At-a-Glance

- **Proposal to Modify OPO and Transplant Center Requirements for Screening, Communicating and Reporting All Potential or Confirmed Donor-Related Disease and Malignancy Transmission Events.**

- **Affected/Proposed Policies:** Policies 2.0 (Minimum Procurement Standards for An Organ Procurement Organization), 4.0 (Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and Reporting of Potential Diseases or Medical Conditions, Including Malignancies, of Donor Origin), and 5.5 (Documentation Accompanying the Organ or Vessel)

- ***Ad Hoc* Disease Transmission Advisory Committee (DTAC)**

- The proposed modifications are meant 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 are 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

- **Affected Groups**
  Directors of Organ Procurement, Lab Directors/Supervisors, OPO Executive Directors, OPO Medical Directors, OPO Coordinators, Transplant Administrators, Transplant Data Coordinators Transplant Physicians/Surgeons, PR/Public Education Staff, Transplant Program Directors, Transplant Social Workers, Organ Recipients, Organ Candidates, Living Donors, Donor Family Members, General Public

- **Specific Requests for Comment**
  The Committee recognizes that these modifications may not represent all clinical screening and communication practices across Donor Service Areas (DSAs) and transplant programs. Through the public comment process, the DTAC seeks community and public input to aid in developing resulting policy requirements that reflect current clinical practices.

Proposal to Modify OPO and Transplant Center Requirements for Screening, Communicating and Reporting All Potential or Confirmed Donor-Related Disease and Malignancy Transmission Events

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***Ad Hoc* Disease Transmission Advisory Committee (DTAC)**

Summary and Goals of the Proposal:

The proposed modifications are meant 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 are 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

Background and Significance of the Proposal:

In June 2007, the Operations Committee's Disease Transmission Advisory Group (DTAG) developed a public comment proposal to modify Policy 4.0 based upon discussion and review of cases reported to the OPTN Patient Safety System (PSS) since its March 8, 2006 implementation date and related data. Prior to public comment distribution, the OPO and Organ Availability Committees reviewed the proposed modifications and provided feedback, and their suggested revisions were incorporated into the proposal. The Operations Committee/DTAG received extensive feedback on its public comment proposal and, based on this feedback, did not take the proposal to the Board for consideration. DTAG chose to explore additional modifications to policy language based on the many comments received and re-draft a new proposal at a later date.

During the March 2008 Board of Directors meeting, the DTAG was granted ad hoc committee status and renamed the Ad Hoc Disease Transmission Advisory Committee (DTAC).

In an effort to better understand current testing practices and modify current policy language accordingly, the DTAC and OPO Committees partnered in 2008 to survey the OPO community regarding its use and the current availability of Nucleic Acid Testing (NAT) and other serologic tests used for potential deceased donors.

The OPO Committee's survey, sent to all 58 OPOs in March 2008, was developed with assistance from DTAC and the Association of Organ Procurement Organization (AOPO). All 58 OPOs responded to this survey regarding current NAT practices including specifics of which testing is being done and for what indications. Results indicated that:

- 45 (78%) OPOs currently use some form of NAT testing,
- 41 (71%) OPO do some prospective NAT testing, and
- 27 (47%) OPOs do prospective NAT testing on all donors.

Thirteen OPOs reported that they employ no NAT testing. Phone calls to those 13 OPOs were made to further explore why they are using no NAT at this time. In general, survey respondents cited significant logistical problems with prospective NAT and concerns that donors will be lost if prospective NAT becomes required. Most OPOs doing NAT testing at this time are using one of only a handful of labs in the country.

The DTAC's survey **(Exhibit A)**, sent to all 58 OPOs in October 2008, was developed in consultation with members of the OPO Committee and with input from a testing expert in the histocompatibility community. It asked questions about each OPO's specific circumstances regarding availability of screening tests for a number of specific transmissible diseases. Information obtained through this survey regarding specific types of screening and diagnostic tests used (and whether they met FDA requirements) was used by the DTAC in developing modifications to Policy 2.0.

Additionally, the DTAC's review of potential disease transmission events reported to the OPTN PSS have highlighted recent clusters of donor-related infection and malignancy transmission that illustrate potential gaps in both the screening of organ donors and the mechanisms to communicate and investigate transmission events associated with transplantation. A variety of patterns of donor-related disease transmissions exist, including:

- bacterial and fungal infections in donors (often detected **after** transplantation based on blood or other cultures obtained at the time of procurement);
- active viral infections including lymphocytic choriomeningitis virus (LCMV), rabies, herpes simplex virus (HSV), and West Nile virus (WNV)— several cases of transmissible encephalitis are notable because the **symptoms may be absent or masked in the donor** by coincident neurologic events, such as an intracranial bleed;
- parasitic infections including clusters of Chagas' disease (*Trypanosoma cruzi*) and Balmuthia**;**
- fungal infections, particularly Coccidioidomycosis, which may affect donors from endemic regions but for which organs may be shared nationally; and
- malignancies such as adenocarcinoma of the lungs, lymphoma, melanoma, ovarian cancer, and renal cell carcinoma.

Current policy language requires members to report suspected or confirmed donor-related disease transmission, but reporting is inadequate and should, of course, be secondary to ensuring that all transplant centers and the Host OPO are aware as soon as possible regarding the suspicion of a potential donor-derived disease or malignancy.

The DTAC renewed its efforts to develop related policy modifications in June 2009, convening a Policy Rewrite Subcommittee to reconsider feedback from its original proposal and move forward on developing a follow-up proposal based upon what it learned. In July 2009, a representative from the OPO Committee was invited to participate in this process moving forward, to provide additional

feedback and perspective. In reviewing policies 2.0 and 4.0, all agreed that one goal of this effort should include moving any language related to donor evaluation and screening out of policy 4.0 and into 2.0. This would place all donor evaluation language up to the point of recovery in one policy section, making locating language easier for OPOs. Over the next several months, this group completed a line-by-line review of both policy sections.

In November 2009, the Policy Rewrite Subcommittee invited representatives from the OPO and Operations and Safety Committees to join its process and provide specific input and perspective on the proposed modifications and relocation of language drafted thus far. This newly formed Joint Policy Rewrite Working Group reviewed all current and proposed policy sections in 2.0 and 4.0 line-by-line. At this time, the Group's overall goals included moving all donor screening/evaluation language from policy 4.0 into 2.0 and developing or improving language regarding:

- outdated references in current policy to "pre-transfusion" donor specimens;
- potential disease transmission reporting; and
- the development of a patient safety contact at OPOs and transplant centers.

Members recognized that there will be a need for additional guidance to members, perhaps in the form of a guidance or resource document, to replace the list of known conditions that may be transmitted by an organ donor that should be communicated to transplant centers (current policy 4.6.2, which is recommended for elimination). The DTAC believes that this is information that it should review and update yearly to best serve its members without requiring an update of formal policy language. Equally, the Committee recommended striking current language in policy 4.4.1 that provides guidance on the patient safety reporting process in favor of educational efforts and materials. A guidance document will be presented to the Board for consideration along with the final policy proposal.

After a complete review of both policy sections, a final draft was presented to the full DTAC, OPO and Operations and Safety Committees for consideration in January 2010. All feedback from the OPO and Operations and Safety Committees was shared with the DTAC and much of it was incorporated into the final proposed policy language.

The DTAC voted electronically in favor of sending the proposed modifications out for public comment in Spring 2010 (12 for, 0 against, 0 abstentions) after its final review of the public comment proposal and proposed language during a February 11, 2010 conference call.

