17.0 DATA MANAGEMENT

17.1 Overview

Data management will be handled by the NETT-SDMC which is housed in the Division of Biostatistics and Epidemiology in the Department of Medicine at the Medical University of South Carolina (MUSC). All activities will be conducted in coordination with the UCSF CCC, the NINDS NETT Network, and the NINDS CRC.

The data is managed the WebDCU™ system. This web-based database system is developed and validated by the NETT-SDMC. It enables web-based real-time subject randomization, data entry and validation, project progress monitoring, subject tracking, drug shipment tracking, user customizable report generation and secure data transfer.

17.2 Data Acquisition and Central Study Database

The entire study will be conducted using an electronic data acquisition method where all clinical data on enrolled subjects will be entered by the Spoke/Site personnel via a web-based Clinical Trial Management System. In order to provide user-friendly and easy-to-navigate interfaces, the WebDCU™ data capture screens are designed based on individual CRFs.

The latest version of each CRF is available as a PDF file on the study website for use as worksheets and source documents by study personnel. The most current version of the case report forms can be found on the study website.

The data validation procedure is implemented in two stages. The study database has extensive consistency checks programmed into the forms during the development of the database. These checks are in place to flag potential data entry errors and protocol violations, including missing required data, data out of a pre-specified range, data conflicts and disparities within each CRF and across different CRFs.

When data that violates the consistency check is entered, a rule violation message appears on the data entry screen alerting the data entry person to address it. The choices are to:
(1) correct the entry immediately;
(2) correct the entry at a later time; or
(3) dismiss the rule with an explanation if the entered data is confirmed to be correct.

Secondly, for some checks that are more complicated, additional consistency checks are periodically run after data entry occurs at the site. All data items that fail these secondary consistency checks are queried via the data database by NETT-SDMC data managers. Site monitors are also able to generate Data Clarification Requests (DCRs) when discrepancies are found during source to database verification. The DCRs will be generated, communicated to the Spokes/Sites, and resolved on the secure study website. Any changes made in the system have a full audit trail.

17.3 Modules

17.3.1 Randomization

The NETT-SDMC developed a web-based randomization module that will be used by all authorized Spoke/Site personnel for the purpose of randomizing eligible patients. The WebDCU™ subject randomization module automatically generates unique subject IDs without storing any personal identifying information. The Spoke/Site personnel log onto the WebDCU™ POINT web-based system using a unique username and confidential password. Then, the user enters the required information into the Randomization CRF including eligibility criteria. The computer program checks for accuracy and completion of this information prior to assigning a unique randomization number. In addition, an automatic e-mail notification of enrollment is sent to the appropriate parties (e.g., the POINT Executive Committee, UCSF CCC, the NINDS NETT Network, and the NINDS CRC). If, under rare circumstances the web system is not available, the Study Coordinator can call the emergency hotline to obtain the randomization number.

For more information, see the WebDCU™ User Manual.

17.3.2 Drug Accounting

The Drug Accounting module of the WebDCU™ is designed to facilitate communication between the Spokes/Sites and the UCSF Investigative Drug
Center. WebDCU™ contains a web-based study drug shipping and management component which allows for automated maintenance of the appropriate amount of study drug at the Spokes/Sites, web-based confirmation of drug receipt, and reporting of damaged study drug kits.

Prior to study start up at each Spoke/Site, the Central Pharmacy will send an initial shipment of approximately 4 bottles of investigational product. The shipping is entered into WebDCU™ by the Central Pharmacy. The Spokes/Sites will receive notification on WebDCU™ once the study drug kits have been shipped. When the shipment is received, the Spoke/Site staff will confirm receipt of each study drug bottle in the website. The Spokes/Sites will also document Study Drug Preparation and Study Drug Retirement in the Drug Accounting Module. After the initial distribution of study drug, additional study drug will be sent on an ‘as needed’ basis. The WebDCU™’s automated drug distribution system informs the Central Pharmacy when additional kits are needed at a Spoke/Site.

For more information, please see the WebDCU™ User Manual.

17.3.3 Reporting Module

The WebDCU™ system also has a real-time reporting component which allows authorized users the ability to view protocol specific reports as data listings and in a summary format, overall and by Spoke/Site, at any time during the study via the password protected system. The Report Module includes reports on enrollment, SAEs, CRF processing, and subject progress. The reports are presented in a manner that protects the integrity of the study (e.g., blinded).

For more information, see the WebDCU™ User Manual.