Scleroderma Clinical Repository
SCaR

User Manual
for
Main SCaR Website
(Clinical Data System)

Version date: 5/22/2015

Boston University School of Public Health
Data Coordinating Center

Table of Contents

I. Introduction

The objective of this user manual is to provide an easy-to-follow, step-by-step, comprehensive guide to assist you in data collection, data entry, and the maintenance of SCaR repository data. This section of the user manual will focus on the main SCaR website, which handles subject tracking and clinical data entry.

The website URL is: https://dccweb.bumc.bu.edu/SCaR/login.aspx

II. Contact Information

For questions regarding the website or study data, please contact any of the following people at the Data Coordinating Center (DCC):

Clara Chen, *Project Manager* **[Primary Contact]**
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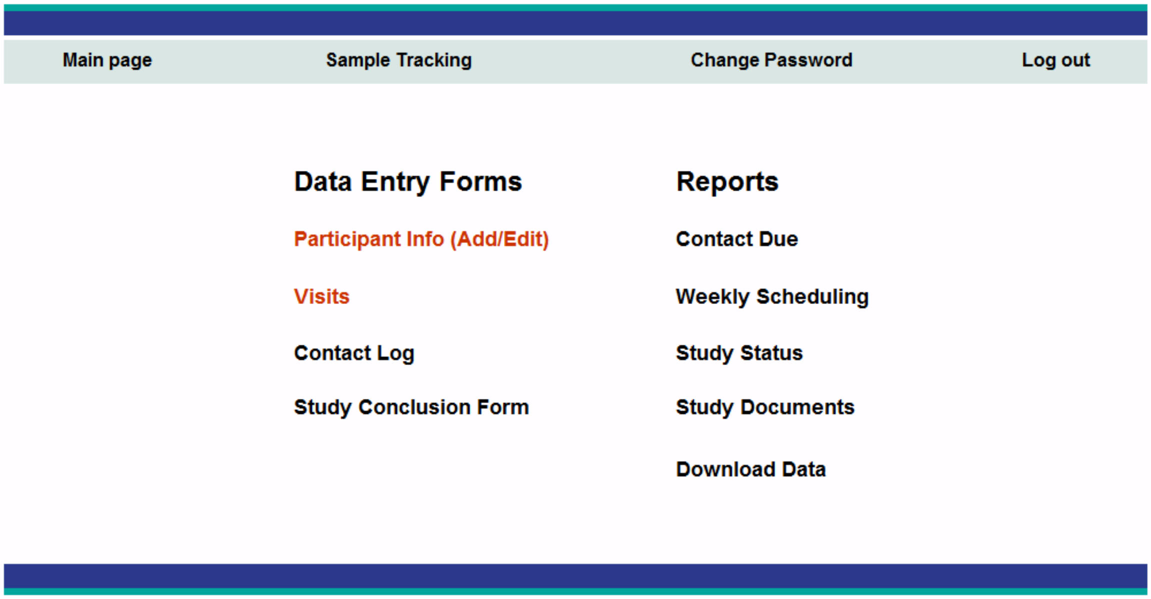
III. General Overview of Clinical Data Website

The main SCaR website is used to enter clinical data and participant questionnaires. Lab specimen tracking uses a separate sample tracking website (https://dccweb.bumc.bu.edu/ CORTSamplesTracking/login.aspx).

You will be provided with a username and password for the websites. Your password should not be shared with anyone. You will be required to log in again if you are inactive on the site for 30 minutes.

