

CHAPTER 7

MEDICAL COORDINATING CENTER PROCEDURES

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7.1 STAFFING AND ORGANIZATION

The Medical Coordinating Center (MCC) for the COBLT Study is located at The EMMES Corporation in Potomac, Maryland. The staff at the MCC include the following:

- ! Principal Investigator (PI)
- ! Biostatisticians
- ! Immunologist
- ! Administrative Coordinator
- ! Data Coordinator
- ! Protocol Monitor
- ! Computer System Group

The PI directs the MCC in its responsibility to provide study design, statistical analysis, project reporting, data collection and administrative coordination. He or she works closely with the project biostatisticians who assist in protocol development, data analysis, report generation, and publications. The Data Coordinator is responsible for maintaining the currency, accuracy, and integrity of the COBLT Study databases and the training and certifying of Transplant Center and Cord Blood Bank personnel in COBLT Study forms completion. The Data Coordinator is also available for support, directly or as a liaison, in defining and solving problems associated with forms completion. The Protocol Monitor assists in training and certifying of Transplant Center and Cord Blood Bank staff in registration and laboratory procedures and participates in periodic Protocol Review Visits. The Protocol Monitor also serves as a staff specialist for dealing with problems associated with patient accrual. The Computer System Group is responsible for the design, development, installation, and maintenance of the COBLT Study data system. The hardware and software components of the COBLT Study data system are located at the MCC. The Administrative Coordinator is responsible for all logistical and administrative support.

7.2 COORDINATION AND ADMINISTRATION

One of the routine functions of the MCC is to meet the many administrative, logistic, and communications requirements of the COBLT Study.

7.2.1 Roster of COBLT Study Personnel

To maintain efficient communication among the participating Transplant Centers, the Steering Committee and other various COBLT Study subcommittees, and the NHLBI, the MCC maintains a roster of all COBLT Study personnel (Appendix A). This roster lists the names and addresses of all participating units, and the names and telephone numbers of all COBLT Study members. COBLT Study personnel also are listed alphabetically.

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7.2.2 Committee Support

The COBLT Study is supported by a network of committees. For most committee meetings, the MCC provides logistical support. The MCC collaborates with the NHLBI Program Office to:

- ! Determine optimal meeting dates
- ! Select meeting sites based on cost and convenience
- ! Communicate information about meetings to committee chairperson
- ! Prepare meeting materials
- ! Provide logistical support during the meeting
- ! Duplicate and distribute materials prior to each meeting
- ! Prepare and distribute minutes of the meetings
- ! Follow-up on all action items after each meeting
- ! Coordinate conference calls

7.2.3 Documentation

The MCC supports the preparation, duplication, and dissemination of administrative and technical reports and manuscripts. These documents may include:

- ! Manual of Procedures
- ! Protocols
- ! Patient recruitment materials
- ! Meeting minutes
- ! Statistical reports
- ! Bibliographies
- ! Abstracts
- ! Manuscripts for publication
- ! Roster of COBLT Study personnel

MCC staff work closely with clinicians, statisticians, writing committees, protocol development subcommittees, scientists, and authors. The staff routinely helps to:

- ! Compile and organize materials
- ! Coordinate reviews and incorporate comments
- ! Summarize background materials

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- ! Write administrative reports
- ! Maintain a chronology of revisions and modifications of the Manual of Procedures, the CBB SOP, and the COBLT Study protocol

7.3 STUDY PLANNING

The design of the COBLT Study is a collaborative venture that involves physicians and other health care personnel from the Transplant Centers, biostatisticians and other staff from the MCC, and the NHLBI. MCC staff participate on various COBLT Study committees involved with the design of the study. The MCC has primary responsibility for 1) evaluating the impact of protocol decisions on the scientific integrity of the study (e.g., feasibility of obtaining and maintaining patient compliance with study procedures, etc.); 2) determining the minimum required sample size, confidence limits, and power (to the extent that protocol decisions affect sample size requirements); and 3) establishing resource (personnel and equipment) requirements.

