

## HEALTH ABC DATA USER'S GUIDE

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## 1. Overview

### 1.1 Purpose of data management system

The overall goal of our data management and quality assurance system is to provide study management tools as well as high-quality and timely data to the study investigators. Machine-readable forms and internet technology are utilized to provide data access.

### 1.2 Data system overview

The Health ABC data system consists of three related components: DATA INPUT, DATA QUERYING, and QUERY ADDRESSING.

The DATA INPUT component starts with data collection forms that are filled out by study staff and then scanned or faxed into the UCSF Coordinating Center database. Reports on the study website provide feedback on the data input process.

The second component is DATA QUERYING, also known as edits reporting. It consists primarily of a query generation program that is run regularly against the entire database. The results are available on the study web site. The website also provides a means for study staff or sponsors to originate (post) their own queries (i.e., potential errors or missing data).

The third component is QUERY ADDRESSING. Using the “edit report” (query list) on the website, study staff are able to make changes to the data in the study database in order to fix errors or inconsistencies in the data.

### 1.3 Data flow from the clinical centers

Study forms will be filled out at the clinical sites and scanned or faxed to the UCSF Coordinating Center. An operator at UCSF will then verify the forms by viewing the image on a monitor. This important step corrects many misinterpretations in the automated data input. Verified data are then stored in the database. UCSF does not receive any paper in the data acquisition process.

All of the study data are subjected to a set of regular error-checking programs. This routine includes checks for completeness, data consistency, and invalid ranges. The results are posted to the study website. *Clinical site personnel should check the website daily to confirm that UCSF has received all of the transmitted forms and to address any posted errors.*

## 1.4 Clinic procedure

Study forms should be checked and scanned or faxed to the Coordinating Center daily. The data coordinator at each site should carefully track and log all study forms and document when forms are successfully transmitted. 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 scanned or 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 a form is not present, an e-mail message should be sent to the Health ABC Help Desk

[HABChelp@psg.ucsf.edu](mailto:HABChelp@psg.ucsf.edu)

listing the ID, acrostic, form, date sent, and if necessary the visit or otherid (visit and otherid are only necessary for unique identification on repeated forms). Please send this as a secure e-mail.

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

- Form set review completed by clinic staff member
- ID, acrostic, visit number, and otherid (when necessary) verified as correct by clinic staff member
- Form set scanned or faxed in successfully
- Use scan log and check that forms are present in Data Inventory report
- All edit queries addressed
- All hard copy forms accounted for and filed

## 2. Accessing the website

### 2.1 User name and password

In order to download study forms and view/update study data, you will need to access the Health ABC website. To do this requires a unique user name and password. If you have not yet received this information, please notify your study coordinator. Study coordinators should contact the Health ABC Help Desk at the Coordinating Center to request user names, access levels, and passwords for new clinic data users and to report logon/password/access problems. Included in the request should be the first and last name of the person who needs access and their e-mail address. Also included should be the level of access the person needs.

Your user name 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).

For example:     Anne Lamott  
User name:       alamott

A temporary password will be assigned to you by the Coordinating Center. Please note that the password is case sensitive.

Access levels affect what features of the website the user is able to access. The different levels are based on the ability to see or change participant data. Please inform the Health ABC Help Desk as to what level access a new user needs.

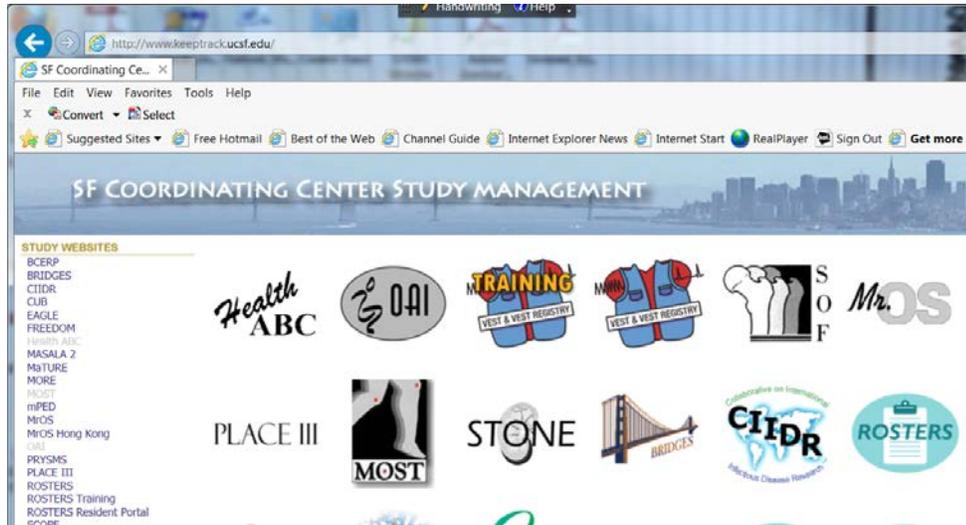
## **2.2 Changing your temporary password**

Once you have sent in a HABC Help Desk request for access to the Keeptrack website you will receive a secure e-mail from the Coordinating Center IT department and an e-mail alert that includes instructions for activating your access. Open the alert and print out the instructions. Open the secure e-mail and follow the instructions using the printed out instructions sent separately as a supplement.

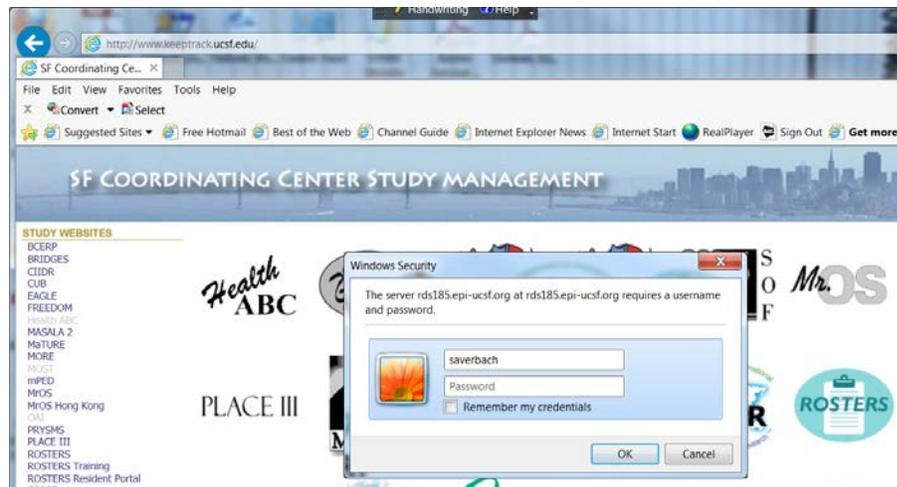
## **2.3 Logging on to the Health ABC website**

\* Please note that the Health ABC website works optimally when used with Microsoft Internet Explorer version 8 or 9. Alternatively, Firefox and Chrome may be used.

A link to the private Health ABC site is found on the UCSF Coordinating Center homepage at <http://www.keeptrack.ucsf.edu/>. Simply click on the Health ABC logo.



A box will then pop up, asking for your Network Password. You must now enter your user name and the password you created in step 2.2

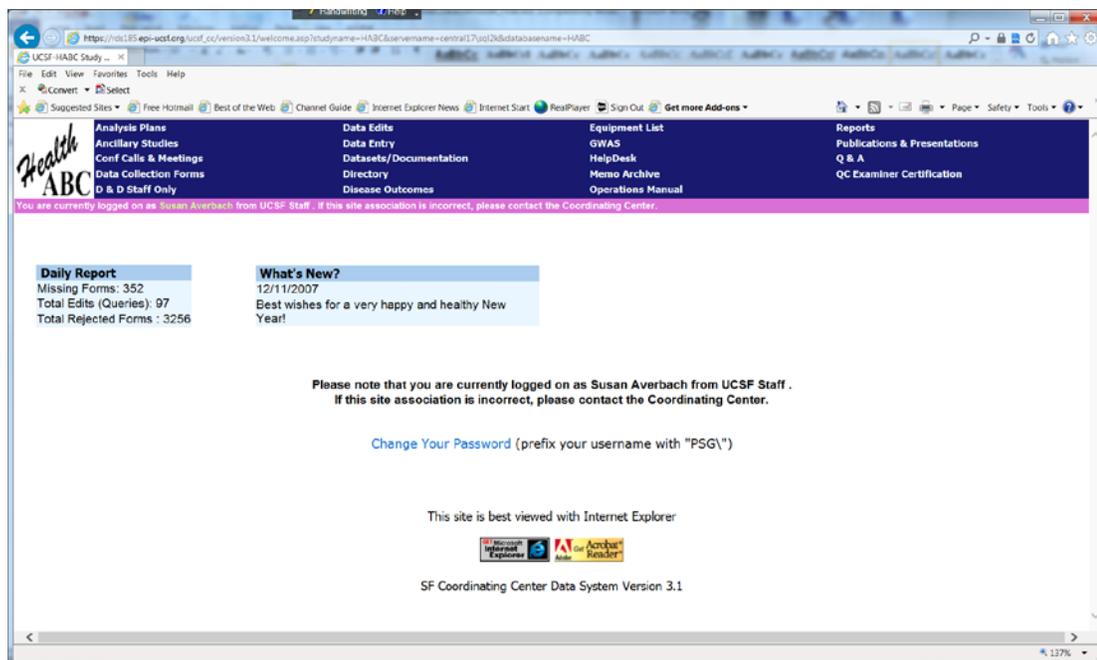


If you type in your information incorrectly, you will simply be re-prompted to try again. If you attempt to log-on three times without success, your account will be locked by the system. After the third failed attempt, you must wait 2 hours before you may try to log on again.

Therefore, please be careful when logging in and be sure that, for example, you do not have the CAPS LOCK on. Please have your data manager notify the Health ABC Help Desk if you do not have an account or if you have forgotten your password.

## 2.4 Welcome page

If the system accepts your account information, you will receive a welcome message giving your name and affiliation (study site or other institution). 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 Health ABC Help Desk.



In order to ensure the security of the study website, you must close Internet Explorer when you have finished using the Health ABC website. If you are going to use the web for other purposes after accessing the Health ABC website, please close your browser and then re-open it to browse the web.

## 2.5 Features of the website

The following features are available by clicking the appropriate link in the study banner. Note that the availability of these features depends on your access level.

<i>Analysis Plans</i>	Interactive tool to view details about current Health ABC analysis plans
<i>Ancillary Studies</i>	Interactive tool to view details about current Health ABC ancillary studies
<i>Conference Calls &amp; Meetings</i>	Calendar listing face-to-face meetings and conference calls; call-in information
<i>Data Collection Forms</i>	Study-related current data collection forms
<i>D&amp;D Staff Only</i>	Direct data entry forms for Disease and Death (D&D) and D&D tracking
<i>Data Edits</i>	Includes audit trail, data edits for D&D system, data edit summary report, data inventory, data edits remaining, edit report, edit report notes, and post queries.
<i>Audit Trail</i>	Tool for viewing changes made to forms and variables
<i>Data Edits for D&amp;D</i>	Lists edits and missing Event Forms
<i>Data Inventory</i>	Inventory by form and participant of all data entered
<i>Data Edits Remaining</i>	Lists participant ID#s of participants with edits – by visit
<i>Edit Report</i>	Tool for addressing queries (edits) generated by the data system or posted by others.
<i>Post Queries</i>	Tool for creating individual custom queries to change data errors
<i>Data Entry</i>	Data entry totals, data inventory, incomplete data entry reports, rejected forms.
<i>Data Entry Totals</i>	Data entry totals by form
<i>Data Inventory</i>	Inventory by form and participant of all data entered
<i>Incomplete Data Entry reports</i>	Missing forms by visit and for D&D
<i>Rejected Forms</i>	List of forms rejected by system due to missing or invalid identifier, duplication, or other fatal error
<i>Datasets/Documentation</i>	Current datasets; log of year-by-year exam measurements and questionnaire questions; reliability studies; dataset documentation.
<i>Directory</i>	Contact information for study personnel
<i>Disease Outcomes</i>	Data reports and event adjudication protocols
<i>Equipment List</i>	Equipment needed for various visits
<i>GWAS</i>	GWAS analysis plans, publications, and presentations
<i>Help Desk</i>	Link to Health ABC Help Desk e-mail
<i>Memo Archive</i>	Numbered study memos
<i>Operations Manual</i>	Operations manuals for exams and interviews – by year and visit
<i>Reports</i>	Study Reports; e.g., Visit Scheduling Report, Data from Prior Visits Report, Participant Results Report; Summary Status
<i>Publications &amp; Presentations</i>	Analysis Proposal and Publication Guidelines, Abstract/Presentation Approval Form/ Manuscript Approval Form; Calculated Variables Worksheet; GWAS Analysis Proposal and Publications Guidelines; GWAS Abstract/Presentation Approval Form; GWAS Manuscript Approval Form; Health ABC Publications (in Word, PDF, and EndNote library file)
<i>Q &amp; A</i>	Tool to view, search, and submit questions about the study to the Coordinating Center. All questions and answers are searchable by topic and date.
<i>QC Examiner Certification</i>	Certification Exam Forms and Staff Certifications

### 3. Study data collection forms

Health ABC data collection forms are all available for download from the Health ABC website. We strongly suggest that you download the forms to your local drive and print in Acrobat Reader. If you do not want to download the forms and would like to print the forms from the website, be sure to use the PRINT icon in the Acrobat menu, not the PRINT icon in the Microsoft Explorer menu.

