# OPTN/UNOS Ethics Committee
# Report to the Board of Directors
# December 1-2, 2015
# Richmond, VA

**Peter Reese, MD, Chair**
**Elisa Gordon, PhD, MPH, Vice Chair**

**Contents**

# OPTN/UNOS Ethics Committee
# Report to the Board of Directors
# June 1-2, 2015
# Atlanta, GA

**Peter Reese, MD, Chair**
**Elisa Gordon, PhD, MPH, Vice Chair**

*This report reflects of the work of the OPTN/UNOS Ethics Committee between April 2015 and November 2015.*

## Action Items

1. Living Non-Directed Organ Donation White Paper

   Public Comment: *N/A*

   The OPTN website provides access to eleven white papers developed by the Ethics Committee. The oldest white paper on the site was approved in 1993, and it is unclear when the resources have been reviewed for accuracy and relevancy. The Committee will review each of the white papers. Four papers have been reviewed and determined not to require revision. One white paper addressing the Ethical Principles to be considered in the Allocation of Human Organs was approved by the Board in June 2015.

   The Committee has completed revision on another white paper which addresses Living Non-Directed Donation. Major changes in this revised version include:

   - Adding an extensive list of references to support the recommendations. The original version did not contain references.
   - Recognizing that NND is now an acceptable option. The prior white paper presented NDD with skepticism which at the time the white paper was written, was commonly construed as such.
   - Highlighting the unique aspects of the informed consent process for potential NDDs e.g., new risks to disclose to the potential donor and dispelling antiquated concerns regarding coercion with evidence-based sources now cited.

   The white paper was endorsed by the Living Donor Committee. A mini-brief and this white paper is provided as (**Exhibit A**).

   The remaining white papers will be updated and prepared for Board reconsideration over the next year.

   **RESOLVED, that the white paper titled Living Non-Directed Organ Donation is hereby approved effective December 1, 2015.**

### Committee Projects

2. Review White Papers for Accuracy and Relevancy

   Public Comment: *N/A*

   Board Consideration: *June 2016 (Estimated)*

Over several years, the Board has approved a series of white papers on bioethical issues that the Committee developed. These are available on the OPTN website. Some of the topics addressed in the white papers include:

- An Evaluation of the Ethics of Presumed Consent
- Financial Incentives for Organ Donation
- The Ethics of Organ Donation from Condemned Prisoners

These resources have not been regularly reviewed to ensure they remain accurate and relevant. In response, the Committee has reviewed the white papers for accuracy and relevancy, and has determined if each white paper should be maintained in its current form, is in need of minor or major revision or should be eliminated because it is no longer relevant.

Some of the other questions being considered for each white paper include:

- What is the overall purpose of the paper? (e.g., inform UNOS policy versus educational purposes)
- Who is the target audience?
- Does the resource continue to reflect and inform current practice?
- Is the resource written in plain simple language?
- Are the citations and data current?
- Does the Committee still support the resource?

The Committee reviewed the status of each white paper during its spring 2015 meeting and will continue to work on the white papers during a series on monthly conference calls. The Committee plans to have other revised white papers ready for Board consideration in December 2015 and June 2016.

3. Imminent Death Donation (IDD)

Public Comment: *N/A*

Board Consideration: *TBA*

The Committee continues to examine the ethical considerations of imminent death donation. Imminent death donation has occurred in the past but is currently prohibited under existing policy. Imminent death donation involves the removal of transplantable organs prior to an imminent, planned withdrawal of support expected to result in death and is a donation alternative to donation after cardiac death for patients who are not brain dead.

The Committee is leading a work group with representatives from the OPO, Living Donor, and Operations and Safety Committees to investigate this issue. At this point, the path forward is unclear, as there is no consensus on the workgroup regarding when, if ever, IDD may be appropriate. In response, the work group has identified the ethical or practical concerns that may need to be addressed in order for IDD to be considered as a potential new option for organ donation.

The work group prepared a report outlining areas of concern and proposed solutions that was provided to the Committees represented on the work group for review and feedback.

During the October 2015 meeting, the Committee considered a draft report that is being finalized for presentation to the OPTN/UNOS Board in December 2015. The report will address the:

- Potential for the perception that IDD erodes the Dead Donor Rule
- Appropriateness of surrogate consent for IDD

- IDD candidates as a vulnerable population
- Identifying appropriate candidates for IDD
- Public trust
- Operational, practical and policy considerations
- Potential benefits
- Potential harms
- Potential unintended consequences

On November 16, 2015, the Committee Chair provided an overview of IDD to the Executive Committee of the Board. The Executive Committee supported providing a report to the Board in December 2015 (**Exhibit B**). The Committee will use any feedback from the Board as it continues work on IDD.

**Committee Projects Pending Implementation**

None

**Implemented Committee Projects**

None

**Review of Public Comment Proposals**

The Committee reviewed 2 of the 13 proposals released for public comment from January to March 2015.

4. Membership Requirements for VCA Transplant Programs

   The Chair of the VCA Committee provided a presentation on the proposal to the Committee. The Committee did not prepare a formal response regarding this proposal.

5. Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act

   The Ethics Committee limited its review of the proposal to aspects of the proposal relevant to living donors.

   The Committee supports the proposed policy modification of *Table 14-9 (Living Donor Exclusion Criteria)* which would be modified to read:

   - HIV, unless the requirements for a variance are met, according to *Policy 15.5 Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors*

   The Ethics Committee is concerned that the proposal does not address the special informed consent and medical evaluation requirements that should be necessary for potential HIV positive living donors.

   Additionally, the Committee is concerned that the proposal does not address post-donation follow-up requirements for HIV positive living donors. The two-years of required follow-up for living donors required under current policy will not be sufficient to understand the longer term effects of organ donation for HIV positive living donors.