Home Page Navigation

1. Immediately after logging in to the clinical website, the main page will display:

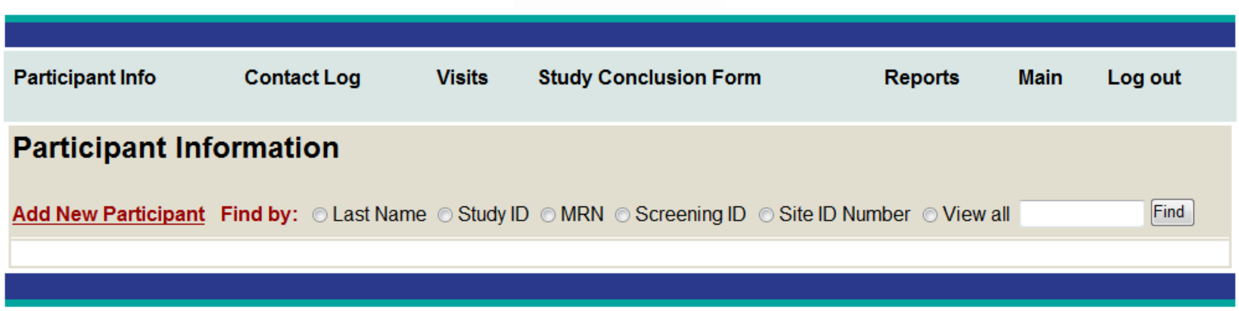


2. In the navigation bar at the top, one may navigate to the sample tracking website (login will be required again), change one's password, or log out by clicking on the appropriate link.
3. The data entry form links in red are required when adding new participants to the repository; the other links (both data entry and reports) are optional. Please note that the Contact Log is only available for the Boston site.

IV. Data Collection

Adding/Editing Participants

1. From the home page of the clinical data website, click on the red link "Participant Info (Add/Edit)" in order to add a new participant or edit participant information for an existing participant. This will bring up the Participant Information search page.



2. Click on "Add New Participant" to add a new participant, or you can "Find by" to check if the participant already has a record in the database. To

display the list of participants already in the database, select one of the fields to search by and enter the search criterion in the text box next to the "Find" button; then click the "Find" button. Alternatively, selecting "View all" will show all participants already entered from your site. Searches by Last Name or MRN are only available for the Boston site.