The proposed modifications represent the efforts of the DTAC to:

- Relocate policy language in a way that will be easier for members to locate, understand and follow by moving language related to donor evaluation and screening in current section 4.0 into section 2.0;
- Standardize informed consent and recipient notifications requirements and responsibilities, as well as to clarify that special informed consent is required when hemodiluted specimens are used for donor Human Immunodeficiency Virus (HIV), Hepatitis B virus (HBV), and Hepatitis C virus (HCV) screening; this is consistent with current policy related to "high risk" donors since hemodilution is a "high risk" factor;
- Bring policy language in line with current practice already in place at many OPOs and transplant centers across the country, including the removal of the term "pre-transfusion" specimen in favor of considering whether a specimen is "qualified" based upon its level of hemodilution; and

- Enhance patient safety (and ultimately improve recipient outcomes associated with potential donor-derived disease transmission events) by: (1) introducing a requirement for a Patient Safety Contact representative at OPOs and transplant centers; and (2) providing clearer direction to both OPOs and transplant centers regarding the reporting of potential disease transmissions to the OPTN.

Supporting Evidence and/or Modeling:

The proposed changes reflect the DTAC's expertise and knowledge on current testing practices as well as recommendations and feedback from the OPO and Operations and Safety Committees. The three committees reviewed both policy sections line-by-line and discussed all proposed modifications during a series of conference calls. All agreed that moving all language related to donor evaluation and screening into one policy section was a practical way to provide more streamlined policy language for OPOs to follow without having to move between two sections of current policy.

Several new areas of policy were recommended through the course of this overall review:

In Policy Section 2.0

1. **Change of terms from "high risk" to "increased risk for blood borne pathogens" and inclusion of Hepatitis B (HBV), Hepatitis C (HCV) and prion disease (proposed policy section 2.2.2.1)**
    a. Current policy language in 4.1.1 refers to determining whether a donor is in a "high risk" category as defined by the **Centers for Disease Control and Prevention (CDC)**. In actuality, the CDC's *Guidelines for Preventing Transmission of Human Immunodeficiency Virus through Transplantation of Human Tissues and Organs*[1] refer only to risks related to HIV.
    b. Proposed modifications move this language to Policy 2.0 and modify it to also include HBV, HCV and prion[2] disease. All are blood borne pathogens that could transmit to recipients.
    c. The CDC is currently re-evaluating its current guidelines and anticipates the inclusion of HBV and HCV in the new version, anticipated for release in late 2010.
    d. A number of cases of potential HBV and HCV disease transmission have been reported to the Patient Safety System and reviewed by the DTAC.

[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] Prion diseases or transmissible spongiform encephalopathies (TSEs) are a family of rare progressive neurodegenerative disorders that affect both humans and animals. Creutzfeldt-Jakob Disease (CJD) is a human prion disease. http://www.cdc.gov/ncidod/dvrd/prions/

2. **Updating References to Pre- and Post-Transfusion Samples to reflect terminology used in tissue and blood banking (proposed policy section 2.2.3.1)**
    a. Terminology in current policy is outdated and does not reflect ways, other than the transfusion of blood products, that a potential donor's blood specimen may be diluted to the point that screening test results could be false negative.
    b. Hemodilution is a recognized risk factor for getting false negative donor screening tests. It is one of several factors that may make a donor "high risk" yet there is no clear policy language requiring assessment for this factor.
    c. The **U.S. Food and Drug Administration (FDA)** provides oversight for blood and tissue banking. The FDA's terminology[3] includes the definition of hemodiluted and qualified specimens.
        - Hemodilution occurs when an increase in plasma volume (due to blood products, colloids and/or crystalloids administered to bring a person's blood volume back up to a normal level after suffering trauma, etc.) and can result in a reduced concentration of red blood cells (RBCs) in the blood. Hemodilution can result in false negative serology testing because not enough of the donor's own serum is present to test for viruses and other pathogens.
        - A qualified specimen is a specimen that has not been hemodiluted.
        - A hemodilution calculation can be completed to assess whether a sample has an acceptable level of hemodilution to be used in serologic screening tests. FDA-approved hemodilution calculations are the standard.
    d. Communication between the Host OPO and transplant programs regarding the type of specimen that was tested and the characteristics of this specimen is critical to decision making. While it may not be necessary to require qualified specimens for all donor screening tests, it is critical that everyone talks "in the same language." It is important to also recognize that qualified specimens cannot be required because they are not always available.
    e. Recommended policy modifications require that all blood samples obtained and used for screening tests required by OPTN policy must be assessed for hemodilution. It notes that qualified samples should be used for donor screening if available, but requires that transplant programs must be informed when a hemodiluted sample is used for this testing, including:
        - Which test(s) were completed using the hemodiluted specimen, and
        - A copy of the hemodilution calculation used (if requested).
    f. Modifications to require a complete history of all transfusions received by the donor since admission must be documented in the donor medical record were also recommended.

3. **Addition of toxoplasma serology for all potential heart donors (within proposed policy 2.2.4.4)**
    a. Currently, several tests to facilitate recipient selection and management, including CMV and EBV serologies, are currently required for all potential donors. There are clear community standards for post-transplant management based on donor and recipient serostatus for these conditions.

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[3] Code of Federal Regulations Title 21." *U.S. Department of Health and Human Services*. April 1, 2009. U.S. Food and Drug Administration, Web. 22 Jan 2010.
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=1271.80

b. Current guidelines recommend that heart transplant recipients receive anti-Toxoplasmosis prophylaxis unless both the donor and recipient are seronegative.[4] Fifty to seventy percent of seronegative heart recipients of seropositive donors will develop symptomatic infection without prophylaxis. About 13% of organ donors are seropositive for Toxoplasmosis.[5] Since the parasite typically infects muscular tissue, only heart and other muscle containing transplants (i.e. vascularized tissue transplants) and since there is no standard for prophylaxis of other organ recipients, screening need only be done for donors who will have hearts procured. Currently, this testing is done variably by OPOs and transplant centers and there are numerous instances in which no samples are collected or samples are lost in transit. Since Toxoplasmosis serology allows key decisions about recipient management and recipient selection – similar to CMV and EBV – the DTAC supports modifications that Toxoplasmosis screening should be added as a requirement for all potential heart donors.

c. The DTAC has reviewed several cases of potential toxoplasma transmission where donor status was unclear and recipients were adversely affected before receiving appropriate prophylactic treatment.

4. **Follow-up on Donor Testing (proposed policy 2.2.5)**
    a. The DTAC has reviewed a number of reports of potential disease transmission where disease was diagnosed in the donor post-recovery after receipt of final culture results.
    b. Proposed new language requires OPOs to establish a procedure defining their process for obtaining post-recovery donor testing results, and requires that all positive donor screening or diagnostic tests (including cultures and other updated test results received post-recovery) must be shared with recipient transplant programs within 24 hours of Host OPO receipt. The OPO should then provide updates such as identification of organism and sensitivities to the transplant program(s) as new information is received.
    c. Joint Working Group members agree that this practice is already in place in many OPOs, and that this language would not place undue burden on members.

5. **Addition to current requirements for maintaining donor information on any and all organs recovered (proposed policy 2.5.6)**
    a. Language was modified to specifically require that this information must be maintained for seven years per the **Final Rule**. Current language did not include a time requirement.

6. **New Requirement for Maintaining Donor Serum Samples (proposed policy 2.5.7)**
    a. In several cases of potential disease transmission reviewed by the DTAC, the Host OPO has not had donor serum available for testing to rule out donor-derived transmission of disease confirmed in a donor.