**Other Committee Work**

6. Living Donor Prioritization under KAS

   During the September 2015 meeting, the past Chair of the Kidney Committee provided a report on living donor prioritization under the new kidney allocation system. The Committee was asked to consider if prioritization of sensitized candidates may be negatively impacting the availability of organs for living kidney donors who later need a transplant. Some Committee members voiced philosophical concerns over prior living donors not receiving prioritization over highly sensitized candidates, but most members did not support changing the current system. The Committee wants to reconsider this issue after the new allocation system has been in effect for one year.

7. Review of Existing and Proposed new Committee Projects

   During its September 2015 meeting, the Committee conducted a "brainstorming" session to identify potential new projects that align with the new strategic plan with special emphasis on projects that have the potential to increase the number of transplants. The Committee considered all potential projects recommended by members and favored exploring potential projects to address:

   - Public education regarding living donation
   - Developing guidance concerning recognition of first person authorization for donation on a national level
   - Donor champions
   - Reducing hospital and OPO incentives
   - Living donation by the terminally ill

   The Committee also supported investigating a project recommended by the Executive Committee of the Board to consider the ethical issues in retransplantation when an organ shortage exists. The Committee will prepare project forms for some projects for review by the Policy Oversight Committee.

**Meeting Summaries**

The committee held meetings on the following dates:

- September, 2015
- April, 2015
- September, 2014

Meetings summaries for this Committee are available on the OPTN website at:
http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=3

*OPTN/UNOS Ethics Committee*

# Living Non-Directed Organ Donation White Paper

*Lee Bolton*
*UNOS Policy Department*

# Living Non-Directed Organ Donation White Paper

*Mini-Brief*

## Executive Summary

Beginning in 1993, the Ethics Committee has developed a series of 11 white papers that are available through the OPTN website. In 2014, the Ethics Committee began a systematic review of its white papers so these documents could continue to be valuable resources for the transplant community. The white paper addressing non-directed living donation was completed in June 2004 and was determined to require revision. Members of the Committee revised this white paper during the past year and it is now presented to the Board for consideration.

# Living Non-Directed Organ Donation White Paper

*Affected Policies:* None

*Sponsoring Committee:* Ethics Committee

## What problem will this proposal solve?

The Committee developed a series of thirteen white papers on bioethical issues that are available on the OPTN website. Some of the topics addressed in the white papers include:

- An Evaluation of the Ethics of Presumed Consent
- Financial Incentives for Organ Donation
- The Ethics of Organ Donation from Condemned Prisoners

These resources have not been regularly reviewed on a regular basis. In response, the Committee has reviewed the white papers for accuracy and relevancy and has determined if each white paper should be maintained in its current form, is in need of minor or major revision or should be eliminated because it is no longer relevant.

Based on this review the Committee determined that four papers do not require updates, one paper addressing charges for pancreata recovered for islet transplantation, should be removed and archived, and the eight remaining papers need either minor or substantive revisions.

Work on one white paper requiring substantive revisions has been completed. In June, 2015 the Board approved a revised white paper addressing the ethical principles to be considered in the allocation of human organs.

## Why should you support this proposal?

Over the past year, Ethics Committee members revised a white paper addressing living non-directed donation (NDD). Major changes in this revised version include:

- Adding an extensive list of references to support the recommendations. The original version did not contain references
- Recognizing that NND is now an acceptable option. The prior white paper presented NDD with skepticism which at the time the white paper was written, was commonly construed as such.
- Highlighting the unique aspects of the informed consent process for potential NDDs e.g., new risks to disclose to the potential donor and dispelling antiquated concerns regarding coercion with evidence-based sources now cited.

The Living Donor Committee reviewed and endorsed this revised white paper.

The Board is asked to consider and approve a revised white paper addressing Living Non-Directed Organ Donation.

## How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal

2. *Improve equity in access to transplants:* There is no impact to this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* The white paper addresses living non-directed organ donation donor safety and transplant recipient safety.
5. *Promote the efficient management of the OPTN:* There is no impact to this goal.

## How will the OPTN implement this proposal?

If this resource is approved by the Board, this revised version will replace the current version on the OPTN website.

## How will members implement this proposal?

Members will be able to read and use this ethical resource by accessing it on the OPTN website.

## How will members be evaluated for compliance with this proposal?

This resource does not affect member compliance. Because this proposal is a white paper, consideration and utilization of this resource is voluntary.

## Proposed Modified Resource

**RESOLVED, that the white paper titled Living Non-Directed Organ Donation is hereby approved effective December 1, 2015.**

**Living Non-Directed Organ Donation**

Categories and Definitions

The two basic types of donation of human organs for transplantation are by deceased donors and living donors. Living organ donations can be either: “directed” (i.e., the organ is intended for an individual named or specified by the living organ donor), or “non-directed” (i.e., the organ is intended for an individual neither named nor specified by the donor). Other terms sometimes applied to living “non-directed” donation include “anonymous,” “unspecified,” “community,” “good Samaritan,” and “altruistic” donations. The first three alternate terms for “non-directed” are neutral and do not connote a comparison to directed donation; but the fourth and last terms connote some greater moral value as compared to directed donation. This paper uses only the term “non-directed” donor and donation (NDD) to avoid implying any comparative value to the donation.

The history of living kidney donation is relevant to the ethics of living non-directed donation. The drive to accept non-directed living organ donation came not from transplant programs or candidates, but rather from potential non-directed donors themselves volunteering to be non-directed donors.[1-3] Transplant programs initially did not recruit them, but in recent years non-directed living donor transplants are more commonly accepted, comprising 184 (3.32%) of the 5,536 living donor kidney transplants performed in 2014.[4] (During this same year, there were 280 living liver donors including four cases of non-directed living liver donation). However, some programs remain reluctant to accept non-directed living kidney (or liver) donors.

