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 the following policies for minimum procurement standards.

2.1 HOST OPO. The 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 authorization for the removal of organs, complying with 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 is executed for each donor organ.

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 written documentation of donor evaluation, donor maintenance, authorization 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 disease transmission, including blood borne pathogens HIV, Hepatitis B, and Hepatitis C. If the donor meets the criteria set forth in the current US

Public Health Service (PHS) guidance[1], the Host OPO must communicate

[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.

this information regarding donor history to all transplant programs receiving organs from the donor.

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

2.2.2.2 Reviewing the donor's medical record.

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

2.2.3 SCREENING POTENTIAL ORGAN DONORS.

2.2.3.1 All blood samples obtained and used for screening tests required by OPTN policy must be assessed for hemodilution (defined as a sample with plasma dilution sufficient to affect the results of communicable disease testing) utilizing 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 PHS guidelines. As hemodilution can result in false negative serology testing, any screening results from such a specimen must be communicated to the accepting Transplant Program(s) and additional information including:

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

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

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

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

2.2.3.3 NOTA and the Final Rule require standards for preventing the acquisition of organs from individuals known to be infected with human immunodeficiency virus/acquired immune deficiency virus. As a result, OPTN Members shall not knowingly participate in the procurement or transplantation of organs from donors who are known to be infected with HIV OPTN members may only recover organs if the laboratory data and medical- social history indicates that the donor is not HIV infected.

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

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

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

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

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

2.2.4 **DONOR EVALUATION**. Donor evaluation must be performed or coordinated by the Host OPO. All donor laboratory testing must be performed in an appropriately accredited laboratory utilizing FDA licensed, approved, or cleared serological screening tests. In the event that a required screening test is not commercially available prior to transplant, then a FDA-licensed, approved or cleared diagnostic test is permissible, and the Host OPO must document in the donor record which assay was utilized to assess the potential donor and must also provide this information to the transplant program(s).

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

2.2.4.1 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:

2.2.4.2 For potential renal donors:
- Creatinine; and
- B.U.N.

2.2.4.3 For potential liver donors:
- AST;
- ALT;
- Alkaline phosphatase;
- Direct and total bilirubin
- INR (PT if INR not available); and
- PTT.

2.2.4.4 For potential heart donors:
- 12 Lead ECG; and
- Cardiology consult and/or echocardiogram.

2.2.4.5 For potential pancreas donors:
- Serum amylase.

2.2.4.6 For potential lung donors:
- Sputum gram stain.

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

The Host OPO must establish a procedure that defines its process for obtaining post-recovery donor testing results.

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

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

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

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

2.3 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 AUTHORIZATION. The Host OPO must provide evidence of authorization 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 Complete information must be maintained by the Host OPO for seven years per the Final Rule on any and all organs recovered.

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

2.5.8 The Host OPO is responsible for 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 Model Elements for Controlled DCD Recovery Protocols

Introduction: Donation after Cardiac Death (DCD) has been accepted by the Institute of Medicine and the transplant community as an ethically and medically acceptable option for patients and families making end of life decisions.

The intent of developing model elements for OPO and transplant hospital DCD recovery protocols is to establish model elements for OPOs and transplant hospitals to meet in developing, reviewing and improving their respective DCD recovery protocols. This outline is intended to set standards of what must be addressed in a DCD recovery protocol by OPOs and hospitals without being prescriptive regarding practice; each hospital and each DSA is specific in its practice, culture, and resources. The continuing collaboration between OPOs and transplant hospitals is encouraged to allow for the constant development of DCD best practices. The joint OPO Committee/MPSC Working Group is available as a continuing resource for OPTN member hospitals that experience delay or difficulty in adopting a DCD recovery protocol.

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 below.

Controlled Donation after Cardiac Death Recovery Protocol Model Elements

A. Suitable Candidate Selection:

1. A patient (aged newborn to DSA's defined upper age limit if applicable) who has a non-recoverable and irreversible neurological injury resulting in ventilator dependency but not fulfilling brain death criteria may be a suitable candidate for DCD.
2. Other conditions that may lead to consideration of DCD eligibility include end stage musculoskeletal disease, pulmonary disease, and high spinal cord injury.
3. The decision to withdraw life sustaining measures must be made by the hospital's patient care team and legal next of kin, and documented in the patient chart.
4. The assessment for DCD candidate suitability should be conducted in collaboration with the local OPO and the patient's primary health care team. OPO determination of donor suitability may include consultation from the OPO Medical Director and Transplant Center teams that may be considering donor organs for transplantation.
5. An assessment should be made as to whether death is likely to occur (after the withdrawal of life-sustaining measures) within a time frame that allows for organ donation.

B. Authorization/Approval

1. The legal next of kin may elect to authorize procedures or drug administration for the purposes of organ donation (e.g. heparin, regitine, femoral line placement, lymph node excision, ECMO, and bronchoscopy). No donor related medications shall be administered or donation related procedures performed without authorization.
2. Clearance from medical examiner/coroner must be obtained when applicable.
3. There should be a plan for patient care if death does not occur within the established timeframe after the withdrawal of life sustaining measures. This plan

should include logistics and provisions for continued end of life care, including immediate notification of the family.

4. For purposes of these model elements, “legal next of kin” shall also include the patient, a designated health care representative, legal next of kin, or appropriate surrogate.

C. Withdrawal of Life Sustaining Measures/ Patient Management

1. A timeout is recommended prior to the initiation of the withdrawal of life sustaining measures. The intent of the timeout is to verify patient identification, roles and the respective roles and responsibilities of the patient care team, OPO staff, and organ recovery team personnel.
2. No member of the transplant team shall be present for the withdrawal of life-sustaining measures.
3. No member of the organ recovery team or OPO staff may participate in the guidance or administration of palliative care, or the declaration of death.
4. There must be a determination of the location and process for withdrawal of life sustaining measures (e.g. ETT removal, termination of blood pressure support medications) as a component of the patient management.
5. If applicable, placement of femoral cannulas and administration of pharmacologic agents (e.g. regitine, heparin) for the sole purpose of donor organ function must be detailed in the authorization process.

D. Pronouncement of Death

1. The patient care team member that is authorized to declare death must not be a member of the OPO or organ recovery team.
2. The method of declaring cardiac death must comply in all respects with the legal definition of death by an irreversible cessation of circulatory and respiratory functions **before** the pronouncement of death.

E. Organ Recovery

Following the declaration of death by the hospital patient care team, the organ recovery may be initiated.

F. Financial Considerations

OPO policy shall ensure that no donation related charges are passed to the donor family.

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