4.0 IDENTIFICATION OF TRANSMISSIBLE DISEASES IN ORGAN RECIPIENTS

4.1 SCREENING POTENTIAL TRANSPLANT RECIPIENTS FOR BLOOD-BORNE PATHOGENS. 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.

4.1.1 HIV Positive Transplant Candidates. A potential candidate for organ transplantation whose test for HIV is positive should not be excluded from candidacy for organ transplantation unless there is a documented contraindication to transplantation based on local policy.

4.1.2 Informing Personnel. Health care personnel caring for candidates, potential candidates and recipients who test positive for HIV should be so informed only when necessary for medical decision-making purposes.

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

4.2.1 If additional donor risk (infectious or neoplastic) is identified pre-transplant, 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
- follow the recipient of such an organ for the development of potential donor-derived disease after transplantation.

4.2.2 Transplant programs must offer the recipients of organs from donors at increased risk for blood borne pathogens:

- additional post-transplant testing for HIV, HCV, and/or HBV (as appropriate based upon the recipient's pre-transplant status); and
- 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.

4.2.3 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.

The transplant program must:

- explain these 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; and

- document this consent in the recipient medical record and make it 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 and is noted as clinically relevant by the recipient's care team .

- 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

- Follow a recipient at increased risk for disease and/or malignancy for the development of this potential condition after transplantation, offering the recipient additional testing, monitoring and/or therapy as appropriate in addition to their routine follow-up care.

4.3.1 Transplant programs must offer the recipient of an organ from a donor found after transplant to pose increased risk for blood borne pathogens:

- Additional post-transplant testing for HIV, HCV and/or HBV (as appropriate based upon the recipient's pre-transplant status); and

- 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.

4.4 PATIENT SAFETY CONTACT. Each Host 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 make this information available to the OPTN contractor if requested.

4.5 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 deceased donor organ or recovery and transplant of a living donor organ must be reported to the OPTN Improving Patient Safety Portal.

- When an organ recipient 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 Living Donor Recovery Center (for living donor recipients) or Host OPO (for deceased donor recipients) by phone and provide available documentation to the Living Donor Recovery Center or Host OPO as soon as possible, but, at the latest, within 24 hours of their knowledge of the event. The transplant center that suspects potential transmission should not wait for all medical documentation that may eventually be available, but must inform:

    - the Living Donor Recovery Center or Host OPO and
    - the OPTN Improving Patient Safety Portal .

- If a Host OPO learns new information regarding a deceased donor (including but not limited to final culture results, information from autopsy report) as part of its donor follow-up (See Policy 2.2.5) that indicates risk of potential transmission of disease or malignancy, the Host OPO must report the donor result through the OPTN Patient Safety Portal.

- If a Recovery Center learns new information regarding a living donor, during the first two years post donation, (including but not limited to new or follow-up testing results, donor death or autopsy reports) that indicates risk of potential transmission of disease or malignancy, then the Recovery Center:

    - may need to report the new information to local, state or federal public health authorities;
    - must disclose to the living donor that a potential disease transmission or malignancy must be reported to the recipient transplant center and the OPTN Improving Patient Safety Portal;
    - must notify the recipient transplant center; and
    - must report the potential transmission through the OPTN Improving Patient Safety Portal.

4.5.1 Living Donor Recovery Center and Host OPO Responsibilities. The Living Donor Recovery Center or Host OPO shall be responsible for:

i. Communication of 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 or recovery (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.

ii. Notification of the event to the OPTN Improving Patient Safety Portal as soon as possible, not to exceed 24 hours.

iii. Follow-up Communication of Potential Disease Transmission

- For deceased donors, 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 the OPTN Patient Safety Portal) to OPTN Patient Safety Staff within 24 hours of reporting the event through the Patient Safety Portal 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.
- For all donors, the Ad Hoc Disease Transmission Advisory Committee may request submission of a Potential Disease Transmission Donor Follow-Up Report (a form that will be sent by OPTN contractor staff) 45 days after the initial reporting date; OPTN Patient Safety Staff may request additional information related to the donor beyond 45 days, including pending test results depending on the potentially transmitted disease or condition.

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.

4.5.2 Transplant Program Responsibilities. Any transplant program treating recipient(s) that received organ(s) from a donor who is the subject of a potential disease transmission report is responsible for:

i. Responding to Host OPO, Living Donor Recovery Center, 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 OPTN Patient Safety Staff.

iii. Notifying recipient(s) involved in cases of confirmed transmissions and documenting this notification in the recipient medical record as required in Policy 4.3.

iv. If requested by the Ad Hoc Disease Transmission Advisory Committee, submission of a Potential Disease Transmission Recipient Follow-Up Report (a form that will be sent to the transplant program by OPTN staff) within 45 days of the initial reporting date.

OPTN Patient Safety Staff may request additional information related to the recipient beyond 45 days, (including pending test results, long term follow-up testing, and/or screening results, etc.) depending on the potentially transmitted disease or condition in an effort to determine the probability of donor-derived disease transmission.