The Organ Procurement and Transplantation Network (OPTN), through its contract with the United Network of Organ Sharing (UNOS), requires transplant centers to report the relationship between the donor and recipient for every organ transplanted. These relationships must be reported through one of 12 categories or subcategories as described in the following table:

| Major Category | Subcategories | Relationship between donor and recipient |
|---|---|---|
| Biological, blood related | 6 | Parent, child, identical twin, full sibling, half sibling or other relative |
| Non-biological | 2 | Spouse, Life Partner |
| Non-biological, unrelated | 4 | Paired Donation, Anonymous Donation, Domino, Other Unrelated Directed |

The two subcategories of non-biological, unrelated donors not considered non-directed donors include paired donation and domino donation and are described below:

- Paired Donation (Kidney) is the donation and receipt of human kidneys under the following circumstances:
    - An individual (the first living donor) desires to make a living donation of a kidney specifically to a particular patient (the first patient), but the first living donor is biologically incompatible as a donor for the first patient.
    - A second individual (the second living donor) desires to make a living donation of a kidney specifically to a second particular patient (the second patient), but the second living donor is biologically incompatible as a donor for the second patient.
    - The first living donor is biologically compatible as a donor of a kidney for the second patient, and the second living donor is biologically compatible as a donor of a kidney for the first patient. If there is any additional donor-patient pair as described above, each living donor in the group of donor-patient pairs is biologically compatible as a living donor of a kidney for a patient in the group.
    - All donors and patients in the group of donor-patient pairs enter into a single agreement to donate and receive the kidneys, respectively, according to biological compatibility within the group.

Other than described as above, no valuable consideration is knowingly acquired, received, or otherwise transferred for the donation of the kidneys

- Anonymous Donation involves living donors who are not related to or known by the recipient. This type of donation is also referred to as anonymous, or altruistic, non-directed living kidney donation.
- Domino Donation describes two types (heart and liver) of rare transplant procedures. Domino donors include individuals who are undergoing organ transplantation as treatment for a medical problem and whose organ is suitable for transplant to another transplant candidate. [5,6] Domino donors are typically categorized as non-directed donors but it also might be possible for a domino donor to direct the placement of their donated organ. Historically, the term “domino” may have been used to describe participants in kidney paired donation systems. For the OPTN reporting system, domino donation only applies to individuals who are undergoing organ transplantation as treatment for a medical problem and whose organ is suitable for transplant to another transplant candidate.

Anonymous donation is the only subcategory of non-biological, unrelated donors that is considered living non-directed donation. Anonymous donation involves living donors who are not related to or known by the recipient.

Two key characteristics are common to non-directed donors.

1. Non-directed donors give their organ to a stranger; they know neither the identity nor (usually) any characteristics of the recipient before their donation. Most transplant programs do not tell non-directed donors anything about the recipient before the donation, and tell the recipient at most, only general characteristics, e.g., if there is a marked age differential. If, after the surgery, either the donor or recipient does not permit the transplant program to give or receive information

about the other, both the non-directed donor and recipient may never learn any information about the other person and thus never meet. (Given the widespread use of social media and of articles written about living organ donors and recipients, especially when the donor is unusual – i.e., not family - donors or recipients who refuse to let the transplant program give their contact information to the other party may, nevertheless, reveal enough information about themselves that the other party can identify them.) We recommend that the possibility that the donor and recipient may never know or meet each other should be included in the informed consent process for all non-directed donors. Two components of informed consent are distinct for non-directed donors. One is that the donor may never learn who the recipient is, or how well the recipient is doing, etc. If the recipient chooses to remain anonymous to the donor, some donors may become disappointed to not correspond with the recipient. Additionally, if the donor learns about the recipient, the donor may become disappointed learning about certain personal characteristics of the recipient.[7]

2. Non-directed donors initially receive only an indirect benefit from their donation, being self-generated psychological-emotional benefits of helping an unknown person.[8-12] At least initially, non-directed donors (Anonymous subcategory) do not receive a tangible benefit as directed donors could from having a member of their family who is in need of a transplanted organ receiving one (e.g., relief from caregiving, extended time with their loved one). The fact that non-directed donors (Anonymous subcategory) do not receive the tangible benefit of helping a family member was one reason why many transplant professionals were intensely skeptical that such donors were psychologically stable, and some remain skeptical.[13] The initial indirect benefits received by non-directed donors are similar in kind, however, to those received by blood donors and many monetary donors to charities.[1] It is important to point out that potential non-directed donors in a study from the Netherlands, did not fail psychological screening any more than directed donors, had better mental health scores than the general population, and did not develop more mental health problems after donation than did matched non-living-donor controls.[14]

The data for those 12 categories reported to UNOS help us further understand the nature of non-directed living organ donation in the US. The following OPTN data http://optn.transplant.hrsa.gov include data for non-directed donors, defined as those marked as “Non-Biological, Unrelated: Anonymous Donation.” Transplant programs began identifying living donors as non-directed donors in 2002.

- **KIDNEY:** Non-directed donors totaled 1,683 (2.0%) of 82,400 total living kidney donors from January 1, 2002 to June 2015. The percentage of non-directed kidney donations in the period 2010 through June 2015 has been appreciably higher: 3.1% (983) of the 31,631 living kidney donors.

- **LIVER:** From January 1, 2002 through June 2015, 43 (1.1%) of 3,833 living liver donors were non-directed. The percentage increased to 1.4% (20 of 1,480) in the years 2010 through June 2015.

- **LUNG:** The first living lung donation was performed in 1990. From January 1, 2002 through June 2015, only one living lung donation has been from a non-directed donor, but living lung donation in general has become increasingly rare in the past decade.

