DATA SYSTEM, MANAGEMENT, AND ANALYSIS

1   **MrOS Web site**

To access the MrOS web site, go to http://www.keeptrack.ucsf.edu and click on the MrOS logo and log in (see section 28.5).

* Please note that the MrOS web site works optimally when used with the Microsoft Internet Explorer 4.0 or later browser.

Please also 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   **Features**

Analysis Plan Listing	• Listing of current MrOS analysis plans
Directory	• Contact information for study personnel
Meetings/Conference calls	• Information for future meetings and dial-in instructions for conference calls
Memo Archive	• Numbered study memos
Operations manual	• Up to date copy of operations manual
	• Current protocol and amendments
Publication Guidelines	• Information for publication submission and review process
Publications Listing	• Listing of current publications from the study
Recruitment Reports	• Summary of current recruitment numbers

*Note: Many of the features on the MrOS web site are currently in development.   The clinic sites should check the web site frequently for updates. The coordinating center will alter the clinic to major changes to protocols.

1.2   MrOS Memos

All MrOS numbered study memos will be available on the web site. To access the memos, click on "Memo Archive" in the banner located at the top of the MrOS web pages. This will automatically connect you to the Microsoft Outlook web site. To log-on to the Outlook site:

Enter your User ID (first initial of your first name followed by your last name). A box will then pop up and prompt you to enter your name and password.

NAME: Type in your User ID

For example: Peggy Mannen
User name: pmannen

PASSWORD: Type in your password, provided by the Coordinating Center via Fed Ex.

After you have logged in, it will bring you into Outlook. Click on the "Public Folders" Icon on the left side of the page and then go to "MrOS Memos."
When you are finished viewing the memos, please log-off the Outlook site by clicking on the icon on the bottom left side of the page.

2   DATA MANAGEMENT SYSTEM

The overall goal of our data management and quality assurance system 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 MrOS data system consists of three related components: DATA INPUT, DATA QUERYING, AND QUERY ADDRESSING. The DATA INPUT component starts with questionnaires that are filled out by study staff or participants and then faxed in to 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 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. Examples of each of the reports found on the web site are shown at the end of this User's Guide.

3.1   Data System Reports

Froms Inventory   • List of all forms correctly received at the coordinating center

Memo Archive   • Archive of all study memos

Rejected forms   • List of forms received at the coordinating center that were unable to be processed

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

Data Entry Totals   • Summary report of all forms received by site

Incomplete sets   • List of participant ID's with some, but not all forms for a visit.

Each night, all of the study data is subjected to a set of error-checking programs. These error routines include checks for completeness, data consistency and invalid ranges. The results are posted to the study website. Clinical site personnel will check the website daily to confirm that the CC has received all of the faxed forms and to address the errors that may be posted.

Data from other sources will be received and edited in other ways. The data from the densitometers is received through the UCSF CC Hologic workstations.

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).   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 (see section 28.5.1) by following these steps:

1. Log-on to the web site (see section 28.5)
2. Log-on to the Microsoft Outlook web site(see section 28.1.2)
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. pmannen)
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.

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 CC in occurrence with FDA-mandated requirements for pharmaceutical studies.

5   LOGGING ON TO THE MROS WEB SITE

5.1   UCSF Coordinating Center Home Page

A link to the private MrOS site is found on the UCSF Coordinating Center homepage at (WWW.KEEPTRACK.UCSF.EDU) Simply click on the MrOS logo. Please note that your computer must accept cookies in order to log onto the site.

5.2 Entering your User ID and password
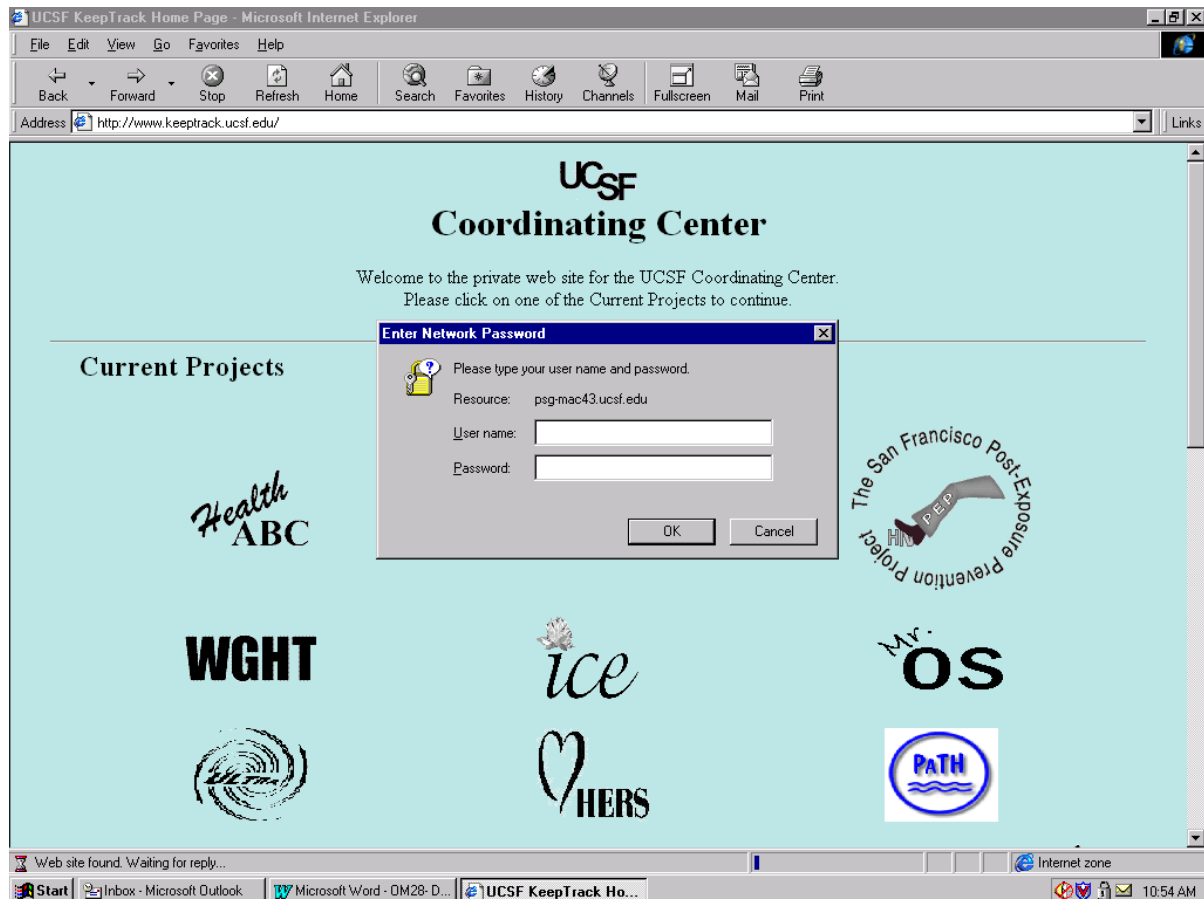
Enter your User ID and password.

5.1.6 Logging On Incorrectly

If you type in your information incorrectly, you will simply be re-prompted to try again.

If you attempt to logon three times without success, your account will be locked by the system. Please contact the CC if this happens, as your account will have to be reset.

Therefore, please be careful when logging-in and be sure that, for example, you do not have the CAPS LOCK on. Please have your Project Director notify Peggy Mannen at the Coordinating Center if you do not have an account or if you have forgotten your password.

