OPTN/UNOS *Ad Hoc* Disease Transmission Advisory Committee
AMENDED Report to the Board of Directors
November 8-9, 2010
St. Louis, Missouri

Summary

I. Action Items for Board Consideration

- The Board is asked to approve modifications to Policies 2.0 (Minimum Procurement Standards for an Organ Procurement Organization) and 4.0 (Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and Reporting of Potential Disease or Medical Conditions, Including Malignancies) to clarify and improve current OPO and transplant center requirements for screening for, communicating, and reporting potential or confirmed donor-related disease and malignancy transmission events. (Item 1, Page 3).

II. Other Significant Items

- The Committee reviewed progress made on its 2010-11 Goals as assigned by the Board of Directors. (Item 2, Page 24).

- The Committee completed its semi-annual review and classification of potential disease transmission events reported to the Patient Safety System. (Item 3, Page 25).

- The Committee received an update on the Malignancy Subcommittee's draft manuscript that offers categorizations for donor tumor risk transmission and reviewed malignancy data requested during the September 2009 meeting. (Item 4, Page 26).

- The Committee reviewed an updated report on living donors reported as having post-transplant malignancy and received a copy of the memo outlining potential screening recommendations to the living donor committee. (Item 5, Page 26).

- The Committee received an update from each of the specialty area groups to outline progress made in developing guidance documents on bacterial, tuberculosis, fungal and HTLV transmission from donors. (Item 6, Page 27).

- The Committee discussed the upcoming retirement of a commonly used HIV-1/HIV-2 enzyme immunoassay test kit for potential deceased donors. (Item 9, Page 27).

This page is intentionally left blank.

OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee
AMENDED Report to the Board of Directors
November 8-9, 2010
St. Louis, Missouri

Emily A. Blumberg, MD, Chair
Michael Green, MD, MPH, Vice Chair

This report reflects the work of the Ad Hoc Disease Transmission Advisory Committee (DTAC) during its September 1, 2010, meeting in Chicago, Illinois, as well as all monthly case review conference calls. Additionally, the Committee's Policy Rewrite Subcommittee met by teleconference and LiveMeeting® since the DTAC reported to the Board in June 2010.

I. Action Items for Board Consideration

1. Proposed Modifications to Policies 2.0 (Minimum Procurement Standards for an Organ Procurement Organization) and 4.0 (Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and Reporting of Potential Disease or Medical Conditions, Including Malignancies). Proposed modifications to policies 2.0 and 4.0 were developed by the Committee with input from both the Organ Procurement Organization (OPO) and Operations and Safety Committees to clarify and/or improve current OPO and transplant center requirements for screening for, communicating and reporting all potential or confirmed donor-related disease and malignancy transmission events. These changes were expected to:

- Help improve patient safety and recipient outcomes by making policy consistent with current clinical testing practices in the organ recovery transplant communities and creating a Patient Safety Contact;
- Place all content related to donor evaluation and screening into one policy section;
- Further define and standardize the elements of informed consent and the communication of clinically significant information regarding potential disease transmission events; and
- Provide a clear, plain language policy format that will be easier for members and other readers to understand and follow.

The Committee circulated its proposed modifications for public comment from March 19, to July 17, 2010 (see Briefing Paper, **Exhibit A**). Upon completion of the public comment period, the Committee's Policy Rewrite Subcommittee met by teleconference on July 19, and 26, 2010, and again on August 23, 2010, to review all feedback and make additional modifications to the proposal for consideration by the full Committee during its September 1, 2010 meeting in Chicago. While much of the feedback received on this lengthy proposal was positive, there were four general areas of the proposal that received the majority of comment:

- Qualified Specimens and Hemodilution
  Several respondents noted concern regarding how to calculate whether a donor is considered hemodiluted, based upon the number of blood products and other fluids administered and whether this may impact screening test results. Hemodilution is **currently** considered an increased risk for donation, and is a longstanding part of the US Public Health Service (PHS) Guidelines. Based upon some of the feedback received, it appears that some OPTN members are not familiar with

this, which leads the Committee to believe that there is a need for this language in policy and also for further education. When a potential donor's plasma sample is diluted to a level sufficient to affect the results of communicable disease testing, then serologic test results cannot be considered as necessarily reliable. Hemodilution calculations have been a longstanding requirement for tissue donation, and many OPOs that are actively involved in tissue donation are already completing this information and even including it in DonorNet® attachments for transplant programs to consider at time of offer.

A link to the FDA's current guidance regarding hemodilution was added as a footnote to the proposed policy modifications that will go to the Board of Directors. See the appendices for an example of a hemodilution calculation:
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm073964.htm#DONORTESTING:GENERAL1271.80

This information will also be included in the Evaluation Plan, a document that is updated regularly to provide guidance to members on how to comply with specific policies. The Committee also plans to develop a guidance document to provide members with additional information on this important topic.

A subset of these respondents requested additional guidance on how to explain the risk of potential transmission to potential organ recipients. A subgroup from the 2009 NAT Consensus Conference is addressing issues related to consent. The committee defers to this group regarding explaining risk as part of the consent process.

- Toxoplasma Screening for Potential Heart Donors
  Some respondents noted concern regarding time and expense related to testing potential heart donors for toxoplasma. Several noted that this policy change may ultimately necessitate that this test be performed on all donors since it may not be apparent at the beginning of case if thoracic organs will be allocated and accepted. While the Committee appreciates the burden of additional testing costs, it stands by its recommendation to bring toxoplasma screening in line with other screenings tests (EBV and CMV) for which there is a standard prophylactic regimen that may affect recipient management issues. Requiring this screening for potential heart donors will also, hopefully, help reduce the number of expected but untreated transmissions to recipients where testing of blood sent with a heart was not completed by the transplant center or blood for testing was lost in transit.

- Patient Safety Contact
  While there was little negative feedback regarding the creation of a patient safety contact process, comments were received regarding the necessity of sharing donor information within 24 hours. The committee believes that it is important that the OPO not be responsible for determining what donor information is clinically relevant to acute care of the recipient. Instead, OPOs should share any new information efficiently with the recipient transplant program's patient safety contact who will in turn share information with the recipient's care team. The recipient's care team can then determine whether patient care should be modified as a result of this new information. The committee does not believe that 24 hours is onerous in this respect, and believes that this only promotes patient safety.

- Informed Consent
  The American Society of Transplant Surgeons (ASTS) raised concerns related to new language regarding additional testing and therapy impacts informed consent. ASTS maintains that informed consent is best managed by the individual transplant center and is concerned that this proposal

may result in organ wastage by negatively impacting the informed consent process. The Committee considered this feedback and modified the language to requiring notification of recipient of risk of transmissible disease when it is noted as clinically relevant by the recipient's care team. The Committee believes that this and other minor modifications in sections 4.2 and 4.3 of policy place management back into the hands of the transplant center staff caring for affected recipients while still setting minimum criteria to enhance patient safety.

- OPO Responsibilities Related to Reported Potential Transmission Events
  Feedback was received from a number of sources that OPOs may be duplicating UNOS staff efforts in collecting recipient information as related to cases of potential donor derived disease transmission reported to the Patient Safety System. Because the original policy language was drafted prior to the current case load and number of UNOS staff involved in Patient Safety, the committee evaluated these concerns and agreed that completion of a 45 Day Report, completed by the OPO, may no longer be critical. Generally, staff has much of the information if not more than what is reported currently by OPOs placing follow-up calls to recipient centers. As a result, language was modified to require that OPOs complete donor follow up information if requested to follow up on any outstanding donor testing information as related to a potential transmission. Patient Safety Staff will follow up with recipient centers, and may request centers to complete a recipient follow up form if there is still outstanding information that the committee needs to properly classify the likelihood of donor derived disease transmission. The committee believes that this new format, outlined in Policies 4.5.1 and 4.5.2 will be less onerous for OPO staff and result in less duplicative effort for recipient centers.

The Committee reviewed further modifications suggested by the Policy Rewrite Subcommittee based upon public comment feedback during its meeting in Chicago. After the meeting, language was circulated for consideration, and several additional housekeeping recommendations were made by committee members to improve upon the final draft. These additional modifications were finalized and circulated again to the full committee for consideration, with all changes made after public comment noted in double strikethrough or double underline. The Committee voted electronically in support of taking the revised language to the Board of Directors for consideration (15 For, 0 Against, 0 Abstentions).

The Committee Chair sought feedback from Chairs of the OPO, Operations and Safety and Transplant Administrators Committees on the amended policy proposal as it prepared to take the proposal to the Board for consideration. Specific areas discussed included: (1) hemodilution and qualified specimens, (2) toxoplasma screening for potential heart recipients, (3) patient safety contact, (4) informed consent, and OPO responsibilities related to reporting cases to the Patient Safety System.

- Participants had no concerns regarding hemodilution and the use of qualified specimens. They only requested that appropriate guidance be available for members unfamiliar with hemodilution in the Evaluation Plan.

- The OPO Committee still held the unanimous opinion that that toxoplasma screening should take place at the heart recipient center. It was noted that OPOs may ultimately have to test all donors if it is unknown if a heart will be placed. Many OPOs may not have STAT access to toxoplasma screening results, which could result in a time lag in organ offers and placement and unnecessary expense. A surgeon participating on the call noted that donor toxoplasma status is of interest to the lung team as well as the heart team. If the heart team completes testing (as is currently done in most heart transplants), it would be helpful to have this information shared. The group discussed whether it would be appropriate to amend policy to require that the heart recipient center report donor toxoplasma status back to the OPO. Based upon the continued disagreement

on how this screening test should be handled, the decision was made to invite the OPO Committee Chair to participate in a conference call with the Committee to further discuss whether the toxoplasma screening requirement should remain in the proposal.

- A participant suggested that member organizations will need internal policy to show that they have addressed this OPTN policy requirement for the addition of a patient safety contact, should this be a policy that is audited during site surveys. All agreed that there is still a need for educating members regarding the importance of reporting potential disease transmissions and clarification that not every piece of information reported between patient safety contacts warrants a report to the Patient Safety System. The Patient Safety System is a means to investigate when a recipient develops a disease that is suspected to be of donor origin.

- Participants appreciated the recommended modifications to OPO and transplant programs related to reporting potential transmission events to the Patient Safety System and required follow-up with patient safety staff.

The Committee reconvened for its monthly call on October 14, 2010, and was joined by the Chair of the OPO Committee. Ongoing concerns regarding the proposed modification to require all potential heart donors be screened for toxoplasmosis were shared, and it was noted that the OPO Committee voted unanimously against this requirement. Members believed that it could result in a time lag in organ offers and placement and unnecessary expense due to difficulty in obtaining STAT results for this test.

While the Committee agreed that the current community practice of sending a tube of blood along with the heart for toxoplasma screening completion at the recipient center is effective in most circumstances, it was still concerned regarding the fact that this piece of donor data was not included in the donor record. Committee members agreed that STAT testing for toxoplasmosis is unnecessary, but noted that there have been occasions where the blood was not sent or was lost and testing was not completed, resulting in disease transmission. While the Committee still believes that toxoplasma should be a required donor test, it agreed to remove the requirement from this proposal. It will include questions related to availability of toxoplasma screening in its follow-up donor screening survey of all OPOs in 2011, and work with representatives from the OPOs and transplant centers to develop a new policy modification that may better suit the needs of the transplant community while still working to enhance patient safety in this area.

After careful review, the Committee voted to recommend the following resolution for consideration by the Board:

***** RESOLVED, that Policies 2.0 (Minimum Procurement Standards for an Organ Procurement Organization) and 4.0 (Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and Reporting of Potential Disease or Medical Conditions, Including Malignancies) shall be modified as set forth below, effective pending notice to the membership:**

2.0 MINIMUM PROCUREMENT STANDARDS FOR AN ORGAN PROCUREMENT ORGANIZATION (OPO)

In order to maximize the gift of donation and optimize recipient outcomes and safety, the Organ Procurement Organization (OPO) must comply with ~~T~~the following policies ~~provide the~~ for minimum procurement standards ~~for an Organ Procurement Organization (OPO)~~.

2.1 **HOST OPO.** The ~~Organ Procurement Organization (~~OPO~~)~~ responding to an organ donor call from a hospital is the "Host OPO" for that particular donor. The Host OPO is responsible for identifying, evaluating and maintaining the donor, obtaining consent for the removal of organs, complying with ~~accepted practice and~~ OPTN policy throughout the donation process, and organ allocation.

Additionally, the Host OPO is responsible for ensuring that donor tissue typing information is entered into UNet^{SM} and that the approved OPTN automated organ allocation computer algorithm ~~program~~ is executed for each donor organ.

~~Reasonable attempts shall be made~~ The Host OPO shall make reasonable attempts to obtain a medical/behavioral history from individual(s) familiar with the donor.

The Host OPO is responsible for organ procurement quality including appropriate preservation, and packaging of the organs, and assurance that adequate tissue typing material is procured, divided, and packaged.