3. If the participant already exists, click on the "Open Record" link next to the appropriate search result.

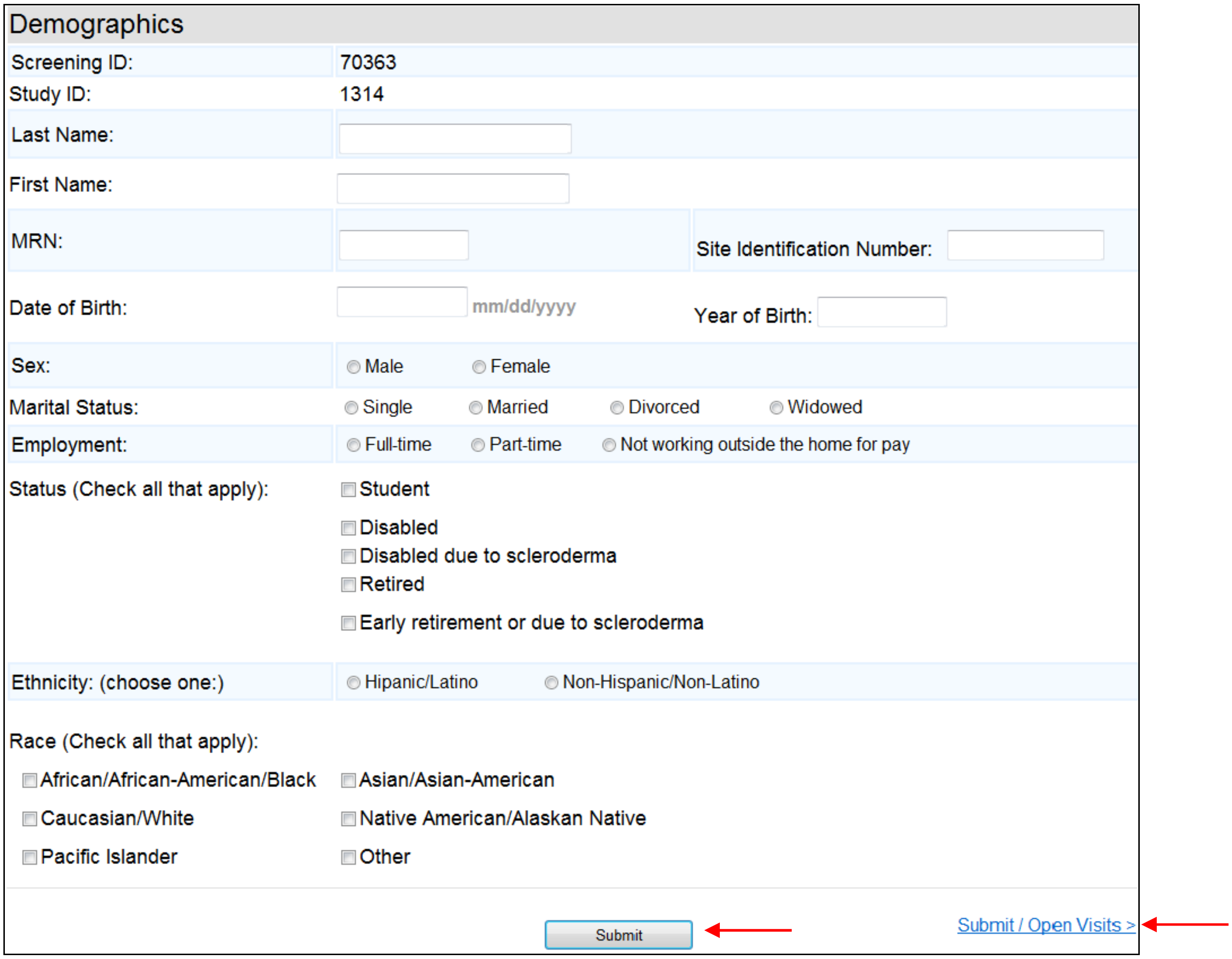
Participant Information

Add New Participant Find by: Last Name Study ID MRN Screening ID Site ID Number View all Find

Study ID	Last Name	First Name	MRN	Screening ID	Site ID Number	
1310				70359	999ZZZ	Open Record
1313				70362	ABC123	Open Record

The Participant Info form will display for that participant, already populated with existing data. Make any changes you wish, and then either click on the "Submit" button at the bottom of the page to save the data and stay on this page, or click on the "Submit/Open Visits" link to save changes and immediately move to that participant's visit level information.

4. If the participant is new, clicking on "Add New Participant" will automatically generate a study ID for the participant and open a blank Participant Info/Demographics form for that participant. Complete the form and click the "Submit" button to stay on this page, or click on the "Submit/Open Visits" link to go directly to this participant's visits page. Note that some fields will be grayed out for non-Boston sites and cannot be entered (last name, first name, MRN, full date of birth). Site Identification Number is provided as a way for sites to enter their own IDs for these participants; users are able to search for participants based on the site identification number.



Demographics			
Screening ID:	70363		
Study ID:	1314		
Last Name:			
First Name:			
MRN:		Site Identification Number:	
Date of Birth:	mm/dd/yyyy	Year of Birth:	
Sex:	Male, Female		
Marital Status:	Single, Married, Divorced, Widowed		
Employment:	Full-time, Part-time, Not working outside the home for pay		
Status (Check all that apply):	Student Disabled Disabled due to scleroderma Retired Early retirement or due to scleroderma		
Ethnicity: (choose one:)	Hipanic/Latino, Non-Hispanic/Non-Latino		

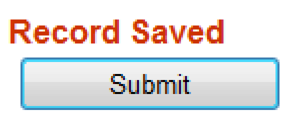
Race (Check all that apply):

African/African-American/Black	Asian/Asian-American
Caucasian/White	Native American/Alaskan Native
Pacific Islander	Other

