At-a-Glance

- **Proposal to Modify Requirements for Mandatory HTLV-1/2 Testing for All Potential Deceased Donors**

- **Affected/Proposed Policy:** Policy 2.2.3.1 (For All Potential Donors)

- **Sponsoring Committee: *Ad Hoc* Disease Transmission Advisory Committee**

- Current policy requires anti-HTLV-1/2 antibody testing on all potential donors. Most OPOs currently use an enzyme immunoassay test system. This system will no longer be manufactured effective 12/31/2009. This leaves a high throughput testing platform as the only FDA-licensed commercially available alternative, which may not be amenable to the time constraints and logistics associated with prospective testing for organ donation at most OPOs. Based on the extremely low incidence (0.035-0.046% of blood donors) of HTLV-1/2 confirmed in donors, and the fact that there are no reported cases in the U.S. of transplant recipients infected with HTLV-1 that actually develop the disease, the OPTN/UNOS Board of Directors voted to discontinue the requirement to perform prospective screening of deceased donors during its June 22-23, 2009 meeting. In response, the *Ad Hoc* Disease Transmission Advisory Committee recommends that retrospective HTLV-1/2 screening tests be required for all deceased donors, and that all screen positive tests be followed with confirmatory testing to differentiate between HTLV-1 and HTLV-2.

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

- **Specific requests for comment**
  Based on the prevalence of this disease as reported in the available data, do you agree that it is appropriate to recommend retrospective donor HTLV-1/2 testing for all deceased donors?

Proposal to Modify Requirements for Mandatory HTLV-1/2 Testing for All Potential Deceased Donors

Affected/Proposed Policy: Policy 2.2.3.1 (For All Potential Donors)

***Ad Hoc* Disease Transmission Advisory Committee**

Summary and Goals of the Proposal:

Current policy requires anti-HTLV-1/2 antibody testing on all potential donors. Most OPOs currently use a specific enzyme immunoassay (EIA) test system. This system will no longer be manufactured effective 12/31/2009. This leaves a high throughput testing platform as the only FDA-licensed commercially available alternative; there are no FDA-approved diagnostic tests for HTLV-1/2. This testing platform is designed to test large numbers of samples in a high volume setting which may not be amenable to the time constraints and logistics associated with prospective testing for organ donation and requires investment in expensive equipment and reagents that may be wasted when used as OPOs currently test donors. Alternately, the time required to collect samples, ship them to a lab equipped with HTLV screening capacity, and receive pre-transplant results in an appropriate stat turn-around time would be challenging and could ultimately reduce the number of donor organs available for transplant. Based on the extremely low incidence (0.035-0.046% of blood donors) of HTLV-1/2 confirmed in donors, and the fact that there are no reported cases in the U.S. of transplant recipients infected with HTLV-1 that actually develop the disease, the OPTN/UNOS Board of Directors voted to discontinue the requirement to perform prospective screening of deceased donors during its June 22-23, 2009 meeting. The *Ad Hoc* Disease Transmission Advisory Committee (DTAC) recommends that retrospective testing be required for all deceased donors. Retrospective testing and a follow-up algorithm to include nucleic acid based or western blot testing to confirm or rule out any initially positive test results will allow only those recipients of confirmed HTLV+ organs to be informed of the potential risk of transmission. Further, careful follow-up of these patients with collection of post-transplant malignancies and neurologic outcomes may inform future policy.

Background and Significance of the Proposal:

Human T-lymphotropic virus Type 1 (also called Adult T-cell lymphoma virus type 1), or HTLV-1 (former nomenclature abbreviated HTLV-I), was first identified in the United States in 1979 (Gallo 2005). HTLV-1 is a retrovirus endemic in the Caribbean, parts of South America, West Africa, Asia, and Oceania. In the Caribbean, 2 to 5% of adults are infected. In the United States, less than 0.1% of individuals are infected with HTLV-1 or HTLV-2 (0.035-0.046% of blood donors) (Glynn, Kleinman, et al. 2000). Breast feeding, intravenous drug use, sexual intercourse, solid organ transplantation, and transfusion of cell containing blood products (14.4% to 47.3% of recipients) may result in transmission of infection.