The Host OPO is responsible for ~~ensuring that~~ written documentation of donor evaluation, donor maintenance, consent for donation, death pronouncement, and organ procurement quality accompanies the organ as described in Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials).

2.2 **EVALUATION OF POTENTIAL DONORS.** The Host OPO is responsible for performing the following activities and communicating this information to the importing OPO or transplant center for every donor:

2.2.1 Verifying that death has been pronounced according to applicable laws.

2.2.2 The Host OPO must perform the following evaluations and provide this information to the OPO or transplant center. The Host OPO must document in the donor record circumstances when such information is not available.

The Host OPO must determine whether there are conditions which may influence donor acceptance by:

2.2.2.1 Obtaining the donor's medical/behavioral history.

The Host OPO will attempt to obtain a history on each potential donor to screen for medical conditions that may affect the donated organ function and for the presence of transmissible diseases and/or malignancies, treated and untreated, or any other known condition that may be transmitted by the donor organ that may reasonably impact the candidate or recipient.

This history should also be used to identify whether the potential donor has factors associated with increased risk for ~~blood-borne pathogens~~ disease transmission, including blood borne pathogens HIV, ~~(as defined by the US Public Health Service (PHS)), and also~~ Hepatitis B, and Hepatitis C ~~or prion disease~~. If the donor meets the criteria set forth in the current US

Public Health Service (PHS) guidance[1], the Host OPO must communicate this information regarding donor history to all transplant programs receiving organs from the donor.

Potential donors who have received Human Pituitary Derived Growth Hormone (HPDGH) from human tissue (not recombinant) carry potential risk of prion disease. The Host OPO will attempt to obtain information regarding whether a potential donor has history of risk of prion disease (prior exposure or receipt of non recombinant HPDGH). If so, the Host OPO must communicate this information to all transplant programs receiving organs from the donor.

2.2.2.2 Reviewing the donor's medical ~~chart~~ record.

2.2.2.3 Performing a physical examination of the donor~~.~~, including obtaining the potential donor's vital signs.

~~Obtaining the donor's vital signs.~~

2.2.3 Screening Potential Organ Donors.

2.2.3.1 All blood samples obtained and used for screening tests required by OPTN policy must be assessed for hemodilution (defined as a sample with plasma dilution sufficient to affect the results of communicable disease testing) utilizing a FDA-approved hemodilution calculation. Any specimen without evidence of hemodilution will be referred to as a qualified specimen, and should be used for donor screening tests if available.

If a qualified (non-hemodiluted) specimen is not available for testing, a hemodiluted specimen should be used for testing purposes. In such cases, the donor will be considered as having increased risk for disease transmission per US PHS guidelines. As hemodilution can result in false negative serology testing, any screening results from such a specimen must be communicated to the accepting Transplant Program(s) and additional information including:

- which tests were completed using hemodiluted specimens; and
- The hemodilution calculation used for this donor's specimen (if requested).

A complete history of all transfusions received by the donor since admission must be documented in the donor medical record.

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

2.2.3.2 All potential donors are to be tested by use of a screening test licensed by the U.S. Food and Drug Administration (FDA) for Human Immune Deficiency Virus (HIV-1 and HIV-2).

If the sample is qualified, the screening test for HIV is negative, and blood for subsequent transfusions has been tested and found to be negative for HIV, re-testing the potential donor for HIV is not necessary.

2.2.3.3 NOTA and the Final Rule require standards for preventing the acquisition of organs from individuals known to be infected with human immunodeficiency virus/acquired immune deficiency virus. As a result, OPTN Members shall not knowingly participate in the procurement or transplantation ~~or sharing~~ of organs from donors who are known to be infected with ~~identified as~~ HIV ~~positive by an FDA-licensed screening test~~ OPTN members may only recover organs if~~unless subsequent confirmatory testing unequivocally indicates that the original test's results were falsely positive for HIV.~~ the laboratory data and medical-social history indicates that the donor is not HIV infected.

If ~~additional~~ multiple tests related to HIV are performed, the results of all tests must be communicated ~~immediately~~ directly to~~ the Organ Center and~~ all institutions receiving organs from the donor. Exceptions for cases in which the testing cannot be completed prior to transplant are provided in paragraph 2.2.3.4 below.

2.2.3.4 Exceptions to the guidelines set forth above may be made in cases involving non-renal organs, when, in the medical judgment of the staff of the Host OPO and recipient institution, an extreme medical emergency warrants the transplantation of an organ which has not been tested for HIV.

The Host OPO must provide all available information regarding donor medical and social history to the transplant program and treat this as a donor with increased risk for disease transmission based upon USPHS Guidelines due to the inability to obtain donor testing.

The transplant program must obtain and document informed consent from the recipient or next of kin, the legal next of kin, designated health care representative or appropriate surrogate before use in such cases (See Policy 4.2).

2.2.3.5 Informing Personnel. Health care personnel caring for potential donors or donors who test positive for HIV should be so informed only when necessary for medical decision making purposes.

2.2.~~3~~4 DONOR EVALUATION.~~The Host OPO~~ Donor evaluation must be performed or coordinated by the Host OPO. All donor laboratory testing must be performed in an appropriately accredited laboratory utilizing ~~following pertinent~~ FDA licensed, approved, or cleared serological screening tests ~~and provide this information to the OPO or transplant center.~~ In the event that ~~such~~ a required screening tests~~ are~~ is not commercially available prior to transplant, then a FDA-licensed, approved or cleared diagnostic test is permissible, and ~~a FDA approved diagnostic test is~~

~~permissible to assess the donor. T~~the Host OPO must document in the donor record ~~that a FDA-approved diagnostic test~~ which assay was utilized to assess the potential donor and must also provide this information to the transplant program(s). ~~circumstances when such information is not available. In all cases, the transplant center will make the clinical decision whether to accept or reject the organ based on the available data or identify the need for additional information. The Host OPO may be requested to provide additional information if possible in addition to the information required on all donors. Required tests should include:~~

Exceptions: Diagnostic testing is NOT acceptable for Anti-HIV.
FDA-approved diagnostic testing IS acceptable for VDRL/RPR.

2.2.~~3~~4.1 For all potential deceased donors:

- ABO typing (and confirmation as outlined in Policy 3.2.4) with sub-typing for ABO-A donors;
- FDA licensed Anti-HIV I, II (diagnostic testing not acceptable);
- CBC;
- Electrolytes;
- Hepatitis screen serological testing; including HBsAg, HBcAb, and Anti-HCV;
- VDRL or RPR (FDA-approved diagnostic tests are acceptable);
- Anti-CMV;
- EBV serological testing;
- Blood and urine cultures;
- Urinalysis within 24 hours prior to cross clamp;
- Arterial blood gases;
- Chest x-ray; and
- Serum Glucose.

If a Host OPO completes additional testing in addition to what is required in policy for a potential donor, the results of these tests must be communicated immediately to all recipient institutions.

Additional Organ Specific information is required as follows:

2.2.~~3~~4.2 For potential renal donors:

- Creatinine; and
- B.U.N.

2.2.~~3~~4.3 For potential liver donors:

- AST;
- ALT;
- Alkaline phosphatase;
- Direct and total bilirubin
- INR (PT if INR not available); and
- PTT.

2.2.~~3~~4.4 For potential heart donors:

- 12 Lead ECG; and

- Cardiology consult and/or echocardiogram~~,~~;
- ~~Toxoplasma serology;~~

2.2.3~~3~~4.5 For potential pancreas donors:

- Serum amylase.

2.2.3~~3~~4.6 For potential lung donors:

- Sputum gram stain.

2.2.5 Follow-up on Donor Testing. The Host OPO is responsible for timely follow-up and reporting of any new or changed ~~clinically relevant information regarding the~~ donor test results to the transplant program(s).

The Host OPO must establish a procedure that defines its process for obtaining post-recovery donor testing results. ~~from the hospital where donor recovery took place.~~

The Host OPO must establish and implement a process to report all positive screening or diagnostic tests received to the transplant center's Patient Safety Contact (as defined in Policy 4.4) within 24 hours of receipt by the OPO. The OPO must report updates such as identification of organism and sensitivity to the transplant program(s) as the OPO receives the information.

If during this follow-up a new disease or malignancy is discovered in the donor that may potentially be transmitted to organ recipients, the Host OPO must report the event to the OPTN Patient Safety System, as outlined in Policy 4.5.

2.2.6 Reporting Disease. The Host OPO is responsible for ~~making~~ collecting historical (i.e. medical-social history), testing and laboratory assessments to identify malignant and infectious conditions that may adversely affect a potential organ recipient and sharing this information with the transplant program(s).

The Host OPO must communicate to the transplant program(s) any known or suspected infectious or neoplastic conditions that may be transmitted by the donor organ(s).

~~**2.2.7 Human Pituitary Derived Growth Hormone.** Individuals who have received Human Pituitary Derived Growth Hormone (HPDGH) from human tissue (not recombinant) may be evaluated as potential organ donors with organs used at the discretion of the accepting transplant center and with informed consent from the potential recipient related to potential risk of prion disease. The transplant program must obtain and document informed consent from the recipient or next of kin, the legal next of kin, designated health care representative or appropriate surrogate in the recipient medical record before use in such cases (See Policy 4.2).~~

2.3 DONOR MAINTENANCE. The Host OPO must make reasonable efforts to maintain the deceased donor, document these efforts, and communicate this information to the OPO or Transplant Center as follows:

2.3.1 Blood pressure is adequate to maintain perfusion of vital organs;

2.3.2 Vital signs are monitored;

2.3.3 I.V. therapy or drugs are administered as required (i.e. vasopressors, vasodilators; etc.);

2.3.4 Antibiotic therapy is administered as required; and

2.3.5 Intake and output.

2.4 **OBTAINING CONSENT.** The Host OPO must provide evidence of consent for donation according to applicable legal authority.

2.5 **ORGAN PROCUREMENT QUALITY.** Minimum standards of quality shall include documentation of the following:

2.5.1 All items in section 2.2.

2.5.2 Use of standard surgical techniques in a sterile operating environment.

2.5.3 Maintenance of flush solutions and preservation media at appropriate temperatures and recording of flush solutions and additives with their respective lot numbers; organ anatomy, organ flush characteristics, flush solution amount and type, and organ abnormalities or surgical damage if any.

The Host OPO is responsible for ensuring that the donor medications are given at appropriate times and that medication administration, including flush solutions and additives, is recorded during the retrieval process.

2.5.4 Each OPO, and their respective histocompatibility laboratory(s), will define and document the minimum tissue typing material required to generate match runs for local or regional placement of all organs. In view of the frequent need for regional shipment of pancreas and kidney allografts, however, sufficient specimens for several crossmatches are required. Minimal typing material to be obtained for each kidney and pancreas will include the following:

- One 7 to 10ml. clot (red top) tube for ABO verification, plus
- 2 ACD (yellow top) tubes
- 3 to 5 lymph nodes
- One 2 X 4 cm. wedge of spleen in culture medium, if available

For all other organs, the OPO will provide lymph nodes if requested and available.

2.5.5 Proper packaging of organs for transport (see Policy 5.0).

~~**2.5.6** Properly packaged documentation containing complete donor information shall accompany each organ to the recipient transplant center.~~

~~**2.5.6.1** Documentation accompanying each organ must include:~~

- ~~ABO typing source documents;~~

- ~~Serology results;~~
- ~~Medical/Behavioral History form;~~
- ~~Donor evaluation;~~
- ~~Complete record of donor;~~
- ~~Consent form; and~~
- ~~Organ quality as described in section 2.5.~~

2.5.~~7~~6 Complete information must be maintained by the Host OPO for seven years per the Final Rule on any and all organs recovered. ~~The Host OPO is responsible for ensuring that non-local procurement teams have transportation to and from the local airport.~~

2.5.7 The Host OPO must maintain a serum sample for each donor from which organs were transplanted for a period of at least 10 years after the date of recovery. This serum must be available for use for retrospective testing if needed. The Host OPO must document the type of specimen that has been archived in the donor chart. The specimen should be a qualified (not hemodiluted) specimen if possible.

2.5.8 The Host OPO is responsible for ~~ensuring~~ determining that non-local procurement teams have transportation to and from the local airport.

2.6 INITIATING ORGAN PROCUREMENT AND PLACEMENT. In order to maximize the number of transplantable donor organs, tissue typing and crossmatching of an organ donor shall commence as soon as possible, ideally pre-procurement.

2.7 REMOVAL OF NON-RENAL ORGANS. When a non-renal organ is offered for transplantation, the recipient center procurement team must be given the option of removing the non-renal organ unless extenuating circumstances dictate otherwise. This policy also applies to non-renal organs from controlled donation after cardiac death (DCD) donors.

2.7.1 Multiple Abdominal Organ Procurement. It is expected that all authorized organs should be procured from a donor if each organ is transplantable and/or recipients are identified for each organ. The OPO will document the specific reason for non-recovery of an authorized organ. Cooperation between all organ recovery teams is required.

