Appendix A

About the OPTN
United Network for Organ Sharing (UNOS) operates the nation's Organ Procurement and Transplantation Network (OPTN) under contract with the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services. The OPTN is a network managing the allocation of deceased donor organs for transplantation throughout the United States, as well as the collection of clinical data for every organ donor and recipient nationwide. The OPTN is also responsible for developing guidelines that are necessary to promote the safety and efficacy of living donor transplantation for the donor and recipient. All U.S. transplant centers, organ procurement organizations and histocompatibility laboratories involved in organ transplantation are members of the OPTN.

The OPTN relies on the expertise and perspectives of more than 300 volunteers who serve at any one time on its Committees and Board of Directors. These volunteers represent all professional disciplines involved in organ recovery and transplantation, as well as those with personal experience as a living donor, a family member of a deceased donor or a transplant recipient.

In addition, all OPTN policies and by-laws involve public review and discussion. Any new or revised policy is circulated for public comment by any interested individual or organization. At times the OPTN seeks additional input through public hearings or forums for significant issues affecting allocation policy.

The OPTN acts under authorization granted by the National Organ Transplant Act (P.L. 98-507) and federal regulation (42 CFR 121). The majority of funding for the OPTN comes from a one-time computer registration fee of $459. This fee is assessed when a transplant center accepts a candidate for a deceased donor transplant, or when a center performs a living donor transplant on a candidate who had not been listed for a deceased donor transplant.

Additional information about the OPTN is available on its website, www.optn.org.

Living Donation Issues and Trends
In the early history of transplantation, virtually all living donors were genetic relatives of their recipient (most commonly siblings, parents or children). This occurred because the likelihood of transplant success was highest among those who share an identical or highly compatible immune system. This high level of immunologic matching is more likely to occur among relatives than non-relatives.

Even as medical therapies have boosted transplant survival and lessened the reliance on highly-matched relatives, most living donors continue to be genetic relatives. Currently, about two out of every three living donors are biological relatives. Several hundred additional living donors each year are the recipient's spouse. Many transplant professionals believe that relatives have the strongest social and emotional motivation to

help the recipient and are best able to understand and accept the potential risks of living donation. These risks include donor death or complications related to surgery, as well as the possibility that the transplanted organ may fail in the recipient.

Transplants from unrelated living donors were relatively few in number 10 years ago but have increased considerably in the last five years. This is a result of multiple findings and trends:

- Scientific studies have demonstrated that the odds of long-term kidney graft survival (function of the transplanted organ) are generally better from living donors than from deceased donors, even with a low degree of immunologic match between donor and recipient.
- Transplant centers have become more accepting of non-familial relationships between donor and recipient, such as coworkers or long-time acquaintances.
- The increasing demand for transplantation, and the lengthening average waits for deceased donor transplants, have spurred many transplant candidates and their loved ones to pursue living donation. In some instances, living kidney donation can be timed to spare recipients from having to begin dialysis. Living donation of a liver segment is sometimes an option for candidates with malignancies that will worsen if they must await a deceased donor liver.

It is uncommon for a living donor and recipient to have no previous personal relationship. At the same time, the frequency of such transplants is increasing as new approaches are applied to facilitate living donor transplants:

- Anonymous donations involving a volunteer who approaches a transplant center with no knowledge of a specific recipient. In 2004, 87 such transplants were recorded nationwide.
- Paired donations, where person A wants to donate to candidate B but is not a biologic match. The transplant center can sometimes find a comparable pair of individuals (potential donor C, candidate D) who will match if the donors and candidates are switched. Thus person A donates to candidate D and person C donates to candidate B. In one recent instance, a paired donation involved three living donors and recipients. There were 27 paired donation transplants recorded in 2004.
- Intended recipient protocols, again involving a potential living donor who does not match a specific candidate. With the involvement of the local transplant center and/or organ procurement organization, a compatible candidate is found for the living donor among those awaiting a deceased donor transplant. The originally intended candidate who was not a match for the living donor receives some extra allocation priority for a deceased donor organ. In 2004, 16 transplants in this category were reported.
- Instances where donor and recipient have met for the purpose of living donation, with no prior personal relationship. The OPTN does not collect data to indicate how often this occurs, but a handful of cases have been publicly reported in the last two years.