Risk factors for HTLV-1 infection other than residence in an endemic area include a history of intravenous drug use, a sexual partner with known HTLV-1 infection, and a history of hemodialysis.

Most individuals infected with HTLV-1 do not develop clinical disease. Two to five percent of infected persons develop adult T-cell leukemia (ATL), a cancer of the immune system, or lymphoma, a cancer that develops in the immune system's lymphocytes. A smaller percentage develops a slowly progressive neurological disease termed HTLV-1 associated myelopathy / tropical spastic paraparesis (HAM/TSP)

(Martin-Davila, Fortun, et al. 2008). Other inflammatory disorders have been associated with HTLV-1. There is no reliably effective treatment for these disorders.

HTLV-2 is primarily found in intravenous drug users and sexual contacts of infected persons. It is endemic in American Indian populations and in West and Central Africa. Unlike HTLV-1, the link between HTLV-2 and human disease has not been established, although there have been rare case reports of neurological disease, inflammatory disorders, and leukemia in infected patients.

Currently, testing of donors for HTLV is required for all blood and organ donors in the United States; HTLV testing is not required for all types of donated tissue. HTLV testing requirements in OPTN/UNOS policy were based upon similar requirements in blood banking, when HTLV and autoimmune deficiency syndrome (AIDS) were originally thought to be linked. Specific screening requirements regarding HTLV-1/2 were added for blood screening in 1988 and added to OPTN/UNOS policy in June 1989. At that time, HTLV positive organ donors were deemed not suitable for transplant. As scientific understanding of both human immunodeficiency virus (HIV) and HTLV improved, OPTN/UNOS policy was modified in November 2004 to allow transplantation of HTLV-1/2 organs at the discretion of the transplant program with the informed consent of the recipient.

It is important to note that there are no approved therapies for HTLV-1 or HTLV-2. Likewise, the natural history of disease when transmitted through organ transplantation is not well described. As a result, there are no standard recommendations on how to monitor patients exposed to HTLV-1 or HTLV-2 through organ donation.

There are currently 3 FDA-licensed tests for screening for anti-HTLV-1/2 antibodies among potential organ donors:

http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/TissueSafety/ucm095440.htm

Tests for organ donors are optimally single patient kits that are easy to perform. Most OPOs currently use an HTLV-1/2 EIA test system. This system will no longer be manufactured effective December 31, 2009. One of the test systems listed is no longer commercially available, even though it retains FDA licensure. This leaves only a high throughput testing platform designed to test large numbers of samples in a high volume setting that will require an investment in expensive equipment and reagents that may be wasted when used as OPOs currently test donors. None of the current assays can differentiate between antibodies for HTLV-1 and HTLV-2; therefore, a combined result is always provided.

The DTAC was tasked with determining whether changes in OPTN/UNOS policy are needed based on the upcoming changes to HTLV testing kit availability. As a result, the DTAC requested the formation of an *Ad Hoc* HTLV Donor Screening Advisory Group, including representatives from the OPTN/UNOS DTAC, OPO, Operations, and Organ Availability Committees. Additional members included representation from the Association of Organ Procurement Organizations (AOPO), experts in the field of HTLV, as well as representatives from several large commercial labs that support many OPOs' testing needs. The formal findings of this group have been submitted for publication so that the entire transplant community will be able to review the data.

The Advisory Group considered possible strategies to pursue once the current HTLV-1/2 EIA test kits are no longer available:

- Use the only remaining FDA-licensed test.
- Discontinue requirement for testing prior to transplant.
- Utilize Research Use Only (RUO) assays to continue prospective testing.
- Pursue retrospective testing.

The Advisory Group agreed that continuing to require prospective HTLV-1/2 testing would not be practical. The high throughput testing platform may not be widely available to OPOs to provide results in a timely manner. Reasons for this include:

- logistics associated with prospective testing for organ donation,
- significant costs related to expensive equipment, and
- significant waste of the reagents (test substances required for chemical analysis) used to test small numbers of samples on a testing platform meant to handle more than 100 samples at a time.