Submit

Submit / Open Visits >

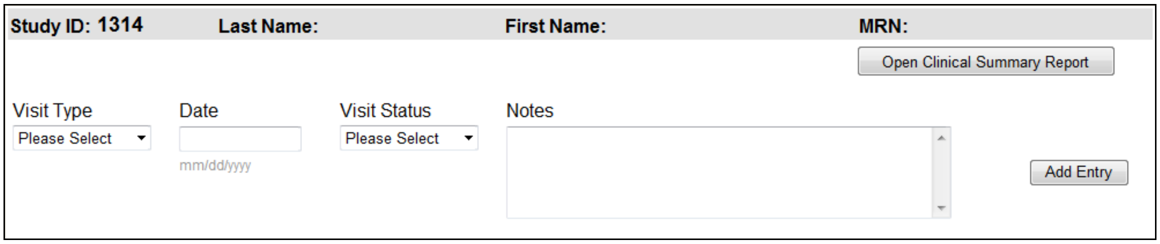
5. If you click on the "Submit" button, the webpage will indicate that the record has been saved.



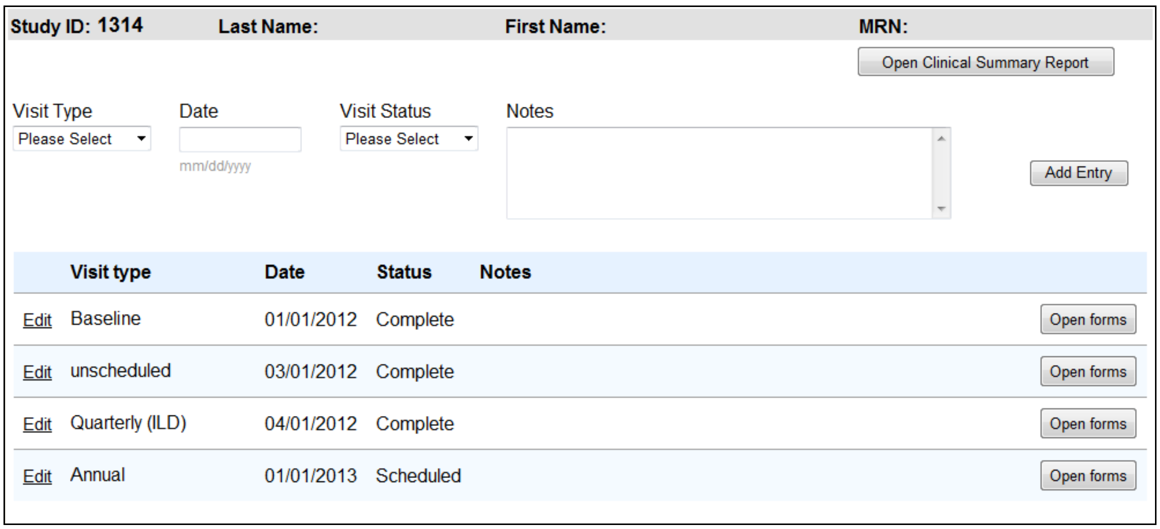
6. If you click on the "Submit/Open Visits" link, the data will be saved and the website will automatically open that participant's visit level information.
7. To enter clinical data for this participant, please navigate to the participant's Visits Page either by clicking the "Submit/Open Visits" link or return to the main page and select the "Visits" link.

Visit Level Data

Once a participant's general demographic information has been completed, users may add visits for that specific participant. Visit data may be entered for visits that have occurred in the past, visits currently in progress, as well as scheduled dates for future visits.

