

OPTN/UNOS ETHICS COMMITTEE REPORT

SUMMARY

I. Organ Availability Issues

Action Items For Board Consideration:

- The Board is asked to consider a resolution to endorse the Committee white paper, *Living Non-directed Organ Donation*, as an educational document. (Item 2, Page 1).

Other Significant Items:

- The Committee examined the February 11, 2004, JAMA articles relating to surrogate decision-making and living organ donation. (Item 4, Page 1)
- The Committee discussed recent medical school anatomical gift cases. (Item 5, Pages 1-2).

II. Patient Access Issues

Action Items For Board Consideration:

- The Board is asked to consider a resolution to acknowledge public solicitation of organs for donation as an emerging phenomenon and to create an ad hoc committee to explore and formulate standards of conduct regarding public solicitation of organs for donation. (Item 7, Pages 2-3).
- The Board is asked to consider a resolution to philosophically oppose the program being marketed by matchingdonors.com as it exploits vulnerable populations and subverts the equitable allocation of organs for transplantation. (Item 7, Page 2-3).
- The Board is asked to consider a resolution to work toward developing a national living non-directed donation system. (Item 7, Pages 2-3).

Other Significant Items:

- The Committee reaffirmed its position on directed donation and will draft a letter to be sent to the National Conference of Commissioners on Uniform State Laws outlining this opinion following appropriate appeals. (Item 6, Page 2).

III. Other Issues

Action Items For Board Consideration:

- None.

Other Significant Items:

- The Committee explored the issue of medical tourism and agreed that emergent cases should be treated. (Item 9, Page 3).

**REPORT OF THE
OPTN/UNOS ETHICS COMMITTEE
TO THE BOARD OF DIRECTORS**

**Minneapolis, Minnesota
June 24-25, 2004**

**Mark D. Fox, M.D., Ph.D., Chairman
Margaret I. Allee, R.N., J.D., Vice Chair**

Organ Availability Issues:

1. Ad Hoc Living Donor Committee Ethics Subcommittee. Chairman Fox updated the Committee regarding the progress of the Ad Hoc Living Donor Committee and its Ethics Subcommittee. He addressed the topics of informed consent for potential living donors and living liver segment and kidney donor evaluation guidelines.
2. Living Non-directed Donation. Appropriate OPTN/UNOS Committees provided feedback regarding the white paper draft, *Living Non-directed Organ Donation*. The feedback was taken under advisement, revisions made, and the Committee discussed submitting the white paper to the Board of Directors for approval as an education document. As a result, the Committee voted unanimously in support of the following resolution for Board consideration:

**** RESOLVED, that the Board of Directors hereby endorses the Ethics Committee white paper, *Living Non-directed Organ Donation* (Appendix A), as an educational document for persons and entities interested in this issue.**
3. Cloning Organs/Stem Cell White Paper. The Committee's white paper, *Therapeutic Cloning Research*, was submitted to the Board of Directors at its November 2003 meeting. The Executive Committee is currently reviewing the document.
4. Surrogate Decision-Making and Living Organ Donation. The Committee examined in great detail the February 11, 2004, JAMA articles regarding surrogate decision-making and living donation. The Committee engaged in a vigorous discussion that included issues concerning decision-making based on best interests vs. substituted judgment, Guardian ad Litem conditions, patient advocacy, hospital ethics consultation services, state surrogacy laws, advance directives, therapeutic benefit to patients, patient autonomy vs. generalized benefit to the overall community, personhood, "doing no harm," and more. The Committee agreed that anything other than explicit evidence that the patient wanted to be an organ donor is barely better than chance. Furthermore, the Committee concluded that Drs. Wendler and Emanuel were unable to satisfy their own suggested standards in the article that accompanied the UCLA case study. When discussing that surrogates should derive no benefit from the decision to donate, the group could not discount the fact that there was a direct benefit to the cousin. The Committee could reach no consensus regarding this topic, yet did recognize that individual state's surrogacy laws will cause distinct variations regarding these cases, that the individual circumstances of each case will vary, and that this is a category of donors that has not been acknowledged until now. The Committee will continue to discuss this topic at future meetings.
5. Anatomical Gifts to Medical Schools. The Committee reviewed articles regarding the UCLA and Tulane anatomical gift cases. While the Committee recognized these situations are not directly related to organ donation and the business of the OPTN, they did acknowledge that the general public does not differentiate

between tissue, organ, bone marrow, anatomical gifts to medical schools, or any other type of bodily donation. The Committee reviewed its previous work with the OPO Committee regarding informed consent and considered this opinion an appropriate reference for these circumstances.