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[4] Kotton CN, Lattes R, and the AST Infectious Diseases Community of Practice. Parasitic infections in solid organ transplantation. ***Am J Transplant***. 2009;9(Suppl4):S234–S251.

[5] Gourishankar S, Doucette K, Fenton J, Pur ych D, Kowalewska- Grochowska K, Preiksaitis J. The use of donor and recipient screening for toxoplasma in the era of universal trimethoprim sulfamethoxazole prophylaxis. ***Transplantation***. 2008; 85: 980–985.

b. **AOPO's current Standards and Accreditation Manual** (Safety Standard 2.0) requires that a serum sample be maintained from every donor from which organs were transplanted for a period of at least ten years after the date of recovery. This serum must be available for retrospective testing.
c. The DTAC agreed with this standard and felt it appropriate for inclusion in policy. It also recommended language that the sample should be a qualified specimen, if possible.
d. The DTAC recognizes that if a sample is depleted for testing that an OPO should not be held responsible for not meeting the full 10 year requirement.

<u>In Policy Section 4.0</u>

1. **Informed Consent for Risk of Donor Derived Disease Transmission (proposed policy 4.2)**
    a. Language from current policy 4.1.1 was more specifically defined.
    b. New language was proposed to require that additional testing, monitoring and/or therapy as appropriate be offered to minimize the risk of infection and/or neoplasia in addition to routine post-transplant follow-up care.
    c. In order to emphasize the point that comprehensive screening for all potential transmissible diseases is impossible, new language is proposed that requires informing candidates of <u>general risks</u> of potential infection and/or tumor acquisition outside of the standard donor screening requirements.
    d. The DTAC recommends that specific informed consent be obtained when a hemodiluted specimen is used for donor HIV, HBV, and/or HCV screening. It was noted that a number of OPOs have already adopted this practice consistent with current policy related to "high risk" donors.
    e. Currently, the practice of testing recipients of organs from "high risk" donors is not standardized and appears to be variable.[6] As a result, a recipient may be informed of risk of infection and then not re-assessed to determine if a transmission has occurred. This is critical to allow appropriate, early intervention and to more fully assess the true risk of disease transmission with these organs.

2. **Recipient Notification of Post-Transplant Discovery of Donor Disease or Malignancy (proposed policy 4.3)**
    a. Because final results of some donor testing may be completed or change post-transplant, and/or new findings are sometimes recognized post-transplant (i.e. donor autopsy), the DTAC recommends policy to require recipient notification of such information (and documentation of this new information and the notification within the recipient medical record) after transplant program is notified (per proposed policy 2.2.5).
    b. Additional language requiring appropriate testing, monitoring, and/or therapy be offered in addition to routine post-transplant follow-up is also proposed.

3. **Designating a Patient Safety Contact (proposed policy 4.4)**
    a. In reviewing reports to the PSS, both OPTN members and OPTN staff have voiced frustration in finding the "right" person to share information with regarding a potential

1. [6] Ison MG, Stosor V. Transplantation of high-risk donor organs: a survey of US solid organ transplant center practices as reported by transplant infectious diseases physicians. ***Clin Transplant***. 2009; epub ahead of print.

disease transmission or safety event. As a result, the DTAC's Joint Working Group developed the idea of a Patient Safety Contact at each OPO and within each transplant program or center to be the "go to" person in such events.

b. Joint Working Group members agreed that a responsible person may be more critical than a clinical person to promote efficient communication and timely sharing of information. Staff noted that it may not be practical to name one specific person to this position, as it really is a 24-hour position, involving night and weekend call. The role may ultimately fall to whomever is taking call at a specific time or an OPO call center, so Joint sWorking Group members agreed that formalizing expectations is critical.

c. The Patient Safety Contact 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.

d. The Patient Safety Contact is meant to designate a person or specific number for contact related to patient safety communication. There are no specific requirements or qualifications that must be met to fulfill the position. This designation is not intended to be part of membership criteria and is not expected to become part of the membership process. As a result, it is not included in bylaw language.

e. Patient Safety Contact information must be exchanged between the OPO and transplant center to facilitate effective communication should a potential disease transmission or patient safety situation arise. This information should be made available to the OPTN contractor upon request.

f. Joint Working Group members considered a number of different time requirements for communicating this information, ranging from one to 24 hours. Ultimately the group agreed that not all information would rise to a level that would require communication within an hour, and noted that the inclusion of "as soon as possible and not to exceed 24 hours" was a reasonable first step in developing this policy.

4. Reporting Potential Disease or Malignancy Transmissions to the Patient Safety System (proposed policies 4.5, 4.5.1, and 4.5.2)

a. Based upon what it has learned since the implementation of the PSS in March 2006, the DTAC proposed modifications and additions to policy language which it believes will clarify Host OPO and transplant center responsibilities when a potential disease transmission event is reported.

b. Changes to current time requirements for reporting have been proposed, reducing current requirement of one working day to 24 hours.

c. Transplant center responsibilities include the proposed requirement of recipient notification as outlined in proposed policy 4.3.

If policy changes are ultimately approved by the Board of Directors, minor updates will be required for several other policy sections to update numbering:

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 as part of the OPO Committee's previous rewrite of Policy 2.0 and will also need to be addressed appropriately, as this language no longer exists in current policy language.

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

It is anticipated that by modifying and clarifying the policies, OPOs and transplant centers will have a more straightforward and consistent interpretation of the policy language. This is expected to result in improved patient safety and a more consistent approach to OPO and transplant center responsibilities in reporting potential disease transmission while reducing the possibility of non-compliance.

The DTAC's proposal addresses the following HHS Program Goals:

- Patient Safety
- Best Use
- Maximum Capacity
- Operational Effectiveness

The DTAC's proposal will address four of the OPTN/UNOS Strategic Plan Goals:

- Promote safe, high quality care for transplant candidates, transplant recipients and living donors by improved identification of potential infection or malignancy in potential donors and clearer guidance on reporting potential transmissions to the Patient Safety System.
- Achieve the best use of donated organ by clearly identifying donor testing requirements to help transplant centers better identify donor risk/quality versus benefit to their recipient(s).
- Maximize the number of transplants through careful screening of potential donors and clear requirements for communicating these results and any additional information the OPO may obtain post-transplant (i.e. culture results, autopsy findings, etc.).
- Improve upon the timely operational effectiveness of the OPTN Patient Safety System, by more clearly defining expectations for both OPOs and transplant centers in sharing information with each other and reporting findings to the OPTN.

The Committee's goals for these policy modifications meet provisions of the Final Rule as outlined in §121.6(a)[7].

[7] To view the full text of the Final Rule, please visit the following link:
http://optn.transplant.hrsa.gov/policiesAndBylaws/final_rule.asp

Plan for Evaluating the Proposal:

The DTAC will consider the following information:

- **What questions or hypotheses are guiding the evaluation of the proposal?**
  - How many OPOs are using hemodiluted samples for donor screening?
  - How many of these donors result in reports of potential disease transmission to the Patient Safety System?
  - Is information regarding potential disease transmission events being communicated more efficiently through the adoption of Patient Safety Contacts?

- **Policy Performance Measures:**
  - Number of overall potential disease transmission events versus the total number of donors per year;
  - Number of potential disease transmission events involving diseases for which potential donors are screened; and
  - Number of confirmed donor derived disease transmissions versus the total number of potential cases reported and the total number of transplants per year.
  - Is there a noticeable improvement in timely communication and contact noted by OPTN staff involved in DTAC case review facilitation?