#### 3.1 Downloading study forms

If you plan to save the forms to your hard drive, create a folder to store the forms. We recommend that you store the forms in a folder called: "C:\HealthABCForms."

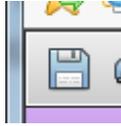
1. Double-click the 'My Computer' icon on the desktop of your computer.
2. Double-click the C: folder.
3. Under the File menu, go to New, and then select Folder.
4. Name the new folder 'HealthABCForms'.
5. Close all the open windows.

To download the forms:

- Go to [www.keeptrack.ucsf.edu](http://www.keeptrack.ucsf.edu)
- Log onto the Health ABC website.
- Click on the 'Data Collection Forms' link in the page header.



- Click on the link for the form you would like to print.
- Click the “Save a Copy” icon on the Acrobat menu (do NOT save from “file” menu above.)



- When prompted, save the file to the folder that was created above (C:\HealthABCForms).

### 3.2 Printing study forms and pre-printing the ID#, acrostic, and visit

The Health ABC study data forms have been converted to PDF files for easy printing. Forms that may need to be printed individually, such as the CT tracking form, will also be available separately in PDF format.

By following the steps below, the Participant ID, acrostic, and visit (if needed) can be entered once and then that information will be duplicated throughout the entire packet.

1. Open the form file from your hard drive that you want to print the information on. Double click on the file, and it should open into Adobe Acrobat Reader (in C:\HealthABCForms folder – if you've decided to store the form on your hard drive).
2. Once the file is open, go to the first page of the file where the Participant ID # and acrostic boxes appear.
3. Click the first box of the Health ABC Enrollment ID # field. Type in the Health ABC Enrollment ID # by tabbing from one box to the next.
4. Hit TAB, the cursor will jump to the Acrostic box. Fill out the participant's acrostic (upper case only).
5. If there is a visit designation on the form, click on the appropriate bubble for the Type of Visit (this is usually pre-filled so you will not have to click on this in most cases).
6. Go to the File menu and Print.
7. Click 'OK'.
8. The file will print with the Health ABC Enrollment ID # and acrostic on every page, the same visit for each form.
9. Close the file. If prompted 'Do you want to save changes before closing,' select 'NO.'
10. Repeat **Steps 3-10** to print a form for another participant.

### 3.3 Completing study forms

#### 3.3.1 The basics

Health ABC data forms are created using Cardiff Teleform software which allows the data to be scanned or faxed directly into the Health ABC database. In order for the software to “read” in and translate the data properly, a few basic guidelines must be followed when filling out the forms.

**a. Use a black pen**

- Do not use a felt tip pen that bleeds
- Do not use a pencil
- Do not use any other color pen

**b. Avoid making any stray marks**

- Do not mark or write in or around the four corners of the page. Specifically, do not mark on the form anchor boxes or on the form ID code box.
- Do not make any extraneous notes anywhere on the form. Record notes only in designated areas.
- Do not make any stray marks on the forms.

**c. Fill in the bubbles completely**

- Stay within the lines
- Do not use an “X” or a “√”

**d. Do not fold, “dog-ear,” staple, or mutilate the data forms.**

**e. When writing letters and numbers:**

1. Print in capital letters
2. Print only one letter or number per box
3. Keep the letter/number completely inside the box
4. The letter/number should not touch or cross any of the box lines

## LETTER AND NUMBER EXAMPLES

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

0	1	2	3	4	5	6	7	8	9
---	---	---	---	---	---	---	---	---	---

5. The Cardiff Teleform software removes the box lines and may remove part of the character.
6. Do NOT cross your zeros (0), sevens (7) or 'Z.'
7. Avoid "curly-cues" on letters and numbers.
8. Pay particular attention to the following groups of letters and numbers that are often difficult to distinguish from each other: [ P,D,O], [J,L,C], [U,O], [U,V], [1,7], [4,9]. The computer might have difficulty reading a person's handwriting, even if that person has 'neat' handwriting to the human eye.

**f. Filling out "Comments" boxes and "Please specify" fields**

Some of the forms contain a large box or lines to write on and give instructions to provide "Comments," "Describe..." or to "Specify." These fields should be filled with the following rules in mind:

- Use only black pen
- Print clearly, no cursive handwriting
- Try to be as concise as possible

**3.3.2 Correcting a mistake****DOs:**

- DO** cross out the wrong answer by drawing a line through the mistake.
- DO** fill in the correct answer in the appropriate bubble or box.
- DO** circle the correct answer.
- DO** initial and date the correct answer.
- DO** leave questions blank that the participant cannot or refuses to answer, unless a "refused" option is available.

★ 2. Since we last spoke to you about [# months since last interview] most of the day because of an illness or injury? Please include

11/25/13  Yes  No  Don't know

★ a. About how many days did you stay in bed all or most of the time? Please include days that you were a patient in a hospital.  
(Examiner Note: If necessary, probe - "If you are uns

**DO NOTs:**

**DO NOT** use erasable pen.

**DO NOT** use correction tape or white out (i.e., Liquid Paper)

The appropriate Health ABC data forms should be filled out at each visit.

- After the data forms for a visit have been completely filled out by the examiner, the entire participant visit packet should be reviewed for completeness and accuracy. Any problems or mistakes found on the forms should be addressed before the forms are entered into the data system. **DO NOT RELY ON THE DATA SYSTEM TO FIND ERRORS.**
- The data forms should be sent to the UCSF Coordinating Center on the day of the visit if at all possible.
- The original forms are to be kept as source documents in the participant's clinic file, along with any lab reports or examiner visit notes.

**3.3.3 ID and acrostic**

ID number ranges have been assigned to the Health ABC clinical sites. These numbers are in the format AANNNN, where the first 2 letters designate which clinic (H for both clinics; A for Memphis; B for Pittsburgh), and the last four identify the specific participant.

The acrostic is in the format AAAA. The acrostic is the first letter of the participant's first name and the first three letters of the participant's last name. For example, the acrostic for Karen Armstrong is "KARM."

Once the participant has been given an Enrollment ID#, it will remain the same throughout the study. This is a “gold standard” ID# and if the wrong number is entered on data collection forms these forms will be rejected by the data system.

### 3.3.4 Staff ID

The staff ID # of the clinic examiner administering each test should be entered for each measurement. The Staff ID number is composed of: Clinic ID Letter (A for Memphis; B for Pittsburgh) + two digit staff number.

## 4. Scanning/faxing data forms

Completed data forms should be scanned or faxed in and transmitted daily from the clinical sites. Using the scanning software ScandAll, you will scan the documents to an image document (TIFF file). On any given day, you may create several TIFF files, depending on the number of scanning sessions you initiate. At the end of each day, you will connect to the Coordinating Center website and transfer the files created that day to the Coordinating Center. Alternatively, you will fax in the forms to a special fax number.

## 5. Data system reporting tools

<i>Data Inventory</i>	• List of all forms correctly received at the Coordinating Center
<i>Rejected Forms</i>	• List of forms received at the Coordinating Center that were unable to be processed
<i>Audit Trail</i>	• List of all changes made to data in the study database
<i>Resolve Queries</i>	• List of outstanding queries (potential errors) in the study database
<i>Post Queries</i>	• Tool to post queries to the database
<i>Data Entry Totals</i>	• Summary report of all forms received from your site
<i>Missing Forms</i>	• List of Health ABC Enrollment IDs with some, but not all forms for a visit.

Clinical site personnel need to check the website daily to confirm that the Coordinating Center has received all of the scanned or faxed forms logged the previous day, to address the errors that may be posted, and to check for rejected and missing forms.

### 5.1 Confirming receipt of scanned or faxed forms

Once the system has “evaluated” the data form, it is “verified” by an operator. During the verification process, a UCSF operator does an on-screen inspection of all questionable aspects of

the scanned image of the form. Once the form has been successfully verified, it will be available for viewing and editing on the study web site.

It is anticipated that sites will want to confirm the receipt at the Coordinating Center of all scanned forms. Occasionally, a data form is received that is not readable by the system. This may be caused by pages sticking together when fed through the scanner, by damage to the form identifier box in the lower right-hand or upper left-hand corners, or other problems encountered during the scanning or faxing process. The forms may need to be re-scanned or re-faxed in these cases.

Additionally, clinics should check the data inventory daily to ensure that all forms scanned or faxed have been accepted by the data system. Forms not found in inventory are NOT in the system.

### 5.1.1 Rejected forms

Even when a form is successfully processed by the verifier it may not be added to the database. All such rejected forms will be listed in the “rejected forms” list on the website, along with the reason for the rejection.

There are a number of criteria that you can choose that will allow you to generate a variety of different reports. Simply clicking the “submit” button will generate a list of all your Rejected forms or the search can be fine-tuned by choosing one or more of the options listed.

The report will show the reason the form was rejected by the system.

**Problem:** *ID does not match Gold Standard ID*

**Explanation:** This means that there isn't a gold standard form in the system with the Health ABC Participant ID # listed on this form

**Action:** Check the participant's file to see what the correct ID is and fix the form and then rescan the rejected form

**Problem:** *Acrostic does not match*

**Explanation:** The acrostic on the form does not match the acrostic on the corresponding gold standard form for this Health ABC Participant ID #

**Action:** Check acrostic, fix and rescan

**Problem:** *No Acrostic or No Visit*

**Explanation:** Acrostic or Visit field not filled out

**Action:** Fill in the missing data and rescan

**Problem:** *Primary keys match form in table*

**Explanation:** A form with the identical Health ABC ID#, acrostic and other unique information (e.g., visit or date) is already in the database

**Action:** Check data inventory to view the form already in the system. If the form in the database is NOT an exact duplicate of the form you are trying to scan, check to make sure that all identifying information is correct on BOTH forms: Health ABC Participant ID #, Acrostic, Visit, and/ or other ID. If an error is found on the form you are trying to scan, correct the error and rescan. If an error is found on the form already in the system, notify the Health ABC Help Desk. Corrections to unique identifiers cannot be made through the query system. Coordinating Center staff only are authorized to make these type of changes.

Once the problem with the form has been identified and, if necessary, the form has been re-submitted, the form should be removed from the rejected forms report by clicking on the “hide” button.

### **5.1.2 Missing forms**

The Incomplete Data Edit Reports link displays a list of all missing forms. This report is organized by visit and by events (D&D). 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 nightly. Consequently, it is possible for a form that has been verified that day to still show up on the missing forms report. It will disappear from the list the next time the data checks are run.

Occasionally, there is a form is missing, and you know it is missing, but you can't do anything about it. For example, the form was never completed, and it is now impossible to go back and complete it. Or the form was completed and then lost before entering, and it can't be completed again (the visit is over and the participant refuses to return for a repeat visit, or the participant has died or been lost to follow up). If such a situation arises and you want to get rid of the entry on the Missing Forms report so you don't have to keep remembering to ignore it, you can “comment out” that entry. Next to each missing form in the report there is a drop-down menu with a choice of comments to use.

## **6. Data Inventory Report**

Most forms will be received, read, and verified successfully and will be added to the study database. All such forms are listed on the Data Inventory report on the website. 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 rapidly become a very lengthy report, there are a number of options for selecting specific participants, forms, or receipt dates to home in on the information you are looking for. The report is sorted by receipt date (most recent at the top) and then by participant ID. This report will generally be used to confirm that a form has been successfully received and processed at the Coordinating Center.

**Health ABC**

- Analysis Plans
- Ancillary Studies
- Conf Calls & Meetings
- Data Collection Forms
- D & D Staff Only
- Data Edits
- Data Entry
- Datasets/Documentation
- Directory
- Disease Outcomes

You are currently logged on as **Susan Averbach** from UCSF Staff . If this site association is incorrect, please contact your system administrator.

### DATA INVENTORY

**SELECTION CRITERIA**

SPECIFIC ID: ALL

SPECIFIC FORM: ALL

SPECIFIC VISIT: ALL

FORMS RECEIVED BETWEEN: ALL AND 11/18/2013

DISPLAY FIRST 20 RECORDS: YES

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 their Health ABC Enrollment ID#. To choose only a specific form and/or visit, choose it from the “specific form” and/or “specific visit” drop-down list. The “forms received between” 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 have scanned, you will probably be interested in using the date fields to limit the report to show only those forms scanned in over the last few days.

Once you have made your selection criteria, click the submit button. You will then see all the forms that match your criteria.

You are currently logged on as **Susan Averbach** from UCSF Staff . If this site association is incorrect, please contact your system administrator.

### DATA INVENTORY

**SELECTION CRITERIA**

SPECIFIC ID: ALL

SPECIFIC FORM: ALL

SPECIFIC VISIT: ALL

FORMS RECEIVED BETWEEN: 11/17/2013 AND 11/18/2013

DISPLAY FIRST 20 RECORDS: YES

You are currently logged on as **Susan Averbach** from UCSF Staff. If this site association is incorrect, please contact the Coordinating Center.