Patient Access Issues:

6. Directed Donation. The Committee reaffirmed its position concerning directed donation and its desire to draft a letter to the National Conference of Commissioners of Uniform State Laws (NCCUSL) requesting needed changes to the Uniform Anatomical Gift Act (UAGA). This letter would be reviewed by the Executive Committee and endorsed by the OPTN/UNOS President. The recommended language changes will prevent discrimination against a person or class of persons on the basis of race, national origin, religion, gender or similar characteristic. The Committee had sent such a letter to the NCCUSL in 1997 that resulted in no changes to the UAGA. Recently the NCCUSL has opened the UAGA for possible revision and the Committee is hopeful that the direction donation portion of the act will be revised appropriately.
7. Public Solicitation of Organs for Donation. The Committee reviewed an OPTN/UNOS press release regarding matchingdonors.com, material from matchingdonors.com's website, and articles related to matchingdonors.com and LifeSharers. The Committee's discussion expanded from the public solicitation of organs for donation to a much broader scope that included donor family issues as well. Some Committee members disclosed that certain OPOs have policies by which they do not approach donor families regarding publicity opportunities until they are at least one year out from their donation event. The fragility of the donor family is more important to the OPO than the press or public relations impact from a single story.

The Committee acknowledges that the public solicitation of organs for donation is an actual phenomenon. As a result, the Committee voted unanimously in support of the following resolution for Board consideration:

**** RESOLVED, that the Board of Directors acknowledges that the public solicitation of organs for donation is an emerging phenomenon and poses enormous potential problems to organ donation as a whole and therefore will establish an ad hoc committee to explore and recommend standards of conduct regarding public solicitation of organs for donation. The ad hoc committee will include representation from the Ethics, Communications, Membership and Professional Standards, Patient Affairs, and Minority Affairs Committees, as well as medically related organizations and regional representation.**

The Committee focused its further discussion on matchingdonors.com and LifeSharers. The Committee concluded that the matchingdonors.com website is not offering services that people cannot otherwise obtain. Additionally, there is a fee associated with participation, and the website purports the services offered are free. Some Committee members referred to this website as an "Internet scam." As a result of this discussion, the Committee voted unanimously in support of the following resolution:

**** RESOLVED, that the Board of Directors philosophically opposes the program being marketed by matchingdonors.com as it exploits vulnerable populations (i.e., donors, transplant candidates, etc.) and subverts the equitable allocation of organs for transplantation.**

The Committee continued its deliberations focusing on a possible solution regarding the promotion of a non-directed donation program under the proper auspices of the OPTN. As a result, the Committee determined that currently there is no system that properly manages living non-directed donation, therefore, the Committee voted unanimously in support of the following resolution:

**** RESOLVED, that the Board of Directors actively work toward developing a national system**

that facilitates living non-directed donation within the mandates of the OPTN and meets the needs of the transplant community.

Other Issues:

8. OPTN/UNOS November Board of Directors Meeting Update. Chairman Fox updated the Committee regarding the November Board of Directors meeting. The Ethics Committee had four action items for the Board. The Board approved three of the Committee's four resolutions. The members unanimously approved the Committee report.
9. Medical Tourism. While the Committee members voiced various negative opinions and gave many horrible examples of this practice, they agreed that in emergent situations the patients should be treated. First and foremost, the Committee agreed that medical professionals should "do no harm." In non-emergent instances, the doctor has the right to offer a list of alternative care providers to the patient and can dissolve the contract in 30 days and is no longer legally obligated to care for the patient.
10. Public Comment Document. In reviewing the policy proposals for public comment, the Committee's comments are as follows:

March 15, 2004 Public Comment Document

- a. **Proposed Modifications to Local Voluntary Alternative System for Assigning Priority in Kidney Allocation to Original Intended Candidates of Living Donor Kidneys.** The Committee found the proposal to be ethically acceptable based on current and historical practice.
- b. **Proposed Modifications to OPTN/UNOS Policies 3.5.3.3 (Mandatory Sharing) and 3.5.5 (Payback Requirements) ("Exemption of Kidneys Recovered from Donation after Cardiac Death (DCD) Donors from Sharing Requirements for Zero Antigen Mismatched Kidneys or Payback).** The Committee found the proposals ethically acceptable. However, there was some concern voiced that a possibility exists for abuse of this proposal. Some potential donors, who were in the process of being declared brain dead, could conceivably be recovered as DCD donors in an effort to keep the kidneys for local use.
- c. **Proposed Modifications to OPTN/UNOS Policies 3.5.5.1 (Payback Requirements) ("EDS Kidney Exemption from Payback Sharing Requirements").** The Committee found the proposal ethically acceptable based on current and historical practice.
- d. **Proposed Modifications to OPTN/UNOS Policies 3.5.5.1 (Payback Requirements) and 3.5.5.2 (Deferment of Voluntary Arrangements).** The Committee found the proposals ethically acceptable based on current and historical practice.
- e. **Proposed Modifications to OPTN/UNOS Policies 3.5.5.1 (Payback Requirements) and 3.11.5.1 (Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals).** The Committee found the proposals ethically acceptable based on current and historical practice.
- f. **Proposed Modifications to OPTN/UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch).** The Committee found the proposal ethically acceptable based on current and historical practice.
- g. **Proposed Implementation Protocol for Modifications to OPTN/UNOS Policy 3.8.1.5 (Islet Allocation Protocol).** No position taken.

- h. **Proposed Modifications to OPTN/UNOS Policy 3.8.1.6 (Mandatory Sharing of Zero Antigen Mismatch Pancreata).** The Committee found the proposal ethically acceptable based on current and historical practice.
- i. **Proposed Modifications to OPTN/UNOS Policy 3.6.2.1 (Allocation of Blood Type O Donors).** The Committee found the proposal ethically acceptable based on current and historical practice.
- j. **Proposed Modifications to OPTN/UNOS Policy 3.6.4.4.1 (Adult Patient Reassessment and Recertification Schedule) and 3.6.4.2.1 (Pediatric Patient Reassessment and Recertification Schedule).** The Committee found the proposals ethically acceptable based on current and historical practice.
- k. **Proposed Modifications to OPTN/UNOS Policy 3.6 (Adult Donor Liver Allocation Algorithm).** The Committee found the proposal ethically acceptable based on current and historical practice.
- l. **Proposed Modifications to OPTN/UNOS Policy 3.6.4.1 (Liver Allocation, Adult Patient Status).** The Committee found the proposal ethically acceptable based on current and historical practice.
- m. **Proposed Modifications to OPTN/UNOS Policies 3.6 (Pediatric Donor Liver Allocation algorithm Allocation Sequence for Patients with PELD or MELD Scores Less than or Equal to 6 (All Donor Livers)), 3.6.4.2 (Pediatric Patients Status), 3.6.4.3 (Pediatric Patient Reassessment and Recertification Schedule), and 3.6.4.4.1 (Pediatric Liver Transplant Candidates with Hepatoblastoma).** The Committee found the proposals ethically acceptable based on current and historical practice.
- n. **Proposed Modifications to the Region 5 Status 1 sharing Agreement.** The Committee found the proposal ethically acceptable based on current and historical practice.
- o. **Proposed Modification to Standard H3.100 of the OPTN/UNOS Bylaws Appendix B Attachment 1 (Standards for Histocompatibility Testing), Standard H3.100 and Proposed New Policies for Kidney Transplantation - 3.5.17 (Prospective Crossmatching), and for Pancreas Transplantation - 3.8.8 (Prospective Crossmatching), and Proposed Appendix D to Policy 3.** No position taken.
- p. **Proposed New OPTN/UNOS Policy 3.7.17 (Crossmatching for Thoracic Organs).** No position taken.
- q. **Proposed Modifications to OPTN/UNOS Policy 6.4 (Exportation and Importation of Organs - Developmental Status).** The Committee found the proposal ethically acceptable based on current and historical practice.
- r. **Proposed Guidelines for Living Liver Donor Evaluation (Item 1 of 2).** The Committee voted unanimously to endorse the guidelines in principle. However, they found the guidelines confusing as written and requested clarification. Additionally, they offer the following recommendations: in item 2.a.iii.1 add Surgeon (the item would then read Physician/Surgeon); in item 2.a.iii.4 strike the phrase as appropriate and add Psychologist (the item would read Psychiatrist/Psychologist); in item 2.a.iii.5 strike the phrase “as appropriate;” and change the item 2.c.i to “Dedicated medical professional familiar with transplantation and living donation and qualified to evaluate the potential donor for:.” Additionally, the committee asserts that section 2.a.vii is the responsibility of the