- **Time Line for Evaluation:**
  The DTAC will continue its yearly review of numbers and trends in cases of potential disease transmission reported to the Patient Safety System and reviewed by the committee to determine if additional policy modifications regarding donor screening requirements and/or reporting should be considered.

Additional Data Collection:

If approved by the Board of Directors, implementation of the full proposal will require the collection of two new data elements:

1. A Yes/No field in DonorNet® will be added for OPOs to denote whether a qualified sample was used to complete each of the required donor serologic screening tests. In some cases, there will not be enough qualified sample to complete all required tests, so this information is important in determining whether a donor carries an increased risk for blood borne pathogens.

   <u>Data Collection Principle</u> = Ensure patient safety when no alternative sources of data exist

2. An addition to the list of required donor serology tests in DonorNet® to capture toxoplasma serology screening results for potential heart donors as Positive/Negative/Unknown/Not Done/Indeterminate/Pending.

   <u>Data Collection Principle</u> = Ensure patient safety when no alternative sources of data exist

Expected Implementation Plan:

If approved by the Board of Directors, additional programming of DonorNet® to: (1) add fields to collect yes/no response on whether a qualified specimen was utilized to complete each required donor serologic test; and (2) collect toxoplasma serologic testing results as positive/negative/not done/indeterminate/pending on the organ data tab. The DTAC will work together with UNOS IT Staff to develop and review specification documents as well as to determine priority among other committee policy changes awaiting implementation. Actual implementation dates will be determined based on overall project priorities.

OPOs and transplant centers should familiarize themselves with the new policy requirements and designate Patient Safety Contacts for their organizations.

DEQ staff will make appropriate changes to OPO and transplant center site survey protocols to monitor changes related to these policy changes.

Communication and Education Plan:

If approved by the Board of Directors, the transplant community will receive information regarding new policy language via the Policy Notice that follows each Board meeting. Additional details regarding the final implementation date will be sent to members through a UNet℠ Systems Notice.

The DTAC will provide additional review of the changes and give an avenue for questions that may arise after Board consideration in its electronic newsletter. This newsletter is part of the monthly e-newsletter sent to members on the third Monday of each month.

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy Notice [This notice informs community that policy modifications were approved by the OPTN/UNOS Board of Directors.]	Directors of Organ Procurement, Lab Directors/Supervisors, OPO Executive Directors, OPO Medical Directors, OPO Coordinators Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers,	Electronic – Included in the monthly e-newsletter sent on the 3rd Monday of each month	30 days after the board approves the change.

	Transplant Data Coordinators		
UNet[SM] System Notice	UNet[SM] users	Through UNet[SM]	8 weeks, 4 weeks, and 2 weeks before implementation, and upon implementation

Education/Training Activities			
Education/Training Description	**Audience(s)**	**Deliver Method(s)**	**Timeframe and Frequency**
DTAC Newsletter - Notice to OPOs and Transplant Programs explaining the changes and providing an avenue for questions	OPTN members	Electronic – Included in the monthly e-newsletter sent on the 3rd Monday of each month	Within 3 months of Board approval

Monitoring and Evaluation:

The OPTN Department of Evaluation and Quality (DEQ) currently monitors member compliance with the existing requirements of Policies 2.0, 4.0 and 5.0 during member site surveys and as part of the allocation analysis process. DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review. If these policy modifications are approved and implemented, then DEQ staff would incorporate the new and modified requirements into monitoring procedures.

The following modifications to the OPO site review process may include but not be limited to:

- Review of the donor's medical behavioral history
- Review of hemodilution worksheets
- Review documentation of communication of hemodiluted samples to transplant centers
- Verify the types of serology tests used by the Host OPO
- Review communication to transplant centers regarding results of all positive post-recovery donors screening tests
- Verify donor records are maintained for seven years
- Verify that the OPO archived a serum sample for each donor for ten years
- Verify the OPO has notified transplant centers of post-recovery positive culture results

The following modifications to the transplant center site review process may include but not be limited to:

- Review of informed consent for recipients of donors at high risk for disease transmission

DEQ staff also monitors complaints received through the Patient Services Line, the confidential Member Reporting Line, and any other UNOS employees. Any complaints received through these mechanisms

that have the potential for policy or bylaw violation are forwarded to the MPSC[8] If the MPSC identifies the need for clarification, education, or additional changes related to this policy, the MPSC may forward its recommendations to the appropriate Committees.

OPTN Patient Safety Staff monitor reporting of potential and confirmed donor related disease transmission events, as defined in Policy 4.0, through reports submitted to the Patient Safety System in UNet[sm]. Staff follows up on these reports with additional information collected through initial and final report submissions by the Host OPO and communication with transplant centers as needed. OPTN staff provides this information (redacted for any OPO, transplant center, or patient identifiers) to the DTAC at the time of report submission and again monthly and bi-annually to determine:

- Whether a potential transmission event was expected or unexpected based upon information available prior to transplant. (Unexpected transmissions occur from a pathogen that was either unrecognized or not screened for in the donor.); and

- The probability of the event being a donor-derived disease transmission. Once a final report is received from the donor OPO, each potential transmission report is also categorized as to the likelihood of being donor-derived and recipient outcomes are assessed.

Any finding or reported event that may rise to the level of a potential Category I violation (as defined by OPTN Bylaws Appendix A 2.05A) will be immediately reported to the OPTN Executive Director (or his designee), MPSC Chair and OPTN/UNOS President for further consideration. If all agree that the event poses a substantial threat to patient health and/or public safety and is determined to be a Category I potential violation, the Secretary of Health and Human Services (HHS) or his/her designee will be notified that the matter is under investigation and a rapid review of the matter will proceed.

Policy Proposal:

For the convenience of the reader, a crosswalk follows the proposed modifications to Policies 2.0, 4.0, and 5.5.1. This crosswalk highlights whether current sections of policy have been recommended for relocation or elimination and also highlights new policy language for consideration.

To view current policy language, please visit the OPTN website at:
http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp

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)~~.

[8] The Membership and Professional Standards Committee performs confidential medical peer review, and any recommendations or information reported to Committees is only reported in aggregate (i.e. non-identified, not case specific) data.

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 including HIV (as defined by the US Public Health Service (PHS)), and also Hepatitis B, Hepatitis C or prion disease. If the donor meets the criteria

set forth in the current US PHS guidance[9], the Host OPO must communicate this information regarding donor history 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[10]) utilizing an 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.

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.

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).

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[9] 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

[10] Code of Federal Regulations Title 21." *U.S. Department of Health and Human Services*. April 1, 2009. U.S. Food and Drug Administration, Web. 22 Jan 2010. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=1271.80

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 OPTN Members shall not knowingly participate in the transplantation or sharing of organs from donors who are identified as HIV positive by an FDA licensed screening test unless subsequent confirmatory testing unequivocally indicates that the original test's 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 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 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 test~~s are~~ is not commercially available prior to transplant, then ~~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 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~~4.2For potential renal donors:

- Creatinine; and
- B.U.N.

2.2.~~3~~4.3For 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~~4.5For potential pancreas donors:

- Serum amylase.

2.2.~~3~~4.6For 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 to the transplant program(s).

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

The Host OPO must 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.

2.2.6 Reporting Disease. The Host OPO is responsible for making historical 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 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 A, 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.

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

[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

~~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 (**including** when a hemodiluted specimen is used for donor HIV, HBV, and/or HCV screening (see Policy 2.2.3.1)).

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, 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
- 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.
- 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.

