At-a-Glance

- **Proposal for the Placement of Non-Directed Living Donor Kidneys**

- **New Proposed Policy: Placement of Non-Directed Living Donor Kidneys (Policy 12.5.6)**

- **Living Donor Committee**

  This proposal would establish procedures for the placement of non-directed living donor kidneys. Under the proposal, transplant centers would select the recipient of non-directed living donor kidneys based on a match run.

- **Affected Groups**

  Lab Directors/Supervisors
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  PR/Public Education Staff
  Transplant Program Directors
  Transplant Social Workers
  Transplant Coordinators
  Independent Donor Advocates
  Organ Recipients
  Organ Candidates
  Living Donors
  Donor Family Members
  General Public

- **Specific Requests for Comment**

  The Living Donor Committee welcomes feedback on all aspects of this proposal.

Proposal for the Placement of Non-Directed Living Donor Kidneys

New Policy: Placement of Non-Directed Living Donor Kidneys (Policy 12.5.6)

Living Donor Committee

Summary and Goals of the Proposal:

This proposal would establish procedures for the placement of non-directed living donor kidneys. Under the proposal, transplant centers would select the recipient of non-directed living donor kidneys based on a list generated by the OPTN computer system used to identify potential recipients for transplant. This list is referred to as a match run. The goal of this proposal is to foster equitable organ placement and safety of the recipient.

Background and Significance of the Proposal:

Currently, there is no existing Organ Procurement and Transplantation Network/United Network for Organ Sharing (OPTN/UNOS) policy to direct the placement of organs from non-directed living donors. Due to the infrequency of non-directed liver and lung donation, the Living Donor Committee is proposing a policy limited to living kidney donors at this time. Additionally, the current proposal will not apply to non-directed living kidney donors who consent to participate in a Kidney Paired Donation arrangement. Based on available information, the Committee understands that the transplant center providing the non-directed living donor evaluation typically also selects the recipient when donation occurs.

As one of its 2007-2008 goals, the Committee was asked to consider if components of the OPTN/UNOS Ethics Committee white paper titled Living Non-Directed Organ Donation (2004) should become policy. The white paper proposed "*that non-directed organs from living donors be allocated according to the existing algorithm governing the allocation of cadaveric organs within the appropriate sharing unit,"* and is available for review at http://www.unos.org/resources/bioethics.asp.

The Ethics Committee white paper was published prior to the 2006 federal regulation that directed the OPTN to develop policies for the equitable allocation of living donor organs. The Committee determined that policies for the placement of non-directed living donor organs were needed, and considered whether those policies should be based on the existing algorithm used to direct allocation of deceased donor organs.

Over the past several years, the Committee worked to develop an evidence based policy proposal to direct the placement of non-directed living kidney donors. Work on this policy issue was complicated and the Committee struggled with the following issues:

- Does the provision and financing of the medical evaluation of a potential living kidney donor entitle a transplant center to direct placement of that kidney?

- Should non-directed living donor kidneys be offered to the best candidates on a local, regional or even national level?

The Committee reviewed studies on the effects of cold ischemia time on living donor kidneys and did not find that the biological risk to the organ was great enough to warrant limitation to the recovery center. However, there is a small but increased risk of damage or loss of a living donor kidney if transported outside of the organ recovery center. Therefore, the Committee determined that placement at the evaluating and recovery center is appropriate.

Due to the high cost associated with evaluating a potential living kidney donor (estimated at $15,000 to $25,000 by Committee members familiar with the evaluation of living donors), the Committee ultimately supported allowing the center that evaluates a non-directed living kidney donor to place that kidney with one of its own candidates on the waiting list. Additionally, the LD Committee is proposing that the placement of non-directed living donor kidneys be based on the existing algorithm used for allocation of deceased donor organs. In developing this recommendation, the Committee considered the small but increased risk of damage or loss of a living donor kidney if transported outside the organ recovery center.

The proposal will not affect how transplant centers select, evaluate and/or approves potential non-directed living kidney donors. When a transplant center approves a non-directed living kidney donor for donation, the center would continue to add donor information in UNet^{sm} with the Living Donor Feedback Form in Tiedi to obtain a donor identification (ID) number.

This proposed policy outlines the following process for placement of a kidney from a non-directed living kidney donor:

- The transplant center will contact the Organ Center to request a match for a non-directed living kidney donor;
- The transplant program will complete and return a form to the Organ Center with the following required donor information:
    - the donor ID
    - ABO testing, including two separate verifications and supporting documentation
    - HLA typing with supporting documentation
    - donor height and weight
    - serological testing (Anti-HCV, Anti-HBcAb, and optional Anti-HTLV I/II)
    - history of hypertension or diabetes

- The Organ Center will update the donor's record in DonorNet with the data required for the match run;
- The transplant center will be asked to verify all information that will be used for the match run;
- If verified, the Organ Center will complete the match run to generate the match ID;
- The Organ Center will close the match at zero, and forward the Match ID to the Transplant Center (closing the match at zero, will prevent the match from appearing on any reports generated by the Organ Procurement Organization);
- The transplant center will use the Match ID to access a list of potential recipients on its waitlist;
- The center will select a recipient from its waitlist candidates to receive the non-directed living donor kidney; and
- If the center deviates from the match run, it must document the criteria used to direct placement of the kidney, and make the documentation available if requested by the OPTN contractor.