transplant team and not the independent donor team.

- s. **Proposed Guidelines for Living Kidney Donor Evaluation (Item 2 of 2).** The Committee voted unanimously to endorse the guidelines in principle. However, they found the guidelines confusing as written and requested clarification. Additionally, they offer the following recommendations: in item 2.a.iii.1 add Surgeon (the item would then read Physician/Surgeon); in item 2.a.iii.4 strike the phrase as appropriate and add Psychologist (the item would read Psychiatrist/Psychologist); in item 2.a.iii.5 strike the phrase “as appropriate;” and change the item 2.c.i to “Dedicated medical professional familiar with transplantation and living donation and qualified to evaluate the potential donor for:.” Additionally, the committee asserts that section 2.a.vii is the responsibility of the transplant team and not the independent donor team.
- t. **Proposed Modifications to OPTN/UNOS Policy 3.1.4 (Patient Waiting List).** The Committee found the proposal ethically acceptable and prudent.
- u. **Proposed Modifications to OPTN/UNOS Policy 3.2.3 (Match System Access).** The Committee found the proposal ethically acceptable and prudent.
- v. **New OPTN/UNOS Policies 3.4.7 (Allocation of Organs During Regional/National Emergency Situations), 3.4.7.1 (Regional/National Transportation Disruption), and 3.4.7.2 (Regional/National Communications Disruption).** The Committee found the proposals ethically acceptable and prudent.
- w. **Proposed Modification to the Criteria for Institutional Membership, OPTN/UNOS Bylaws, Appendix B, Section III (C) (Transplant Programs): Proposed Modifications to Item (15) (Social Support).** No position taken.
- x. **Proposed Modification to the Criteria for Institutional Membership, OPTN/UNOS Bylaws, Appendix B, Section III (C) (Transplant Programs): Proposed New Item (20) (Clinical Transplant Pharmacist).** No position taken.

March 25, 2004 Public Comment Document

- y. **Allocation of Lungs: Proposed Amended OPTN/UNOS Policy 3.7.6 (Status of Patients Awaiting Lung Transplantation), Policy 3.7.9 (Time Waiting for Thoracic Organ Candidates), Policy 3.7.9.2 (Waiting Time Accrual for Lung Candidates with Idiopathic Pulmonary Fibrosis (IPF), and Policy 3.7.11 (Allocation of Lungs).** The Committee supports the intent of this proposal and the general principles of medical urgency (justice) and transplant benefit (utility). The Committee has historically supported balancing justice and medical utility in the organ allocation process. Additionally, the Committee suggested that outcome data be collected and evaluated routinely to assess whether the intent of the proposals are being met.

Attendance at the Ethics Committee Meeting

September 12, 2003

Committee Members Attending:

Mark D. Fox, M.D. Ph.D.
Margaret R. Allee, R.N., J.D.
John McNab, P.A.-C., M.H.S.
Michael E. Shapiro, M.D.
William H. Marks, M.D., Ph.D.
Alain Heroux, M.D.
Mark I. Aeder, M.D.
Leslie A. Neve, R.N., M.B.A.
Michael Rees, M.D., Ph.D.
Timothy L. Pruett, M.D.
Grace L. Chang, Esq.
Elmahdi A. Elkhammas, M.D.
Jeffrey Kahn, Ph.D., M.P.H.
Paul E. O'Flynn

Chair
Vice Chair
Region 1
Region 2
Region 6
Region 7
Region 8
Region 9
Region 10

At Large
At Large
At Large
At Large

Committee Members Unable to Attend:

Jade B. Robinson, R.N., M.H.A., CCTC Region 3
Nelda L. Gutierrez At Large

UNOS Staff Attending:

Gloria Taylor, R.N., M.A., CPTC

Region 11

Liaisons Attending:

Renee Dupee, J.D.
Melissa J. Doniger, J.D.

HRSA
Board of Directors

Attending Via Conference Call:

Meladee Still, R.N., M.B.A.
M. Janelle London, Esq.
Caroline Jones, M.D., M.A.
Laura Christensen, M.S.

Region 4
Region 5
At Large
SRTR

OPTN/UNOS Ethics Committee Living Non-directed Organ Donation

The OPTN/UNOS Ethics Committee has endorsed non-directed living donation as morally commendable and ethically acceptable. The Committee has historically expressed concerns regarding the allocation of non-directed donor organs. The purpose of this white paper is to discuss the ethical principles that apply to living non-directed organ donation. This paper will define living non-directed donation and review the concepts of donor motivation, informed consent, risk/benefit analysis, allocation, transplant program considerations and donor follow-up.

Categories and Definitions:

There are three types of non-directed donation: 1) deceased-donor donation, 2) live donor/deceased-donor exchange protocol under an OPTN/UNOS allowed variance, and 3) living non-directed donation. With deceased-donor donation, the current OPTN/UNOS policy allows the next of kin the option to direct the donation to a specific individual or transplant center. There is generally no pre-existing relationship between the donor and the recipient and, while typically an anonymous process; anonymity may be waived if both the recipient and the donor family consent. With the live donor/deceased donor exchange protocol, the donation is conditioned on a “payback in-kind” to a specified individual. This approach falls under a specific allocation variance, which has been adopted according to OPTN/UNOS policy. In its final form, living non-directed donation is the only form of donation operationally designed to be truly altruistic and non-directed at the same time. Under a living non-directed donation model, the organ is donated as a gift and placed for distribution through the established allocation system. There are no expectations of return for the gift and no connections between the donor and recipient.

Informed consent:

Potential living donors are healthy individuals who rarely receive medical gain and who would not otherwise be considered “patients.” However, as potential donors they assume a special classification as a result of undergoing the donation evaluation process.¹ The informed consent process should seek to protect these individuals by assuring that they have appropriate decision-making capacity, accurate and complete information, and freedom from coercion.

Information provided to both the donor and transplant candidate must be presented in a manner that is clearly understandable and will vary dependent on the educational background and intellectual capacity of the individual. It is incumbent on the transplant center to provide accurate disclosure to potential donors of all pertinent information regarding known risks, as well as benefits to both the donor and the candidate.

Recognizing that transplant techniques are continuously evolving, the prospective donor needs accurate and coherent information regarding his/her risks for morbidity and mortality. In addition, the individual considering the option to donate needs to understand that the potential risks for donation extend beyond the event of the surgery. It is important to explain that the procedure may carry long-term risks, which are not yet appreciated. The potential for psychological, financial, and insurance risks should also be disclosed and understood.

¹ Consensus Statement for Live Organ Donors, page 2920.

In addition to understanding the risks of the procedure, the potential donor should have a realistic understanding of the transplantation process. To this end, donors should be made aware of pertinent patient and graft survival data, as well as possible risks to potential candidates post transplant. Additionally, they should be informed of organ allocation policies that will determine how the non-directed donation will be allocated.

Informed, valid consent must reflect autonomous and stable preferences. The transplant center should attempt to identify any potential sources of coercion that may influence a donor's decision. This process may actually be less complicated than with living-directed donation because non-directed donation lacks the inherent, potentially coercive nature present in the familial/emotional relationships. Therefore, the living non-directed donation decision may be considered more of a voluntary act. Given the absence of reproducible health benefits for the donor, the transplant team must ensure that the donor is free from coercion, particularly any form of illegal financial compensation. In living organ donation, a "cooling off period" between the consent decision and the scheduled donor operation is critical to the process of informed consent. This period will allow time for the transplant center to perform a thorough evaluation and for the potential donor to assimilate the information being provided.² Further, if the individual's commitment to donation persists through this period, it provides evidence of the stability of her/his preferences.

Living non-directed donors represent a unique subset of donors who do not medically benefit from the surgical procedure yet who elect to place themselves at risk for a stranger's benefit. Informed consent for living non-directed donation must be established at a strict standard to protect this unique group of donors. This standard of informed consent should resemble a research standard. The Institutional Review Board (IRB), Hospital Ethics Committee or Hospital Risk Management Program may assist in playing a key role in providing guidance in the development of the protocol and consent documents prior to implementation of the living non-directed donation program.

Risk/Benefit Analysis:

Primum non nocere ("First, do no harm") is one of the most widely recognized principles of medical ethics. Early opponents objected to living donor transplantation on the grounds that it violates a strict interpretation of this principle. In living organ donation, as in other areas of medicine, interpretation of this fundamental precept has evolved. The anticipated benefit is considered, rather than focusing solely on the avoidance of harm.

Thus, one of the primary ethical concerns in living donor transplantation is the need to achieve an appropriate balance of benefit and risk. In the case of living donors, this risk/benefit analysis is extremely complex because it requires deciding if the benefit to one individual justifies the risk to another. The recipient enjoys a disproportionate share of the benefits (improved health and life expectancy), while the donor assumes the burden of an invasive surgical procedure and its potential long-term adverse consequences. In living related transplantation, just as the emotional connection between donor and candidate can introduce an element of coercion, that same connection makes more apparent the donor's participation in the benefits accruing to the candidate. In living, non-directed donation, absent that connection, the donor assumes risk without an obvious

² Consensus Statement for Live Organ Donors, page 2920.

or immediate opportunity to share in the recipient's good fortune. This lack of obvious and direct benefit raises questions concerning the non-directed donor's motivation.

Not only should the theoretical and statistical risk for the donor and candidate be considered, but also the geographical location for the donation plays a role in the ethical considerations of its appropriateness.

Donor Motivation:

The ethical issues discussed in preceding sections are pertinent to both living non-directed donation and living-directed donation. However, discussions of these issues have traditionally assumed that a relationship exists between the donor and candidate. The unique challenge posed by non-directed donation stems from the difficulty in understanding a person's motivation to donate an organ to a "stranger." When a relationship exists between the donor and candidate, it is easy to appreciate the extent to which the donor is invested in the situation. The experiences of the two individuals are intertwined such that the donor may benefit directly from the improved health of the candidate or to possibly suffer if the recipient's condition deteriorates.

Motivation to donate outside the context of such a relationship is more difficult to discern. For this reason, offers by non-directed donors are frequently met with skepticism. One potentially confounding factor is the expectation that a donor's motivation stems from pure altruism (i.e. the desire to help another person without expectation of personal gain). It is important to realize that, even in living-directed donation, attainment of the ideal may be rare.

Maintaining a standard based on altruism may result in a tendency to downplay the extent to which individuals benefit from the act of donating. Multiple publications over the past twenty-five years have explored the living donor's decision-making process, and authors have noted increased self-esteem and other beneficial changes.³ While most reports pertain to living related donation, one would expect non-directed donors to experience similar benefits. In fact, it has been suggested that non-directed donors may actually experience a greater sense of satisfaction because the act is considered beyond the call of duty. An individual may hope to achieve a heightened sense of meaning or feeling of accomplishment through the act of donating. Thus, the benefits of donating an organ may be unanticipated or they may actually serve as a source of motivation.

Considerations of donor motivation should acknowledge that organ donation is morally commendable and ethically sound. Living non-directed donation does not require strict adherence to an altruistic ideal. Rather than attempting to strictly define acceptable motivations to donate, it may be more useful to rule out unacceptable circumstances. For example, expectation for financial compensation or the desire to form an emotional bond with the candidate would be unacceptable motivations. In addition, emotional or intellectual instability, which would impede the individual's ability to make an informed decision about donation, would be cause to refuse an offer from a non-directed donor. Most importantly, the evaluation process should be a collaboration between the potential donor and the transplant center to insure that the donor's goals and expectations are realistic.

