

DATA SYSTEM

1. MrOS Web Site

The MrOS Sleep Study will use the same site used for the Osteoporotic Fractures in Men study (MrOS). To access the web site go to <http://www.keeptrack.ucsf.edu> 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. Those sections in **bold** directly pertain to the MrOS Sleep Study.

<i>Directory</i>	Contact information for study personnel. Individuals involved with the Sleep Study are listed among study-wide personnel.
<i>Calls/Meetings</i>	Information for future meetings and dial in information for conference calls.
<i>Memo Archive</i>	Numbered study memos. Memos specifically for the Sleep Study will include identifying information in the memo title.
<i>Study Documents</i>	Up-to-date copy of operations manuals, data collection forms, etc. Sleep documents are located under “Sleep Visit Forms” and “Sleep Visit Protocols.”
<i>Publications</i>	Publication guidelines and information for publication submission and review process.
<i>Data Inventory</i>	Lists forms successfully received by the Coordinating Center data system.
<i>Rejected Forms</i>	Lists forms that were not accepted by the Coordinating Center data system.
<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
<i>Edit Report</i>	List of outstanding queries (potential errors) in the study database.
<i>FU Quest. Late List</i>	List of follow-up questionnaires that are late.
<i>Reports</i>	Recruitment and endpoint reports are listed for the MrOS study including recruitment reports for the Sleep Study.
<i>Ancillary Studies</i>	Ancillary study policies and procedure guidelines
<i>Data Entry Totals</i>	Summary report of all forms received by site
<i>Data Entry Summary</i>	Displays the number of each form that has been received by the data system within specified dates

<i>Incomplete Sets</i>	Lists of participants by ID with some, but not all data for a visit
<i>Missing Endpoints</i>	Lists missing forms related to endpoints
<i>Medications</i>	Medication Database listing codes for medications collected on the Medication Inventory Forms
<i>Post Queries</i>	Add an edit on the web site so data can be changed

*Note: Many of the features on the MrOS web site are being updated or changed. The clinic sites should check the web site frequently for updates. The Coordinating Center will alert clinics to major changes to protocols.

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.

Some data for the MrOS Sleep Study will be received and edited in other ways. Detailed descriptions of the Actigraphy and Polysomnography data management and quality assurance is described in the respective operations manuals located on the MrOS web site.

3. Data System Overview

The data system used for the MrOS Sleep Study will be the same system that was used for the MrOS baseline visit and Interim Questionnaire. Data from the sleep study will be housed with data from the main cohort. Each site will continue to only be able to access their site's data, but they will be able to look at the data from the sleep visit and other data from the MrOS study at the same time.

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 or sponsor 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.

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:

Data Input
Rejected Forms

Data Querying
Originating a Query

Forms Inventory Report
Data Inventory
Viewing Form Data
Data Entry Totals
Incomplete Sets

Query Addressing
Edit Reports: Selection Criteria
Viewing Edits
Fixing Edits
Making Comments
Audit Trail

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. A password 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.** You may change it by following these steps:

- 1) Go to the following website: <https://psg-mac43.ucsf.edu/IISADMPWD/aexp.htr>
- 2) You will be asked to enter your username. You should enter PSG\username (i.e. PSG\scummings)
- 3) The site will ask for your old password (this is the tem password). Enter psg597.
- 4) And then you can enter a new password.
- 5) And then you will have to confirm it.
- 6) Click on 'Okay'
- 7) Wait 10-15 minutes before logging on to the MrOS website.

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 the sleep study. Any new study personnel will need to receive a username and password from the Coordinating Center. This username and password will allow for access to documents and data pertaining to the sleep study as well as documents and data pertaining to the main MrOS study.

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.