4.4 PATIENT SAFETY CONTACT. Each 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.~~

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 UNet^{SM}) to OPTN Patient Safety Staff within 24 hours of reporting the event through the Patient Safety System^{SM} 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.

- Submission of a **Potential Disease Transmission Follow-Up Report** (a form that will be sent to the Host OPO by OPTN staff) 45 days after the initial reporting date; OPTN Patient Safety Staff may request additional Potential Disease Transmission long-term follow-up depending on the 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 receives 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.)

Language struck 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.

PLEASE NOTE: Proposed modifications to Policy 5.5.1 also appear in the OPO Committee's public comment proposal to modify sections of Policy 5.0. The OPO Committee agreed that including these changes with its own would provide the reader/commenter with more continuity.

Crosswalk of Proposed Modifications to OPTN Policies 2.0 and 4.0

The proposed reorganization/rewrite of Policies 2.0 and 4.0 is listed in summary form in the table below. Efforts were made to move language related to donor evaluation in 4.0 up to 2.0. This table can be used to find the location of the new proposed policy language that corresponds to the existing policy language.

Current Policy Number	Proposed language location (if applicable)	Summary of Proposed Changes
2.0 Minimum Procurement Standards for an OPO	n/a	• Expanded upon current language to clarify the intent of the policy section is to maximize the gift of donation and optimize outcomes and safety.
2.1 Host OPO	n/a	• Added a sentence, "complying with accepted practice and OPTN policy throughout the donation process." • Broken down into several short paragraphs rather than one dense one for easier reading
2.2 Evaluation of Potential Donors	n/a	Added "importing" to OPOs for clarification
2.2.1	n/a	No changes
2.2.2	n/a	No changes to remaining language, but broke down current categories into separate numbered sections and added additional language to each
	2.2.2.1 *(New section)*	• Added a policy number to current language • expounds upon obtaining the donor's medical/behavioral history by pulling related language in from 4.1.1 and 4.6.1). • Introduces HCV and HBV as blood borne pathogens (rather than using high risk terminology) in addition to HIV and also adds prion disease.
	2.2.2.2 *(New section)*	• Added a policy number to current language that was already included under 2.2.2 • Changed medical "chart" to medical "record" to reflect current terminology.
	2.2.2.3 *(New section)*	• Added a policy number to current language already included under 2.2.2 • Added "obtaining vital signs" to language requiring physical

		examination of the donor instead of keeping it as a separate line
	2.2.3 Screening Potential Organ Donors *(New section)*	Proposed 2.2.3 includes all information related to screening potential organ donors (pulling a number of sections from 4.0 into 2.0 for OPO convenience, rather than having to flip back and forth between the sections).
	2.2.3.1 *(New section)*	• New requirement that all blood samples used for screening tests be assessed for hemodilution. • provides definition of a "qualified sample." This replaces "pre-transfusion" language in current policy. • If sample is hemodiluted, OPOs must inform TX center(s) of which test(s) were completed with said sample and provide a copy of the hemodilution calculation if requested. • OPO must document complete history of all transfusions received by the donor since admission in the donor chart.
	2.2.3.2 *(New section)*	• Language adapted from 4.1 regarding screening potential organ donors for HIV • Outlines whether retesting is necessary on qualified samples
	2.2.3.3 *(New section)*	• Adapted from 4.1 and all of 4.1.2 to address the fact that members should not knowingly participate in sharing HIV+ organs.
	2.2.3.4 *(New section)*	• Pulled directly from 4.1.3 regarding exceptions to HIV guidelines. • New specific requirement that the transplant program must obtain and document informed consent in these cases as specified in proposed policy 4.2.
	2.2.3.5 *(New section)*	• Adapted from 4.2.2 and changed only to reference potential donors and donors instead of also including candidates and recipients. • Added language "only when necessary for medical decision making purposes"

2.2.3	2.2.4 Donor Evaluation	Former Section 2.2.3 (now 2.2.4) includes: • A statement that donor evaluation must be performed or coordinated by Host OPO • New requirement that labs must be appropriately accredited; • Requirement that the Host OPO to document when a FDA-approved diagnostic test was utilized in place of a screening test in the donor record, and also share this information with the TX program, BUT includes exceptions (based upon DTAC Survey findings and current FDA test approval) that: ○ Diagnostic testing for Anti-HIV is **NOT** acceptable ○ FDA-approved diagnostic testing for VDRL/RPR **IS** acceptable. • Elimination of the sentence regarding TX centers making clinical decision to accept organs based on available data
2.2.3.1	2.2.4.1	• Added the word deceased for clarity • Included reference to Policy 3.2.4 for ABO confirmation • Added that diagnostic testing is NOT an acceptable alternative for Anti-HIV screening • Added that FDA-approved diagnostic testing for VDRL/RPR **IS** acceptable. • Added new language to require that any additional testing completed on a donor (i.e. Chagas, WNV, HTLV-1/2) be communicated to all recipient centers in addition to required testing.
2.2.3.2	2.2.4.2	No changes
2.2.3.3	2.2.4.3	No changes
2.2.3.4	2.2.4.4	• Added new toxoplasma screening requirement for all potential heart donors
2.2.3.5	2.2.4.5	No changes
2.2.3.6	2.2.4.6	No changes
	2.2.5 Follow-up on Donor Testing.*(New section)*	• Specific language that makes OPOs responsible for timely follow-up and reporting of any new or changed clinically relevant information regarding the donor to the TX

		program. (If the OPO is not sure whether information is considered clinically relevant, the Medical Director should be consulted.) • Requires OPOs to establish a procedure to define its process for obtaining final post-recovery donor testing results from donor hospital • Specific requirement that all positive donor screening and diagnostic tests received must be reported to the TX program's Patient Safety Contact (which is defined in Policy 4.4) within 24 hours of Host OPO receipt. Additional updates including identification of organism and sensitivities must be shared with the transplant program as the OPO receives this information.
	2.2.6 Reporting Disease. *(New section)*	• Adapted from policy 4.6.2, making OPOs responsible for making historical and laboratory assessments to identify malignant or infectious conditions that could affect potential recipients, and sharing this information with TX programs. • 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). • A list of disease was included in Policy 4.6.2. This list was eliminated in these modifications, but will be included in a guidance document that will be presented to the Board with the final policy proposal.
	2.2.7 Human Pituitary Derived Growth Hormone *(New section)*	• Adapted from 4.5, outlining the risk of prion disease related to the use of organs from donors who have received HPDGH (not recombinant) and the need for informed consent. • Transplant program must document informed consent as required in proposed policy 4.2
2.3 Donor Maintenance	n/a	No changes
2.3.1	n/a	No changes