- **OTHER, with living organ donors:** Data from January 1, 2002-June, 2015 for the following organs showed no non-directed donors: **Kidney / Pancreas** (6 living donors from January 1, 2002-June, 2015); Pancreas (3 living donors from January 1, 2002-June 2015); **Intestine** (29 living donors from January 1, 2002-June, 2015); and **Heart** (1 living donor, a “domino heart-lung donor” from January 1, 2002-June, 2015).

- **OTHER, with no living donors: Heart-Lung** had no living donors.

Informed Consent

The informed consent process for all potential living donors should assure that directed and non-directed donors are competent to make treatment decisions (according to each state’s criteria), have been provided with accurate information, comprehend the information, and are free from undue inducement and coercion.

All the following are required by either or both CMS and OPTN rules and regulations for living donation. Recognizing that transplant surgical techniques are continuously evolving, potential living donors must be given accurate and coherent information regarding their risks of morbidity and mortality, and the post-operative and long-term risks, and be informed that some risks may not yet be known. The potential for psychological, financial, and insurance risks must also be disclosed and understood. In addition, transplant programs must disclose realistic information about the transplantation process, including donor evaluation, surgery, and post-operative follow-up care. Because donation outcomes can significantly affect the donor, transplant programs must provide potential donors with current pertinent post-transplant recipient survival and graft survival data, and clinical risks to potential candidates. The informed consent process must assess that potential living donors comprehend the disclosed information.

The transplant center must assess whether the decision to donate is free from undue inducement, coercion, and other undue influence by exploring the reasons for donating and the nature of the relationship, if any, to the transplant candidate.[15] This process may actually be less complicated with living non-directed donors than with living directed donors because the potential non-directed donors tend to not experience undue influences that can occur in familial/emotional relationships.[16] Therefore, the living non-directed donor's decision may more likely be a voluntary act.

In non-directed donations and paired exchanges, hospitals are required to keep the identities of donors and recipients confidential in order to comply and OPTN and Federal regulations. Ensuring confidentiality should help allow the potential donor to discontinue the donation process, without pressure or possible coercion. However, some programs performing paired donation transplants may have exerted pressure on potential donors to not back out of the chain or to not donate outside the chain.[17] Transplant programs should take steps to avoid such pressure or perceptions of pressure by potential living donors, as well as remind potential donors that they may withdraw from the evaluation process at any time up until the point of surgery.[10,18] Additionally, programs should provide potential non-directed donors in particular with an explanation of how organ allocation policies determine the recipient of their organ. Informed consent must reflect autonomous preferences.

Risk/Benefit Analysis

*Primum non nocere* ("First, do no harm") is one of the most widely recognized principles of medical ethics. Early opponents of living donor transplantation contended that it violated a strict interpretation of this principle. Living donation surgery is an elective procedure for living donors. In living donation, as in other areas of medicine, interpretation of this fundamental precept has evolved. Harm is no longer considered in isolation. The anticipated medical and psychosocial benefit to the recipient is considered in relation to the anticipated harm and potential benefit to the potential living donor, rather than focusing solely on the avoidance of harm to the living donor.

Thus, one of the primary ethical concerns in living donor transplantation is the need to achieve an appropriate balance between risks and potential benefits to living donors. This risk/benefit calculus is complex because it requires deciding if the potential benefits to the recipient and donor justify the risks to the donor and recipient. 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. There are no direct medical benefits to the living donor, but there may be substantial psychosocial benefits, and these benefits vary from person to person, context, and by whether the donation is directed or non-directed.

In directed donor transplantation, because the potential living donor generally knows the recipient as a family relative, friend, or acquaintance, there is an emotional or biological connection between the potential donor and recipient that motivates the potential donor to offer to donate. Thus, the recipient, the donor, and their relationship all may benefit through the living donor transplantation.

Studies show that when the recipient's health improves through a transplant, the donor may take joy in seeing a loved one or friend improve. Some studies report that donors can benefit from donating by gaining self-esteem after donating. This finding applies to both directed and non-directed donation.[11,19]

There are also risks specific to directed donors. For example, the donor-recipient relationship may experience new frictions as some donors negotiate new identities and roles.[11,19] Studies have shown that spousal donations have resulted in divorce due to changes in roles.[20]

By contrast, in non-directed donation, the potential living donor does not know the recipient, which may lead the potential donor to consider different benefits and risks to the recipient and donor. In paired non-directed donation, there are 2 recipients of concern: the recipient of the donor's organ and the donor's intended recipient who will benefit from the donor's donation. However, studies show no significant differences between directed and non-directed donors in their demographic profiles, and physical and psychosocial outcomes.[21,22]

If the donor and recipient are known to each other, the emotional connection between donor and recipient may introduce an element of undue influence or coercion. That same connection may allow the donor to appreciate, gain satisfaction or enjoy the improved health status and quality of life for the recipient after transplant. In living non-directed donation, absent that connection, the donor assumes risk without an obvious or immediate opportunity to share in the recipient's good fortune. However, non-directed donors may perceive other types of psychological and emotional benefits (e.g., self-esteem, religious duty).[11,13,23] Thus, the traditional concern about a lack of obvious potential benefit among non-directed donors that has previously raised questions concerning the non-directed donor's motivation, no longer seems applicable to all or most non-directed donors.

Some scholars have raised comparable concerns about coercion by transplant programs among non-directed donors entering into kidney paired donation exchanges.[17]

Some research has showed that there was no difference in perceived coercion between directed and non-directed donors.[24] However, other reports document that some "compatible donor/recipient pairs" who initially agreed to participate in kidney exchanges have felt pressured by the transplant program to wait for the kidney exchange in order to find a compatible donor in spite of their changed desire for the compatible donor or of their changed preferences to donate to the originally intended recipient immediately.[18] For ethical reasons, programs should avoid exerting such pressure on, and also the perception of being pressured by, the compatible pair.

