UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

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IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: James B. Alcorn

Director, Policy

RE: Summary of actions taken at OPTN/UNOS Executive Committee Meeting (August 27, 2013)

Date: August 29, 2013

The attached report summarizes changes to OPTN Policy and Bylaws approved by the OPTN/UNOS Executive Committee. This policy notice provides the specific Policy and Bylaws changes and the corresponding implementation dates. When reviewing the language changes, please note that underlined language is new and what will be in effect upon implementation and language that is ~~struck~~ will be deleted upon implementation. The policy language used to denote the changes approved at this meeting reflects the most recent version of policy that has been approved, but not necessarily what is currently implemented.

This policy notice, as well as changes from previous Board of Directors meetings, can be found at optn.transplant.hrsa.gov (click on "News," and then select "View all Policy Notices").

The Evaluation Plan, which reviews specific details regarding how members will be assessed for compliance with OPTN Policies and Bylaws, has also been updated to reflect the changes resulting from the this meeting. It can also be found at optn.transplant.hrsa.gov (click on "Policy Management," and then select "Evaluation Plan").

Thank you for your careful review of this policy notice. If you have any questions about a particular Executive Committee action, please contact your regional administrator at (804) 782-4800.

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Removal of ASN from AST/ASN Renal Transplant Training Accreditation Program OPTN Bylaw Reference

Sponsoring Committee: Membership & Professional Standards Committee

Bylaw Affected: Appendix E, Section E.4 (Approved Kidney Transplant Surgeon and Physician Fellowship Training Programs)

Distributed for Public Comment: No

Effective Date: August 27, 2013

Problem Statement
The American Society of Transplantation (AST) submitted a letter to UNOS stating that, effective June 30, 2013, the American Society of Nephrology (ASN) will no longer co-sponsor a renal transplant training accreditation program with the AST.

Changes
The ASN reference has been removed from the Bylaws. This training program is now represented as the AST Adult Renal Transplant Training Accreditation Program in the primary kidney transplant physician qualifying pathway. This change is in name only and does not negate the program's validity for meeting primary kidney physician criteria under either fellowship title.

Member Actions
Kidney programs should make themselves aware of this change in accreditation program sponsorship.

Click here to view the modified bylaw language.

Policy Clarifications Resulting from June 19, 2013, Release of the PHS Guideline for Reducing HIV, HBV, and HCV through Organ Transplantation

Sponsoring Committee: Ad Hoc Disease Transmission Advisory Committee (DTAC)

Policies Affected: 2.2.2.1 (Obtaining the donor's medical/behavioral history), 2.2.3.1, 2.2.3.4, 3.1.14 (PHS Guideline), 4.2 (Requirements for Informed Consent Regarding Risk of Transmissible Disease), 5.4.3 (Vessels), 5.10.2 (Vessel Storage), 12.3.3 (Psychosocial Evaluation of the Living Kidney Donor), 12.3.4 (Medical Evaluation of the Living Kidney Donor), and 12.7.4.3 (Vessels)

Distributed for Public Comment: No

Effective Date: October 1, 2013

Problem Statement
The *PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B (HBV), and Hepatitis C (HCV) Through Organ Transplantation* was released on June 19, 2013. This release made current policy ambiguous in terms of identifying "high risk" organ donors that may be at increased risk for transmitting these diseases to organ recipients. Some policy sections reference the 1994 PHS Guideline. Other sections refer simply to the PHS Guideline or the "current" PHS Guideline.

Changes
All references to the PHS Guideline have been updated with uniform language. Programming is underway to update references to "CDC high risk" donors in DonorNet® and on the Deceased Donor Registration so that they match terminology used in the 2013 PHS Guideline. The Board of Directors will consider a timeline for implementing use of only the 2013 Guideline during its November 11-12, 2013 meeting.

Member Actions
OPOs may use either the 1994 or the 2013 PHS Guideline for medical-social evaluation questions to determine if a deceased donor is at increased risk for HIV, HBV, or HCV transmission. OPO staff must document in the donor highlights section of DonorNet® which Guideline it used to evaluate each particular donor. **Living Donor Recovery Hospitals** may use either the 1994 or the 2013 PHS Guideline for medical-social evaluation questions to determine if a living donor is at increased risk for HIV, HBV, or HCV transmission. The recovery hospital is encouraged to document in the donor record which Guideline it used to evaluate each particular donor.