**DATA INVENTORY**

Page 1 of 11  Note: PDF View requires Acrobat version 5

DATE/TIME RECEIVED	DATE/TIME VERIFIED	PARTICIPANT ID	FORM NAME	VISIT/OTHER ID	VIEW
11/18/2013 10:56:30 AM	11/18/2013 12:02:56 PM	HA	Y15+ Telephone Interview p01	Year 17 Q1	<a href="#">html</a> <a href="#">pdf</a>
11/18/2013 10:56:34 AM	11/18/2013 12:03:31 PM	HA	Y15+ Telephone Interview p02	Year 17 Q1	<a href="#">html</a> <a href="#">pdf</a>
11/18/2013 10:56:41 AM	11/18/2013 12:03:33 PM	HA	Y15+ Telephone Interview p05	Year 17 Q1	<a href="#">html</a> <a href="#">pdf</a>
11/18/2013 10:56:47 AM	11/18/2013 12:09:04 PM	HA	Y15+ Telephone Interview p06	Year 17 Q1	<a href="#">html</a> <a href="#">pdf</a>
11/18/2013 10:56:53 AM	11/18/2013 12:09:05 PM	HA	Y15+ Telephone Interview p07	Year 17 Q1	<a href="#">html</a> <a href="#">pdf</a>
11/18/2013 10:56:58 AM	11/18/2013 12:09:07 PM	HA	Y15+ Telephone Interview p08	Year 17 Q1	<a href="#">html</a> <a href="#">pdf</a>
11/18/2013 10:57:04 AM	11/18/2013 12:09:09 PM	HA	Y15+ Telephone Interview p09	Year 17 Q1	<a href="#">html</a> <a href="#">pdf</a>

You can choose to view the data as an html page (as shown below). Data cannot be changed or updated in the Data Inventory view.

You are currently logged on as **Susan Averbach** from UCSF Staff

**Y15+ Telephone Interview p01**

**HA**

Page 01	Current Data
Form_Id	9000
ID	HA
Acrostic	WCAS
Date Interview Completed	11/18/2013
Staff ID#	A97
Year and Quarter of Interview	38:17Q1
First name	W
Last name	CAS
Suspense	8BMX6K0000.TIF
Orig_File	T:\TELEFORM\sus\8TNFHA0000.tif

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.

## 7. Data queries

Periodically, throughout the day, all of the study data is subjected to a set of error-checking programs. These edits include checks for completeness, skip pattern adherence, data consistency, and invalid ranges. The results are posted to the study website. All such queries are displayed on the website under “Resolve Queries” in the Data Edits / Edit Report link. These queries are designed to check that the form logic has been followed.

## 7.1 Resolving queries

Required data fields or data fields that should be answered depending on the answer to some earlier question or series of questions will be noted as “missing.” If the response to the earlier question indicates that a secondary question should not be answered, it will be noted as a “skip pattern error.” Data that does not match other data collected will be noted as “inconsistent.” More complex queries will have their own unique description. The strategies for resolving primary types of errors are described below:

## 7.2 Addressing queries

Sites are expected to address all the queries on the website. 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 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.

As with the Data Inventory report, the list of data edits can be limited to a specific ID, a particular form, visit, or originator. The various selections can also be used in any combination. For example, you could enter a specific ID then select a visit and find all the edits relating to that participant for that particular visit. If you would like to print out the edits you have selected, choose the “Printable Version.” Only the Screen Version can be used to make corrections.

Most of the time, you will want to view and address the complete edit report. By keeping up with the edits as they appear, you can keep the length of this report short and manageable.

The screenshot shows the 'RESOLVE QUERIES' interface. At the top, there is a navigation menu with the following items: Analysis Plans, Ancillary Studies, Conf Calls & Meetings, Data Collection Forms, D & D Staff Only, Data Edits, Data Entry, Datasets/Documentation, Directory, Disease Outcomes, Equipment Lists, GWAS, HelpDesk, Memo Archive, and Operations Manual. Below the menu, a message states: 'You are currently logged on as Susan Amersbach from UCSF Staff. If this site association is incorrect, please contact the system administrator.' The main heading is 'RESOLVE QUERIES' in red. Below this is a 'SELECTION CRITERIA' section with the following fields: 'SPECIFIC ID' (dropdown menu set to 'ALL'), 'SPECIFIC FORM' (dropdown menu set to 'ALL'), 'SPECIFIC VISIT' (dropdown menu set to 'ALL'), 'SPECIFIC ORIGINATOR' (dropdown menu set to 'ALL'), and 'DISPLAY FIRST 20 RECORDS' (checkbox set to 'YES'). A 'VIEW EDITS' button is located at the bottom of the selection criteria section.

The Edit Report lists all outstanding queries for your site. The date the query was generated appear at the left, followed by information describing the edit: Participant ID, form, visit, question, problem that generated the query, originator, and comment field.

<b>Error type</b>	<b>Problem/Resolution</b>
Missing	If this data is required, then the correct answer to the question should be filled in. If it is only required when a previous field is completed, it may be that the previous data field was incorrectly completed. Check all associated fields to ensure that the correct skip pattern was followed. If the missing data cannot be entered, then a comment needs to be added to account for the missing data.
Out of range	The value for the data is not within the allowable normal range. For instance, a date of 1/2/2341 would be noted as out of range. In this case, the data should be corrected. Range checks are designed to catch both impossible and very unlikely data. It is therefore possible that the data are correct but out of the range of normal and a comment (Not an error) needs to be added to indicate that this has been checked and is not an error.
Inconsistent	The question has been answered but is not consistent with the answer to another question or set of questions. In this case, all involved fields need to be reviewed and the data adjusted so that the data are consistent. Note: the related data may not be on the same form. For example if a question asks about whether the person had a BMD scan at an earlier visit, the related variable would be on the form from the earlier visit.
Skip pattern error	Data has been entered that does not follow the correct skip pattern logic of the form. All involved fields need to be reviewed and the data adjusted so that the skip pattern is correctly followed. For example, if a follow-up question should not have been asked, based on the response to the previous question, then the follow-up question response should be deleted.

To address a query by changing the answer to a question in the database, begin by clicking in the red “go” button in the fix column next to the query. This will bring you to the page containing the data that needs to be corrected.

**EDITS/QUERY RESOLUTION**

Page 1 of 2 Next

save comments

QRY DATE	ID	FORM	VISIT	QUESTION	PROBLEM	ORIG	COMMENT	FIX
11/18/2013 2:17:45 PM	HA9999	Y15+ Proxy p02	38	Q3 Most frequent type of contact?	Inconsistent with Q2 How often contact?	CC	<input type="text"/>	<span style="color: red; font-weight: bold;">go</span>
11/18/2013 2:17:45 PM	HA8888	Y15+ Proxy p11	38	Q31b Medications decision?	Missing	CC	<input type="text"/>	<span style="color: red; font-weight: bold;">go</span>

**HA9999**

**Y15+ Proxy p02**

**Visit: 38:17Q1**

**Problem: Inconsistent with Q2 How often contact?**

SAVE CHANGE

Page 2

Q3 Most frequent type of contact?	<input type="text"/>
Q4 Did you stay in bed all/most of day?	1:Yes <input type="text"/>
Q4a How many days did you stay in bed?	2 <input type="text"/>
Q5 Did you cut down on things you do?	1:Yes <input type="text"/>
Q5a # of days you cut down on things?	2 <input type="text"/>
Q6 Overnight as patient in nursing home	1:Yes <input type="text"/>
Q7 Receive care from visiting nurse?	0:No <input type="text"/>

137%

Only the fields involved in the query will be displayed. These are the only fields that can be corrected by this particular query. Correct any erroneous data. In order to save any changes you made, you must click on the “SAVE CHANGE” button above the first question on the page. Most fields consist of drop-down lists allowing the user to choose from a list of allowable answers. However, some answers must be typed in directly. With these fields, it is possible to type in something that is inappropriate for the respective field, for example a number in a date 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 and why.

Note that the query listed in the Edit Report turns yellow after successfully saving the changes. The edit will disappear next time that the edits are run. Until then, you can still view/change these "yellow" queries.

### 7.3 Posting 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 some may be ad hoc queries posted by Coordinating Center or clinic staff. If, for example, you know there is a problem with part of the data, but it was not caught by the data system (for example, the wrong weight was recorded, but it was still within the allowable weight range), you will have to post a query before changing the data. This serves to leave a record of why the data were changed. The process of originating a query is as follows:

(1) Click on the "Data Edits" link on the header bar - then on "Post Queries"

The screenshot shows the Health ABC Data User's Guide interface. On the left is the 'Health ABC' logo. To its right is a dark blue navigation menu with white text listing various sections: Analysis Plans, Ancillary Studies, Conf Calls & Meetings, Data Collection Forms, D & D Staff Only, Data Edits, Data Entry, Datasets/Documentation, Directory, and Disease Outcomes. Below the menu is a pink status bar that reads 'You are currently logged on as Susan Averbach from UCSF Staff'. Underneath the status bar, the 'Data Edits' section is expanded, showing a list of options: Audit Trail, Data Edits for D & D System, Data Edit Summary Report, Data Inventory, Data Edits Remaining, Edit Report, Edit Report Notes, and Post Queries.

- (2) Enter selection criteria for the participant and form to which you want to address a query.

**POST QUERY**

**SELECTION CRITERIA**

SPECIFIC ID

SPECIFIC FORM

SPECIFIC VISIT

DISPLAY FIRST 20 RECORDS

- (3) Click on the red “go” button in the view column next to the desired form. In the rare case that a form has more than 1 page, you will have to pull down the “page” menu to the desired page before clicking “go.”

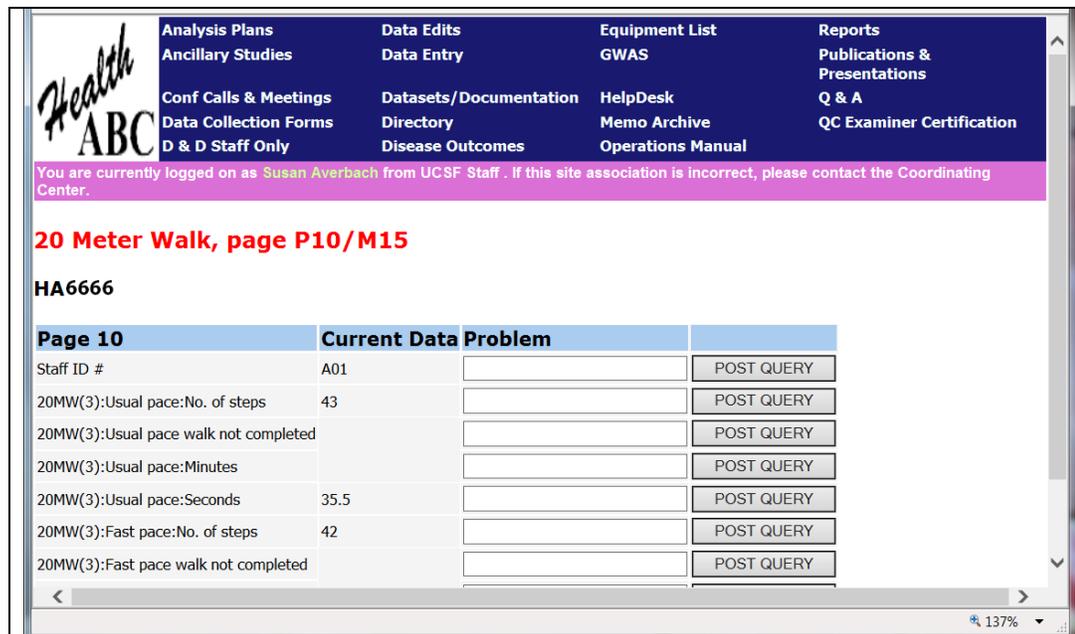
**POST QUERY**

Page 1 of 6

DATE/TIME RECEIVED	PARTICIPANT ID	FORM NAME	VISIT/OTHER ID	PAGE	VIEW
11/18/2013 12:48:03 PM	HA.6666	20 Meter Walk, page P10/M15	Year 16 Clinic Visit	10	go
11/18/2013 12:39:55 PM	HA 8888	20 Meter Walk, page P10/M15	Year 16 Clinic Visit	10	go
11/14/2013 12:24:59 PM	HA 7777	20 Meter Walk, page P10/M15	Year 16 Clinic Visit	10	go
11/14/2013 11:11:27 AM	HA 9999	20 Meter Walk, page P10/M15	Year 16 Clinic Visit	10	go

137%

- 4) Type in the problem or concern in the “problem” box. Please use a meaningful message, not just “wrong” or the value you want to enter. This “problem” will be recorded in the Audit Trail to indicate why the data were changed.



- (5) Click on the ‘POST QUERY’ button

You should get a message that your query was successfully posted. If you are ready to make the change to the data you can do so now. Otherwise, the query will be added to the “Resolve Queries” report and be available to correct at a later date.

To make changes to the data now, simply:

- (6) Correct the data. Always use a 4 digit year when changing dates.
- (7) Click on the “SAVE CHANGE” button
- (8) You should see a message that your update was successfully performed.

#### **7.4 Adding “Comments” to unresolved queries**

Comments should be used only when a query cannot be addressed. Adding a comment to a query will cause the query to be removed from the edit report. There are currently four possible choices for the comment field:

- Irretrievable*
- Not an error*
- Participant ineligible*
- Other*

To add a comment, select an option from the dropdown and press the "Save Comments" button (top right corner).

"Not an error" is largely used to verify that "out-of-range" values have been checked and are indeed correct. Otherwise, the "Not an error" comment should be rarely used. Sometimes a query will be generated when there is not an error due to a problem with the query generating program. These may be commented out as "Not an error," but it is also very helpful to notify the Health ABC Help Desk if you think the edit was inappropriate. The Help Desk will review the query logic and make any necessary corrections. The Coordinating Center will also periodically review the edit system looking specifically at queries marked "not an error" and make appropriate changes or notify the sites that this comment is being used inappropriately.

If some data are 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.

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.

## 8. Documenting changes made on the website

**Important:** If a change made to the database reflects a change made to how the form was filled out (i.e., it is not simply a correction to data that was written correctly on the form), the change must be also be made on the paper form, dated, and initialed.

### 8.1 Audit trail

All changes made to the database are tracked and recorded in an "Audit Trail." The audit trail includes the first initial and last name of the person making the change, the date and time the change was made, a description of the item changed, the old value, the new value, and the reason the change was made. Records are viewed based on selection criteria. This report is primarily of interest to the auditors of the study but can be used by the study staff to track changes to a particular field, form, or participant or to check corrections made by a particular user.

You are currently logged on as Susan Averbach from UCSF Staff . If this site association is incorrect, please

**AUDIT TRAIL**

**SELECTION CRITERIA**

SPECIFIC ID

SPECIFIC FORM

SPECIFIC OPERATOR

FIELDS MODIFIED BETWEEN  AND

DISPLAY FIRST 20 RECORDS

You are currently logged on as Susan Averbach from UCSF Staff . If this site association is incorrect, please contact the Coordinating Center.

**AUDIT TRAIL**

Page 1 of 4

DATE	ID	FORM	VISIT	VARIABLE CHANGED	OPERATOR	OLD VALUE	NEW VALUE	REASON	COMMENT	ORIG
11/18/2013 1:51:39 PM	HA	Y15+ Telephone Interview p28	38	Q72d Whole family agrees on decision(s)?(BRDMDFH)	PSG\L.Martin		0	Missing(BRDMDFH)		CC
11/18/2013 1:51:29 PM	HA	Y15+ Telephone Interview p28	38	Q72c Family helped decision(s)?(BRDMAFH)	PSG\L.Martin		0	Missing(BRDMAFH)		CC
11/18/2013 1:51:14 PM	HA	Y15+ Telephone Interview p26	38	Q67 Did doc provide enough info?(BNICDRIN)	PSG\L.Martin		2	Missing(BNICDRIN)		CC
11/18/2013 1:49:16 PM	HA	Year 16 Clinic/Home Visit Workbook,Checklist, M1	54	Ppt agree to have a CT?(D8CT)	PSG\L.Martin		2	Missing(D8CT)		CC
11/18/2013 1:49:07 PM	HA	Year 16 Clinic/Home Visit Workbook,Checklist, M1	54	Send a copy of test results to doctor(D8DOC)	PSG\L.Martin		0	Missing(D8DOC)		CC
11/18/2013 1:48:55 PM	HA	Year 16 Clinic Visit Workbook, MME, Page M8C	54	16b. Folds paper in half(CWPFLD)	PSG\L.Martin		1	Missing(CWPFLD)		CC
11/18/2013 1:48:47 PM	HA	Year 16 Clinic Visit Workbook, Medications, M4/M5	54	Total # of pages(DKPAGES)	PSG\L.Martin		2	Missing(DKPAGES)		CC
11/18/2013 1:48:40 PM	HA	Year 16 Clinic Visit Workbook, Medications, M4/M5	54	Total # of pages(DKPAGES)	PSG\L.Martin		2	Missing(DKPAGES)		CC
11/18/2013 1:48:32 PM	HA	Year 16 Clinic Visit Workbook, Medications, M4/M5	54	Total # of pages(DKPAGES)	PSG\L.Martin		2	Missing(DKPAGES)		CC
11/18/2013 1:48:23 PM	HA	Year 16 Clinic Visit Workbook, Medications, M4/M5	54	Total # of pages(DKPAGES)	PSG\L.Martin		2	Missing(DKPAGES)		CC
11/18/2013 1:48:16 PM	HA	Year 16 Clinic Visit Workbook, Medications, M4/M5	54	Total # of pages(DKPAGES)	PSG\L.Martin		2	Missing(DKPAGES)		CC
11/18/2013 1:48:05 PM	HA	Year 16 Clinic Visit Workbook, Med Banner, pM4	54	Total # of pages(DJPAGES)	PSG\L.Martin		2	Missing(DJPAGES)		CC

**9. Website administrative features**

**9.1 Memo archive**

All Health ABC numbered study memos will be available on the website. To access the memos, click on “Memo Archive” in the banner located at the top of the Health ABC web pages. Click the “Basic” bubble under “Client.” To log onto the Outlook site, use the same login information you use to log onto the web site. This will automatically connect you to the Microsoft Outlook website. After you have logged in, you will be automatically directed to Outlook. Click on the “Health ABC Memos” link on the left to view memos.

## 9.2 Health ABC Q & A

All Health ABC study questions (e.g., questions about study procedures, inclusion/exclusion, addressing queries, etc.) should be submitted through the Health ABC Question and Answer Form on the web site. The Health ABC Question & Answer (Q & A) Form is to be used for the documentation of all study/protocol inquiries.

**To submit a question:** To access the Q & A form, click on the Question and Answer Icon in the banner located at the top of the Health ABC web pages and then click on the "Ask a Question" link to pull up the Q & A Form. Please use a separate form for each question and be as detailed and clear as possible. If applicable, send supporting documentation or examples, or refer to specific forms or sections of the Health ABC Operations Manual. Please complete the form on the web and press the "Submit" button ONCE. This will email the form to someone at the Coordinating Center, who will triage the question to the appropriate person(s) who can answer it. Answers to your questions will be distributed as a numbered study memo and will also be posted on the website.

**Viewing previous questions and answers:** The answers to questions submitted to the Coordinating Center will be posted on the website by date and topic category. This listing will be available for viewing by anyone with access to the site. To view previous questions and answers, click on the Q & A Icon in the banner located at the top of the Health ABC web pages.

## 9.3 Reports

Reports on the Health ABC Keeptrack website include:

- Visit Scheduling Report – select a visit and a list of target dates, window start, and window end will be displayed
- Data from Prior Visits Report – for each visit currently being administered – put in Health ABC ID number and information from prior visits that will be useful for the current visit will be included on this report
- Participant Results Report – for clinic visits, if applicable
- Summary Status Reports – for quarterly interviews – shows number of interviews completed, number of proxy interviews, number of missed interviews and the reason for the missed visits.

## 9.4 Directory

The Health ABC Study Directory contains contact information for Health ABC investigators, staff, project office personnel, consultants, reading center personnel, and others who may need to be contacted about Health ABC study matters. If you find an error or omission in the directory, please email the Health ABC Help Desk.

## 9.5 Conference calls and meetings

The Conference Call / Meeting Schedule page can be accessed by clicking on Conf Calls & Meetings in the Health ABC Keeptrack website header. This listing shows all scheduled future face-to-face meetings or conference calls. Select a committee or group from the drop-down menu to see the schedule of interest.