7.4 DATA MANAGEMENT

Data management is one of the main functions of the MCC. In the COBLT Study, Transplant Centers will submit data to the MCC using forms developed by the National Marrow Donor Program (NMDP) and International Cord Blood Transplant Registry (ICBTR) and supplementary forms designed and developed at the MCC in collaboration with the Steering Committee.

NMDP Forms. The following NMDP forms will be completed at the Transplant Centers using NMDP instructions and coding:

- ! Recipient Baseline and Transplant Data (Form 120 and appropriate ICBTR insert)
- ! 100-Day Follow-Up Visit of Recipient (Form 130)
- ! Post Transplant Follow-up Form Insert I – Severe Combined Immunodeficiency (SCIDS) (Form 130 Insert I) when applicable
- ! Post Transplant Follow-up Form Insert II – Wiscott Aldrich Syndrome (WAS) (Form 130 Insert II) when applicable
- ! Post Transplant Follow-up Form Insert III – Information for Hodgkin and Non-Hodgkin Lymphoma (Form 130 Insert III) when applicable
- ! Six-Month to Five-Year Follow-Up Visit of Recipient (Form 140)
- ! Post Transplant Follow-up Form Insert I – Severe Combined Immunodeficiency (SCIDS) (Form 140 Insert I) when applicable
- ! Post Transplant Follow-up Form Insert II – Wiscott Aldrich Syndrome (WAS) (Form 140 Insert II) when applicable

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- ! Post Transplant Follow-up Form Insert III – Information for Hodgkin and Non-Hodgkin Lymphoma (Form 140 Insert III) when applicable
- ! Yearly Follow-up for Greater than Five Year Post Transplant (Form 150) when applicable
- ! Leukemia and MDS Yearly Follow-up for Relapse Post Stem Cell Transplant (Form 160) when applicable
- ! Recipient Death Information (Form 190)

Copies of these forms will be submitted to the Data Coordinator at the MCC.

Supplementary Forms. Supplementary forms will be completed at the Transplant Centers using instructions and coding detailed in the COBLT Study Manual of Procedures - Chapter 10. The original form will be submitted to the Data Coordinator at the MCC. A copy of the form will be kept in the patient's COBLT Study file at the Transplant Center.

Criteria for forms submission timeliness have been developed by the MCC for NMDP, ICBTR, and supplementary forms; see Chapter 10. Forms that are not received at the MCC within the specified criteria will be considered delinquent. Each month, Transplant Centers will receive a listing of delinquent forms. A missing form will continue to be requested either until the data for the form is submitted and integrated into the MCC's master database, or until an exception is granted and entered into the Missing Forms Exception File.

The MCC trains and certifies Clinic Coordinators in forms completion and submission. Certification is designed to ensure that clinical staff responsible for submitting data are familiar with the forms, instructions for supplementary forms completion, and the criteria for timeliness of 1) forms submission and 2) response to queries. Clinic Coordinators who attend a data management training session at a COBLT Study Clinic Coordinators meeting will be considered certified. Clinic Coordinators who have not attended a data management training session can be granted certification by the Data Coordinator at the MCC.

7.5 DATA ANALYSIS AND REPORTING

In providing statistical support for the COBLT Study, MCC biostatisticians are responsible for developing the analysis plan for the COBLT Study protocol in collaboration with the Data and Safety Monitoring Board (DSMB) and the representatives from the Biostatistics Scientific Research Group, Division of Epidemiology and Clinical Applications, NHLBI, as detailed in Chapter 4. The plan carefully monitors patient accrual, patient eligibility rates, adverse reactions, and other outcomes. Detailed analyses will be performed periodically and study progress will be monitored continuously. The biostatisticians will play a key role in reviewing the findings of the study and defining ancillary studies. They are fully trained and understand the medical aspects of the COBLT Study. They are expected to help ensure that the COBLT Study is conducted properly, progresses appropriately, and establishes the most accurate results based on the data gathered.

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The COBLT Study requires continuous and comprehensive technical and administrative reporting which will be overseen by the MCC. Such reports will constitute important interim and final products of the scientific effort.

Database assessments conducted by the MCC will be targeted at maintaining the integrity of the database, monitoring adherence of the clinics to the protocol, and developing cumulative baseline and outcome assessments.