OPTN/UNOS actions to support living donation

The OPTN is not involved in a transplant center's medical decision-making process to evaluate or accept any specific transplant candidate or a potential living donor. However, the OPTN collects and manages data for every living donor and recipient once the transplant is performed. The OPTN also addresses any living donation issues that potentially affect the allocation of deceased donor organs or the quality of service provided by transplant centers.

Recognizing the potential for living donation to meet the needs of many transplant candidates, the OPTN and UNOS have actively supported and promoted living donation. Since 2002, many of these recommendations have been developed by an Ad Hoc Living Donor Committee, which has cooperated closely with other entities interested in living donation, such as state boards of health, the U.S. Department of Health and Human Services (HHS) and an advisory committee convened by HHS on transplant issues (the Advisory Committee on Organ Transplantation, or ACOT). The Ad Hoc Living Donor Committee and OPTN standing committees have advanced a number of recommendations ultimately adopted by the OPTN/UNOS Board of Directors.

Some of the following OPTN and UNOS actions supporting living donation have been implemented already; others are in development or the final stages of implementation:

- An extensive set of revisions and additions to clinical data collection on living donors, with the goal of better documenting post-donation medical complications and assessing medical risks for potential donors.
- Development of a survey instrument to be sent to all living donors six months post-donation to assess their quality of life and determine any further actions to optimize it.
- Establishment of OPTN membership criteria for living donor kidney and liver transplant programs, to ensure that these programs have staff with rigorous training and current expertise in living donor surgery.
- Planned establishment of a resource center to provide potential living donors with current printed and Internet-based information about the living donation process, risks and benefits.
- Establishment of guidelines for evaluation of living donors, including an independent team with at least one representative not directly involved in the transplant candidate's medical care. The goal of the team is to educate and counsel potential donors and ensure that the donation is voluntary.
- Advocacy for paid employee leave for living organ donation, beginning with employees of state and local government agencies. The federal government and about half the states in the U.S. already provide this benefit, as do many transplant-related organizations.

Issues and perspectives regarding solicitation of potential living-unrelated donors

It is not new, nor inherently unethical, for a transplant candidate or his or her advocates to publicly seek a living-unrelated donor. In the last several years, however, people seeking living donors have much greater media access and have pursued a variety of approaches to generate publicity. As this is an emerging trend, it deserves careful study and an attempt to develop consensus among those involved in donation and transplantation. The

Ad Hoc Committee on Public Solicitation of Organs was formed to study this trend and issue recommendations to the Board of Directors on this topic.

The Committee previously met to discuss public solicitation for deceased donor transplants. Upon the Committee's recommendation, the Board of Directors adopted a position statement addressing deceased donation, which is attached to this document as Exhibit B. The Committee acknowledges that solicitation for living donation has different implications and resolved to address this issue separately.

Recent attention has been focused on the use of the Internet for living donor solicitation, whether through web sites dedicated to this specific purpose or through online listserves or discussion forums. Some sites/services are free of charge to the user, others are not. It is important to note that the Internet is not the sole medium of interest to the Committee, nor will its conclusions be limited only to Internet solicitation.

Public solicitation must be considered in light of several related perspectives affecting the practice of donation and transplantation. These perspectives are outlined below.

Equity. One of the OPTN's founding principles is equity among transplant candidates. Given current levels of organ donation, not every transplant candidate will be able to receive an organ transplant. In addition, not every available organ will have the same characteristics (blood type, size, distance from candidates, etc.) Given these realities, the OPTN's goal is to ensure that when deceased donor organs become available, compatible transplant candidates have an equitable chance of receiving a transplant according to appropriate medical criteria. Candidates for deceased donor organs are prioritized for organ offers only on the basis of medical and logistical characteristics, not on personal/social/economic factors such as wealth, underlying cause of organ failure, celebrity status, etc.