2.3.2	n/a	No changes
2.3.3	n/a	No changes
2.3.4	n/a	No changes
2.3.5	n/a	No changes
2.4 Obtaining Consent	n/a	No changes
2.5 Organ Procurement Quality	n/a	No changes
2.5.1	n/a	No changes
2.5.2	n/a	No changes
2.5.3	n/a	• Added a requirement to record lot numbers for flush solutions and additives.
2.5.4	n/a	No changes
2.5.5	n/a	No changes
2.5.6	5.5.1	• STRUCK and moved to policy section 5.5.1, to remove the reference back to 2.0 for OPO convenience, placing list of required documents in one location. • *This language will also be included in OPO public comment proposal where other modifications to Policy 5.0 are recommended to make review easier for the reader.*
2.5.6.1	5.5.1	• STRUCK and added list of specific documentation requirements to 5.5.1 • Changed "serology results" to "infectious disease testing results" to be more inclusive of other types of testing that may be included (NAT, etc)
2.5.7	2.5.6	• Added language to define that donor records must be maintained for seven years per the Final Rule. • Struck language related to transportation for non-local teams. This was relocated to new policy 2.5.8
	2.5.7 *(New Section)*	• Requires Host OPO to maintain a serum sample for each donor from which organs were transplanted for a period of at least 10 years. • This serum must be available to use for retrospective testing if needed. • OPO must document the type of specimen that has been archived in the donor chart. • The specimen should be a qualified specimen (as defined in new policy section 2.2.3.1), and not hemodiluted if

		possible.
	2.5.8 *(New Section)*	• Created a separate policy section to address the requirement for Host OPOs to ensure transport to/from airport for non-local procurement teams (formerly located within current 2.5.7, no language changes)
2.6 Initiating Organ Procurement and Placement	n/a	No changes
2.7 Removal of Non-Renal Organs.	n/a	No changes
2.7.1	n/a	No changes
2.8 Recovery of DCD Organs.	n/a	• Added title to policy section (Recovery of DCD Donor Organs)
2.9 Multi-Cultural and Diversity Issues	n/a	No changes
4.0 AIDS, HPDGH, and Reporting of Potential Recipient Diseases or Medical Conditions, Including Malignancies, of Donor Origin	n/a	• Title edited to reflect that re-location of information related to AIDS and HPDGH to section 2.0. Now "**Identification of Transmissible Diseases In Organ Recipients**"
4.1 Screening Potential Organ Donors for HIV	2.2.2.1, 2.2.3.2, and 2.2.3.3	See related documentation in corresponding policy sections above. Language was broken down and moved into the sections listed.
4.1.1	2.2.2.1 (second paragraph) for donors, 4.2.1 for candidate and recipients	See related documentation in corresponding policy sections above
4.1.2	2.2.3.3	See related documentation in corresponding policy sections above.
4.1.3	2.2.3.4	See related documentation in corresponding policy sections above.
4.1.4	Recommended for elimination	Language struck from the section. This language is not enforceable, as it "encourages" members.
4.2 Screening Potential Transplant Recipients for HIV	4.1 Screening Potential Transplant Recipients for Blood-Borne Pathogens	• Title expanded to include other blood borne diseases beyond HIV, adding HCV and HBV
4.2.1	4.1.1	• Removed language regarding whether the candidate is asymptomatic

		• Removed language regarding advising the candidate that he/she may be at increased risk of morbidity/mortality due to immunosuppression. • Added language that such candidates should not be excluded from candidacy unless there is a documented contraindication to transplantation based upon local policy.
4.2.2	2.2.3.5 for donor-related language) 4.1.2 for candidate and recipient-related language	• Divided this up to move donor-related language to 2.2.3.5 to keep all donor evaluation-related language in one policy section. • Added the phrase "only when necessary for medical decision-making purposes"
4.2.3	Recommended for elimination	Language was not up-to-date with current medical practice
4.3	Recommended for elimination	Language was a recommendation and not enforceable.
4.4	Recommended for elimination	A general recommendation, not enforceable.
4.5	2.2.8	See related documentation in corresponding policy sections above
4.6	Sections appear in 2.1, 2.2, and 2.2.3	See related documentation in corresponding policy sections above
4.6.1	2.2.2.1	See related documentation in corresponding policy sections above
4.6.2	2.2.6	• See related documentation in corresponding policy sections above. Language was adapted slightly.
4.6.3	2.2.3.4 for donors, new sections 4.2.1 and 4.2.3 for recipients (see below)	See related documentation in corresponding policy sections above
4.6.4	Recommended for elimination.	Specifically related to donor consent, and not enforceable because it is a recommendation.
	4.2 Requirements for Informed Consent Regarding Risk of Transmissible Disease *(New section)*	• Includes requirements for obtaining and documenting informed consent prior to transplant when donor has known medical condition that may be transmissible or recognized increased risk for blood borne viruses (including when a hemodiluted specimen is used for HIV, HBV and/or HCV screening.

		• Includes requirements for obtaining and documenting informed consent regarding general risk of potential infection or tumor acquisition outside of the standard donor screening requirements. • Provides a list of specific requirements related to: ○ Explaining risks and obtaining informed consent. ○ Documenting consent in recipient medical record ○ Offering the recipient addition post-tx testing, monitoring and/or therapy or prophylaxis to minimize the risk of infection in addition to routine post-tx follow-up.
	4.3 Disclosure of Post-Transplant Discovery of Donor Disease or Malignancy and Notification of Recipients. *(New section)*	• Disclosure of Post-TX Discovery of Donor Disease or Malignancy and Notification of Recipients • Because results from donor testing samples may be completed or change after transplantation, and/or new clinically relevant findings are sometimes recognized post-tx, transplant program must: ○ Notify recipient of a risk of transmissible disease that was not previously identified ○ Document new donor info and potential risk for disease/malignancy in recipient medical record ○ Offer recipient additional testing, monitoring, and/or therapy as appropriate in addition to routine follow-up. Related documentation should be maintained in the recipient medical record.
	4.4 Patient Safety Contact *(New section)*	• Requires OPOs and transplant programs to develop a process for identifying a patient safety contact • Lists responsibilities for the patient safety contact • Requires that patient safety contact information must be exchanged to facilitate effective communication

		should a patient safety situation or potential disease transmission arise, and make this information available to the OPTN if requested.
4.7	4.5 Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions, Including Malignancies.	• Current language modified based upon questions from members directed to OPTN Patient Safety Staff related to reporting potential disease transmission events.
	4.5.1 Host OPO Responsibilities *(New section)*	• New section of policy created to specifically outline OPO responsibilities in reporting cases to the PSS • Includes language adapted from former 4.7 directions to OPOs.
	4.5.2 Transplant Program Responsibilities *(New section)*	• New section of policy created to specifically outline TX program responsibilities • Specifically includes reference back to Policy 4.3, requiring centers to notify recipients of potential or confirmed transmission and document notification in the medical record.

UNOS Organ Donor Infectious Disease Testing

Please complete the survey before October 24th, 2008.

The Ad Hoc Disease Transmission Advisory Committee (DTAC) is interested in how organ donor infectious disease testing is currently being performed. Additionally, we hope to understand the current and future limitations locally if policy was changed to require FDA approved, licensed, or cleared screening tests. To understand the current practices and potential challenges to donor testing, we are conducting a survey of all OPOs. We recognize that this is a rather lengthy survey, but your complete participation will greatly help DTAC and will inform policy decisions related to organ donor screening using serologic testing.

The Committee thanks you in advance for helping out and completing the form.

If you have questions, please feel free to contact Shandie Covington covingsh@unos.org, Kimberly Taylor taylorki@unos.org or the chair of the Committee, Dr. Michael G. Ison mgison@northwestern.edu.

Donor Testing: Screening vs. Diagnostic tests

Please enter your 4-letter UNOS code

Do you feel that all donors should be tested with FDA approved screening tests?

- Yes
- No

Why or Why Not?

If donor screening using FDA-approved, licensed, or cleared screening (but not diagnostic) tests were required by policy, could you comply?

- Yes
- No

Why or Why Not?

Would you use centralized donor infectious disease-testing lab that offered screening tests, if the testing could be performed in a timely manner for organ placement?

- Yes
- No

Why or Why Not?

Anti-HIV I, II Screening Testing

What screening test are you currently using for Anti-HIV I, II testing?

Manufacturer	
Test Name	
Version	

Is this test FDA approved for

- Screening
- Diagnostics
- Not Sure

Did you use a different screening test for this pathogen before June 30th, 2008?

- Yes
- No

Are you planning to use a different screening test within the next 3-6 months?

- Yes
- No

If yes, which test will you use?

Manufacturer	
Test Name	

What, if any, are the challenges you face with regard to continuing to use the current test?

Do you perform this test in house or send to an outside facility for testing?

- [ ] In-House
- [ ] Send Out Local Lab - Hospital lab
- [ ] Send Out Local Lab - Independent Lab
- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab
- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

If you send this test to an outside facility

What test does the facility use? (Please include manufacturer and test name)

What is the turnaround time when you send this out?

HBsAg Screening Testing

What screening test are you currently using for HBsAg testing?

Manufacturer	
Test Name	
Version	

Is this test FDA approved for

- ○ Screening
- ○ Diagnostics
- ○ Not Sure

Did you use a different screening test for this pathogen before June 30th, 2008?

- ○ Yes
- ○ No

Are you planning to use a different screening test within the next 3-6 months?

- ○ Yes
- ○ No

If yes, which test will you use?

Manufacturer

Test Name

What, if any, are the challenges you face with regard to continuing to use the current test?

Do you perform this test in house or send to an outside facility for testing?

- ☐ In-House
- ☐ Send Out Local Lab - Hospital lab
- ☐ Send Out Local Lab - Independent Lab
- ☐ Send Out Local Lab - OPO
- ☐ Send Out Regional Lab - Hospital Lab
- ☐ Send Out Regional Lab - Independent Lab
- ☐ Send Out Regional Lab - OPO
- ☐ Other

If you send this test to an outside facility

What test does the facility use? (Please include manufacturer and test name)	
What is the turnaround time when you send this out?	

If your OPO does donor screening on donors for both organ and tissue use, do you do different tests for tissue donors than you do for organ donors?

- ○ Yes
- ○ No

If yes, what test do you use?

Manufacturer	
Test Name	

Do you do the test in house or as a send out?

- ☐ In House
- ☐ Send Out Local Lab - Hospital Lab
- ☐ Send Out Local Lab - Independent Lab
- ☐ Send Out Local Lab - OPO
- ☐ Send Out Regional Lab - Hospital Lab
- ☐ Send Out Regional Lab - Independent Lab
- ☐ Send Out Regional Lab - OPO
- ☐ Other

Anti HBc Total (IgG & IgM) Screening Testing

What screening test are you currently using for Anti HBc Total (IgG & IgM) testing?

Manufacturer

Test Name

Version

Is this test FDA approved for

- Screening
- Diagnostics
- Not Sure

Did you use a different screening test for this pathogen before June 30th, 2008?

- Yes
- No

Are you planning to use a different screening test within the next 3-6 months?

- Yes
- No

If yes, which test will you use?

Manufacturer

Test Name

What, if any, are the challenges you face with regard to continuing to use the current test?

Do you perform this test in house or send to an outside facility for testing?

- In-House
- Send Out Local Lab - Hospital lab
- Send Out Local Lab - Independent Lab
- Send Out Local Lab - OPO

- [ ] Send Out Regional Lab - Hospital Lab
- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

If you send this test to an outside facility

What test does the facility use? (Please include manufacturer and test name)

What is the turnaround time when you send this out?

If your OPO does donor screening on donors for both organ and tissue use, do you do different tests for tissue donors than you do for organ donors?

- ( ) Yes
- ( ) No

If yes, what test do you use?

Manufacturer

Test Name

Do you do the test in house or as a send out?

- [ ] In House
- [ ] Send Out Local Lab - Hospital Lab
- [ ] Send Out Local Lab - Independent Lab
- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab
- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

Anti HBc IgM Screening Testing

What screening test are you currently using for Anti HBc IgM testing?

Manufacturer	
Test Name	
Version	

Is this test FDA approved for

- ○ Screening
- ○ Diagnostics
- ○ Not Sure

Did you use a different screening test for this pathogen before June 30th, 2008?

- ○ Yes
- ○ No

Are you planning to use a different screening test within the next 3-6 months?

- ○ Yes
- ○ No

If yes, which test will you use?

Manufacturer	
Test Name	

What, if any, are the challenges you face with regard to continuing to use the current test?

Do you perform this test in house or send to an outside facility for testing?

- [ ] In-House
- [ ] Send Out Local Lab - Hospital lab
- [ ] Send Out Local Lab - Independent Lab
- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab
- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

If you send this test to an outside facility

What test does the facility use? (Please include manufacturer and test name)

What is the turnaround time when you send this out? _____

If your OPO does donor screening on donors for both organ and tissue use, do you do different tests for tissue donors than you do for organ donors?

- ( ) Yes
- ( ) No

If yes, what test do you use?

Manufacturer _____

Test Name _____

Do you do the test in house or as a send out?

- [ ] In House
- [ ] Send Out Local Lab - Hospital Lab
- [ ] Send Out Local Lab - Independent Lab
- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab

- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

Anti-HCV Screening Testing

What screening test are you currently using for Anti-HCV testing?

Manufacturer	
Test Name	
Version	

Is this test FDA approved for

- ( ) Screening
- ( ) Diagnostics
- ( ) Not Sure

Did you use a different screening test for this pathogen before June 30th, 2008?

- ( ) Yes
- ( ) No

Are you planning to use a different screening test within the next 3-6 months?

- ( ) Yes
- ( ) No

If yes, which test will you use?

Manufacturer	
Test Name	

What, if any, are the challenges you face with regard to continuing to use the current test?

Do you perform this test in house or send to an outside facility for testing?

- [ ] In-House
- [ ] Send Out Local Lab - Hospital lab
- [ ] Send Out Local Lab - Independent Lab
- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab
- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

If you send this test to an outside facility

What test does the facility use? (Please include manufacturer and test name)

What is the turnaround time when you send this out? _____

If your OPO does donor screening on donors for both organ and tissue use, do you do different tests for tissue donors than you do for organ donors?

- ( ) Yes
- ( ) No

If yes, what test do you use?

Manufacturer _____

Test Name _____

Do you do the test in house or as a send out?

- [ ] In House
- [ ] Send Out Local Lab - Hospital Lab
- [ ] Send Out Local Lab - Independent Lab
- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab

- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

Syphilis Screening Testing

What screening test are you currently using for Anti-HCV testing?

Manufacturer	
Test Name	
Version	

Is this test FDA approved for

- ( ) Screening
- ( ) Diagnostics
- ( ) Not Sure

Did you use a different screening test for this pathogen before June 30th, 2008?

- ( ) Yes
- ( ) No

Are you planning to use a different screening test within the next 3-6 months?

- ( ) Yes
- ( ) No

If yes, which test will you use?

Manufacturer	
Test Name	

What, if any, are the challenges you face with regard to continuing to use the current test?

Do you perform this test in house or send to an outside facility for testing?

- [ ] In-House
- [ ] Send Out Local Lab - Hospital lab
- [ ] Send Out Local Lab - Independent Lab
- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab
- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

If you send this test to an outside facility

What test does the facility use? (Please include manufacturer and test name)

What is the turnaround time when you send this out?

If your OPO does donor screening on donors for both organ and tissue use, do you do different tests for tissue donors than you do for organ donors?

- ( ) Yes
- ( ) No

If yes, what test do you use?

Manufacturer

Test Name

Do you do the test in house or as a send out?

- [ ] In House
- [ ] Send Out Local Lab - Hospital Lab
- [ ] Send Out Local Lab - Independent Lab

- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab
- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

Anti-HTLV I/II Screening Testing

What screening test are you currently using for Anti-HTLV I/II testing?

Manufacturer	
Test Name	
Version	

Is this test FDA approved for

- ○ Screening
- ○ Diagnostics
- ○ Not Sure

Did you use a different screening test for this pathogen before June 30th, 2008?

- ○ Yes
- ○ No

Are you planning to use a different screening test within the next 3-6 months?

- ○ Yes
- ○ No

If yes, which test will you use?

Manufacturer	
Test Name	

What, if any, are the challenges you face with regard to continuing to use the current test?

Do you perform this test in house or send to an outside facility for testing?

- [ ] In-House
- [ ] Send Out Local Lab - Hospital lab
- [ ] Send Out Local Lab - Independent Lab
- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab
- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

If you send this test to an outside facility

What test does the facility use? (Please include manufacturer and test name)

What is the turnaround time when you send this out?

If your OPO does donor screening on donors for both organ and tissue use, do you do different tests for tissue donors than you do for organ donors?

- ( ) Yes
- ( ) No

If yes, what test do you use?

Manufacturer

Test Name

Do you do the test in house or as a send out?

- [ ] In House
- [ ] Send Out Local Lab - Hospital Lab

- [ ] Send Out Local Lab - Independent Lab
- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab
- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

Anti-CMV Total (IgG & IgM) Screening Testing

What screening test are you currently using for Anti-CMV Total (IgG & IgM) testing?

Manufacturer	
Test Name	
Version	

Is this test FDA approved for

- ○ Screening
- ○ Diagnostics
- ○ Not Sure

Did you use a different screening test for this pathogen before June 30th, 2008?

- ○ Yes
- ○ No

Are you planning to use a different screening test within the next 3-6 months?

- ○ Yes
- ○ No

If yes, which test will you use?

Manufacturer

Test Name

What, if any, are the challenges you face with regard to continuing to use the current test?

Do you perform this test in house or send to an outside facility for testing?

- [ ] In-House
- [ ] Send Out Local Lab - Hospital lab
- [ ] Send Out Local Lab - Independent Lab
- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab
- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

If you send this test to an outside facility

What test does the facility use? (Please include manufacturer and test name)

What is the turnaround time when you send this out?

If your OPO does donor screening on donors for both organ and tissue use, do you do different tests for tissue donors than you do for organ donors?

- ( ) Yes
- ( ) No

If yes, what test do you use?

Manufacturer

Test Name

Do you do the test in house or as a send out?

- [ ] In House
- [ ] Send Out Local Lab - Hospital Lab
- [ ] Send Out Local Lab - Independent Lab
- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab
- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

Anti-CMV IgM Screening Testing

What screening test are you currently using for Anti-CMV IgM testing?

Manufacturer	
Test Name	
Version	

Is this test FDA approved for

- ( ) Screening
- ( ) Diagnostics
- ( ) Not Sure

Did you use a different screening test for this pathogen before June 30th, 2008?

- ( ) Yes
- ( ) No

Are you planning to use a different screening test within the next 3-6 months?

- ( ) Yes
- ( ) No

If yes, which test will you use?

Manufacturer

Test Name

What, if any, are the challenges you face with regard to continuing to use the current test?

Do you perform this test in house or send to an outside facility for testing?

- [ ] In-House
- [ ] Send Out Local Lab - Hospital lab
- [ ] Send Out Local Lab - Independent Lab
- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab
- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

If you send this test to an outside facility

What test does the facility use? (Please include manufacturer and test name)

What is the turnaround time when you send this out?

If your OPO does donor screening on donors for both organ and tissue use, do you do different tests for tissue donors than you do for organ donors?

- ( ) Yes
- ( ) No

If yes, what test do you use?

Manufacturer

Test Name

Do you do the test in house or as a send out?

- [ ] In House
- [ ] Send Out Local Lab - Hospital Lab
- [ ] Send Out Local Lab - Independent Lab
- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab
- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

Anti EBV IgG Screening Testing

What screening test are you currently using for Anti EBV IgG testing?

Manufacturer	
Test Name	
Version	

Is this test FDA approved for

- ( ) Screening
- ( ) Diagnostics
- ( ) Not Sure

Did you use a different screening test for this pathogen before June 30th, 2008?

- ( ) Yes
- ( ) No

Are you planning to use a different screening test within the next 3-6 months?

- ( ) Yes
- ( ) No

If yes, which test will you use?

Manufacturer

Test Name

What, if any, are the challenges you face with regard to continuing to use the current test?

Do you perform this test in house or send to an outside facility for testing?

- [ ] In-House
- [ ] Send Out Local Lab - Hospital lab
- [ ] Send Out Local Lab - Independent Lab
- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab
- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

If you send this test to an outside facility

What test does the facility use? (Please include manufacturer and test name)

What is the turnaround time when you send this out?

If your OPO does donor screening on donors for both organ and tissue use, do you do different tests for tissue donors than you do for organ donors?

- ( ) Yes
- ( ) No

If yes, what test do you use?

Manufacturer

Test Name

Do you do the test in house or as a send out?

- [ ] In House
- [ ] Send Out Local Lab - Hospital Lab
- [ ] Send Out Local Lab - Independent Lab
- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab
- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

Anti EBV IgM Screening Testing

What screening test are you currently using for Anti EBV IgM testing?

Manufacturer	
Test Name	
Version	

Is this test FDA approved for

- ( ) Screening
- ( ) Diagnostics
- ( ) Not Sure

Did you use a different screening test for this pathogen before June 30th, 2008?

- ( ) Yes
- ( ) No

Are you planning to use a different screening test within the next 3-6 months?

- ( ) Yes
- ( ) No

If yes, which test will you use?

Manufacturer

Test Name

What, if any, are the challenges you face with regard to continuing to use the current test?

Do you perform this test in house or send to an outside facility for testing?

- [ ] In-House
- [ ] Send Out Local Lab - Hospital lab
- [ ] Send Out Local Lab - Independent Lab
- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab
- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

If you send this test to an outside facility

What test does the facility use? (Please include manufacturer and test name)

What is the turnaround time when you send this out?

If your OPO does donor screening on donors for both organ and tissue use, do you do different tests for tissue donors than you do for organ donors?

- ( ) Yes
- ( ) No

If yes, what test do you use?

Manufacturer

Test Name

Do you do the test in house or as a send out?

- [ ] In House
- [ ] Send Out Local Lab - Hospital Lab
- [ ] Send Out Local Lab - Independent Lab
- [ ] Send Out Local Lab - OPO
- [ ] Send Out Regional Lab - Hospital Lab
- [ ] Send Out Regional Lab - Independent Lab
- [ ] Send Out Regional Lab - OPO
- [ ] Other

Testing in Triplicate

If a donor were available for both organs and tissues, do you perform the tissue procurement and donor testing?

	Yes	No
Procurement	○	○
Testing	○	○

If you perform testing for donors of both tissues and organs, and if you perform tests that require you to repeat in duplicate, do you instead run the initial test in triplicate?

- ○ Yes
- ○ No

Does your OPO/Transplant center repeat serologies on organs imported from another OPO?

- ○ Yes
- ○ No

If Yes, under what circumstances?

If yes, do you share the results of each test performed in triplicate with tissue processors?

- Yes
- No

Do the tissue banks you work with repeat serologies performed on organ donors that are also tissue donors?

- Yes
- No

If Yes, under what circumstances?

Thank you for taking the time to fill out our survey. Your input is greatly appreciated.