Donor Motivation

The ethical issues discussed in the preceding sections are pertinent to both living non-directed donation and living-directed donation. However, discussions of these issues originally assumed that a relationship exists between the donor and candidate. The unique challenge posed by non-directed donation stems from the difficulty by some transplant professionals in understanding a person's motivation to donate an organ to a person unknown to the donor.[1-3] When a relationship exists between the donor and candidate, observers more easily appreciate the extent to which the donor is invested in the situation.

Motivation to donate outside the context of such a relationship is more difficult for some transplant clinicians to discern as part of the donor evaluation process. For this reason, offers by non-directed donors are sometimes met with skepticism by transplant providers. 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). The extent to which "altruism" includes psychological self-satisfaction is still debated in ethics and behavioral economics.[25-27]

Maintaining a strict conceptual standard that "altruism" means absolutely no benefit to the donor, 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. Studies have reported that non-directed donation affords non-directed donors the opportunity to improve the life of another human being, personal growth, spiritual benefit, feelings of accomplishment, increased self-esteem, and other beneficial changes in both directed and non-directed donors.[8-12]

Considerations of donor motivation should acknowledge that living organ donation is morally commendable and ethically sound. Rather than attempting to strictly define acceptable motivations to be a non-directed donor, transplant programs should rule out unacceptable circumstances, as they do with all potential living organ donors. For example, expectations of financial compensation, or the desire for recognition or attention, or the desire to form an inappropriate emotional bond with the potential recipient, would comprise unacceptable motivations to proceed with surgery. In addition, emotional or intellectual instability or developmental delays may impede the individual's ability to make an informed decision about donation, and that might be cause for a transplant team to refuse an offer from a non-directed as well as

directed donor. Most importantly, the evaluation process should be collaborative between the potential donor and the transplant center to ensure that the donor's goals and expectations are realistic.

Transplant programs need to respond to inquiries about living non-directed donation according to protocols and policies to ensure that inquiries are handled in an objective, standardized, and thoughtful manner. Such offers should not be dismissed simply because they do not conform to the accepted explanation of why people are living non-directed donors. 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

Non-directed living donor organs are donated with the understanding that, in most cases, the organ recovery center controls the recipient selection process. The recipient should not receive information about the donor. Both donors and recipients understand that the donation process must be anonymous.

If a living non-directed donor and the recipient are in the same center, care should be taken to limit the chance of disclosure of the candidate’s identity. Centers should identify plans to maintain anonymity around vulnerable times of surgery and appointments. Even when these plans are in place, maintaining anonymity is challenging and cannot be guaranteed.

If a non-directed donor or the recipient wish to break anonymity, hospitals should consider all applicable rules or regulations and available guidance on exchanging information between non-directed donors and recipients.

Transplant Program Considerations

A significant number of transplant centers have reported performing non-directed donor transplants with regularity. Therefore, various approaches dealing with non-directed donation are already operational and the practices at these centers must be taken into consideration. Such transplant centers should not exploit the donor and/or the candidate for the private, monetary, or other personal motives of the center or its practitioners. Program marketing, advertising, or the use of media appeals must be based on increasing successful transplants while maintaining safety for donors, and otherwise follow strict standards to prevent the perception of conflicts of interest.

Allocation Considerations

When allocating living non-directed organs to the waiting list, it is important that there be a commitment 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. For non-directed donations to the waiting list, the organs 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.

Donor Follow-Up

Donor follow-up is integral to safety of the donor and the success of any living non-directed donor program. Follow-up cannot be imposed on a donor, but every effort should be made to secure a donor’s agreement to regular follow-up, for the sake of their own health, and for the benefit of future living donors. For those reasons, the current UNOS reporting requirements for living donor follow-up must be followed.

Conclusions

We believe that in most cases, living non-directed donation is an ethically justifiable form of organ donation, so long as:

- A strict standard of informed consent that incorporates information disclosure specific to the non-directed donor is followed;
- The competent potential donor undergoes appropriate medical, psychosocial, and ethical evaluation and screening;

- Donors are protected from undue influence and coercion;
- Respect is given to the individual's autonomous decisions while minimizing her/his exposure to risk;
- Benefits outweigh the risks to the potential donor by donating, regardless of the kinds of benefits to be differentially gained by the non-directed donor compared to the directed donor;
- Safeguards are followed to assure anonymity between the potential donor and the candidate unless both agree to contact each other;
- Organs are allocated in an equitable manner according to existing policies.

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**Report – Ethical Considerations of Imminent Death Donation**

**Revised November 3, 2015**

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## Executive Summary:

An inter-committee work group was formed to consider the ethical implications of Imminent Death Donation (IDD). IDD is a term that has been used for the recovery of a living donor organ immediately prior to an impending and planned withdrawal of ventilator support expected to result in the patient's death.[1] IDD applies to at least two types of potential donors:

(1) IDD might be applicable to an individual with devastating neurologic injury that is considered irreversible and who is not brain dead. The individual would be unable to participate in medical decision-making; therefore decisions about organ donation would be made by a surrogate or might be addressed by the potential donor's advanced directive. We will refer to this specific type of organ donation as follows: Live Donation prior to Planned Withdrawal of Mechanical Life Support from a Neurodevastated Patient (LDPWMLS-NP) to replace IDD. For this report, we will use the shorthand phrase "live donation prior to planned withdrawal" or LD-PPW. This document will limit its focus to LD-PPW.

(2) IDD might also be applied to a patient who has capacity for medical-decision making, is dependent on life-support, has decided not to accept further life support and indicates the desire to donate organs prior to foregoing life support and death. In such cases, no surrogate decision making is needed. An example of this case might be an individual with high cervical spinal cord injury.[2] This report will not address that scenario.