5.1.7 Welcome Page
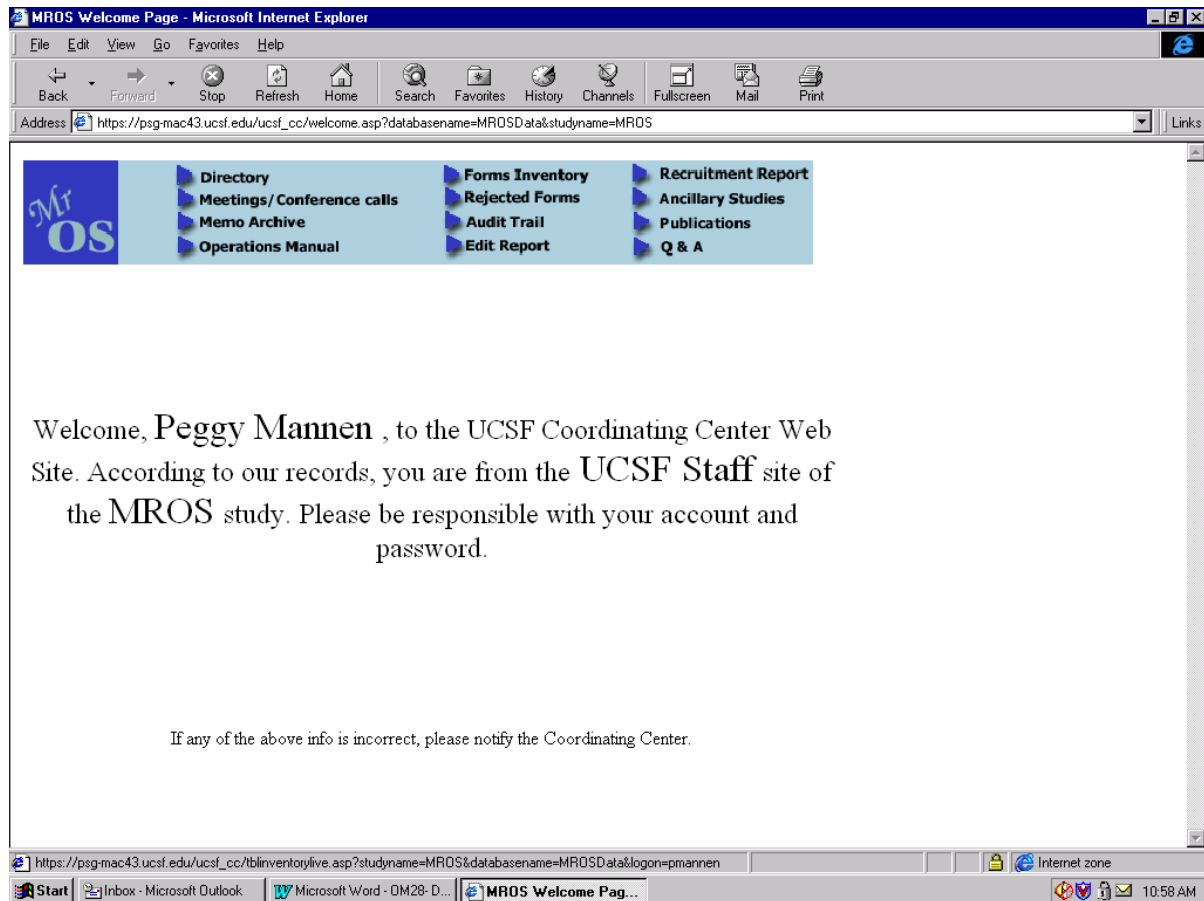
If the system accepts your account information, you will generally be welcomed as above. However, it is possible that the system may not be fully configured for you. If you get a message saying you are not in the database, or if you do get the above welcome page but some of the information is wrong, please notify the Coordinating Center.

5.2   Previous Users

When logging on to the web site anytime thereafter, you will only need to perform steps 3 – 4.

Any deviation from the security system requirements could compromise the system. Study staff members must not share their passwords with anyone else.

6   DATA INPUT

Completed questionnaires should be faxed in daily from the clinical sites. The sites should keep a log noting that the questionnaire has been faxed and that the fax was successful. At UCSF, the questionnaires are received by a fax server and then processed by software that attempts to read what has been written on the forms. Questionnaires must be filled in neatly in order for this system to excel. For example, characters should be capital letters and should not touch the borders of the boxes. (Please see Scannable Forms Guidelines). Once the system has "evaluated" the questionnaire, it is "verified" by an operator. This is a process whereby a UCSF operator does an on-screen inspection of all questionable aspects of the faxed in form. Once the form has been verified, it will be available on the study web site.

6.1   Confirming Fax Receipt of Forms

It is anticipated that sites will want to confirm the receipt at the Coordinating Center of the respective forms that are faxed and insure that their records of data collection efforts are in-synch with those of the Coordinating Center. While the normal fax confirmation might insure that the fax server has received the fax, other things can happen that would prevent the form from proceeding all the way to the study database. Sometimes, for example, a questionnaire is not readable by the system. Pages sticking together when feed through the fax machine or damage caused to the form identifier box in the lower right-hand corner may cause this. A questionnaire may need to be re-faxed in these cases. If so, the UCSF data verifier will inform the respective site. This may occur via phone or email; preferably, it will occur via the "rejected forms" report on the web site.

6.2   Rejected Forms Report

Even when a form is successfully processed by the system it may not be added to the database. Forms, which have been verified, but have an error in critical fields will appear here. Hopefully you will never see any forms here. All such rejected forms will be listed in the "rejected forms" list on the web site. If a form appears in this report it can indicate that one of the following problems has occurred and may warrant follow-up by clinic site.

- There is no Enrollment Form on file in the data system for the participant screening ID# on the form, which has been faxed in. The screening ID# and acrostic on Enrollment Form establish the key information that identifies the man as a unique participant in the study. The Enrollment form should be faxed to the Coordinating Center at least 24 hours before any additional forms are faxed.
- The acrostic doesn't match the Screening ID# as established on the Enrollment Form. If the key unique identifiers are wrong, they must be fixed before we can accept the data as valid.
- A form with the identical Screening ID#, acrostic, and visit number have already been received and processed by the coordinating center. It can be viewed by looking up the same form and ID using the Forms Inventory report.