It must be acknowledged that the OPTN's primary authority is over deceased donor organ allocation. The OPTN also has authority to allocate kidneys donated by a living donor to the pool of waiting candidates without donating to a specified recipient, and principles of equity likewise apply in those situations. However, equity may not apply the same way to other instances of living organ donation. For example, nearly all living donations occur through the donor's personal desire to help a specific candidate, even if other candidates are needier or a better biological match. But to the degree that living donation can reduce some transplant demand for those awaiting deceased donor organs, the effect on equity should be considered.

Freedom of choice. In deceased donation there are only a few hours upon the potential donor's death to make all the decisions related to donation. These choices may be specified by the donor prior to his or her death, or the family may make certain decisions in the absence of their loved one's wishes.

Living donation is more dependent on the choice of the potential living donor. He or she may choose to help a specific person needing a transplant, regardless of the fact that other

candidates are as likely or more likely to benefit. Or the donor may choose to donate anonymously to a recipient selected by medical professionals. The donor may express an intent to donate and later change his or her mind. Any of these decisions may be made or changed over time. Transplant professionals should support the living donor's decision-making process with the best and most valid information available.

Exploitation. While the potential living donor has freedom of choice, he or she may be influenced by certain motivations against his or her self-interest. The two most frequently noted by transplant professionals are coercion and compensation.

Overt coercion might include blackmail or an imposed obligation upon the potential donor. More subtle coercion may be a potential donor's feeling of low self-esteem and the idea that only through donation could he or she be worthy in the eyes of others.

The purchase and sale of organs is specifically forbidden by the National Organ Transplant Act. The living donor's direct medical costs and expenses such as travel or lodging directly related to the donation may be reimbursed as an exception to the purchase/sale prohibition.

Where services such as web sites and chat rooms are available free of charge to transplant candidates, some have alleged that those who charge significant fees for the similar services are exploiting a vulnerable population.

Transplant professionals must respect and support the potential donor's choice while ensuring that he or she is not unduly influenced and that the decision does not violate federal law.

Informed Consent. Living donation is elective surgery and has inherent medical risk, including the potential of death or serious medical complications. While the risk of death is low, the OPTN continues to study the incidence rate of various post-donation complications. It is key to the donor's self-interest to have accurate and thorough information about potential medical risks and to weigh them in the decision to donate.

For additional information

For additional information relating to the Ad Hoc Committee on Public Solicitation of Organs Committee or the call for public input, please contact Joel Newman, Assistant Director of Communications, UNOS, at newmanjd@unos.org.

Appendix B

OPTN/UNOS Board of Directors Statement Regarding Solicitation of Deceased Donation

(Adopted November 19, 2004)

The overwhelming majority of deceased donor transplants occur anonymously and without specifying an intended recipient of the donated organ. The existence of a personal bond that would cause a donor or donor family to favor a named transplant candidate is rare. Attempts to develop such a personal bond through unsolicited contact with or public appeals to families of deceased donors are problematic.

The national system for allocating organs from deceased donors for transplantation is founded on the principles of equity and medical benefit. All involved in the OPTN/UNOS work diligently to increase organ donation in ways that contribute to fairness for all transplant candidates and uphold the national standards developed and approved after thorough review and consensus-building among all affected groups, including donor and patient representatives.

Recognizing that organ donation and transplantation are founded on altruism and equity, the OPTN/UNOS Board of Directors opposes any attempt by an individual transplant candidate (or his/her representatives) to solicit organ donation from a deceased donor ahead of other waiting candidates in a manner that subverts the established principles and objectives of equitable organ allocation. This is a particular concern when commercial space is utilized to solicit directed donation from a member of the public for a specific candidate. Such efforts may divert organs from patients with critical need to those who are less ill. In addition, such appeals, although well-intentioned, compromise the principle of fairness.

The Board encourages anyone considering a public appeal to promote the overall need for organ donation and not solicit an organ donation for an individual candidate.

If an OPTN member institution is involved in a situation concerning a public plea for donation of deceased donor organs to a specific individual, the Board recommends that the member reinforce to the candidate and/or donor family that the OPTN system is designed to allocate organs equitably according to the greatest need and/or benefit of all candidates. Should the candidate or donor family persist in their wishes, the member institution should act foremost to ensure equity within the transplant system, with additional consideration of relevant medical facts, ethical guidelines, and applicable laws and allocation policies.