

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 the UNetsm application, beginning January 1, 2003. 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. Each OPO also is responsible for submission of hospital-specific death notification, donor eligibility and consent information. 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, Living Donor Feedback information, Living Donor Registration Forms, Living Donor Follow-up Forms, Transplant Candidate Registration Forms, organ-specific Transplant Recipient Registration Forms, organ-specific Transplant Recipient Follow-up Forms, and Recipient Malignancy Forms for each recipient on the waiting list, transplanted or followed at the center.

7.1 REPORTING DEFINITIONS

- 7.1.1** For form submission purposes, a solid organ transplant has occurred once any initiation of anastomosis has taken place during the intended transplant. The transplant procedure shall be considered complete when the chest and/or abdominal cavity is closed and the final skin stitch and/or staple is applied. Extracorporeal transplants and transplantation of islet cells are not considered solid 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** The follow-up period for all transplant recipients will be until death or retransplantation. Following graft failure, every reasonable effort should be made to follow surviving patients for a minimum of two years.
- 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** The follow-up period for living donors will be a minimum of one year.
- 7.1.6** Timely data on all patients shall be based on patient status at a time as close as possible to the specified transplant event anniversary. For example, patient 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.

7.2 GENERAL SUBMISSION OF OPTN FORMS

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

7.5 SUBMISSION OF DONOR INFORMATION

Information pertaining to deceased donor feedback must be submitted to UNOS within five working days of the procurement date. All living donors must be registered with UNOS via the living donor feedback form prior to surgery.

7.6 SUBMISSION OF POTENTIAL TRANSPLANT RECIPIENT FORMS

Potential Transplant Recipient Forms 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 Validation of Offers. Potential recipient refusal reasons for all offers shall be validated. Patient-specific refusal reasons for all offers shall be entered by the OPO and validated by the transplant center using the online procedure available in UNetsm.

7.6.1.2 Validation of Offers of Organs Placed Through the UNOS Organ Center. Patient-specific refusal reasons for offers made by the UNOS Organ Center (including offers of all mandatory kidney shares for zero mismatched recipients) will be recorded by the UNOS Organ Center staff to assure accuracy, and will be considered validated as recorded. The Organ Center staff will use the online procedure available in UNetsm 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 UNOS.

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

All monthly death notification information must be submitted by the OPO for each donor hospital before the close of the subsequent calendar month.

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 UNOS 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.