6.3 Forms Inventory Report

Most forms will be received successfully, read and verified successfully and will be added to the study database. All such forms are listed on the Forms/Data Inventory report on the web site. Any form that appears on this report is in the database. The report includes the date the form was received as well as other identifying information. Since this will eventually become a very lengthy report, there are a number of options for selecting specific participants, forms, or receipt dates. The report is sorted in descending receipt-date order assuming that this report will generally be used to simply confirm that a form has been successfully received and processed at the coordinating center.

6.4 Data Inventory Report: Selection Criteria

The inventory of forms will grow to be quite large, so it is recommended that you learn to use some or all of the selection criteria to limit the size of your list. To limit your list to data from a particular participant, simply enter his MrOS ID#. To choose only a specific form, choose it from the "specific form" drop-down list. The dates refer to the date that a form was received at the Coordinating Center. If you are using this report regularly as a way to verify

that the Coordinating Center has received the data you faxed, you will probably be interested using the date fields to limit the report to show only those forms faxed in over the last 2 days.

6.4.1 Downloading the "Smart" Excel File: Data Inventory Report

The Excel file download option will give you a "smart" excel file that can be saved on your hard disk. Click on the blue "DOWNLOAD EXCEL FILE" and save it on your hard disk. Then open the spreadsheet in Excel and choose "Refresh Data" under the "Data" menu. By choosing "Refresh Data" within this Excel file, the complete inventory will be brought into Excel. You can update the data in this file without going to the MrOS web site. Simply choose "Refresh data" any time you have this spreadsheet open and Excel will connect to the database at the Coordinating Center and download the most recent list (after you enter your logon and password). You can then use the full power of Excel to generate any reports that you find useful. For instance, you can sort the forms by ID and date to see what forms have been processed by the coordinating center for each participant from your site. Alternatively, you may sort the list by date received at the coordinating center and review the top of the list to verify that all forms faxed from your site in the last few days have been processed by the coordinating center.

6.5   Data Inventory Report: List

This is an example of what the data inventory report looks like on the web site. By clicking on the red button under "View", you can review all of the data from that particular form as interpreted by the data system at the Coordinating Center (see next page).
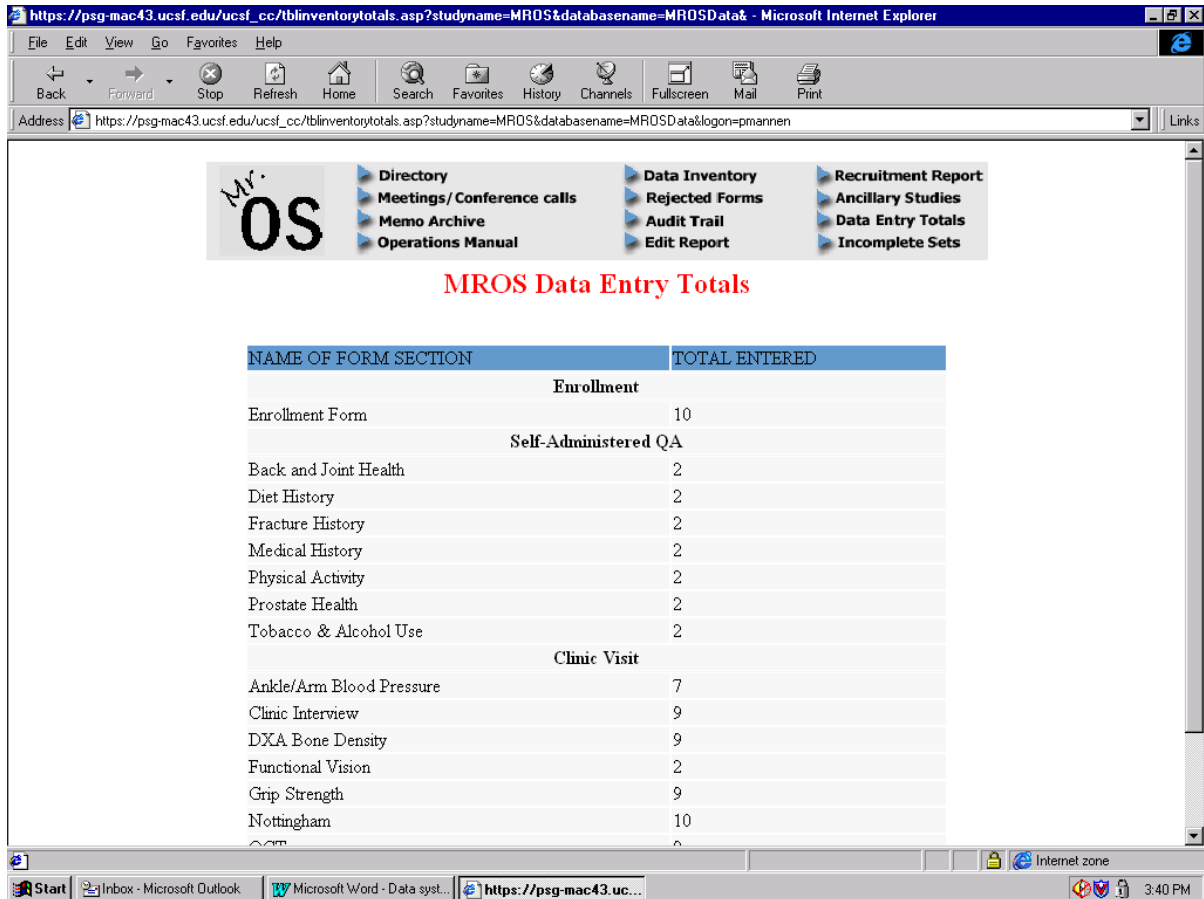
Note: This report is updated continuously, each time a form is verified at the coordinating center. It may change on a minute to minute basis as forms are received and verified.