2.8 RECOVERY OF DCD DONOR ORGANS In order to recover organs from a DCD donor, an OPO must follow an established protocol that contains the standards of the DCD Model Elements as adopted in the OPTN Bylaws, Appendix B, Attachment III.

2. 9 MULTI-CULTURAL AND DIVERSITY ISSUES. Each OPO must develop and implement a plan to address a diverse population related to organ donation.

4.0 ~~ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS), HUMAN PITUITARY DERIVED GROWTH HORMONE (HPDGH), AND SCREENING FOR HUMAN~~

~~IMMUNODEFICIENCY VIRUS (HIV), IDENTIFICATION OF TRANSMISSIBLE DISEASE RISK FACTORS AND REPORTING OF POTENTIAL DONOR-DERIVED RECIPIENT DISEASES OR MEDICAL CONDITIONS, INCLUDING INFECTIONS AND MALIGNANCIES, OF DONOR ORIGIN~~ IDENTIFICATION OF TRANSMISSIBLE DISEASES IN ORGAN RECIPIENTS

~~4.1 SCREENING POTENTIAL ORGAN DONORS FOR HIV.~~ ~~All potential donors are to be tested by use of a screening test licensed by the U.S. Food and Drug Administration (FDA) for Human Immune Deficiency Virus (HIV). If the potential donor's pre-transfusion test for HIV is negative and blood for subsequent transfusions has been tested and found to be negative for HIV, retesting the potential donor for HIV is not necessary. If no pre-transfusion sample of the potential donor's blood is available, the Host OPO (as defined in Policy 2.1) must provide, to the recipient transplant center the screening test results and a complete history of all transfusions received by the donor during the ten (10) day period immediately prior to removal of the organ. Organs from donors with a positive screening test are not suitable for transplantation unless subsequent confirmation testing indicates that the original tests' results were falsely positive for HIV. If additional tests related to HIV are performed, the results of all tests must be communicated immediately to the Organ Center and all institutions receiving organs from the donor. Exceptions for cases in which the testing cannot be completed prior to transplant are provided in paragraph 4.1.3 below.~~

~~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.~~

~~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. 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.~~

~~4.1.2 Organ Sharing~~. ~~Members shall not knowingly participate in the transplantation or sharing of organs from donors who are confirmed HIV positive by an FDA licensed screening test unless subsequent confirmation testing unequivocally indicates that the original test's results were falsely positive for HIV.~~

~~[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~~

~~**4.1.3 Exceptions**. Exceptions to the guidelines set forth above may be made in cases involving non-renal organs, when, in the medical judgment of the staff of the Host OPO and recipient institution, an extreme medical emergency warrants the transplantation of an organ, the donor of which has not been tested for HIV. The transplant surgeon is obligated to obtain informed consent from the recipient or next of kin in such cases.~~

~~**4.1.4 Donor Consent Forms**. Member institutions are encouraged to include in each donor consent form a notice that all potential donors will be screened for medical acceptability for organ donation and that results of such tests may be the basis for not using the organ in transplantation.~~

4.~~2~~1 SCREENING POTENTIAL TRANSPLANT RECIPIENTS FOR BLOOD-BORNE PATHOGENS ~~HIV~~. Testing for HIV, Hepatitis B, and Hepatitis C, shall be a condition of candidacy for organ transplantation except in cases where such testing would violate applicable state or federal laws or regulations. Candidates whose test results are confirmed positive should undergo appropriate counseling.

~~**4.2.1**~~**4.1.1** **HIV Positive Transplant Candidates.** A potential candidate for organ transplantation whose test for HIV is positive ~~but who is in an asymptomatic state~~ should not ~~necessarily~~ be excluded from candidacy for organ transplantation~~, but should be advised that he or she may be at increased risk of morbidity and mortality because of immunosuppressive therapy.~~ unless there is a documented contraindication to transplantation based on local policy.

~~**4.2.2**~~**4.1.2** **Informing Personnel.** Health care personnel caring for ~~donors, potential donors~~, candidates, potential candidates and recipients who test positive for HIV should be so informed only when necessary for medical decision-making purposes.

~~**4.2.3**~~ ~~**Candidate and Recipient Treatment.** Administering treatment to candidates and recipients who test positive for the HIV should not be optional or discretionary for health care personnel.~~

~~**4.3**~~ ~~**Disclosure of Information About HIV Status.** Member institutions are urged to comply with state and federal statutes and regulations applicable to the disclosure of personalized data on actual or potential organ donors, candidates or recipients.~~

~~**4.4 GENERAL RECOMMENDATIONS.** All member institutions are requested to adopt an overall health care policy addressing special HIV-related problems with regard to transplant candidates and recipients. It is recommended that each institution's HIV-related health care policies incorporate the specific Policies 4.1, 4.2, and 4.3 set forth above. It is also recommended that member institutions make their policies available upon request to the press and the public.~~

~~**4.5 HUMAN PITUITARY DERIVED GROWTH HORMONE.** People who have received Human Pituitary Derived Growth Hormone (HPDGH) from human tissue (not recombinant) shall be evaluated as organ donors with potential organs used at the discretion of the accepting transplant center and with informed consent from the potential~~

~~recipient. The transplant surgeon is obligated to obtain informed consent from the recipient or next of kin in such cases. The use of recombinant HPDGH carries no additional risk of transmissible disease.~~

~~**4.6 SCREENING POTENTIAL ORGAN DONORS FOR TRANSMISSION OF DISEASES OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES.** All potential donors are to be screened for transmissible diseases or medical conditions, including malignancies, through the collection of medical/social history information. Donor testing for the purpose of organ allocation **must** use a FDA licensed, approved or cleared test if commercially available.~~

~~Medical conditions that should be screened for by history include the presence of malignancies, treated and untreated, or any other known condition that may be transmitted by the donor organ that may reasonably impact the candidate or recipient. In addition, donors shall be tested for recognized transmissible diseases, as defined in policy 2.2.8.1, using FDA-licensed, approved, or cleared serological screening tests capable of determining whether the donor is or has been infected with these specific diseases. In the event that such screening tests are not commercially available prior to transplant, then a FDA approved diagnostic test is permissible to assess the donor.~~

~~If additional testing is performed, the results of these tests must be communicated immediately to all recipient institutions. The OPO is responsible for timely follow-up of donor screening tests.~~

~~Documentation of any suspected or confirmed transmissible disease or medical condition identified prior to or following procurement must be communicated by the Host OPO to all potential recipient centers and the OPTN according to Policy 4.7.~~

~~**4.6.1 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. The Host OPO must communicate the donor history to all recipient institutions.~~