The Committee recognizes that some transplant centers work with a local OPO to match non-directed living kidney donors and recipients. In such cases, the transplant center may obtain the match run of its waitlist candidates from the OPO. Transplant centers, that do not work with an OPO to match non-directed kidney donors with potential recipients will not have the ability to generate a match run of their wait list candidates, and consequently would be required to use the OPTN/UNOS Organ Center. The Committee would support possible future enhancements to DonorNet to permit transplant centers to complete match runs of their own waitlist candidates.

An overarching goal of the policy proposal is that a match run is generated and followed for the placement of all non-directed living donor kidneys. The current matching system used for deceased organ donors was designed to improve patient safety. The system checks for donor/recipient compatibility. Using a match run can improve patient safety by increasing the likelihood that the donor and recipient are truly compatible.

The Committee understands that medical judgment is an important factor in selecting the most appropriate candidate to receive a non-directed living donor kidney. Therefore, the policy proposal permits a center to direct a non-directed living donor kidney to a candidate who may not appear first on the center's match run. If the center deviates from the match run, it must document the criteria for this decision. This policy proposal requires that the center maintain such documentation and that the documentation be made available to the OPTN contractor if requested. The intent of the proposal is that such documentation will only be requested should there be a need to investigate the placement of a non-directed living donor organ.

During the early development of the policy proposal, the Committee asked the Policy Oversight Committee to review and comment on components of the proposal on three separate occasions. The Policy Oversight Committee interpreted the proposal as a recommendation for transplant centers to obtain a match run of their waitlist candidates and that the non-directed kidney would be placed according to the match run, thus allowing the OPTN contractor to verify the non-directed living donor kidney was directed to the most appropriate waitlist candidate. The Committee also sought comment on whether these organs should be offered to the best match at the local, regional or national level.

When the Policy Oversight Committee considered the proposal there were 511 non-directed living donors in the OPTN database. The Policy Oversight Committee commented that 1) the number of non-directed donors could increase with kidney paired donation, 2) we have a fair and equitable national allocation system and should want to ensure fair allocation for non-directed donation, 3) if a person makes a non-directed donation to a center, that act may take the decision out of the realm of the national policy.

During the development of this policy proposal the American Society of Transplant Surgeons (ASTS) Ad Hoc Committee on Living Donation issued a statement regarding the placement of non-directed living donor organs which is similar in scope and intent to this proposal. **(Exhibit A)**

Supporting Evidence

There is very limited evidence available for the development of this proposal. Since 1998, there have been 728 non-directed living donors, and the Committee anticipates that this number will grow with the

general increasing trend of living donation and kidney paired donation. Additionally, the Committee reviewed studies on the effects of cold ischemic time on living donor kidneys and did not find that the biological risk to the organ was great enough to warrant limitation to the recovery center. However, there is thought to be a small but increased risk of damage or loss of a living donor kidney if transported outside of the organ recovery center. Therefore, the Committee determined that placement at the evaluating center is appropriate.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

The Final Rule states that allocation policies shall be designed to achieve equitable allocation of organs among patients through performance goals which include setting priority rankings expressed, to the extent possible, through objective and measurable medical criteria for patients or categories of patients who are medically suitable candidates for transplantation to receive transplants. These rankings shall be ordered from most to least medically urgent, and in particular in accordance with sound medical judgment, that life sustaining technology allows alternative approaches to setting priority ranking for patients)[1].

- Patient Safety
    - The proposed policy would require that non-directed living donor kidneys are placed with a recipient based on a match run. The use of a match run will help to prevent donor and recipient incompatibility. The proposal allows for medical judgment in selecting the most appropriate candidate to receive a non-directed living donor kidney.
- Best Use
    - The proposed policy will help ensure the best use of living donor organs. New record keeping requirements under the proposed policy could contribute to the refinement of future OPTN living donation policies.

- Operational Effectiveness
    - The proposed policy would, for the first time, establish rules and standardization of the placement of non-directed living donor kidneys.

The policy proposal addresses the following four strategic plan goals:

- Refine allocation policies, incorporating concepts of:
    - donor risk
    - recipient benefit, and net benefit

- Optimize a safe environment for living donor transplantation

- Improve compliance with policies to protect patient safety and preserve public trust

- Improve the OPTN data system

---

[1] **ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN) FINAL RULE AS REVISED BY AMENDMENTS.** October 20, 1999. § 121.8 Identification of organ recipient. (b)(2)

Plan for Evaluating the Proposal:

To the extent possible, the LD Committee will monitor complaints involving the placement of non-directed living donor kidneys. Actual investigation of such complaints would be handled by the UNOS Department of Evaluation and Quality (DEQ) and if necessary the OPTN/UNOS Membership and Professional Standards Committee (MPSC).

Additional Data Collection:

Under the proposal, additional data collection would be required. The transplant center would be required to obtain a match run for non-directed living kidney donors. The match run may be obtained from its local OPO or the OPTN/UNOS Organ Center. The transplant center must document the criteria used to place the non-directed living donor kidney. If the center does not follow the match run, it must document the criteria used to select the kidney recipient. The documentation must be maintained and made available to the OPTN contractor upon request.

The proposal meets the following data collection principles:

- Develop transplant, donation and allocation policies
- Determine member-specific performance
- Ensure patient safety when no alternative sources of data exist
- Fulfill the requirements of the OPTN Final Rule

Expected Implementation Plan:

Based on public comment, these proposed new policies may be considered by the OPTN/UNOS Board of Directors at its November 8-9, 2010 meeting. If considered and approved by the Board, the policies would become effective on December 9, 2010. This date would be 30 days after the transplant community receives notification of the OPTN/UNOS Board of Director's approval of the policy.

Communication and Education Plan:

Communication Activities			
Type of Communication	**Audience(s)**	**Delivery Method(s)**	**Timeframe**
Policy Notice	Lab Directors/Supervisors Transplant Administrators Transplant Data Coordinators Transplant Physicians/Surgeons PR/Public Education Staff Transplant Program Directors Transplant Social Workers Transplant Coordinators Independent Donor Advocates Organ Recipients	E-mail	30 days after Board approval

	Organ Candidates Living Donors Donor Family Members General Public Members		

Monitoring and Evaluation:

Current Plan

The DEQ will monitor for the presence of match run documentation during on-site and desk reviews.

All potential policy violations identified will be sent to the MPSC for review.

Future Monitoring Efforts

Once programming is complete and centers are able to run their own match runs, DEQ will monitor all living donor match runs that resulted in a transplant. To ensure equitable allocation, DEQ will verify that the center evaluated the available organ according to the sequential printout of the match for each potential transplant recipient. DEQ will also verify that all candidates appearing before the actual recipient of the organ are documented with an appropriate refusal code. The match run must show acceptance to the candidate for whom the organ is ultimately accepted. All potential policy violations identified will be sent to the MPSC for review.

Policy or Bylaw Proposal:

12.5.6 Placement of Non-directed Living Donor Organs

> Prior to determining the placement of a non-directed living donor kidney, the transplant center must acquire a match run of its waitlist candidates. The transplant center may obtain the match run from its local OPO or the Organ Center of the OPTN Contractor. The transplant center must document the criteria used to place the non-directed living donor kidney. If the transplant center deviates from the sequence defined by the match run, the transplant center must document its rationale for not following the match run in addition to documenting the criteria used to select the kidney recipient. This documentation must be maintained and made available to the OPTN contractor upon request.

Statement on Volunteer Non-Directed Live Donors

Proposed Distribution Guidelines for Kidneys Recovered from Volunteer Non-Directed Live Donors

While the goal of broad sharing of kidneys from volunteer non-directed live donors is felt to be desirable by the ASTS Ad Hoc Committee on Living Donation, the current reimbursement regulations place the financial burden for evaluating potential donors solely on the shoulders of the evaluating hospital. The ASTS Ad Hoc Committee on Living Donation favors modification of these reimbursement policies which would, in turn, remove a potent disincentive for broader sharing. At this time, however***, it is the committee's recommendation that organs recovered from volunteer non-directed live donors be allocated to recipients on the UNOS waiting list as determined by the UNOS match run with priority considered to recipients listed at the donor hospital or entering into a paired donation exchange.***

Although some volunteer non-directed live donors may contact a donor hospital of their choice directly, others will contact an OPO or an organization such as NKF. The ASTS Ad Hoc Committee on Living Donation would suggest that OPOs and the NKF provide patients with a list of transplant centers in the OPO service area which could, and would be willing to, perform the kidney donation and living donor kidney transplant. It is well recognized that only a fraction of potential living kidney donors actually donate an organ and the costs of evaluating these patients can be significant. Centers which do not wish to participate in the evaluation of volunteer non-directed live donors and the subsequent transplantation of kidneys derived from volunteer non-directed live donors should have the option to not participate in such a program. The names of these programs would not be included in the list provided by the OPO or by NKF.

The committee believes that the above policy would provide a fair and equitable means for patients (donors and recipients) to immediately participate in and benefit from kidney transplantation from volunteer live donors while contemporaneous efforts are made modify reimbursement policies that currently inhibit broader sharing at the local, regional, or national levels.

Exhibit A