6.6   Viewing Form Data From the Data Inventory Report
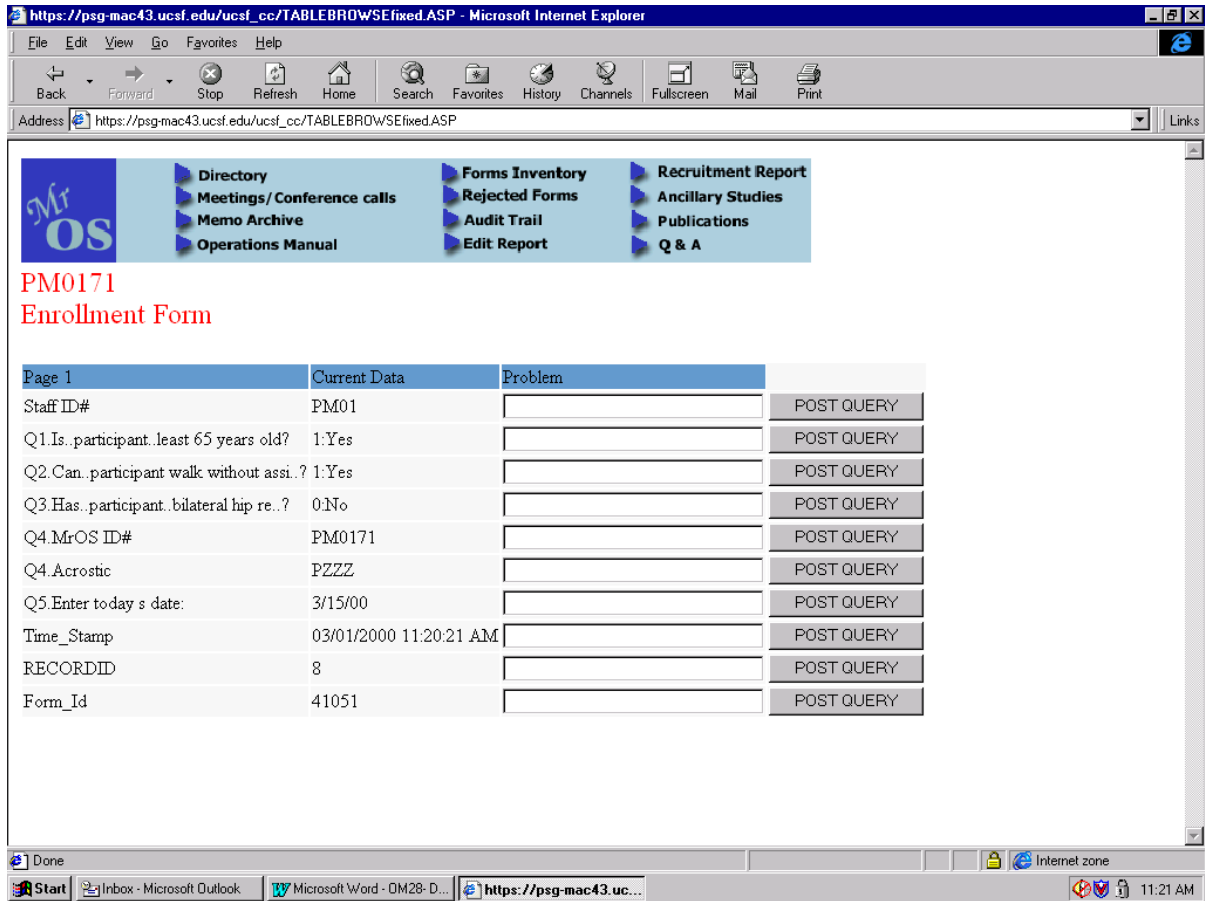
This report displays a description of each field (question on a form), the value for this participant, and allows the user to post a query to the Edit Report by typing in a comment in the column with header "Problem" and then clicking on the "Post Query" button. No data can be changed on this page of the web site.

