At-a-Glance

- **Proposal to modify the high risk donor policy to protect the confidential health information of potential living donors**
- **Policy affected: Policy 4.1.1 (Communication of Donor History)**
- **Living Donor Committee**

  In its current form, Policy 4.1.1 (Communication of Donor History) requires that potential organ recipients be informed if their donor has a high risk status. The proposed policy changes would provide the potential living donor with the ability to discontinue the donation process rather than have their high risk status disclosed to a potential recipient or transplant center. This proposed change is designed to protect the health information of potential living donors.

- **Affected groups**

  Living Donors, Candidates for Living Donor Organs, Transplant Administrators, Transplant Coordinators, Transplant Physicians/Surgeons, Transplant Program Directors, Donor Family Member, General Public

Proposal to modify the high risk donor policy to protect the confidential health information of potential living donors

Policy affected: Policy 4.1.1 (Communication of Donor History)

Living Donor Committee

Summary of the Proposal:

In its current form, Policy 4.1.1 (Communication of Donor History) requires that potential organ recipients be informed if their donor has a high risk status. The proposed policy changes would provide the potential living donor with the ability to discontinue the donation process rather than have their high risk status disclosed to a potential recipient or transplant center. This proposed change is designed to protect the health information of potential living donors.

Background and Significance of the Proposal:

In June 2007, the OPTN/UNOS Operations Committee requested public comment on proposed modifications to the Communication of Donor History Policy. Public comment was being requested on Organ Procurement Organization (OPO) and transplant center requirements for screening, communicating and reporting all potential or confirmed donor-related disease and malignancy transmission events. This proposal was intended to reflect current clinical practices and to standardize reporting of donor-related disease transmission events, thus improving patient safety and recipient outcomes through timely communication of clinically significant information. The modified policy proposal was in response to recent occurrences of donor related infection and malignancy transmission that illustrated potential gaps in both the microbiologic screening of organ donors and the mechanisms to communicate and investigate transmission events associated with transplantation.

At that time, the Living Donor (LD) Committee supported the intent of the proposed changes and agreed that information on **deceased** donors with high risk behavior, or classified as high risk based on CDC criteria, should be communicated to all institutions receiving organs from the donor and to the potential organ recipient. However, during this same public comment period, some UNOS Committees and regions submitted comments questioning if the policy would also apply to living donors.

Since public comment demonstrated confusion about the intent of the policy, the LD Committee became concerned that the policy could be applied to living donors. Specifically, that a potential living donor might not be provided the opportunity to discontinue the donation process rather than have their high risk status disclosed to a potential recipient or recipient transplant center.

In response, the LD Committee commented that the policy proposal should be modified to clarify it did not apply to potential living donors. The concerns of the Committee were not addressed because the proposal was not considered by the OPTN/UNOS Board after the conclusion of the June 2007 public comment period.

In December 2007, the Executive Committee approved policy language to require that transplant centers inform potential organ recipients about any known high risk behavior (as defined by CDC

Guidelines) by the donor. The intent of this policy was to clarify the criteria for high risk behavior that requires transplant professionals to notify potential organ recipients prior to implantation. This policy was approved prior to public comment to address potential patient safety issues.

The Executive Committee did not modify the existing policy language following the conclusion of public comment. Consequently, the policy does not address concerns from the LD Committee because, in its final form, the policy did not specify it would not apply to potential living donors.

Health information for all persons must be protected. The Health Insurance and Portabiltiy and Accountability Act (HIPAA) Privacy Rule (2003) regulates the use and disclosure of Protected Health Information. Wikipedia defines Protected Health Information as any information held by a covered entity which concerns health status, provision of health care, or payment for health care that can be linked to an individual. Protected Health Information is interpreted rather broadly and includes any part of an individual's medical record or payment history (http://en.wikipedia.org/wiki/HIPAA).

In its current form, the policy may be applied to potential living donors. In response, the LD Committee is again seeking a modification for policy 4.1.1 to provide potential living donors an opportunity to discontinue the evaluation or donation process rather than have their health information disclosed to any other institution or potential recipient.

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

The policy proposal addresses 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

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

This policy will not require programming in UNet^{sm}. Implementation would be effective pending OPTN/UNOS Board approval and transplant community notification

Communication and Education Plan:

If approved by the Board of Directors, the transplant community will receive information regarding this new policy language via the notice that follows each Board meeting.

Monitoring and Evaluation:

OPOs and transplant centers will be expected to comply with this policy. The UNOS Department of Evaluation and Quality (DEQ) staff will evaluate member compliance with this policy.

If applicable OPOs are expected to:

- Obtain a donor history for each potential donor
- Evaluate each donor's history to determine if the donor is "high risk" according to the criteria identified by the Centers for Disease Control and Prevention (CDC)
- Inform the transplant center of the donor's specific behaviors or history that places the donor in a "high risk" group according to the CDC criteria defined in the CDC Guidelines
- Indicate in DonorNet® that the donor meets the CDC definition of high risk
- Maintain documentation that the donor's history has been communicated to the transplant center
- Offer living donors the option to discontinue the donation process rather than have their "high risk" status communicated to the institution intended to receive their organs

If applicable Transplant centers are expected to:

- Be familiar with the criterion defined by the CDC that places a donor in a high risk group for transmitting HIV through transplantation
- Indicate in DonorNet® that the donor meets the CDC definition of high risk
- Inform the potential recipient, legal next of kin, designated healthcare representative, or appropriate surrogate of the donor's specific behaviors or history that places the donor in a "high risk" group, as defined by the CDC, prior to implantation of the organ
- Obtain and document informed consent from the potential recipient, legal next of kin, designated healthcare representative, or appropriate surrogate prior to implantation when the organ is from a donor who meets the CDC definition of "high risk"
- Maintain all documentation pertaining to communication of donor history and informed consent, and make this documentation available upon request
- Offer living donors the option to discontinue the donation process rather than have their "high risk" status communicated to the intended recipient

The Department of Evaluation and Quality (DEQ) staff may detect potential violations of this proposed policy by:

- Requesting documentation from OPOs and Transplant Centers for donors who meet the criteria defined by the Centers for Disease Control and Prevention as "high risk" and included in OPTN Policy 4.1.1. UNOS staff will review the documentation to ensure:
    - the OPO communicated the donor's history to all transplant centers that received organs from that donor;
    - the transplant center obtained informed consent from the recipient, legal next of kin, designated healthcare representative, or appropriate surrogate prior to implantation of the organ; and
    - living donors had the option to discontinue the donation process rather than have their "high risk" status communicated to the institution intended to receive their organs or to the intended recipient
- Researching confidential reports of complaints received through the OPTN Member Reporting Line or Patient Services Line;
- Reviewing OPTN data; or

- Receiving referrals from OPTN/UNOS committees, OPTN/UNOS staff, or OPTN/UNOS Members.

DEQ staff will explore all potential policy violations and forward any results to the OPTN/UNOS Membership and Professional Standards Committee for confidential medical peer review.

Policy Proposal:

4.0 ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS), HUMAN PITUITARY DERIVED GROWTH HORMONE (HPDGH), AND REPORTING OF POTENTIAL RECIPIENT DISEASES OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES, OF DONOR ORIGIN

4.1 [No Changes]

4.1.1 **Communication of Donor History**. The Host OPO will obtain a history on each potential donor in an attempt to determine whether the potential donor is in a "high risk" group, as defined by the Centers for Disease Control and Prevention (CDC). If the donor meets the criteria set forth in CDC Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs (CDC Guidelines),[1] the Host OPO must communicate this information regarding donor history to all institutions receiving organs from the donor. A potential living donor must have the option to discontinue the donation process rather than have their "high risk" status communicated to the institution intended to receive his or her organ.

If the transplant center receives information from the Host OPO that the donor meets any of the criteria, the transplant center must inform the potential recipient prior to implantation. A potential living donor must have the option to discontinue the donation process rather than have their "high risk" status communicated to the intended recipient of his or her organ. The transplant center shall maintain documentation of the potential recipient's informed consent to receive an organ from the donor who meets any of the criteria. In the event that the potential recipient is not able to provide informed consent, the legal next of kin, designated healthcare representative, or appropriate surrogate may provide consent on this matter.

[1] Rogers MF, Simonds RJ, Lawton KE, et al. Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs. CDC MMWR Recommendations and Reports. 1994;May 20/ 43(RR-8):1-17.
http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm