DATA SYSTEM

1.   MrOS Web Site

The MrOS Dental Study will use the same site used for the Oseteoporotic 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 chapter in the MrOS baseline Operations Manual)

* 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 Dental Study.

Directory	Contact information for study personnel. Individuals involved with the Dental Study are listed among study-wide personnel.
Meetings and Calls	Information for future meetings and dial in information for conference calls.
Memo Archive	Numbered study memos. Memos specifically for the Dental Study will include identifying information in the memo title.
Study Documents	Up-to-date copy of operations manuals, data collection forms, etc. Dental documents are located under "Dental Visit Forms and Protocols."
Puiblications	Publication guidelines and information for publication submission and review process.
Data Inventory	Lists forms successfully received by the UCSF data system.
Rejected Forms	Lists forms that were not accepted by the UCSF data system.
Audit Trail	List of all changes made to data in the study database.
Edit Report	List of outstanding queries (potential errors) in the study database.
FU Quest. Late List	List of follow-up questionnaires that are late.
Recruitment Report	Summary of current recruitment numbers.
Ancillary Studies	Ancillary study policies and procedure guidelines
Data Entry Totals	Summary report of all forms received by site
Incomplete Sets	Lists of participants by ID with some, but not all data for a visit.
Endpoint Reports	Lists missing forms related to endpoints.

*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 tolls 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 the MrOS Dental Study will be the same system that was used for the MrOS baseline visit. Data from the dental 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 dental data 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 UCSF 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 webs site. The wen 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 Chapter in the MrOS baseline Operations Manual (available on the MrOS web site). The following sections are described in detail in the Data System chapter and should be reviewed:

Data Input	_Data Querying_
Rejected Forms	_Originating a Query_
Forms Inventory Report	_Query Addressing_
Data Inventory	_Edit Reports: Selection Criteria_
Viewing Form Data	_Viewing Edits_
Data Entry Totals	_Fixing Edits_
Incomplete Sets	_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 UCSF 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 will be assigned to you by the Coordinating Center. You may choose to keep this password or you may change it AFTER YOU HAVE LOGGED ONTO THE SYSTEM FOR THE FIRST TIME by following these steps:

1. Log-on to the web site.
2. Log-on to the Memo Archive.
3. After you have logged in, it will bring you into Outlook. Click on the "Options" Icon on the left side of the page. Under the category New Password, click on the "Change Password" button you will receive a box that says "Internet Service Manager." Fill-in the fields:

> DOMAIN: Enter "PSG"
> ACCOUNT: Enter your User ID (e.g. scummings)
> OLD PASSWORD: Enter the password which was assigned to you by the Coordinating Center
> NEW PASSWORD: Enter your new password (and then enter it again to verify it)

4. Click on the "Reset" button.

Study personnel that received a username and password for the baseline MrOS study will continue to use the same ID and password for the dental 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 dental 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 UCSF Coordinating Center in accordance with FDA-mandated requirements for pharmaceutical studies.