Click her to view the modified policy language

Affected Bylaw Language:

Appendix E: Membership and Personnel Requirements for Kidney Transplant Programs

E. 4 Approved Kidney Transplant Surgeon and Physician Fellowship Training Programs

A. Transplant Surgeon Fellowship Training Programs

Surgeons qualifying as primary transplant surgeon based on completion of a 2-year formal transplant fellowship must complete their training at a fellowship program approved by the MPSC. Any program approved for training by the Fellowship Training Committee of the American Society of Transplant Surgeons is automatically accepted by the MPSC, as well as any program that meets the following criteria:

1. The program is at a hospital that transplants one or more organs, including kidneys.
2. The program is at an institution that has a proven commitment to graduate medical education.
3. The program director is a board-certified surgeon who meets the OPTN Contractor requirements for primary kidney transplant surgeon.
4. The program is at a hospital that is affiliated with a histocompatibility laboratory that meets the OPTN Contractor requirements for histocompatibility laboratories.
5. The program is at a hospital that is affiliated with an organ procurement organization (OPO) that meets the OPTN Contractor requirements for OPOs.
6. The program performs at least 60 kidney transplants each year from deceased or living donors.
7. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.

Training programs are reviewed by the MPSC every 5 years or any time the program director changes. If a program has no fellows during the 5 years between reviews, it must re-apply as a new program.

B. Transplant Physician Fellowship Training Programs

A formal training program for primary kidney transplant physicians requires that training must be completed at a program approved by the MPSC. Any training program approved by the AST~~/ASN~~ Adult Renal Transplant Training Accreditation Program is automatically accepted by the MPSC, as well as any program that meets the following criteria:

8. The program must be OPTN approved as a kidney transplant program and be affiliated with an ACGME approved nephrology program. Transplant programs that are not OPTN approved or affiliated with an ACGME approved nephrology program will be evaluated on a case-by-case basis.

9. The program must perform at least 10 kidney transplants per year for each first year, general nephrology fellow in training and an additional 30 transplants per year for each kidney transplant fellow to be trained.
10. The program must have a full-time faculty member or members capable of teaching a curriculum with a broad base of knowledge in transplant medicine. The curriculum must include training and experience in end-stage renal disease, training in the selection of appropriate transplant recipients and donors, experience in the immediate and long term care of the transplant recipient, and training in the performance of kidney transplant biopsies. Additionally there must be an emphasis on the management of immunosuppressive agents and the evaluation of kidney transplant dysfunction. Combined surgical and medical rounds should be conducted on a regular basis.
11. The program must provide patient co-management responsibility with transplant surgeons from the peri-operative through the outpatient period. The kidney trainee must primarily manage the transplant recipient's medical care including hypertension, diabetes, and dialytic problems. Trainees must also serve as a primary member of the transplant team and participate in making decisions about immunosuppression. The transplant renal fellow must be primarily responsible for 30 in-patient renal transplant recipients and 30 outpatient recipients over a period of 12 months. Outpatient follow-up must be continuous for a minimum of at least 3 months. Training must be completed within 12 continuous months; a minimum of 6 months of training must be performed in inpatient clinical service.
12. The transplant nephrology fellow must perform a minimum of 10 transplant biopsies during the training period.
13. The transplant nephrology fellow must observe at least 3 kidney transplants and at least 3 procurement procedures.

To read the complete OPTN Bylaws language visit optn.transplant.hrsa.gov, select the “Policy Management” tab, then select “OPTN Bylaws.” To read the complete UNOS Bylaws language visit www.unos.org, click on the “ABOUT US” box at the top of the screen, and then, in the left margin under “Governance,” select “Bylaws.”

Affected Policy Language:

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 disease transmission, including blood borne pathogens HIV, Hepatitis B, and Hepatitis C. If the donor meets the criteria for increased risk for disease transmission set forth in the ~~US Public Health Service (~~PHS Guideline~~) guidance~~[1], the Host OPO must communicate this information regarding donor history to all transplant programs receiving organs from the donor.

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

2.2.3.1 All blood samples obtained and used for screening tests required by OPTN policy must be assessed for hemodilution (defined as a sample with plasma dilution sufficient to affect the results of communicable disease testing) utilizing 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.

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

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

[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~~

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

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

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

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

3.1.14 PHS Guideline. For requirements that reference the "PHS Guideline," members must use either the United States Public Health Service (PHS) *Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissues and Organs* (1994) or *PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation* (2013). For the purposes of these requirements, "increased risk of disease transmission" is used synonymously with "high risk." For each organ donor, OPOs must document in the donor highlights section of DonorNet® which set of guidelines it used to evaluate that particular donor.

4.2 REQUIREMENTS FOR INFORMED CONSENT REGARDING RISK OF TRANSMISSIBLE DISEASE. Transplant programs must obtain informed consent prior to transplant of an organ when, in the transplant program's medical judgment:

- 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 disease transmission (including but not limited to consideration of ~~U.S.~~ the PHS Guideline~~s~~ or when a hemodiluted specimen is used for donor HIV, HBV, and/or HCV screening (see Policy 2.2.3.1)).