~~**4.6.2 Reporting.** Known conditions that may be transmitted by the donor organ must be communicated to the transplant centers: These may include, but are not limited to, the following:~~

- ~~Unknown infection of central nervous system (encephalitis, meningitis)~~
- ~~Suspected Encephalitis~~
- ~~Hepatitis C~~
- ~~Herpes simplex encephalitis or other encephalitis~~
- ~~History of JC virus infection (causes progressive multifocal leukoencephalopathy)~~
- ~~West Nile virus infection~~
- ~~Cryptococcal infection of any site~~
- ~~Rabies~~
- ~~Creutzfeldt-Jacob disease~~
- ~~Other fungal or viral encephalitis~~
- ~~Bacterial meningitis~~
- ~~Infection with HIV (serologic or molecular)~~
- ~~Active viremia: herpes, acute EBV (mononucleosis)~~

- ~~Serologic (with molecular confirmation) evidence of HTLV-I/II~~
- ~~Active hepatitis A or B~~
- ~~Infection by: Trypanosoma cruzi, Leishmania, Strongyloides, Toxoplasmosis~~
- ~~Active Tuberculosis~~
- ~~SARS~~
- ~~Pneumonia~~
- ~~Bacterial or fungal sepsis (e.g. candidemia)~~
- ~~Syphilis~~
- ~~Multi-system organ failure due to overwhelming sepsis, such as gangrenous bowel~~
- ~~Malignancies-other active malignant neoplasms,~~
- ~~Melanoma, Merkel cell, including Kaposi's~~
- ~~Hodgkins' disease and non-Hodgkin's lymphoma~~
- ~~Multiple myeloma~~
- ~~Leukemia~~
- ~~Aplastic anemia agranulocytosis~~
- ~~Miscellaneous carcinomas~~
- ~~Any new conditions identified by the CDC as being a potentially communicable disease~~

~~**4.6.3** **Exceptions.** Organs from donors with a positive screening test or confirmed medical conditions that may be transmittable, with the exception of HIV, may be transplanted at the discretion of the transplanting program with the informed consent of the recipient.~~

~~**4.6.4** **Donor Consent Forms.** Member institutions are encouraged to include in each donor consent form a notice that all potential donors will be screened for medical acceptability for organ donation and that results of such tests may be the basis for not using the organ in transplantation.~~

4.2 **REQUIREMENTS FOR INFORMED CONSENT REGARDING RISK OF TRANSMISSIBLE DISEASE.** Transplant programs must obtain informed consent prior to transplant of an organ when:

- The donor has a known medical condition that may be transmittable to the recipient, with the exception of HIV (see Policy 2.2.3.3); and/or
- The donor has recognized increased risk ~~for blood-borne viruses~~ disease transmission (including when a hemodiluted specimen is used for donor HIV, HBV, and/or HCV screening (see Policy 2.2.3.1)).

4.2.1 If additional donor risk (infectious or neoplastic) is identified pre-transplant, the transplant program must:

- explain the risks and obtain informed consent from the recipient or next of kin, the legal next of kin, designated health care representative or appropriate surrogate before transplant;

- document this consent in the recipient medical record and make it available to the OPTN contractor if requested; and

- follow the recipient of such an organ for the development of potential donor-derived disease after transplantation.

4.2.2 Transplant programs must offer the recipients of organs from donors at increased risk for blood borne pathogens:

- additional post-transplant testing for HIV, HCV, and/or HBV (as appropriate based upon the recipient's pre-transplant status); and

- monitoring and/or therapy to treat or provide prophylaxis as appropriate to minimize the risk of infection in addition to routine post-transplant follow-up care.

4.2.3 Transplant programs must also inform potential recipients of the **general** risks of potential infection and/or tumor acquisition outside of the standard donor screening requirements (as defined in Policy 2.2.4.1), to include information that:

- there is no comprehensive way to screen potential donors for all transmissible diseases; and

- on occasion, infectious agents, donor-associated tumors or genetic diseases may be identified after transplantation.

~~In all instances, t~~The transplant program must:

- explain these risks and obtain informed consent from the recipient or next of kin, the legal next of kin, designated health care representative or appropriate surrogate before transplant; and

- document this consent in the recipient medical record and make it available to the OPTN contractor if requested; and

- ~~offer the recipient additional post-transplant testing for HIV, HCV and/or HBV (as appropriate), monitoring and/or therapy to treat or provide prophylaxis as appropriate to minimize the risk of infection in addition to routine post-transplant follow-up care. Related documentation should be maintained in the recipient medical record and made available to the OPTN contractor if requested.~~

4.3 **Disclosure of Post-Transplant Discovery of Donor Disease or Malignancy and Notification of Recipients.** Because results from donor testing samples may be completed or change after organ transplantation and/or new clinically relevant findings are sometimes recognized post-transplant, the transplant program must:

- Notify recipient, or next of kin, the legal next of kin, designated health care representative or appropriate surrogate of a risk of transmissible disease that was not previously identified and is noted as clinically relevant by the recipient's care team .

- Document new donor information and potential risk for disease/malignancy in the transplant center's recipient medical record and make this information available to the OPTN contractor if requested; and

- ~~Offer the recipient additional testing, monitoring and/or therapy as appropriate in addition to their routine follow-up care. Related documentation should be maintained in the recipient medical record and made available to the OPTN contractor if requested.~~

- Follow a recipient at increased risk for disease and/or malignancy for the development of this potential condition after transplantation, offering the recipient additional testing, monitoring and/or therapy as appropriate in addition to their routine follow-up care.

4.3.1 Transplant programs must offer the recipient of an organ from a donor found after transplant to pose increased risk for blood bone pathogens:

- Additional post-transplant testing for HIV, HCV and/or HBV (as appropriate based upon the recipient's pre-transplant status); and

- Monitoring and/or therapy to treat or provide prophylaxis as appropriate to minimize the risk of infection in addition to routine post-transplant follow-up care.

4.4 **PATIENT SAFETY CONTACT.** Each Host OPO and Transplant Program must develop a process for identifying a Patient Safety Contact and follow this process for receiving potential disease transmission notifications and any related communication with the OPTN. The Patient Safety Contact must be available 24 hours a day, and is responsible for:

- Receiving pertinent medical information that may affect or change recipient care;

- Communicating information to the appropriate medical professional responsible for clinical care of the recipient(s) at the transplant program **as soon as possible**, and not to exceed 24 hours; and

- Facilitating communication about the current clinical status of any recipient for whom the center is informed of a concern for a possible or proven disease transmission related to the donor.