Setting up consolidated testing labs at high traffic hubs for each region was discussed, but was not seen as practical for many OPOs due to the logistics and time involved in sending out samples for testing and awaiting the results. Blood banks or reference labs do have the capacity to complete FDA-licensed HTLV-1/2 testing, but all may not make the test available commercially with a stat turn-around time 24 hours a day, seven days a week. Available data indicates that the majority of OPO donor testing is not run during the usual day shift. As a result, moving to consolidated labs for donor testing could result in significant delay in testing. This could, in turn, result in significant delay in organ offers, procurement and transplant. The turnaround time for testing blood and tissue (which takes place after procurement) is far greater than that of donor testing and evaluation, which depends on donor stability and the willingness of the donor family to postpone final arrangements in order to proceed with the donation process. Members questioned who would pay for the regional high throughput testing platforms, and noted that the maintenance, shipping and wasted reagents used in the testing process would more than triple the cost of current testing for OPOs.

After review of the available data related to HTLV-1/2 screening rates and the number of HTLV positive organs transplanted and followed for related post-transplant disease (see table and figures 1-3 in the next section of this document), members considered whether <u>not</u> testing for HTLV-1/2 was a viable option. In light of the low incidence of disease, and in the event that an appropriate FDA-licensed testing alternative could not be provided prior to the elimination of the currently used HTLV-1/2 EIA testing kit, members discussed whether it was reasonable for the OPTN to acknowledge HTLV as an acceptable potential consequence of organ donation. It was noted that there are many infectious diseases for which potential organ donors are <u>not</u> tested due to test kit availability, turnaround time appropriate for organ donation and transplantation, or high false positive to infection prevented ratio. West Nile Virus (WNV) was offered as an example that affects transplant recipients.

RUO assays were discussed by the Advisory Group as a short term solution to continue prospective testing of all donors. Commercial labs participating in the Advisory Group offered to assess some HTLV testing systems that use RUO assays against the most currently used HTLV-1/2 EIA testing kit. This idea was later ruled out because RUO assays are not FDA-approved for this type of testing, and based on current FDA regulations, manufacturers may not be allowed to sell to labs if they know the test system

will be used for clinical diagnosis. This idea was abandoned, as it would not help OPOs remain compliant with current policy requirements.

Retrospective testing was viewed as a reasonable interim alternative. OPOs without access to prospective FDA-licensed testing platforms could collect the appropriate samples and then send them to a lab that used FDA-licensed HTLV screening with high throughput testing platforms (consolidated labs, other OPO labs, and/or local blood banks that may be willing to contract for this type of testing). Samples could be batched and run based on lab volume. There may also be opportunity to partner with tissue banks that do test for HTLV in instances where tissue is also recovered from a donor. Information structures are already in place for OPOs to share retrospective test results with transplant centers. Many OPOs already provide retrospective EBV and bacterial culture results to centers. This retrospective testing would also allow time for a follow-up algorithm to include nucleic acid based or western blot testing to confirm or rule out any initially positive test results for donors and to differentiate between HTLV-1 versus HTLV-2 infection in the donor. Confirmed positive results would be shared immediately with transplant centers. Members suggested that all retrospective results and any follow-up information on recipients receiving HTLV-1 positive organs could be studied over time to determine whether retrospective testing should be continued or eliminated altogether.

HTLV-associated disease develops over a number of years. Careful surveillance was recognized as critical in following recipients and determining whether transmission is suspected.

The DTAC reviewed the Advisory Group's recommendations and supported the idea of retrospective donor testing for OPOs. The Committee agreed that prospective testing with the high throughput testing platform as the OPO community's only FDA-licensed option would present significant logistical and financial concerns. In light of the low prevalence of transmission and expected disease, the Committee agreed that reporting of any positive HTLV-1/2 screening results (including any confirmatory testing) and careful follow-up of recipients receiving confirmed HTLV positive organs (with this information captured in the OPTN's Patient Safety System^{SM}) was an appropriate response to the situation. All data collected on donor HTLV-1/2 status, confirmatory testing (including test system used, sample type tested, and results) and recipient follow-up will be reviewed in 2 years and used to make long term decisions regarding whether HTLV testing requirements should be eliminated, continued retrospectively, or if drug companies should be encouraged to develop other HTLV assays that will lend themselves to prospective testing in the future.

The OPTN/UNOS Board of Directors considered the DTAC's plans to address HTLV testing requirements during its June 22-23, 2009 meeting. Members agreed that continuing to require prospective testing when the remaining FDA-licensed test kit still does not differentiate between HTLV-1 and HTLV-2 may not be practical or feasible, considering the logistical barriers.

HTLV testing for potential living donors was also discussed by the Board. Due to the differences in time constraints related to determining deceased donor and living donor eligibility, Board members believed that prospective testing would be reasonable and appropriate for potential living donors. Currently, there are no specific policy requirements related to the medical evaluation of potential living donors. OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII (available for review at: http://unos.org/policiesandbylaws/bylaws.asp?resources=true) requires transplant programs that perform living donor kidney and/or liver transplants to develop, and once developed comply with, written protocols for the medical evaluation of potential living donors. These protocols must include screening for evidence of transmissible diseases such as cancers and infections. While there are no

specific screening tests required for living donors at this point, the OPTN/UNOS Living Donor Committee included a list of infectious diseases typically screened for to identify conditions that may require donor treatment or increase the risk of donation in its "Guidance for the Development of Program-Specific Living Kidney Donor Medical Evaluation Protocols" (available for review at: http://unos.org/living_donation.asp), a guidance document developed to help transplant programs establish organ specific living donor medical evaluation protocols. HTLV-1 testing is included in this list of typical screening tests for transmissible diseases under Item #10. A resource document for the medical evaluation of potential living liver donor is currently out for public comment, and also recommends HTLV-1 antibody testing.

Ongoing discussion regarding future HTLV screening recommendations or requirements for potential living donors is necessary, including whether testing should be completed retrospectively. The DTAC welcomes feedback as part of this public comment proposal, and is happy to partner with the Living Donor Committee on developing requirements for medical evaluation of potential living donors in Policy 12.3 (Medical Evaluation of Living Donors) for future public comment consideration at a later date.

After lengthy discussion, and consideration of the time constraints faced by OPOs as they determine what plans they will need to have in place in order to remain compliant with policy after the elimination of the currently used HTLV-1/2 EIA test kit is discontinued, the Board passed the following resolution (24 for, 7 against, 1 abstention):

> **RESOLVED,** that the OPTN discontinue the requirement of prospective HTLV testing for deceased donors, effective pending notice to the members.
>
> **FURTHER RESOLVED,** that retrospective testing with confirmation shall be performed on all deceased donors. Implementation should be delayed to permit a minimum forty-five day public comment period and review by the Executive Committee. There shall be a two-year window for retrospective testing.

After careful review of the data, the DTAC believes that requiring retrospective testing for all deceased donors and confirmatory testing on all screen positive donor to differentiate between HTLV-1 and HTLV-2 for a period of two years is an appropriate response to the Board's resolution that will require only those recipients of confirmed HTLV+ organs to be informed of the potential risk of transmission. Further, careful follow-up of these patients with collection of post-transplant malignancies and neurologic outcomes may inform future policy.

Supporting Evidence:

OPTN data indicates that there have been 134 donors resulting in 162 transplanted organs that were reported as HTLV-1/2 antibody positive since 1999; there are no data with regard to confirmatory testing on these donors to determine which donors were infected with HTLV-1, HTLV-2, or neither (false positive serology). Likewise, the OPTN data collection does not include the number of potential donors that had positive screening results and were not utilized as a result of the testing. Current FDA-licensed HTLV-1/2 screening tests do not differentiate between the two types of virus, though HTLV-1 is seen as having greater consequences related to transmission in humans.