Transplant programs need to respond to inquiries about living non-directed donation following protocols and policies that will help to ensure that these requests are handled in an objective and thoughtful manner. Such offers should not be dismissed simply because they do not

³ Organ Donation-Psychiatric, Social and Ethical Considerations; page 338.

conform to the accepted explanation of why people donate organs. Offers of non-directed donation warrant serious consideration and a commitment on the part of transplant programs to implement policies that would serve the best interests of the donor, candidate, and transplant community.

Anonymity:

Anonymity for either the donor or the transplant candidate cannot be guaranteed. Nonetheless, attempts should be made to maintain anonymity, and donors and candidates should be advised that maintaining anonymity may be in their best interests. Anonymity should be maintained, if at all possible, as a means to protect both parties from future potential coercion.

Transplant Program Considerations:

A significant number of transplant centers are reportedly performing these procedures with regularity. Therefore, various approaches dealing with non-directed donation are already operational and must be taken into consideration. Nonetheless, it is unacceptable for the transplant center to derive any gain through exploitation of the donor and/or the candidate or to achieve self-aggrandizement through improved economy, prestige, individual ego or career advancement due to this type of donation. Program marketing, advertising or the use of media appeals must follow strict standards to prevent the perception of conflicts of interest.

Allocation Considerations:

When allocating living non-directed organs, it is important that there be an intent to serve the entire transplant candidate pool. Allocation of organs recovered from living non-directed donors should follow the standardized policies of non-discrimination utilized for the allocation of deceased donor organs, which recognizes the option for individuals to direct donation in some cases. Since the potential good from non-directed living donation should be maximized, the transplant community should make an effort to match donors and candidates appropriately. The organ being donated should be allocated to the first compatible transplant candidate on the list as per the existing OPTN/UNOS allocation policies, within both clinical and logistical limits.

Currently, there is no policy governing the allocation of non-directed organs from living donors. Therefore, there may exist a presumption that organs recovered in this manner may be applied for the exclusive benefit of the recovering center's patients. The goal in pursuing non-directed organ donation from living donors should be to derive maximal benefit and equitable distribution. However, this goal needs to be reconciled with the need to ensure autonomy of the donor. For this reason, the OPTN/UNOS Ethics Committee proposes that, within both clinical and logistical limits, non-directed organs from living donors be allocated according to the existing algorithm governing the allocation of deceased donor organs within the appropriate sharing unit.

The proposed allocation policy for non-directed donor organs as currently articulated is restricted to kidney transplantation. The OPTN/UNOS Ethics Committee endorses the concept that this allocation principle be the expectation for the allocation of liver and lung segments recovered from non-directed living donors. However, it is the opinion of the Committee that technical considerations and limited experience and expertise in living donor transplantation of liver and lung segments preclude the broad application of the proposed allocation principle at this time.

Donor Follow-up:

The establishment of a living donor database is necessary as one means to collect information related to the donor, and should include demographic, clinical and outcome information on all living organ donors. The rationale for the development of a living donor database

includes: concern for donor's well-being, limitation of current knowledge regarding the long-term consequences of donation, the evaluation of the impact of donor variables on the outcome, and the need within the transplant community to develop mechanisms to provide for quality assurance assessments.⁴ Living non-directed donors could utilize this information in their decision-making process.

Conclusions:

Living non-directed donation is an ethically justifiable form of organ donation, so long as:

- The potential donor undergoes appropriate evaluation and screening;
- Donors are protected from coercion and undue influence;
- Respect is given to the individual's autonomous decisions while minimizing her/his exposure to risk;
- A strict standard of informed consent is followed;
- Safeguards are followed to assure anonymity between the donor and the candidate;
- Organs are allocated in an equitable manner according to existing policies; and
- A donor follow-up database/registry is established with the goal of increasing available information on donor outcomes.

⁴ Consensus Document for Live Organ Donors, page 2925.