Transplant programs and OPOs must ~~exchange this information to facilitate effective communication should a potential disease transmission or patient safety situation arise and~~ make this information available to the OPTN contractor if requested.

4.~~7~~5 **POST-TRANSPLANT REPORTING OF POTENTIAL TRANSMISSION OF DISEASE OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES.** In order to promote prompt notification of potential risk of disease transmission through organ transplantation, all events involving unexpected potential or proven transmission of

a medical condition, including infections and malignancies, discovered after procurement of a donor organ must be reported to the OPTN Patient Safety System℠.

- When ~~a transplant program is informed that~~ an organ recipient ~~at that program~~ is suspected to have, is confirmed positive for, or has died from a potential transmissible disease or medical condition for which there is substantial concern that it could be from donor origin, then the transplant program must notify the Host OPO by phone and provide available documentation~~,~~ to the Host OPO as soon as possible, and not to exceed 24 hours of this knowledge/concern.~~one complete working day, to the procuring OPO~~. ~~The overall intent is to transfer the knowledge/concern from one transplant center to all other transplant centers who have accepted organs from the same donor as quickly as possible.~~ The transplant center that suspects~~originating the concern of~~ potential transmission should not wait for all medical documentation that ~~will~~ may eventually be available, but must inform the ~~communicate that center's concerns through~~ Host OPO and/or the OPTN Patient Safety System to transfer knowledge/concern as soon as possible to all other centers ~~involved with that~~ that received organs from the same donor. ~~as soon as possible so the other centers could use their medical judgment as to which, if any, investigations or actionsneed to be performed on their recipients.~~

- When a Host OPO learns of new information regarding a donor (i.e. final culture results, information from autopsy report, etc.) as part of its donor follow-up (See Policy 2.2.5) that indicates risk of potential transmission of disease or malignancy, the Host OPO must report the donor through the OPTN Patient Safety System.

4.5.1 Host OPO Responsibilities. The ~~procuring~~ Host OPO shall be responsible for:

i. Communication of ~~the~~ test results and diagnosis from a suspected donor and/or affected recipient(s) that may be pertinent to acute patient care as soon as practicable, not to exceed 24 hours, to any transplant program(s) Patient Safety Contact and tissue bank(s) that received an organ(s) or tissue from the donor who is the subject of the investigation~~;~~. This includes results of all tests that were not available at the time of procurement (i.e. cultures, final pathology, etc) or subsequently performed after recovery and documenting that this information is shared with all recipient centers and tissue banks.

~~iii.~~ii. Notification of the event to the OPTN Patient Safety System℠ ~~in UNet℠~~ as soon as possible,~~; and~~ not to exceed 24 hours.

iii. Follow-up Communication of Potential Disease Transmission

- Completion and submission of the Potential Disease Transmission Report Form (a form that will be sent to the Host OPO after OPTN staff receives the electronic notification from the OPTN Patient Safety System ~~UNet℠~~) to OPTN Patient Safety Staff within 24 hours of reporting the event through the Patient Safety System℠ to identify:

  - The specific Patient Safety Contact at the recipient transplant program(s) and tissue bank(s) personnel that were notified of the potential transmission;
  - Disposition of all organs, tissues and vessels; and

- Any preliminary information available regarding any remaining donor samples for additional testing, notification to state or local health department as appropriate for nationally notifiable infectious diseases, and whether an autopsy was performed on the donor.

- If requested by the Ad Hoc Disease Transmission Advisory Committee, ~~S~~submission of a Potential Disease Transmission DONOR Follow-Up Report (a form that will be sent to the Host OPO by OPTN contractor staff) 45 days after the initial reporting date; OPTN Patient Safety Staff may request additional information related to the donor beyond 45 days, including pending test results ~~Potential Disease Transmission long-term follow-up~~ depending on the potentially transmitted disease or condition ~~potentially transmitted~~.

~~iv. submission of a final written report to the OPTN within 45 days, which specifies the organizations and individuals who were notified, when the notifications occurred, and results of the investigation including test results of the organ recipients who are the subjects of the investigation.~~

~~ii.~~iv. Management of the review, in partnership with OPTN Patient Safety Staff, to determine whether the organ donor was diagnosed with a potentially transmissible disease or condition;

~~The OPTN shall assist the procuring OPO in identifying all organ transplant programs and recipients who received an organ from the donor who is the subject of the investigation. The OPTN will monitor the notification process to verify that the procuring OPO and all recipient organ transplant programs have been notified of the disease or medical condition and will request that any additional diagnostic test results be submitted to the procuring OPO with a copy to the OPTN. The OPTN contractor will forward a copy of the OPO's final report to the recipient transplant centers and the Division of Organ Transplantation of the Health Resources and Services Administration. Note: The identities of the donor and any organ recipient who are the subjects of the investigation shall remain confidential and all correspondence will refer to the donor and recipients by their donor identification number and recipient social security numbers. Under no circumstances should a transplant program or OPO disclose this information in a manner that is contrary to applicable law.~~

4.5.2 **Transplant Program Responsibilities.** Any transplant program treating recipient(s) that received~~s~~ organ(s) from a donor who is the subject of a potential disease transmission report is responsible for:

i. Responding to Host OPO and OPTN Patient Safety Staff requests for information regarding recipient(s) in a timely fashion and communicating updated information regarding recipient condition, test results, diagnosis, and plans for treatment and follow-up.

ii. Submitting copies of any pertinent test results (including cultures, serologies, imaging studies, autopsy results, etc.) to ~~both the Host OPO and the~~ OPTN Patient Safety Staff.

iii. Notifying recipient(s) involved in cases of ~~potential or~~ confirmed transmissions and documenting this notification in the recipient medical record as required in Policy 4.3.

~~iv. Providing the Host OPO with all documentation needed for the Host OPO to complete **Potential Disease Transmission Follow-Up Report** to the OPTN Patient Safety Staff within 45 days after the initial reporting date.~~

~~v. Providing any requested available data to the OPTN Patient Safety Staff for completion of the Potential Disease Transmission Long-Term Follow-Up Reports depending on the disease or condition potentially transmitted. (In cases of potential malignancy transmission, the OPTN Patient Safety Staff may also contact the recipient center within six months of the report to request updated follow-up on a recipient in an effort to determine probability of donor-derived transmission.)~~

iv. If requested by the Ad Hoc Disease Transmission Advisory Committee, submission of a Potential Disease Transmission RECIPIENT Follow-Up Report (a form that will be sent to the transplant program by OPTN staff) within 45 days of the initial reporting date.