6.7   Data Entry Totals Report

The Data Entry Totals report displays site totals for each of the forms. This is a summary report of all forms received at the coordinating center from your clinic grouped by visit in order of occurrence. It is updated immediately, each time a form is verified at the coordinating center.

6.8   Incomplete Sets Report

The Incomplete Sets report displays all participants with "sets' that are missing at least one "form". This report lists the IDs of any participants from your clinic who have at least one form from a form set verified at the Coordinating Center for a particular visit, but the form set for that visit is not complete. These are grouped by visit in order of occurrence. It is updated immediately, each time a form is verified at the coordinating center.

Missing forms are noted by red boxes. As soon as the form has been received and verified at the coordinating center, the red box will disappear. Once all of the forms in a form set have been received, the participant's ID will be removed from this list

6.9   Clinic Procedure

In summary, each day that a questionnaire is completed, it should be faxed to the coordinating center. The data coordinator at the site should document that the fax transmission was successful on a log. The coordinating center will attempt to verify all data the same day that it is received, although this may not always be possible. Once verified, the form should be listed in either the Data Inventory report on the study web site (if no major

problems were noted) or in the Rejected Forms (if there were significant problems). The day after a form has been faxed to the coordinating center, the clinical site data coordinator should verify that the form has been processed by reviewing the Data Inventory report on the study web site. If it a form is not present, an email message should be sent to the coordinating center data verifier listing the ID, acrostic, form, and date sent. The coordinating center staff will resolve the discrepancy and report back to the clinical site within 24 hours.

The checklist below could be used for each visit set of forms:

- ❑   Form set completed
- ❑   ID, acrostic, and visit number verified
- ❑   Form set faxed in successfully (local fax machine log) (Use the Fax tracking form, Appendix A)
- ❑   Forms present on Forms/Data Inventory report
- ❑   Edit report queries addressed
- ❑   Form set filed

7   DATA QUERYING

Each night, a query-generator program is run at the Coordinating Center. All such queries are displayed on the web site as the "Edit Report". These queries attempt to support the logic of the forms. Most "root" questions are considered to be "required", so if any of them have no data, the query generator will create a "missing" query. Questions that should or shouldn't be answered depending on the answer to some other question or questions will be noted as "missing" if the earlier question requires that they be answered or "inconsistent" if the response to the earlier question indicates that the secondary question should not be answered. More complex queries will have their own unique description. The three primary types of errors are described below:

| Error type	Description
Missing	The question should be answered, but there is no data. The correct answer to the question should be filled in.
Out of range	The value for the data is not within the allowable range. For instance a date of 1/2/2341, would be noted as out of range. The correct value should be input.
Inconsistent	The question has been answered, but should not be or is incorrect, based on a response to an earlier question. Answering this question is logically inconsistent with the answer to an earlier question. Either the answer to this question should be deleted/changed, or the answer to the earlier question should be changed. Note: the related question may not be on the same form.

7.1   Originating a Query

Each query generated by the query-generator includes a "CC" in the Originator column to indicate that the Coordinating Center's data system generated this query. The vast majority of queries will be originated by this system, although the sites may originate their own. The process of originating a query is as follows:

(1) Find the specific form in the Data Inventory. This may be, say, the Enrollement Form for participant 001234.

(2) Click on the "view" box. This will bring up a possibly long web page that includes data from all of the pages of that particular form.

(3) Locate the specific question that requires the query and type a brief description of the problem in the "problem" box next to the question.

(4) Click the "post query" box on the same line. The query will then appear with all of the others on the Edit Report page. The originator field will contain the site of the user who entered the query.

7.2   Query Addressing

Sites are expected to address the queries on the web site. The Edit Report page gives the sites two ways to address the queries. They can make a change to the database or they can make a "comment" that will serve to eliminate the query from the list. The primary way to address the queries is to make a change to the database using the Edit Report on the study web site. Comments should only be used as a last resort.

