7.0 DATA SUBMISSION REQUIREMENTS

Members must submit data to the OPTN through use of standardized forms. Data requirements include submission of information on all deceased and living donors, potential transplant recipients, and actual transplant recipients. All transplant data forms must be submitted through UNet[SM], beginning January 1, 2003. All OPOs are responsible for submission of patient level data for all authorized donors, authorized but not recovered potential donors, imminent neurological and eligible deaths in its DSA. All OPOs are also responsible for submission of the total number of reported deaths by donor hospital. The OPO responsible for allocation of the donor organs will be responsible for submission of the Deceased Donor Feedback information, Deceased Donor Registration (DDR) Forms and Potential Transplant Recipient (PTR) Forms. Histocompatibility laboratories will be responsible for submission of the Donor and Recipient Histocompatibility forms for each donor and actual transplant recipient typed by the laboratory. Recipient transplant centers are responsible for submission of Recipient Feedback information, Transplant Candidate Registration Forms, organ-specific Transplant Recipient Registration Forms, the Liver Post-transplant Explant Pathology_Form, organ-specific Transplant Recipient Follow-up Forms, and Recipient Malignancy Forms for each recipient on the waiting list or transplanted at the center.

Transplant centers that recover living donor organs are responsible for submitting Living Donor feedback information, Living Donor Registration Forms, and Living Donor Follow-up Forms for each living donor whose organ was recovered at that center within the time frame established in Policy 12.8.3. The transplant center that intends to recover the living donor organ is responsible for generating the Donor ID and reporting whether the recovery procedure occurred.

7.1 REPORTING DEFINITIONS

7.1.1 For form submission purposes, an organ transplant has occurred once either: any initiation of anastomosis has taken place during the intended transplant, or the initiation of an islet cell infusion has occurred. The transplant procedure shall be considered complete when either (1) the chest and/or abdominal cavity is closed and the final skin stitch and/or staple is applied or (2) the islet cell infusion is complete. For the purposes of this definition, solid organ transplants and islet cell infusions are all considered to be transplants. Extracorporeal transplants are not considered organ transplants for the purposes of this definition.

7.1.2 For all transplants, as defined in 7.1.1, the transplant date for reporting purposes shall be determined by the beginning of the first anastomosis. In the event of a multi-organ transplant procedure, each organ shall be reported with the transplant date as determined by the first organ.

7.1.3 Each organ transplant must be followed until graft failure.

7.1.4 Graft failure is defined as having occurred when organ removal, death, or replacement on chronic allograft support system has occurred.

7.1.5 Timely data on all recipients shall be based on recipient status at a time as close as possible to the specified transplant event anniversary. For example, recipient information collected within 30 days of the six-month follow-up reports, or within three months of the annual follow-up reports, is considered timely.

7.1.6 Imminent Neurological Death is defined as a patient who is 70 years old or younger with severe neurological injury and requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has an absence of at least three brain stem reflexes but does not yet meet the OPTN definition of an eligible death, specifically that the patient has not yet been legally declared brain dead according to hospital policy. Persons with any condition which would exclude them from being reported as an eligible death would also be excluded from consideration for reporting as an imminent death. For the purposes of submitting data to the OPTN, the OPO shall apply the definition of imminent neurological death to a patient that meets the definition of

imminent death at the time when the OPO certifies the final disposition of the organ donation referral.

Brain Stem Reflexes:

- Pupillary reaction
- Response to iced caloric
- Gag Reflex
- Cough Reflex
- Corneal Reflex
- Doll's eyes reflex
- Response to painful stimuli
- Spontaneous breathing

7.1.7 Although it is recognized that this definition does not include all potential donors, for reporting purposes for DSA performance assessment, an eligible death for organ donation is defined as the death of a patient 70 years old or younger who ultimately is legally declared brain dead according to hospital policy independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice, who exhibits none of the following:

Active infections (specific diagnoses) [Exclusions to the Definition of Eligible]

Bacterial: Tuberculosis, Gangrenous bowel or perforated bowel and/or intra-abdominal sepsis, See "sepsis" below under “General”

Viral: HIV infection by serologic or molecular detection, Rabies, Reactive Hepatitis B Surface Antigen, Retroviral infections including HTLV I/II, Viral Encephalitis or Meningitis, Active Herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia, Acute Epstein Barr Virus (mononucleosis), West Nile Virus infection, SARS

Fungal: Active infection with Cryptococcus, Aspergillus, Histoplasma, Coccidioides, Active candidemia or invasive yeast infection

Parasites: Active infection with Trypanosoma cruzi (Chagas'), Leishmania, Strongyloides, or Malaria (Plasmodium sp.)

Prion: Creutzfeldt-Jacob Disease

General [Exclusions to the Definition of Eligible]: Aplastic Anemia, Agranulocytosis

Extreme Immaturity (<500 grams or gestational age of <32 weeks)

Current malignant neoplasms except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease
Previous malignant neoplasms with current evident metastatic disease

A history of melanoma
Hematologic malignancies: Leukemia, Hodgkin's Disease, Lymphoma, Multiple

Myeloma

Multi-system organ failure (MSOF) due to overwhelming sepsis or MSOF without sepsis defined as 3 or more systems in simultaneous failure for a period of 24 hours or more without response to treatment or resuscitation

7.2 GENERAL SUBMISSION OF FORMS

The Transplant Candidate Registration, Deceased Donor Registration, Recipient Histocompatibility, Donor Histocompatibility, and Recipient Malignancy Forms must be submitted to the OPTN within 30 days of the form generation date. The Living Donor Follow-up Form must be submitted to the OPTN within 60 days of the form generation date.