The screenshot shows the Health ABC website header with navigation links: Analysis Plans, Ancillary Studies, Conf Calls & Meetings, Data Collection Forms, D & D Staff Only, Data Edits, Data Entry, Datasets/Documentation, Directory, Disease Outcomes, Equipment List, GWAS, HelpDesk, Memo Archive, Operations Manual, Reports, Publications & Presentations, Q & A, and QC Examiner Certification. Below the header is a login message: "You are currently logged on as Susan Averbach from UCSF Staff. If this site association is incorrect, please contact the Coordinating Center." The main content area is titled "Conference Call / Meeting Schedule" and includes a "View Calendar" link and a "Select a committee or group:" dropdown menu. The dropdown menu lists various committees and groups, including Death Adjudication Meeting, Diabetes Algorithm Working Group, Diagnosis and Disease Ascertainment Committee, Executive Committee Conference Call, Functional Limitation Data Set conference call, Genetics Working Group, GWAS Working Group, HABC nerve conduction data, HABC Y15 sensivity training conf call, HABC Year 15 telephone interview trng conf call, Muscle Biopsy Working Group, Quality Control/Data Managers Conference Call, Steering Committee Meeting, and TICS training conf call.

For convenience, the calls may also be viewed by calendar month by clicking the View Calendar link.

The screenshot shows the Health ABC website header and a calendar view of conference calls for December 2013. The header is the same as in the previous screenshot. Below the header is a login message: "You are currently logged on as Susan Averbach from UCSF Staff. If this site association is incorrect, please contact the Coordinating Center." The main content area is titled "select month: December" and shows a calendar grid. The calendar grid has columns for days of the week and rows for dates. The dates shown are from Monday 12/2/2013 to Friday 12/6/2013, Monday 12/9/2013 to Friday 12/13/2013, Monday 12/16/2013 to Friday 12/20/2013, Monday 12/23/2013 to Friday 12/27/2013, and Monday 12/30/2013 to Friday 1/3/2014. The calendar grid shows two conference calls: one on Wednesday 12/11/2013 at 12:00 PM, Executive Committee Conference Call, and one on Wednesday 12/18/2013 at 12:00 PM, Quality Control/Data Managers Conference Call.

Mon 12/2/2013	Tue 12/3/2013	Wed 12/4/2013	Thu 12/5/2013	Fri 12/6/2013
Mon 12/9/2013	Tue 12/10/2013	Wed 12/11/2013 12:00 PM Executive Committee Conference Call	Thu 12/12/2013	Fri 12/13/2013
Mon 12/16/2013 12:00 PM Quality Control/Data Managers Conference Call	Tue 12/17/2013	Wed 12/18/2013	Thu 12/19/2013	Fri 12/20/2013
Mon 12/23/2013	Tue 12/24/2013	Wed 12/25/2013	Thu 12/26/2013	Fri 12/27/2013
Mon 12/30/2013	Tue 12/31/2013	Wed 1/1/2014	Thu 1/2/2014	Fri 1/3/2014

## 9.6 Analysis plans

Analysis proposal and publications guidelines, proposal forms, and tracking logs; and GWAS analysis proposal and publications guidelines, proposal forms and tracking logs are under the Analysis Plans link in the Health ABC Keeptrack website header.

The screenshot shows the Health ABC website interface. At the top left is the 'Health ABC' logo. To its right is a dark blue navigation bar with white text listing various menu items: Analysis Plans, Ancillary Studies, Conf Calls & Meetings, Data Collection Forms, D & D Staff Only, Data Edits, Data Entry, Datasets/Documentation, Directory, Disease Outcomes, Equipment List, GWAS, HelpDesk, Memo Archive, Operations Manual, Reports, Publications & Presentations, Q & A, and QC Examiner Certification. Below the navigation bar is a pink status bar that reads 'You are currently logged on as Susan Averbach from UCSF Staff'. The main content area is white and features a section titled 'Analysis Plans' with a horizontal line underneath. Under this section, there are three links: 'Analysis Proposal and Publications Guidelines', 'Analysis Plan Form', and 'Analysis Plan Tracking Log'. Below this, there is another section titled 'GWAS Analysis Plans' with a horizontal line underneath, containing three links: 'GWAS Analysis Proposal and Publications Guidelines', 'GWAS Analysis Proposal Form', and 'Analysis Plan Tracking Log'.

## 9.7 Ancillary studies

Ancillary studies policies and procedures guidelines, forms, tracking log, biological specimen request form and tracking log, and genotype submission documents and tracking log are under the Ancillary Studies link in the Health ABC Keeptrack website header.

The screenshot shows the Health ABC website interface. At the top left is the 'Health ABC' logo. To its right is a dark blue navigation bar with white text listing various menu items: Analysis Plans, Ancillary Studies, Conf Calls & Meetings, Data Collection Forms, D & D Staff Only, Data Edits, Data Entry, Datasets/Documentation, Directory, Disease Outcomes, Equipment List, GWAS, HelpDesk, Memo Archive, Operations Manual, Reports, Publications & Presentations, Q & A, and QC Examiner Certification. Below the navigation bar is a pink status bar that reads 'You are currently logged on as Susan Averbach from UCSF Staff'. The main content area is white and features a section titled 'Ancillary Studies' with a horizontal line underneath. Under this section, there are seven links: 'Ancillary Studies Policies and Procedures Guidelines', 'Ancillary Study Form (interactive version)', 'Ancillary Studies Tracking Log', 'Biological Specimen Request Form (interactive version)', 'Biospecimen Tracking Log', 'Genotype Submission Documents', and 'Genotype Tracking Log'.

## 9.8 QC examiner certification

All staff who administer interviews or exams should be certified using the certification forms posted on the website. To download these forms, click on the QC Examiner Certification link in the Health ABC Keeptrack banner.

## 10. Data security

### 10.1 Security procedures

A number of levels of data security have been developed for our systems and use of the UCSF Coordinating Center website is strictly limited to study staff only. Each site will have access only to data associated with that site. Project office and Coordinating Center personnel have access to data associated with all sites. In addition, only limited staff from each site will be able to view and/or change data.

User accounts and passwords are discussed in 2.1. Any deviation from the security system requirements could compromise the system. ***Study staff members must not share their passwords with anyone else, including co-workers who may be having trouble accessing the site or who have been locked out by repeated password errors.*** Such problems should be reported to the Health ABC Help Desk, which will respond as soon as possible and try to fix the problem.

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 Coordinating Center.

### 10.2 Study Coordinator

The security manager at each site will be the Study Coordinator. Any necessary changes to the secure data system (i.e., forgotten password, removing web access, adding web access) must go through your Study Coordinator. The Study Coordinator will request any changes for your site staff via email to the Health ABC Help Desk at the Coordinating Center. The Coordinating Center will track and verify all requested changes to the security system.