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Policy 4.0 Acquired Immune Deficiency Syndrome (AIDS) and Human Pituitary Derived Growth Hormone (HPDGH) and Human T-Lymphotropic Virus Type (HTLV-I)

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These policies apply to the pretransplant consideration of potential organ donors and/or potential organ recipients, with regard to AIDS, HPDGH, and HTLV-1.

4.1 Screening Potential Organ Donors for Anti-HIV Antibody. All potential donors are to be tested by use of a screening test licensed by the U.S. Food and Drug Administration (FDA) for Anti-Human Immune Deficiency Virus (HIV) Antibody (Ab). If the potential donor's pre-transfusion test for the antibody is negative and blood for subsequent transfusions has been tested and found to be negative for HIV-Ab, retesting the potential donor for HIV-Ab 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-Ab. If additional tests related to HIV are performed, the results of all tests must be communicated immediately to the UNOS 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 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 institutions receiving organs from the donor.

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

4.1.3 Exceptions. Exceptions to the guidelines set forth above may be made in cases involving non-renal organs, when, in the medical judgment of the staff of the Host OPO and recipient institution, an extreme medical emergency warrants the transplantation of an organ, the donor of which has not been tested for HIV antibody. 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. UNOS 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 Screening Potential Transplant Recipients for HIV Antibody. Testing for HIV-Ab shall be a condition of candidacy for organ transplantation, except in cases where such testing would violate applicable state or federal laws or regulations. Patients whose test results are confirmed positive should undergo appropriate counseling.

4.2.1 HIV-Ab Sero-positive Transplant Candidates. A potential candidate for organ transplantation whose test for HIV-Ab 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.

4.2.2 Informing Personnel. Health care personnel caring for patients who test positive for AIDS antibody should be so informed.

4.2.3 Patient Treatment. Administering treatment to patients who test positive for the HIV antibody should not be optional or discretionary for health care personnel.

4.3 Disclosure of Information About HIV Antibody Status. UNOS 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 or recipients.

4.4 General Recommendations. All UNOS 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 UNOS 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. People who have received Human Pituitary Derived Growth Hormone (HPDG) shall be deferred as organ donors. An exception to this policy may be made in cases involving non-renal organs, when, in the medical judgment of the staff of the Host OPO and recipient institution, an extreme medical emergency warrants the transplantation of an organ, the donor of which has received HPDG. The transplant surgeon is obligated to obtain informed consent from the recipient or next of kin in such cases.

4.6 Screening Potential Organ Donors for HTLV-I Antibody. All potential donors are to be tested by a screening test licensed by the FDA for Human T-Lymphotropic Virus Type I (HTLV-I) Antibody (Ab). If the potential donor's pre-transfusion test for the HTLV-I antibody is negative and blood for subsequent transfusions has been tested and found to be negative for HTLV-I Ab, retesting the potential donor for HTLV-I Ab is not necessary. If no pre-transfusion sample of the donor's blood is available, the Host OPO must provide to each recipient transplant program 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 HTLV-I-Ab. If additional tests related to HTLV-I Ab are performed, the results of all tests must be communicated immediately to the UNOS Organ Center and all recipient institutions. Exceptions for cases in which the testing cannot be completed prior to transplant are provided in paragraph 4.6.3 below.

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

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

4.6.4 Donor Consent Forms. UNOS 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.

4.7 Post Transplant HIV Reporting. When a transplant program director is informed that an organ recipient at that program is confirmed positive by Western Blot for HIV, or has died from HIV-related causes, the director shall notify as soon as practicable, the medical director or executive director of the procuring OPO and the UNOS Organ Center director by telecopying and mailing a completed UNOS Transplant HIV/Hepatitis B Form. The medical director or executive director of the procuring OPO shall be responsible for:

- i. notification of the positive HIV test results as soon as practicable to any tissue bank and the director of any other transplant program that received tissue or an organ from the donor who is the subject of the investigation;
- ii. management of the investigation to determine whether the organ donor was infected with HIV; and

iii. submission of a final written report to UNOS with 45 days which specifies the organizations and individuals who were notified, when the notifications occurred, and results of the investigation including final HIV serology status of the organ recipients who are the subjects of the investigation.

Upon receipt of a completed UNOS Transplant HIV/Hepatitis B Form that reports a confirmed positive Western Blot HIV test result, UNOS 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. UNOS will monitor the notification process to verify that the procuring OPO and all recipient organ transplant programs have been notified of the positive HIV test results and will request that any additional HIV test results be submitted to the procuring OPO with a copy to UNOS. UNOS 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 under no circumstances should a transplant program or OPO disclose this information in a manner that is contrary to applicable law.