

CHAPTER 6

TRANSPLANT CENTER PROCEDURES

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6.1 STAFFING AND ORGANIZATION

Each COBLT Study Transplant Center is staffed, at a minimum, by a Principal Investigator (PI), a Clinic Coordinator, and a laboratory technician. There may be additional physicians designated as co-investigators, as well as administrative personnel.

6.2 FUNCTIONS OF THE PRINCIPAL INVESTIGATOR

The responsibilities of the PI, who is a physician with substantial experience in both cord blood transplantation and the performance of clinical trials, are to:

- Direct the activities of the COBLT Study personnel in the Transplant Center
- Coordinate the scientific and administrative operations of the Transplant Center
- Ensure adherence by Transplant Center personnel to the procedures described in and required by the COBLT Study Manual of Procedures
- Spend sufficient time in the Transplant Center to adequately observe study procedures
- Assure the Transplant Center's fiscal responsibility in the disposition of COBLT Study funds
- Represent the Transplant Center at meetings of the Steering Committee and Technical Subcommittees

6.3 FUNCTIONS OF THE CLINIC COORDINATOR

The Clinic Coordinator is responsible for supervising daily operations in the Transplant Center and serves as primary contact for the study patients and for the Medical Coordinating Center (MCC). The duties of the Clinic Coordinator are to:

- Coordinate search activities for prospective patients
- Ensure that potential COBLT Study patients receive appropriate information about the study, including the Informed Consent statements
- Register patients in the COBLT Study
- Notify the MCC of changes or impending changes in the Transplant Center personnel, address, telephone number(s) of the Transplant Center

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- Maintain a file of correspondence with the MCC
- Obtain necessary information about deceased patients (e.g., death certificates)
- Maintain an up-to-date COBLT Study Manual of Procedures and COBLT Study protocol
- Check completed data forms for accuracy and completeness
- Ensure that patient names, social security numbers, and any other personal identifiers are removed from all materials sent to the MCC
- Submit complete data to the MCC in a timely manner
- Respond to data queries from the MCC
- Ensure that personnel performing COBLT Study procedures are properly trained and certified
- Monitor Transplant Center activities for conformance to the requirements of the COBLT Study Manual of Procedures and COBLT Study protocol
 - Participate in regularly scheduled telephone calls (Protocol Review Calls) with the Protocol Monitor
 - Meet with the Protocol Monitor during Site Visits at the Transplant Center
- Report irregularities or problems that can affect the data quality to the PI and the Protocol Monitor
- Other duties as defined by the Steering Committee, Technical Subcommittees, or Data and Safety Monitoring Board (DSMB)

Each Clinic Coordinator will be given a copy of the COBLT Study Manual of Procedures - Chapter 10 for completing COBLT Study data forms.

6.4 RECRUITMENT

As described in Section 5.1, each Transplant Center must have a plan for tracking transplants and transplant candidates to ensure meeting the recruitment goals and requirements of the COBLT Study. The monthly recruitment report (Section 10.5) should be part of this plan. This plan will be reviewed during site visits.

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6.5 ELIGIBILITY SCREENING

If a patient appears to be eligible, the following steps should be taken:

1. The plan of the study should be reviewed with the patient and any questions by the patient should be answered.
2. The patient should be asked to sign the Informed Consent statement.
3. If the patient is determined to be ineligible, the reasons for ineligibility should be discussed with the patient.
4. Patients will be followed at designated intervals according to the Follow-Up Schedule in the COBLT Study Protocol.

Once a patient has been assigned a registration number, the number remains associated with the patient and will not be reassigned.

6.6 SCHEDULING PATIENT APPOINTMENTS

After a patient has been registered, the MCC will issue to the Transplant Center a patient schedule for all the COBLT Study follow-up visits. The patient schedule specifies the target appointment dates and the maximum and minimum dates (time windows) for each follow-up visit. When scheduling appointments, the various time windows must be kept in mind. Efforts should be made to avoid missed visits and to keep follow-up visits as close to the target date as possible. If a patient is moving to an area that is not near the Transplant Center, staff should encourage the patient to return to the Transplant Center for their scheduled follow-up visits. At times when a patient is not planning to return to the Transplant Center for a follow-up visit, the Clinic Coordinator should make arrangements to obtain the necessary information through the patient's primary physician.

6.7 CHECKING COMPLETED FORMS

Before submitting data to the MCC, the Clinic Coordinator should carefully check all data for completeness and consistency. The Clinic Coordinator must also ensure that patient names, social security numbers, and any other personal identifiers are removed from all materials sent to the MCC.

Completeness and consistency. Every effort should be made to complete every field on each data form. Each form will be extensively computer-edited at the MCC. Incomplete and inconsistent items will be queried by the MCC and clarification requested.

Numerical responses. Numerical responses such as hematologic values will be computer-edited to determine whether they are within certain limits. If they are not, then an edit message is sent to the Transplant Center. This type of message is not evidence of an error, but simply a request to verify that the number is correct.

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Legibility. Entries on data forms and responses to queries should be typed or clearly printed in ink.

6.8 TRANSFERRING PATIENTS

All follow-up reporting requirements of COBLT Study patients will be the responsibility of the Transplant Center which registers the patient. It is not anticipated that patients will transfer to new transplant centers; thus, no plans are developed to accommodate this situation.