OPTN Patient Safety Staff may request additional information related to the recipient beyond 45 days, (including pending test results, long term follow-up testing, and/or screening results, etc.) depending on the potentially transmitted disease or condition in an effort to determine the probability of donor-derived disease transmission.

Language stricken from Policies 2.5.6 and 2.5.6.1 was relocated to Policy 5.0 to keep all requirements related to organ packaging in one policy section.

5.5.1 Documentation accompanying the organ

- Complete donor documentation, ~~as described in Policy 2.5.6.1,~~ must be sent in the container with ~~all~~ each transported organ~~s~~. This documentation must include:
  - ABO typing source documentation;
  - Infectious disease testing results;
  - Medical/Behavioral History form;
  - Donor Evaluation;
  - Complete record of the donor;
  - Deceased donor consent form; and
  - Organ quality information as noted in Policy 2.5.
- Donor documentation must be placed in a watertight container.
- Donor documentation may be placed in either:
  - a location specifically designed for documentation, or
  - between the outer and inner containers.

- Whenever a deceased donor organ is transported, the Host OPO or the Transplant Center, as applicable, must include in the donor documentation the source documentation.

As noted in the public comment proposal, several other sections of policy will require updates to reflect appropriate policy numbering as a result of the changes to Policies 2.0:

Policy 3.5.9.1, section xiii.	update reference to reflect new policy 2.2.4.1
Policy 3.6.9.1, section xi.	update reference to reflect new policy 2.2.4.1
Policy 3.7.12.1, section v.	update reference to reflect new policy 2.2.4.1
Policy 3.8.6.1, section ix	update reference to reflect new policy 2.2.4.1

Policy 3.5.3.2 contains a reference to artifact policy 2.7 (Expedited Organ Procurement and Placement). This former policy was eliminated prior to the OPO Committee's previous rewrite of Policy 2.0 in 2008 The section referred to here no longer exists in current policy language, and is recommended for removal as a housekeeping edit.

3.5.3.2 Computer Entry. Information regarding each and every deceased kidney donor must be entered into UNet^{SM} prior to kidney allocation, to determine whether there is a zero antigen mismatch between the donor and any candidate on the Waiting List. Pre-procurement tissue typing is expected ~~consistent with Policy 2.7 (Expedited Organ Procurement and Placement)~~ in allocating expanded criteria donor kidneys. In the absence of pre-procurement tissue typing, allocation of expanded criteria donor kidneys shall proceed pursuant to Policy 3.5.12 according to candidate waiting time. If pre-procurement tissue typing is not initiated, the Host OPO shall provide a written explanation of the reasons to the OPTN contractor.

Several other sections of organ specific policy related to essential information required for organ offers will also need to be updated to reflect appropriate policy numbering. These sections all reference donor serology testing requirements as a result of the changes to Policies 2.0, and the same language change is recommended for each of these sections, as noted below in strikethrough and underline format:

3.5.9.1 Essential Information for Kidney Offers. The Host OPO must provide the following information to the potential recipient center with each kidney offer:

(i) Donor name and Donor I.D. number, age, sex, and race;
(ii) Date of admission for the current hospitalization;
(iii) Diagnosis;
(iv) Blood type;
(v) HLAA, B, Bw4, Bw6, and DR antigens;
(vi) Current history of abdominal injuries and operations;
(vii) Pertinent past medical or social history;
(viii) Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria;
(ix) Final urinalysis;
(x) Final BUN and creatinine;
(xi) Indications of sepsis;
(xii) Assurance that final blood and urine cultures are pending;

(xiii) ~~Pre- or post-transfusions~~Serologies as indicated in ~~2.2.7.1~~ 2.2.4.1 (~~pre-transfusion~~ qualified specimens preferred as noted in policy 2.2.3.1);

[no further changes to language in this section]

3.6.9 Minimum Information for Liver Offers.

3.6.9.1 Essential Information Category. When the Host OPO or donor center provides the following donor information, with the exception of pending serologies, to a recipient center, the recipient center must respond to the offer within one hour pursuant to Policy 3.4.1 (Time Limit for Acceptance); however, this requirement does not preclude the Host OPO from notifying a recipient center prior to this information being available:

(i) Donor name and Donor I.D. number, age, sex, race, height and weight;
(ii) ABO type;
(iii) Cause of brain death/diagnosis;
(iv) History of treatment in hospital including current medications, vasopressors and hydration;
(v) Current history of hypotensive episodes, urine output and oliguria;
(vi) Indications of sepsis;
(vii) Social and drug activity histories;
(viii) Vital signs including blood pressure, heart rate and temperature;
(ix) Other laboratory tests within the past 12 hours including:
  (1) Total Bilirubin
  (2) ALT
  (3) INR (PT if INR not available)
  (4) Alkaline phosphatase
  (5) WBC
  (6) HH
  (7) Creatinine;
(x) Arterial blood gas results;
(xi) ~~Pre- or post-transfusion~~ ~~s~~Serologies as indicated in ~~2.2.7.1~~ 2.2.4.1 (~~pre-transfusion~~ qualified specimens preferred as noted in policy 2.2.3.1).

3.7.12 Minimum Information for Thoracic Organ Offers.

3.7.12.1 Essential Information. The Host OPO or donor center must provide the following donor information to the recipient center with each thoracic organ offer:

(i) The cause of brain death;
(ii) The details of any documented cardiac arrest or hypotensive episodes;
(iii) Vital signs including blood pressure, heart rate and temperature;
(iv) Cardiopulmonary, social, and drug activity histories;

(xii) ~~Pre- or post-transfusion~~ ~~s~~Serologies as indicated in ~~2.2.7.1~~ 2.2.4.1 (~~pre-transfusion~~ qualified specimens preferred as noted in policy 2.2.3.1).

[no further changes to language in this section]

3.8.6 Minimum Information for Pancreas Offers.

3.8.6.1 Essential Information Category. The Host OPO or donor center must provide the following donor information, with the exception of pending serologies, to the recipient center with each pancreas offer:

(i) Donor name and Donor I.D. number, age, sex, race and weight;
(ii) Date of admission for the current hospitalization;
(iii) Diagnosis;
(iv) Blood type;
(v) Current history of abdominal injuries and operations including pancreatic trauma;
(vi) Pertinent past medical or social history including pancreatitis;
(vii) Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria;
(viii) Indications of sepsis;
(ix) ~~Pre or post-transfusion~~ ~~s~~Serologies as indicated in ~~2.2.7.1~~ 2.2.4.1 (~~pre-transfusion~~ qualified specimens preferred as noted in policy 2.2.3.1);

[no further changes to language in this section]

Committee vote: ***15 in favor, 0 opposed, and 0 abstentions***