The work group's motivations are to explore whether, compared to existing practices of attempting donation after cardiac death (DCD), the practice of LD-PPW could:

- honor the prior preferences of the potential donor (if known, concerning organ donation or the potential donor's end-of-life care);
- support the preferences of the potential donor's family or surrogate;
- increase the number of potential organ donors
- increase the quality of organs donated for transplantation
- increase the total number of organs available for transplantation

We note that organ donation does not occur among a substantial minority of individuals for whom donation after cardiac death (DCD) is attempted.[3] For these unsuccessful DCD scenarios, withdrawal of life support leads to prolonged warm ischemia time that damages the organs, which are then not procured. While some tools to predict successful DCD exist, their predictive accuracy is uncertain.[4] Occurrences of unsuccessful DCD may be viewed as both a lost opportunity for transplantation, as well as disappointing to the surrogates of the potential donor.[5] In other cases, prolonged warm ischemia may damage organs that are transplanted, leading to post-transplant complications. Additionally, there may be potential non-brain dead donors for whom

organ procurement is never attempted, because of the belief that DCD would be unsuccessful.

lack of data renders the work group unable to conclude whether the net number of transplants might decline or increase if LD-PPW is widely adopted. The effect on the number of transplants may depend, to a substantial degree, on how many organs are typically procured through the practice of LD-PPW. LD-PPW might increase the number of donated organs and transplants if organs were procured from donors who would not have been considered for organ donation if DCD were the only option, or if LD-PPW took place in conjunction with DCD.

After consideration of possible intended and unintended consequences, and if analysis supports LD-PPW as an ethically acceptable practice, then OPTN bylaws and policy modification would be required to accommodate LD-PPW. Additionally, it will be important to determine if LD-PPW would violate any regulations from the Centers for Medicare and Medicaid Services or any other relevant laws or guidelines.

Background:

Beginning in 2013, the Ethics Committee (the Committee) identified IDD as a potential donation practice being discussed in the literature and at national conferences. During its March, 2014 meeting, the Committee began to consider the ethical issues that could be associated with IDD and approved the following position statement:

> The Ethics Committee recognizes that Imminent Death Donation is an emerging donation practice that may be ethical under certain circumstances but understands that significant ethical, clinical and practical concerns must be addressed before policy development can be considered. The Committee therefore recommends that a joint subcommittee be formed including the Kidney, OPO, Living Donation, and Ethics Committees to further explore IDD and address concerns.

In June 2014, the Committee included this position statement in its report to the Board. The Board took no official action regarding the position statement. However, at this same meeting, the Board did approve a set of new proposed projects which included a project to investigate the Ethical Considerations of Imminent Death Donation.

In response to this approved project, a work group was established with representatives from the Operations and Safety, OPO, Living Donor and Ethics Committees.

The work group represented a wide range of opinions with some members initially expressing significant concerns about IDD and whether or not it should ever be permissible, while other members supported IDD as an organ donation option that could increase the availability of organs for transplantation. The work group took into consideration that cases of IDD have occurred in the past in the US.[5] The OPTN is aware of 5 living kidney donors who were reported to have died shortly after donation from conditions that existed before their donations. Their causes of death include coma, brain hemorrhage, infant anencephaly, respiratory failure, and acute hemorrhage. The work group did ultimately support continued discussion regarding IDD.

The work group met several times via conference call and agreed, as a first step, to identify the primary ethical issues and to consider whether these ethical concerns could

be adequately addressed by establishing specific conditions and limitations under which IDD might occur.

The work group subsequently decided to limit its focus to LD-PPW. Revisions to membership requirements in the Bylaws and OPTN policies would be required in order to facilitate LD-PPW-NP, such as accommodating surrogate consent on behalf of the neurodevastated patient. Policy that addresses the recovery and placement of living donor organs and the allocation of non-directed living donor organs would also need modification to facilitate LD-PPW.

Furthermore, under current policy and bylaws, the living donor death could need to be reported as an adverse donor outcome, and would impact a hospital's performance measures unless relevant policies and bylaws were amended.

Analysis:

The work group identified the following ethical concerns, operational considerations and possible policy modifications regarding LD-PPW.

1. Potential for the perception that LD-PPW erodes the Dead Donor Rule - The dead donor rule is an ethical norm related to deceased organ donation that is often expressed as; 1. Organ donors must be dead before procurement of organs begins, or 2. Organ procurement itself must not cause the death of the donor.

   The person being considered for LD-PPW would be categorized as a living donor at the time of organ recovery. It is expected that the living donor would not be adversely impacted by organ procurement and would subsequently die when life support is withdrawn. Additionally, organ procurement through LD-PPW could itself cause the donor's death in the event of a surgical complication. Consequently, preserving the Dead Donor Rule was identified by the work group as a primary concern.

   a ) Initially, LD-PPW should be limited to donating one of two functioning kidneys.
   b) The ability to donate a single kidney, while not risk-free, is routinely performed in living donors and the attendant risks of death have been considered acceptable. However, because the IDD candidate is critically ill, there may be heightened concerns that a nephrectomy could hasten death (as compared to the healthy living kidney donor). If the donor died due to procurement of a kidney (or other organs), this could be viewed as a violation of the Dead Donor Rule. The doctrine of double effect could help address this concern.
   c) The doctrine (or principle) of double effect is often invoked to explain the permissibility of an action that causes a serious harm, such as the death of a human being, as a side effect of promoting some good end. However, this doctrine is not universally accepted.
   d) The work group recognizes that, compared to single nephrectomy, the donation of some other organs or combinations of organs or tissues via LD-PPW may have a higher probability of hastening death. However, if the option for LD-PPW is pursued, a reasonable first step could be to commence the practice using single nephrectomy which presumably has a lower risk of hastening death compared to double nephrectomy, liver lobe donation or multi-organ donation.

e) Most pediatric living donation would be prohibited under existing policy. If pediatric LD-PPW is to be considered, special considerations would need to be established to reduce the likelihood that that IDD could hasten death.

2.Appropriateness of surrogate consent for LD-PPW - Because the potential donor is incapacitated, he or she would not be able to provide informed consent for living donation, and consent for donation would need to be provided by a surrogate in most cases. Some work group members expressed concerns about the appropriateness of surrogate consent for surgery that does not benefit the donor's health or well-being. The work group opined that it could be appropriate for a surrogate to provide authorization for LD-PPW if they knew the potential donor had been supportive of organ donation. However, the work group also noted that surrogates have a high level of responsibility for many other, highly consequential aspects of the potential donor's care, including the decision to withdraw life support.

The following considerations are relevant and may reduce the ethical concerns regarding surrogate consent:

a) The potential donor had previously expressed a desire or had taken prior action towards becoming a living donor. Prior action could include expressed wishes, documented evidence, or prior evaluation for living organ donation. Evidence of this would show the patient's intent to be a living donor and could be considered as part of a substituted judgment.

   The Substituted-Judgment Doctrine is a principle that allows a surrogate decision-maker to attempt to establish, with as much accuracy as possible, what decision an incompetent patient would make if he or she were competent to do so. In theory, the doctrine of substituted judgment looks to the individual to determine what he or she would do in a particular situation if she were competent. This doctrine is applicable to situations where a person, once competent, is rendered incompetent to consent to medical procedures through injury or disease. The once competent person has developed a system of morals and beliefs, and patterns of behavior, which the court can examine when evaluating what he or she would do in a particular situation.

b) The potential donor had registered to be a deceased donor or expressed the desire to be a deceased donor. While authorizing deceased donation is not ethically or legally equivalent to consent for living donation, the fact that the patient wanted to be an organ donor could be relevant to a substituted judgment analysis.

c) It is important that the decision-maker be an appropriate surrogate for the patient. This principle is generally well established by law and hospital policy. In the context of LD-PPW, there is already a surrogate making the decision to withdraw the mechanical support (with death an expected outcome). Additional criteria could be developed to establish requirements that the surrogate knew the background and values of the patient as it relates to donation. One possibility is, as a matter of OPTN policy, to limit surrogate consent for LD-PPW to an appointed durable power of attorney or

health care proxy. However, others questioned why durable power of attorney or health care proxy status would be appropriate, if they were not required for the surrogate to make the decision to withdraw support.

d) Parameters for surrogate consent in cases of potential pediatric donors need to be established. As an alternative, LD-PPW could be limited to adult patients. In the pediatric context, the best interest standard is commonly utilized rather than substituted judgment as the patient may be too young to have formed values or wishes relevant to donation. Also, in most circumstances there will not be a health care proxy agent or power of attorney. Alternatively a guardian ad litem could be appointed although again this would add a significant step beyond what is required for the parents to consent to withdrawal of ventilator support.

e) For initial cases of LD-PPW, an ethics consultation could add value to assess the adequacy of the surrogate and to assist in ensuring a surrogate decision for LD-PPW is ethically appropriate given the specifics of a case.

3.<u>LD-PPW Candidates as a Vulnerable Population</u> - Potential donors being considered for LD-PPW are a vulnerable population because they are neuro-devastated, incapacitated and near death. There are additional related-considerations:

a) A mechanism to ensure adequate perioperative pain management. Pain control would be important both during and after nephrectomy. After nephrectomy, it is not clear how withdrawal of ventilator support would occur. Would the ventilator be discontinued while the potential donor is still under anesthesia to ensure pain relief? This raises similar issues faced at end of life care regarding a balance between pain management and hastening death. Again the doctrine of double effect may be helpful to resolve the ethical issue but some practical considerations remain.

4.<u>Identifying appropriate candidates for LD-PPW</u>

a) Families or surrogates should not be approached regarding IDD as an option until withdrawal of support had been discussed and planned to occur within a relatively short period of time (within days, not weeks).

b) The work group discussed the importance and difficulty of assessing the probability of death after planned withdrawal of life support on a case-by-case basis.

c ) The work group discussed options for presenting LD-PPW and reconciling the practices of LD-PPW and DCD. The decision to withdraw life support must be separated from the discussion of the options for donation, just as has been established for DCD. After the decision to withdraw life support is made, several approaches to discussing LD-PPW could be considered:

- Both DCD and LD-PPW could be presented as equal options without indicating preference for either option
- LD-PPW could only be discussed with surrogates in certain circumstances, such as when DCD is unlikely to be successful

- DCD could be framed as the usual practice (default option), but LD-PPW would also need to be discussed
- LD-PPW could be offered only when the family independently requests this option, however this would limit it to better informed families or surrogates
- Additionally, when LD-PPW is discussed, teams must be prepared to decide whether LD-PPW followed by DCD is an option

5.Public Trust - The work group discussed the possibility that LD-PPW could be perceived by the public as violating the Dead Donor rule. The concern was raised that LD-PPW would reinforce the perception that the donation and transplant community look like "vultures". However, the effect of LD-PPW is difficult to predict. Some ethicists have suggested that practices such as LD-PPW-NP might instead be welcomed by some families if it were perceived as another viable approach to supporting the surrogate's preferences for end-of-life care for the potential donor.[6]

6.Operational / practical /policy considerations - There are a number of operational and practical concerns - some of which raise ethical issues that would need to be carefully considered.

a) Much of the policy and clinical practice of living donor evaluation is focused on establishing that the long-term risks of donation to the donor's health are reasonable in relation to the benefits to be gained (i.e. health benefits for the recipient and non-medical benefits for some donors), and that the donor has a thorough understanding of the potential risks and benefits of the donation decision. However, neither of those considerations pertains to the LD-PPW scenario. In this scenario, the potential donor is not expected to have long-term survival. The potential donor does not have the ability to participate in medical decision-making. The surrogate's decisions about organ donation may be primarily viewed from the perspective of appropriate end-of-life care, rather than weighing adverse long-term health effects due to organ procurement. Given these distinctions between the existing practice of live organ donation vs. LD-PPW, some OPTN policy related to living donation (as it applied to LD-PPW) would merit revision if LD-PPW were to be more widely adopted.
b) As currently considered, LD-PPW could only occur in an OPTN member hospital. This is because OPTN policy restricts recovery of living donor organs to OPTN member transplant centers. Also, transplant surgeons cannot travel to a different hospital to perform a living donor nephrectomy given medical licensure and credentialing requirements under applicable state law and hospital policy. Accordingly, in some cases, an LD-PPW candidate would need to be transferred to an OPTN member hospital to facilitate organ recovery. Transferring a LD-PPW candidate would add a significant step beyond what is required for the candidate's family or surrogate to consent to withdrawal of ventilator support. There would be significant costs and logistical challenges to moving a patient from the primary donation hospital to a transplant center. Other stakeholders, such as anesthesia or hospital leaders responsible for allocation of scarce

resources such as ICU beds and operating room suites would also need to be engaged.

c) Under current policy, OPOs are responsible for the deceased donor authorization process, medical evaluation, organ recovery and allocation of deceased donor organs, while living donor hospitals are responsible for the informed consent process, medical evaluation, organ recovery and placement of living donor organs.
There could need to be reconsideration and potential changes to these roles in the setting of LD-PPW. Aspects of the LD-PPW process could be similar to deceased donation in which the OPO coordinates the evaluation of the potential donor and the organ recovery in a compressed period of time. Aspects of LD-PPW could be similar to DCD which is required to be coordinated by the OPO.

d) As currently envisioned, responsibility for the informed consent of the donor surrogate and medical evaluation of the potential LD-PPW donor would remain the responsibility of the medical staff that could perform the nephrectomy.

e) If the potential donor is an LD-PPW candidate, the OPO could take responsibility for approaching the donor's surrogate to first evaluate the candidate as a potential DCD donor. If the potential living donor does not meet DCD criteria (including the possibility that the family expresses preference for LD-PPW), the OPO could discuss LD-PPW with the donor's surrogates.

f) As described, the OPO could need to coordinate allocation of the donated kidney to the deceased donor waitlist. Under this scenario, the roles and responsibilities of the recovery hospital and the OPO would need to be carefully delineated.

g) The OPTN/UNOS and CMS could need to segregate outcome data from LD-PPW so that the anticipated death after the donation would not be characterized as a living donor death which could negatively impact program's living donor outcome metrics.

h) OPTN policy that covers living donation, including informed consent, medical evaluation, psychosocial evaluation, follow-up, and required reporting of living donor death, would need to be reviewed and modified to accommodate LD-PPW.

7. Potential Benefits -The work group identified potential benefits of LD-PPW to organ recipients, donor families and donor hospitals:

- Potential for increased availability of organs for transplantation; non-progression during attempted DCD results in hundreds or thousands of non-donated organs each year[3]
- Reduced organ ischemic time with better recipient outcomes (less delayed graft failure)
- Fulfilling the patient's previously indicated or document decision to be a donor

- Emotional benefit to donor family's grief process through the increased potential of LD-PPW donation versus DCD. In some cases, the LD-PPW has been requested and driven by donor families
- Better process and timing for some families than DCD
- Avoid wasted hospital resources, reduces costs and staff frustration that may follow when DCD not occur

8. Potential Harms - The work group recognized that the controversy over LD-PPW has the potential to erode public trust in donation in general. There could be a misperception that families will be under undue pressure to donate organs prior to the patient's death and withdraw ventilator support in circumstances where a patient would otherwise recover. This potential harm needs to be carefully considered. Clear requirements for when LD-PPW could proceed could help address this concern.
After the process of evaluation of LD-PPW has begun, the transplant team may decline a donor and an unfulfilled donation request could worsen the family grieving process, if seen as a rejection.

Finally, as described above, LD-PPW would be performed in circumstances where a thorough evaluation has determined that the potential donor's neurological injury is severe and unlikely to reverse. Despite this evaluation, it is possible that, rarely, an individual might still be capable of neurologic recovery and survive withdrawal of life support.[3] That individual's long-term health might be harmed by organ procurement. A recent cohort study of 136 attempted DCD cases reported one individual who survived withdrawal of mechanical life support and was alive 1.5 years later. Minimal information was available about the circumstances of this attempted DCD. To guard against this type of situation, OPTN policy might require that certain standards for neurological prognosis be met before LD-PPW was permitted.

9. Potential Unintended Consequences - The field is not very accurate in predicting whether potential DCD donors will become actual donors. If a potential donor does meet DCD criteria, that donor could donate two kidneys and other organs. Therefore, it is possible LD-PPW could negatively impact the current volume of organs available for transplant. If LD-PPW was viewed as an alternative to DCD or a preferred pathway to DCD (rather than an additional option when DCD is not viable), it could result in a single kidney available for transplant compared to the potential for two kidney and other organs that might be recovered under DCD protocols.

## Conclusion

Ultimately the work group determined that there could be circumstances where LD-PPW may be ethically appropriate and justified by the potential benefits to donors, donor families and recipients. Significant ethical challenges remain but may be possible to adequately address through careful policy development or revision. It is recommended that the potential for LD-PPW, and the associated risks, be better understood before considering policy development in order to support the utility of this emerging and controversial donation practice.

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