7.3 **Edit Report: Selection Criteria**
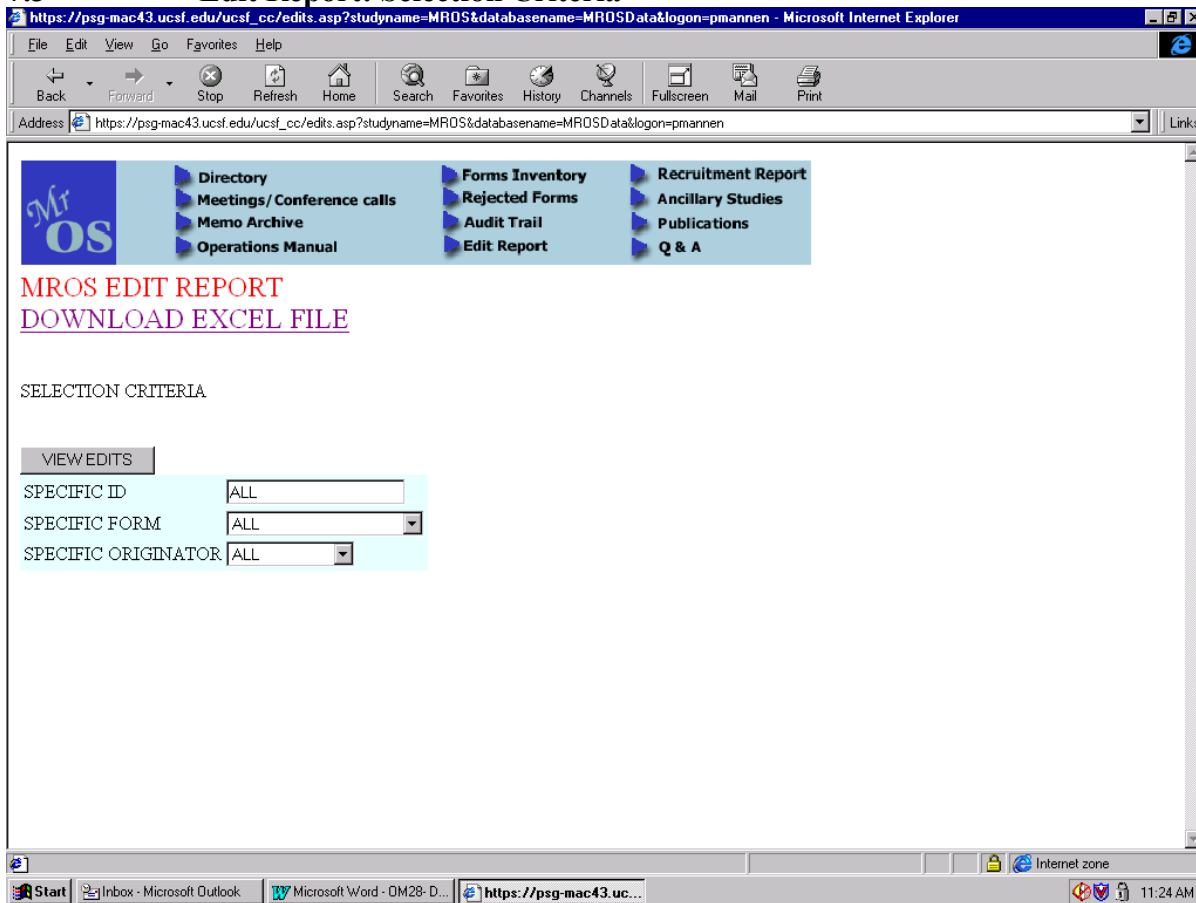
As for the Data Inventory report, the list of data edits can be limited to a specific ID, a particular form, or the originator. Most of the time, you will want to view and address the complete edit report. If the queries have been addressed, they will be removed from the report the next time the report is run (nightly). By keeping up with the queries as they occur, the length of this report will always remain short and manageable.

7.3.1 **Using the "Smart" Excel Spreadsheet: Edit Report**

The Excel file download, like the Inventory-related Excel file described previously, will give you an Excel file that can be saved and used to get the complete Edit report in Excel.

Suggestion: The Edit Report can be saved as an Excel file: click on the "Download Excel File" link on the primary Edit Report web page. Open the spreadsheet with Excel and choose "Refresh Data" from the Data menu. Once you have the spreadsheet on your computer, you can obtain the latest data without having to log on to the MrOS web site again. To do this:

- Choose "Refresh Data" from the spreadsheet (this can only be performed on computers which have the ability to access the Internet, but you do not have to be logged on to the MrOS site at that time.)

- You will be asked to enter your logon and password for the study, and then the latest Edit Report will be downloaded into the Excel spreadsheet.