5.4.3 Vessels

Both the vessel container and outer sterile barrier must be labeled with the standardized vessel labels distributed by the OPTN contractor. The information must contain the: recovery date, ABO, ABO subtype when used for allocation, all infectious disease testing results, container contents, and the UNOS Donor ID. If the donor is at increased risk for disease transmission ~~in a "high risk"[2] group~~ as

[2] ~~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~~

defined by the ~~US Public Health Service (~~PHS Guideline~~) guidance~~[1], the label must indicate that the vessels are from a donor at increased risk for disease transmission. ~~who meets the PHS criteria for high risk.~~ The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state "for use in organ transplantation only." If packaged separately from the organ, the vessels must be protected by a triple sterile barrier, one of which must be a rigid container and the standardized vessel label must be affixed to the outermost barrier and container.

5.10.2 Vessel storage

The Transplant Center must designate a person to monitor and maintain records, destroy, and notify the OPTN of outcome and/or use of vessels. This designated person must maintain information on all donor vessels including monitoring and maintaining all records relating to the use and management of donor vessels (e.g. subsequent positive serology testing, monitor inventory of stored extra vessels). This person must monitor the refrigerator, ensure records are up to date and available with the vessels, destroy the vessels when expired, and report the vessel's use or disposal to the OPTN within 7 calendar days.

- Hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels may not be stored for subsequent use.
- The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial HTK).
- The vessels must be stored in a rigid, sterile sealed container and must be protected by a triple sterile barrier, one of which must be the rigid container, labeled with the recovery date, ABO, ABO subtype when used for allocation, infectious disease results, container contents, and the UNOS Donor ID for tracking. The standardized vessel label distributed by the OPTN contractor must be affixed to the outer most sterile barrier bag and information on the label must include recovery date, ABO, all infectious disease results, container contents, and the UNOS Donor ID. If the donor ~~is in a "high risk"[1] group~~ is at increased risk for disease transmission, as~~as~~ defined by the PHS Guideline ~~the US Public Health Service (PHS) guidance~~[1], the label must indicate that the vessels are from a donor ~~who meets the PHS criteria~~ at increased risk for ~~high risk~~ disease transmission. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state for use in organ transplantation only. If removed from the triple sterile barrier, the transplant center must re-label the vessels prior to storage.
- The vessel(s) must be stored in a secured refrigerator with a temperature monitor and maintained within a range of 2 - 8 degrees Celsius.
- There must be daily monitoring of the vessel(s) with documented security and temperature checks by the transplant center.
- The vessel(s) can be stored up to a maximum of 14 days from the original recovery date.
- The transplant center must maintain a log of stored vessels.
- The transplant surgeon must have around the clock access to the donor information prior to using the donor vessel(s) in a recipient other than the intended recipient.

12.3.3 Psychosocial Evaluation of the Living Kidney Donor This psychosocial evaluation must be performed by a psychiatrist, psychologist, and/or clinical social worker. Documentation of the psychosocial evaluation must be maintained in the donor record. The psychosocial evaluation must include the following components:

- Assess for any psychosocial (including mental health) issues that might complicate the living donor's recovery and identify potential risks for poor psychosocial outcome;

- Assess for the presence of ~~high-risk~~ increased risk for disease transmission behaviors as defined by the ~~US Public Health Service (~~PHS Guideline~~)~~ that have the potential to increase the risk of disease transmission to the recipient;

- Assess history of smoking, alcohol, and drug use/abuse and dependency;

12.3.4 Medical Evaluation of the Living Kidney Donor The medical evaluation must be performed by the recovery hospital and by a physician or surgeon experienced in living donation. The goal of the medical evaluation is to:

- Assess the immunologic compatibility of the donor to the recipient;

- Assess the general health and surgical risk of the donor including screening for conditions that may predict complications from having one kidney in the future;

- Determine if there are diseases present that may be transmitted from donor to recipient; and

- Assess the anatomy and function of the kidneys.

Documentation of the medical evaluation must be maintained in the donor record. The medical evaluation must include the following components:

A) General History:

- Evaluate for a personal history of significant medical conditions which include but are not limited to hypertension, diabetes, genetic renal diseases, lung disease, heart disease, gastrointestinal disease, autoimmune disease, neurologic disease, genitourinary disease, hematologic disorders, bleeding or clotting disorders, history of cancer and history of infections.

