

DATA SYSTEM

1. MrOS Web Site

The MrOS web site used for Sleep Visit 2 will use the same web site used for the other MrOS visits. To access the web site go to <http://www.keeptrack.ucsf.edu> (or <http://rds.sfccc-cpmc.net> and <http://rds.epi-ucsf.org>) and click on the MrOS logo and log in. (For instructions on how to log on, please see the Data System Operations Manual under Study Documents on the MrOS web site.)

* Please note that the MrOS web site works optimally when used with the Microsoft Internet Explorer or later browser.

Please remember that you should completely close down your browser to log-off the MrOS web site. This is necessary to ensure the security of the site. Therefore, it will be necessary to shut down Internet Explorer when you have finished using the MrOS web site, and then open Internet Explorer again to use the web for other purposes.

1.1 MrOS Web Site Features

All features of the MrOS web site are listed below. **Links that will be used regularly during Sleep Visit 2 are in bold.**

<i>Directory</i>	Contact information for study personnel.
<i>Calls/Meetings</i>	Information for future meetings and dial in information for conference calls.
<i>Memo Archive</i>	Numbered study memos.
<i>Ancillary Studies</i>	Ancillary study policies and procedure guidelines
<i>Analysis Plans</i>	Lists analysis plans for the MrOS study
<i>Study Documents</i>	Up-to-date copy of operations manuals, data collection forms, etc. Visit 2 documents are located under “Visit 2 Forms” and “Visit 2 Protocols.”
<i>Reports</i>	Recruitment and endpoint reports are listed for the MrOS study.
<i>Endpoints Tracking</i>	Up-to-date data regarding endpoints adjudication status.
<i>Postcard Late List</i>	Listing of MrOS postcards that are late
<i>Sleep Postcard Late List</i>	Listing of MrOS Sleep postcards that are late
<i>Data Inventory</i>	Lists forms successfully received by the Coordinating Center data system.
<i>Data Entry Summary</i>	Displays the number of each form that has been received by the data system within specified dates
<i>Data Entry Totals</i>	Summary report of all forms received by site
<i>Rejected Forms</i>	Lists forms that were not accepted by the Coordinating Center data system.
<i>Incomplete Sets</i>	Lists of participants by ID with some, but not all data for a visit
<i>Edit Report</i>	List of outstanding queries (potential errors) in the study database.
<i>Post Queries</i>	Add an edit on the web site so data can be changed

<i>Audit Trail</i>	List of all changes made to data in the study database.
<i>Audit Trail Summary</i>	Displays number of addressed queries, number of times data has been changed, and number of query overrides

2. Data Management System

The overall goal of our data management and quality assurance is to provide high quality and timely data to study investigators and to provide study management tools to the Steering Committee. This system uses scannable forms and Internet technology to provide rapid and timely access to accurate and high quality data.

3. Data System Overview

The data system used for Sleep Visit 2 will be the same system that was used for other MrOS visits. Data from the second sleep visit will be housed with data from the other visits. Each site will continue to only be able to access their site's data.

This data system consists of three related components: *Data Input*, *Data Querying*, and *Query Addressing*. The *Data Input* component starts with forms that are filled out by participants and study staff and then faxed into the Coordinating Center database. Reports on the study web site provide feedback on the data input process. The second component is *Data Querying* (also known as the edit report). It consists primarily of a query generation program that is run each night against the entire database. The results are available on the study web site. The web site also provides a means whereby study staff can originate their own queries (i.e. potential errors or missing data). The third component is *Query Addressing*. Using the 'edit report' (query list) on the web site as the gatekeeper, study staff are able to make changes to the data in the study database in order to fix errors or inconsistencies in the data. All changes made to the data are then saved in the audit trail.

For a complete explanation of the data system and descriptions of how to use the data system tools available on the MrOS web site, please refer to Data System Operations Manual located on the MrOS website under Study Documents. The following sections are described in detail in the Data System chapter and should be reviewed:

<i>Data Input</i>	<i>Data Querying</i>
<i>Rejected Forms</i>	<i>Originating a Query</i>
<i>Forms Inventory Report</i>	<i>Query Addressing</i>
<i>Data Inventory</i>	<i>Edit Reports: Selection Criteria</i>
<i>Viewing Form Data</i>	<i>Viewing Edits</i>
<i>Data Entry Totals</i>	<i>Fixing Edits</i>
<i>Incomplete Sets</i>	<i>Making Comments</i>
	<i>Audit Trail</i>

4. Data security

We have a number of levels of data security that we have developed for our systems. Use of the Coordinating Center web site is limited to study staff only.

4.1 User ID and Password

Your user ID will be composed of the first initial of your first name followed by your last name (do not include any spaces between your initial and your last name). Under special circumstances an alternative user ID may be assigned. An username and temporary password will be assigned to you by the Coordinating Center. **YOU MUST CHANGE YOUR PASSWORD BEFORE YOU LOG ON TO THE MrOS WEBSITE.** Please contact the Coordinating Center if you have questions about changing your password.

Please be careful with your username and password. The Coordinating Center will not keep a record of passwords.

Study personnel that have received a username and password as part of the MrOS study will continue to use the same ID and password for sleep visit 2. Any new study personnel will need to receive a username and password from the Coordinating Center.

4.2 Coordinating Center Security Procedures

To insure that the data are secure, the SQL server is backed-up nightly to digital linear tape and monthly copies are stored off-site. The server is physically housed in a limited access security room at the CC.

Computer programs will be carefully documented and tested. Standard operating procedures (SOPs) for system validation have been developed by the Coordinating Center in accordance with FDA-mandated requirements for pharmaceutical studies.