This spreadsheet may be sorted, printed, and manipulated using all of Excel's commands. A useful approach to keeping up with the Edit report would be to refresh the Excel spreadsheet each morning. Sort the queries in a useful order and print the spreadsheet out. Retrieve the necessary forms to address the queries and note any changes on the forms along with your initials and date. Then log on to the study web site, go to the Edit Report, and make the necessary changes to the database.

7.4 Edit Report: View Edits

This page lists all outstanding queries for your site. The date the query was generated is at the left, followed by information describing the ID, form, question, and problem that generated the query.

7.5   Changing an Incorrect Answer or Filling in Missing Information

To address a query by changing the answer to a question in the database, begin by clicking in the red "fix" box next to the query. This will bring you to the page containing the data that needs fixing.

7.6   Edit Report: Fix

The question(s) that generated the query will be highlighted in yellow. Any field on the screen can be changed. In order to save the changes, you must click on the "Save Change" button above the first question on the page.

The question with a potential error will be highlighted in yellow. "Inconsistent" errors will be displayed with both of the related questions highlighted in yellow. Make the desired changes and click on the "Save changes" button at the top of the page. Note that the query listed in the Edit Report will not disappear immediately upon saving the changes. The edit report is only updated when the "Query generator" program is run that night.

Some queries may involve conflicting, or inconsistent data from another form. If this is the case, you will need to go to the Inventory Page, select the form, scroll to the suspected question and create a query by filling in the problem field. (Please see section 7.1 "Originating a Query".)

It will not always be the highlighted field that will need to be changed. Indeed, any field on the screen can be changed. No changes are saved until "save changes" button at the top of the page is clicked. Most fields consist of drop-down lists allowing the user to choose from a list of allowable answers. However, some must be filled in directly. With these fields, it is possible to type in something that is inappropriate for the respective field. If an inappropriate entry is made it will not be saved to the database. A message will state that the change was not saved.

7.7   Making "Comments"

Comments should be used only when a query can not be addressed. They will cause the query to be removed from the edit report. There are currently 5 possible choices for the comment field:

> *Not an error*
> *Irretrievable*
> *Addressed*
> *Participant ineligible*
> *Other*

If, for example, a query is erroneous, you should choose the comment "Not an error" from the list of comments on the same line as the query.   For these specific comments, the Coordinating Center will review the edit system and make appropriate changes.

If some data is indeed missing, but there is no way to retrieve the information, you should choose the comment "irretrievable". For "missing" queries that reflect questions intentionally not answered because a participant was found to be ineligible, the comment "participant ineligible" should be chosen.

Queries generated outside of the query generator (i.e. by a clinical site or sponsor) should be commented "Addressed" by the originator of the query once they are satisfied with the response.

7.8   Documenting Changes Made on the Web Site

Important: If a change made to the database is not simply a correction to data that is written correctly on the form, the change must be made on the form, dated and initialed.

7.9   Non-CC Generated Queries

When the query-generator runs each night it inspects the entire database. If a query has been addressed properly, it will not be re-generated by the program, i.e. it will disappear from the edit report the next day. Therefore, do not enter a "comment" if a query can be addressed. There is one exception to this rule, however. Site or sponsor-originated queries are not generated by the Coordinating Center system. Even when such a query has been addressed it will remain on the list. Therefore, such queries should be commented "addressed", *but only by the originator once they are satisfied with the response*.

7.10 Audit Trail

There may never be a reason for the clinical sites to review the audit trail, although it is available for your review.

All changes made to the database are tracked and recorded in an "Audit Trail". The audit trail includes the user ID of the person making the change, the date and time, a description of the item changed, the old value, the new value, and the reason the change was made (name of the query).

8.0 Examples

Appendix A: Fax Tracking Form

FORM	Date Faxed?	Confirmation of fax?	Received on web site?	Data edits completed?	Comments:
Enrollment Form (EF)					
General Information (GI)					
Medical History (MH)					
Prostate Health (PS)					
Diet History (DH)					
Tobacco & Alcohol (TU)					
Physical Activity (PA)					
Lifestyle (QL)					
Fracture History (FF)					
Back & Joint Health (BH)					
Clinic Interview (CI)					
Trails B (TB)					
Teng Mini-Mental (TM)					
Functional Vision (FV)					
Nottingham (NP)					
Height, Weight, Pulse (HW)					
Grip Strength (GS)					
Neuromuscular Func. (CS)					
Blood Pressure (BP)					
Specimen Collection (SC)					
Lab Processing (LP)					
Ultrasound (US)					
DXA (DX)					
QCT (QC)					
X-ray (XR)					
Medication Use (MU)					