- Evaluate for Kidney Specific Personal History:

  - Kidney disease, proteinuria, hematuria
  - Kidney injury
  - Diabetes including gestational diabetes

  - Nephrolithiasis
  - Recurrent urinary tract infections

- Active and past medications with special consideration for known nephrotoxic medications
- Allergies
- Evaluation for coronary artery disease

B) Family history of coronary artery disease and cancer

C) Kidney Specific Family History:

- Kidney disease
- Diabetes
- Hypertension
- Kidney Cancer

D) Social History:

The medical evaluation must determine:

- Occupation, employment status, health insurance status, living arrangements, and social support
- Smoking, alcohol and drug use/abuse
- ~~High risk behavior as~~ Criteria to assess increased risk for disease transmission as defined by the ~~US~~ PHS Guideline
- Psychiatric illness, depression, suicide attempts

E) Physical Exam:

- Height, weight, BMI
- Examination of all major organ systems
- Blood pressure
  - Taken on at least two different occasions; or
  - Perform 24-hour or overnight blood pressure monitoring

F) General Laboratory Tests:

- Complete Blood Count (CBC) with platelet count
- Blood type and screen
- Prothrombin Time (PT)
- International Normalized Ratio (INR) or Partial Thromboplastin Time (PTT)
- Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin)
- HCG quantitative pregnancy test for premenopausal women without surgical sterilization
- Chest X-Ray
- Electrocardiogram (ECG)

G) Other Metabolic Testing:

- Fasting blood glucose
- Fasting lipid profile (Cholesterol, Triglycerides, HDL Cholesterol, and LDL Cholesterol)
- Glucose Tolerance Test and/or Glycosylated Hemoglobin in first degree relatives of diabetics and in high risk individuals

H) Kidney-Specific Tests:

- Urinalysis; Urine microscopy
- Urine culture if clinically indicated
- Measurement of urinary protein and albumin excretion
- Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection
- Centers must establish a protocol and follow their protocol for screening for Polycystic Kidney Disease or other inherited renal disease as guided by family history
- Patients with a history of nephrolithiasis or nephrolithiasis (>3mm) identified on radiographic imaging must have a 24 hour urine stone panel measuring calcium, oxalate, uric acid, citric acid, creatinine and sodium excretion

I) Anatomic Assessment:

An assessment to determine whether the kidneys are of equal size or have masses, cysts, or stones or other anatomical defects and to determine which kidney is more anatomically suitable for transplantation.

- The choice of test for radiologic imaging may be determined based upon the local radiological expertise and surgical preference, and may include CT angiogram or MR angiogram.

J) Screening for transmissible diseases:

Infectious disease testing must include:

- CMV (Cytomegalovirus) Antibody
- EBV (Epstein Barr Virus) Antibody
- HIV 1,2 (Human Immunodeficiency Virus) antibody testing
- HepBsAg (Hepatitis B surface antigen)
- HepBcAB (Hepatitis B core antibody)
- HepBsAB (Hepatitis B surface antibody)
- HCV (Hepatitis C Virus) antibody testing
- RPR (Rapid Plasma Reagin Test for Syphilis)

For tuberculosis (TB), living donor recovery centers must determine if the potential donor is at increased risk for this infection, and if so testing must include:

- Screening for latent TB using either intradermal PPD or Interferon Gamma Release Assay (IGRA)

For the following infectious diseases, transplant centers must determine if the potential donor is from an endemic area, and if so testing must include:

- Strongyloides
- Trypanosoma cruzi
- West Nile

K) Cancer screening:

Centers must develop protocols consistent with the American Cancer Society (ACS), and once developed follow their own protocols for screening:

- Cervical Cancer
- Breast Cancer
- Prostate Cancer
- Colon Cancer
- Skin Cancer
- Lung cancer

L) Exclusion Criteria:

Transplant programs that perform living kidney donor recoveries may exclude a donor with any condition that, in the Transplant Program's medical judgment, causes the donor to be unsuitable for organ donation.

Transplant programs that perform living kidney donor recoveries must exclude all donors who meet any of the following exclusion criteria:

- Both age less than 18 years and mentally incapable of making an informed decision
- Uncontrollable hypertension or history of hypertension with evidence of end stage organ damage
- HIV
- Diabetes
- Active malignancy, or incompletely treated malignancy
- High suspicion of donor coercion
- High suspicion of illegal financial exchange between donor and recipient

- Evidence of acute symptomatic infection (until resolved)
- Diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality

12.7.4.3 Vessels

The vessels must be labeled with the standardized vessel label distributed by the OPTN contractor. The information must contain the: recovery date, ABO and subtyping (when used to determine transplant compatibility), all serology results, container contents, and the UNOS Donor I.D. If the donor is at increased risk for recent HIV, HBV, or HCV infection ~~in a "high risk" group~~ as defined by the ~~U.S. Public Health Service~~ PHS Guideline~~s~~, the label must indicate that the vessels are from a donor at increased risk for transmission of these blood-borne infections.~~who meets the CDC criteria for high risk~~. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state "for use in organ transplantation only." If packaged separately from the organ, the vessels must be protected by a triple sterile barrier, one of which must be a rigid container and the standardized vessel label must be affixed to the outermost barrier.

To read the complete policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the "Policy Management" tab, then select "Policies." From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner.