital in order to clarify the process to be used and the wishes of the donor and the recipient. It

is acknowledged that donor and recipient are often eager to know that the other is well. However, this may lead to a breach of confidentiality. Nursing staff and/or the social worker will attempt to set up a line of communication between donor and recipient when possible. This is especially important when a parent donor is in a different hospital than the recipient child and has need for frequent updates about the child's condition.

Donors and recipients often want to have an opportunity to be together after the surgery. Staff should be aware of the importance of this and try to facilitate this as soon as it is medically safe to do so and when the two parties indicate that they are ready. However, the program requires, when possible, that anonymous donors and their recipients maintain anonymity for at least a six month period following donation. After this time, such donors and recipients may meet if mutually agreeable.

### **Documentation**

Recipient and donor information is recorded and stored in separate charts. The documentation includes written reports by the professionals who have assessed the donor, attesting to the donor's competence, understanding of the proposed procedure and of its risks and benefits for the donor and the recipient, the disclosure process, the donor's voluntariness and motivation for donation. It should state clearly if the donor is medically and psychologically suitable to donate.

## **3. OUTCOMES**

### **Success**

Evaluation of donor and recipient experience and medical outcomes is an essential part of a high quality ethical living donor program. The minimum requirements include an annual review of early and late morbidity, graft function and mortality. It is also desirable to establish a donor registry and monitor donor and recipient satisfaction rates.

### **Follow-Up**

Donors will be offered medical and psychological care related to the donation process. The length and content of this follow up will vary according to the organ donated and will reflect best practices as determined by the program. Follow up will be provided or arranged by the appropriate member of the transplant team

### **Poor Outcome of Organ Donation**

Staff should discuss with the recipient or family how and when to inform the donor of the failure of the donated organ. If the recipient wishes to inform the donor, support by a member of the transplant team will be offered. The donor will be informed in as

supportive a manner as possible, with attention paid to a suitable place, time and way of imparting the information. A member of the transplant team such as the nurse, social worker or psychiatrist, will be available to provide counseling services as needed, including attention to the fact that the significance of the donor's gift of an organ is not altered by a poor outcome and that the donor is not responsible for the result of the transplant.

### **Bereavement**

In the event that the recipient or donor should die, bereavement counseling will be offered to the surviving patient and involved family members. This will be provided by a member of the psychosocial team (social worker, psychiatric nurse, psychiatrist) or referral will be made to an appropriate service in the community.

## **4. INNOVATIONS IN LIVING ORGAN DONATION**

### **Unrelated Non-Directed Donation**

An unrelated non-directed donation occurs when a person donates his or her organ unconditionally to the general pool of recipients on the waiting list. The donor has neither a genetic nor emotional relationship with the recipient [7]. The donor and the recipient are mutually anonymous at the time of donation. The program requires that the donor and recipient agree to maintain anonymity prior to, and for at least a six month period following, the donation. If the donor and recipient wish to meet after this period of time, the program will help coordinate such a meeting. The donor and recipient are informed about the risks of meeting each other, including unwanted requests or attention. A donor's offer should be motivated by beneficence. A beneficent act is generally one in which a person intends to do good or be kind to others. The beneficence of an act is not necessarily negated if it is performed partly out of self-interest, for example, a desire to discharge a perceived moral duty to help another person.

*Recommended Readings:* [8],[9],[10]

### **Unrelated Directed Donation**

An unrelated directed donation occurs when a donor designates the particular recipient or group of recipients to whom his or her organ is to be given. The donor is a stranger who has neither a genetic nor an emotionally longstanding relationship with the recipient. The program may accept an offer of donation that is directed to a particular *individual* recipient such as a person identified in the public. However, the psychosocial team pays special attention to the donor's motivations and expectations related to his or her offer [11]. The donor is informed about the standard allocation criteria for non-directed organs, and given the option to donate by such criteria instead [12]. The program requires that the donor agree to maintain anonymity prior

to, and for at least a six month period following, the donation. If the donor and recipient wish to meet after this period of time, the program will help coordinate such a meeting. Given that discrimination based on one's membership in a particular group defined by race, sex, lifestyle, and so on, contravenes the principle of justice, the program does not accept offers of donation directed to or excluding particular *groups* of recipients, except those directed to children. It is believed that the potential negative impact of end-stage organ disease on the social and physical development of children warrants accepting a person's offer of donation that favors children. Also, public support of unrelated directed donations to children has been documented in at least one empirical study [13].

*Recommended Reading:* [14]

### **Use of Non-Directed Donors in a Kidney Exchange Program (NDD-LE)**

In a list exchange (LE), the intended recipient of an incompatible donor receives priority on the deceased donor waiting list when the incompatible donor donates a kidney to a recipient on the deceased donor waiting list. A kidney from a non-directed donor (NDD) is usually donated to a recipient on the deceased donor waiting list. In the program's NDD-LE, the NDD donates a kidney to the intended recipient and the incompatible donor donates a kidney to a recipient on the deceased donor waiting list. An NDD-LE increases the number of transplants by one if, and only if, the incompatible pair would not have exercised the LE option without being given the kidney from the NDD. In an NDD-LE, the intended recipient receives a living donor kidney rather than priority for a deceased donor kidney.

*Recommended Reading:* [15]

### **Living Donation from Foreigners**

Living donation from a foreigner occurs when a donor who is not a legal Canadian resident donates an organ to a local recipient. The team assesses each potential foreign donor using the standard robust evaluation, but pays particular attention to the donor's motivations and expectations, as well as any evidence or suggestion of material exchange. The team considers thoroughly the unique set of circumstances surrounding each potential living donation for a foreigner, weighs the various ethical and practical considerations, and exercises its best judgment in deciding whether to accept or reject the donor's offer. The donor is informed, among other standard details, that:

1. material exchange for organs is illegal.
2. reimbursement for transplant related expenses is acceptable, which he or she may apply for through TGLN's reimbursement program (see "Payment/Financial considerations).
3. non-transplant related medical coverage while in Canada is strongly advised.

The program does not accept offers of donation from illegal immigrants.

*Recommended Reading:* [16]

## **Public Solicitations for Organs**

A donor may answer a recipient's need for an organ that is advertised in the public through, for example, print or electronic media or spoken communication. The team assesses the donor using the standard robust evaluation, and pays special attention to the donor's motivations and expectations, as well as any evidence or suggestion of material exchange [17]. When the donor's relationship with the recipient is based solely or primarily on the solicitation, the team informs the donor about the risks associated with his or her lack of knowledge about the recipient (e.g. the recipient's story may be exaggerated or false). See Section 3: "Unrelated Directed Donations".

*Recommended Readings:* [18],[19],[20],[21]

## **Publicity**

The program does not refuse categorically offers of donation motivated by a desire for public recognition. However, the donor's desire to gain publicity is usually regarded as a high risk factor [22]. Therefore the team proceeds carefully and uses its best judgment in deciding whether to accept or reject offers of donation motivated by publicity. The team may decide not to accept a donor's offer if publicity is his or her primary or sole reason for wanting to donate, or if the purpose for the publicity is considered inappropriate (e.g. to enhance one's political profile).

## **Living Donors' Families or Close Others**

The potential donor is strongly advised to inform his or her family or close others about his or her intent to donate. When possible, the attitudes of the family or close others about donation are explored through two separate interviews, one with and one without the potential donor present. If there is conflict between the potential donor's decision and the wishes of the family or close others, counseling is offered and strongly encouraged to help resolve such conflict. Ultimately, the potential donor's autonomous decision takes precedence over the wishes of the family or close others, unless the consequences of accepting an offer against the wishes of the family or close others are believed to place the donor at high risk.

*Recommended Reading:* [23]

## **Repeat Living Donation**

When a previous donor makes a subsequent offer of donation, the team assesses the potential donor (again) using the standard robust evaluation. The team pays special attention to the donor's motivations, for example, whether the donor's offer is based on an excessive desire for attention.

## **5. RESEARCH**

The principles embodied in this document are consistent with those of the University Health Network's Research Ethics Board and are intended to support research into the care of living organ donors.

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