7.3 SUBMISSION OF ORGAN-SPECIFIC TRANSPLANT RECIPIENT REGISTRATION FORMS

7.3.1 The Thoracic, Kidney, Liver, Pancreas and Intestinal Transplant Recipient Registration Forms and the Liver Post-transplant Explant Pathology Form, must be submitted to the OPTN within 60 days of the form generation date. Transplant Centers must complete the form when the transplant recipient is discharged from the hospital or six weeks following the transplant date, whichever is first.

7.4 SUBMISSION OF ORGAN-SPECIFIC TRANSPLANT RECIPIENT FOLLOW-UP FORMS

7.4.1 The appropriate Transplant Recipient Follow-up form must be submitted to the OPTN within 14 days of notification of the recipient's death or graft failure.

7.4.2 In cases other than those cited in Policy 7.4.1, all Transplant Recipient Follow-up Forms must be submitted to the organ-specific registry within 30 days of the form generation date.

7.5 SUBMISSION OF DONOR INFORMATION

Organ procurement organizations must provide donor information required for organ placement to UNet[SM] in an electronic data format as defined and required by the computer system. Donor information required for organ placement must be in UNet[SM] prior to organ allocation.

7.5.1 Information pertaining to deceased donor feedback must be submitted to the OPTN within five working days of the procurement date.

7.6 SUBMISSION OF POTENTIAL TRANSPLANT RECIPIENT FORMS

Potential Transplant Recipient Forms (PTR) must be submitted to the OPTN within 30 days of the match run date by the OPO or the Organ Center for each deceased donor organ that is offered to a potential recipient. PTR refusal codes must be obtained by the OPO or the Organ Center directly from the physician/surgeon or designee involved with the potential recipient rather than from other personnel.

7.6.1 Validation of Potential Transplant Recipient Forms.

7.6.1.1 Entry and Validation of Offers. Entry of patient-specific refusal reasons for all organ offers shall be a shared responsibility of the donor OPO and the transplant center considering the offer. The donor OPO is responsible for ensuring that acceptance or refusal information is documented for each organ offer. Patient-specific refusal reasons, not entered by the transplant center or UNOS Organ Center, shall be validated by the transplant center using the online procedure available in UNet[SM].

7.6.1.2 Validation of Organ Center Offers. Recipient specific refusal reasons recorded by the Organ Center will be considered validated as recorded. The Organ Center staff will use the online procedure available in UNet[SM] for this purpose.

7.6.2 Recording and Reporting of the Outcomes of Organ Offers. Recording and reporting of the refusal reasons must be a cooperative effort between the OPO and the transplant center.

7.6.2.1 The OPO and transplant centers should be familiar with the current refusal reasons and, to the extent possible, should refer to these reasons explicitly during the offer/refusal transaction. If, after 45 days following the date of the match run from which the offer was made, the transplant center fails to verify the refusal reason as entered by the OPO or fails to enter a different refusal reason, the refusal reason as entered by the OPO will be considered accurate and validated. The OPO and the transplant center should make every reasonable attempt to resolve conflicts in recorded refusal reasons. However, in the event of a dispute between the OPO and the transplant center regarding a recorded reason for refusal, the record of the transplant center will take precedence for the purposes of reporting by the OPTN contractor.

7.6.2.2 Each transplant center must cooperate with the OPO in review and verification of the data on all offers of organs for transplantation**.**

7.7 SUBMISSION OF DEATH NOTIFICATION INFORMATION

The OPO shall report to the OPTN the total number of deaths reported to the OPO by donor hospital in addition to patient level data on all imminent neurological deaths and eligible deaths either

- within 30 days from the end of the month in which a death was referred to the OPO by the hospital in which the death occurred, or
- 30 days from the end of the month in which the death was identified by the OPO through a Death Record Review.

7.8 DATA SUBMISSION STANDARD

7.8.1 Each OPO, Transplant Center and Histocompatibility Laboratory must meet the following standard for submission of data collected on all forms to the Transplant Registries: 95% of expected forms complete within three months of the due date and 100% of expected forms complete within six months of the due date. 100% of the potential recipient refusal code data must be submitted within 30 days of the match run date.

7.8.2 Each OPO and Transplant Center must meet the following standard for submission of feedback information: 100% of feedback information complete within 30 days of the transplant date.

7.9 DATA SUBMISSION NON-COMPLIANCE

If after repeated efforts by the OPTN contractor to assist a member in submitting all overdue data, the member continues to remain non-compliant with data submission policies, and after a hearing by the Membership and Professional Standards Committee (MPSC) resulting in a determination that the member continues to be non-compliant with data submission requirements, the MPSC may recommend an onsite audit to retrieve the missing data at the members' expense.