Table 1: Number of donors and organs recovered and transplanted from donors who tested positive for HTLV-1 or HTLV-2 with screening tests

1999-2008

Year of transplant	Donors	Organ						Total
		Heart	Kidney	Kidney-Pancreas	Liver	Lung	Pancreas	
	N	N	N	N	N	N	N	N
1999	3	0	0	0	2	0	0	2
2000	5	1	0	0	2	1	0	4
2001	3	0	2	0	1	0	0	3
2002	8	4	2	0	7	0	0	13
2003	5	0	4	0	4	0	0	8
2004	9	0	2	0	5	0	0	7
2005	23	1	8	1	19	1	0	30
2006	35	2	16	2	31	1	2	54
2007	27	0	5	0	19	0	0	24
2008*	16	0	5	0	11	1	0	17
Total	**134**	**8**	**44**	**3**	**101**	**4**	**2**	**162**

During 2008, the average number of organs transplanted per HTLV-1/2 screen negative donor was 3.0; for HTLV-1/2 screen positive donors, it was only 1.1.

Short term recipient survival, whether receiving HTLV-1/2 positive or negative organs, appears to be more or less equivalent at one year, as reported in the OPTN database. There have been no reports of neurologic complications made by transplant centers caring for recipients of HTLV-1/2 positive organs. Likewise, a review of malignancy data demonstrated that none, to date, have been diagnosed with an HTLV-associated malignancy. There were a total of ten recipients of HTLV+ organs with malignancy reported post-transplant, though none involved ATL or lymphoma, clinical diseases related to HTLV infection.

Organ Received at Transplant	Malignancy reported post transplant
Heart	Squamous cell skin cancer
Kidney (x 2 recipients)	Lung cancer
	Basal cell skin cancer and melanoma
Liver (x 7 recipients)	Recurrent HCC
	Juxtapapillary chorodial melamona in left eye
	Mandicular, type squamous cell
	Basal cell skin cancer
	Three reported squamous cell skin cancer

**Neurological problems were not collected in this data set.*

Figure 1: Post-Transplant Malignancies Reported in HTLV+ Organ Recipients, 1999-2008

The *Ad Hoc* HTLV Donor Screening Advisory Group also reviewed data from seven OPO and/or commercial labs providing testing for OPOs to learn more about screening rates in donors. Additional information was provided on 14,432 potential donors tested for HTLV-1/2.

- Of these 14,432 tested potential donors, only 150 (1.04%) resulted in a positive screening test.

- Three of the seven labs followed a positive result with confirmatory testing (representing 11,003 donors). Of the 108 positive tests that were followed by confirmatory testing:
    - 56 were positive
    - 30 were negative
    - 22 were indeterminate

- Only one of the labs performed confirmatory testing that differentiated between HTLV-1 and HTLV-2 (representing 3,490 potential donors). It was noted that this lab did not complete this testing for all samples, but most were reviewed. Of the 21 samples initially positive by the HTLV-I/II EIA test kit that received confirmatory testing, only one specimen was confirmed as HTLV-1 positive, for a rate of 0.03%.

HTLV Screening Rates Among Potential Organ Donors		
HTLV-1/2 Screening Test Positive (7 OPOs/labs)	**Follow-Up HTLV-1/2 Confirmatory Test Positive (3 OPOs/labs)**	**Further Differentiation to Prove HTLV-1 Positive (1 lab)**
150/14432	**56/11003**	**1/3490**
1.04% total positives	**0.5% confirmed**	**0.03% proven positive HTLV I**

Figure 2: HTLV Screening Rates Among Potential Organ Donors

In reviewing the data supplied by these seven OPOs and/or labs, one could generalize that:

For the **12,000-15,000** potential organ donors each year, there would be:

125-156 positive screening tests

⇩

60-75 positive confirmatory tests

⇩

7-9 HTLV-1 positive donors, with 24-42 indeterminate results (estimated)

This would result in approximately 83-114 potential donors with false positive testing or infection with HTLV-2. Since most of these potential donors currently would not be used and even if they were, fewer organs would be utilized due to HTLV status, this represents a significant number of safe organs that would be utilized that are currently being discarded with resultant impact on candidates awaiting transplant. As some of these donors may be excluded for other reasons (e.g., positive tests for other infectious agents) the number of wasted organs may be less than the above estimate.

If the incidence of disease is approximately 0.03%, the number of transmissions without pre-transplant testing based on this figure would be expected as one potential transmission event every few years.

To put HTLV testing concerns into perspective, the Advisory Group compared HTLV-1 to West Nile Virus (WNV), which has similar neurologic sequelae, and Epstein-Barr virus (EBV) in which there are similar malignancy risks. Published data indicates that the prevalence for WNV in organ donation is 0.024% (Kiberd and Forward 2004). Based on current data, the prevalence of HTLV-1/2 in blood donors is 0.035-0.046% and in organ donors is 0.003-0.5%. Currently, testing is not required for WNV in part because of the concern that the risk of false positive results will result in more organ loss than disease prevention through the use of the test. Likewise, despite the clear link between EBV and post-transplant lymphoproliferative disorder (PTLD) and the current requirement to test all donors and recipients for EBV, screening for EBV is rarely considered in the decision about whether to accept an organ.

Two obvious outcomes to HTLV-1 were noted, with the following risks:

- No infection
- Asymptomatic infection
    - Leukemia or lymphoma (delayed onset)
    - HTLV-associated tropical spastic paraparesis (TSP) (onset can be closer to transplant)

The majority of individuals infected with HTLV do not develop disease, though a significant minority, 3-6% do develop HTLV-1 associated disease, usually over a number of years (Martin-Davila, Fortun et al. 2008). Serious disease can develop that is not easily treated. There is limited data on the sequelae of donor-to-recipient transmission in solid organ transplants.

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

The proposed changes are consistent with the Final Rule[1] and will meet HHS Program Goals by:

- Increasing the number of donors and organs transplanted by eliminating organ wastage due to false positive HTLV-1/2 donor screening results (Maximum Capacity).

- Promoting safe, high-quality care for transplant candidates and recipients by expecting confirmatory testing of positive HTLV-1/2 screening results prior to recipient notification and careful follow-up of recipients receiving HTLV positive organs.

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 completing prospective versus retrospective testing?
    - How many donors are screening positive for HTLV-1? HTLV-2?
    - How many of these donors have additional testing via nucleic acid or Western blot testing to confirm HTLV-1 versus HTLV-2 infection?

[1]The Final Rule, Chapter 1-Public Health Service, Department of Health and Human Services, Part 121- Organ Procurement and Transplantation Network. Section 121.7 Identification of Organ Recipient, Section C Transportation of organ to potential recipient.

- **Policy Performance Measures:**
  - Number of confirmed HTLV-1 positive donors;
  - Number of resulting donor-derived HTLV-1 infections;
  - Number of post-transplant reports of ATL or lymphoma reported in recipients that may be the result of HTLV-1 infection; and
  - Number of post-transplant reports of HTLV-1-associated HAM/TSP reported in recipients.

- **Time Line for Evaluation:**

  The DTAC believes that it will take at least two to three years to collect meaningful data based on the 0.03% incidence rate. Comprehensive data will be reviewed to determine if: (1) prospective HTLV testing should be reinstated in policy, (2) retrospective testing should be continued, or (3) HTLV screening should be eliminated from donor testing requirements altogether. In the interim, the Committee will continue to monitor the testing market for alternate FDA-licensed HTLV-1/2 testing kits that may be more appropriate for prospective donor testing.

Additional Data Collection:

Currently, OPOs report the results of prospective HTLV-1/2 screening on the deceased donor's record pre-recovery in DonorNet[SM] and on the Deceased Donor Registration (DDR) form within 30 days of organ recovery. The proposed policy modifications will allow OPOs to perform retrospective HTLV-1/2 screening on deceased donors. As a result, this proposal will require programming changes and some additional data collection. Assuming that retrospective testing is completed within the 30 days that OPOs have to complete the DDR, a new vehicle for capturing these data may be unnecessary.

The requirement for HTLV-1/2 screeing results being documented in the donor's record in DonorNet[SM] prior to running a match will need to be removed.

Confirmed positive HTLV-1 or HTLV-2 donor results should be reported to the OPTN Patient Safety System[SM] as a potential disease transmission event. The results should be communicated to the transplant center(s). Additional data, including the results of confirmatory testing, will be collected from the OPOs on a regular basis on those donors reported to the OPTN to have had a positive HTLV screening result.

These data meets the data collection principle of ensuring patient safety when no alternative sources of data exist. The data are necessary to track the prevalence of HTLV-1 and HTLV-2 in donors.

Expected Implementation Plan:

If approved by the Executive Committee, the modifications to HTLV testing policy and programming changes to remove the requirement of HTLV-1/2 screening results prior to running a match run should be implemented immediately to address OPOs' needs related to any early shortages of the currently used EIA test kits that will be retired on 12/31/2009.

Communication and Education Plan:

If approved by the Executive Committee (in the interest of time so as to allow OPOs time to finalize plans for sending out samples for retrospective testing), the transplant community will receive information regarding the approval of modifications to HTLV testing requirements via the Policy Notice issued after each Board meeting. The Communications Department will also contact all OPOs via email to provide reminders that they should be working with labs that run the high throughput testing platform to finalize plans for retrospective testing as of January 1, 2010, and before if testing kits are depleted prior to the December 31, 2009 retirement date. Additional details regarding the final implementation date will be sent to members through a UNet[SM] System Notice.

If approved, DTAC will work with the OPO Committee to develop a guidance document to support implementation of this change with OPOs and with the Transplant Administrators Committee to develop a guidance document to support implementation of this change with the transplant center community. These documents should be prepared for review by the Board of Directors during its November 2009 meeting.

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Blast email to suggest that OPOs develop a plan for how they would handle retrospective testing if that is the ultimate outcome of this issue to be prepared for the December 31, 2009 elimination of the currently used kit	OPO Personnel	Email	Approximately 30 days after the June 22-23, 2009 Board meeting
Policy Notice	Members	Email	30 days after passed by the Board
System Notice	Members	Email	Implementation Date
Website	General public, members	Web posting	Prior to implementation date

Education/Training Activities			
Education/Training Description	**Audience(s)**	**Deliver Method(s)**	**Timeframe and Frequency**
Guidance Document to cover informed consent and suggestions for confirmatory testing and follow-up for recipients of confirmed HTLV+ organs	OPO personnel, Transplant surgeons, transplant coordinators, labs	Guidelines posted on website	TBD

Monitoring and Evaluation:

OPTN/UNOS Research Department staff will generate two quarterly reports to capture information regarding HTLV-1/2 screening and will contact OPOs to obtain additional information. The first report will identify all donors recovered with positive HTLV-1/2 screening tests recorded on the DDR. OPOs will be asked to provide confirmatory test results and the specific test type used for confirmation for each donor. The second report will capture all donors where no HTLV-1/2 screening results were recorded on the DDR. OPOs will be asked to provide confirmation that testing was completed as required by policy for each donor identified.

These reports will be generated quarterly for a period of two years at which time the DTAC will review the results of these tests and will consider whether further policy modifications regarding HTLV screening are appropriate.

All donors with confirmed positive test results for either HTLV-1 or HTLV-2 must be reported to the Patient Safety System as a potential disease transmission per OPTN/UNOS Policy 4.7 (Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions, Including Malignancy). OPTN/UNOS Patient Safety staff will confirm that all recipients of positive donor organs have been informed of the donor's HTLV-1 or HTLV-2 infection. These cases will be handled using the standard process for all potential disease transmission events. All donor and recipient data will be collected in the Patient Safety database.

Potential violations of donor HTLV-1/2 screening and confirmatory testing requirements will be referred to the OPTN/UNOS Department of Evaluation and Quality for review.

Policy Proposal:

2.2.3 The Host OPO must perform the 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 screening tests are not commercially available prior to transplant, then a FDA approved diagnostic test is permissible to assess the donor. The Host OPO must document in the donor record 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:

2.2.3.1 For all potential donors:

- ABO typing with sub-typing for ABO-A donors;
- FDA licensed Anti-HIV I, II;
- CBC;
- Electrolytes;
- Hepatitis screen serological testing; including HBsAg, HBcAb, and Anti-HCV;
- VDRL or RPR;
- ~~Anti HTLV I/II;~~ Retrospective HTLV-1/2 antibody testing (Confirmatory testing to differentiate between HTLV-1 and HTLV-2 **must** be completed on **all** screen positive tests.)
- 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.

Additional Organ Specific information is required as follows:
[…]

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