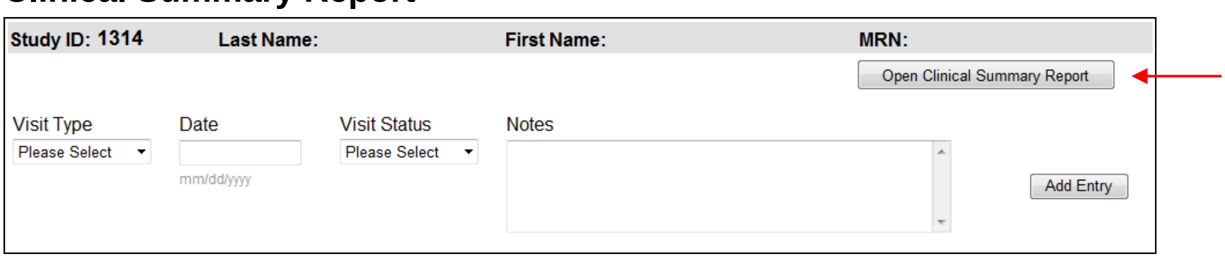


After entering visit-level information (visit type, date of visit, whether visit was completed or not, comments), click on "Add Entry" to save the visit level data. Users may enter multiple visits at one time, clicking on "Add Entry" between each.



Previously entered visits will appear in chronological order underneath the data entry section and visit level data may be edited by clicking on the "Edit" link to the left of the visit to be edited. Click on the "Open forms" button to the right of the visit to open the data collection forms for that particular visit. Each visit has associated with it a Diagnosis page and three categories of forms to be entered (coordinator, physician, and participant).

Clinical Summary Report



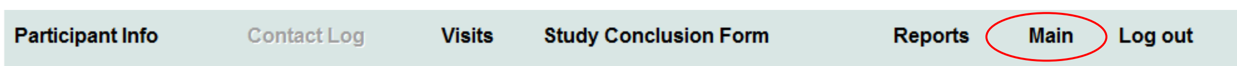
Clicking the "Open Clinical Summary Report" button provides a longitudinal summary report of certain clinical variables over all of the selected participant's visits, in chronological order with the most recent visit at the top. The report can be printed or exported to Excel, using the icons at the top of the report.

Navigation Bars

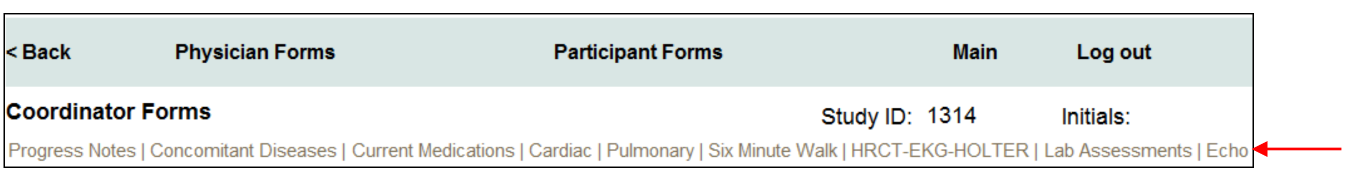
Throughout the SCaR website, navigation bars are available at the top of the webpages. The options shown on these bars changes depending on where you are within the website.

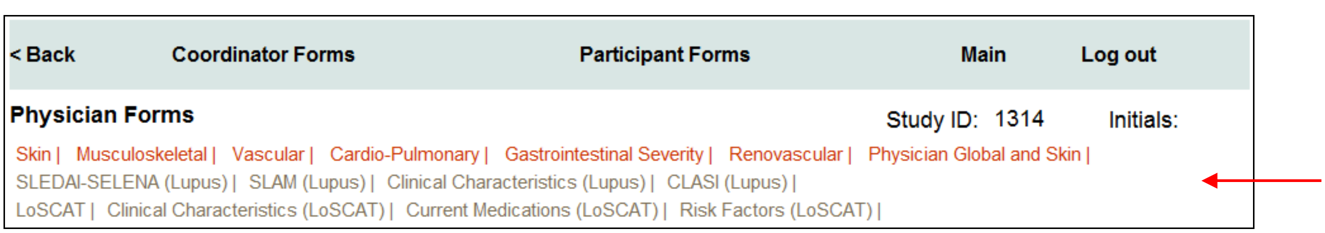
On the main study pages, the navigation bar provides options that allow easy navigation to the main page, sample tracking website, password change, or log out.

Once data entry begins or reports are selected, the navigation bar displays additional options to more easily navigate between data collection forms. To return to the main navigation bar, simply click on the “Main” tab:

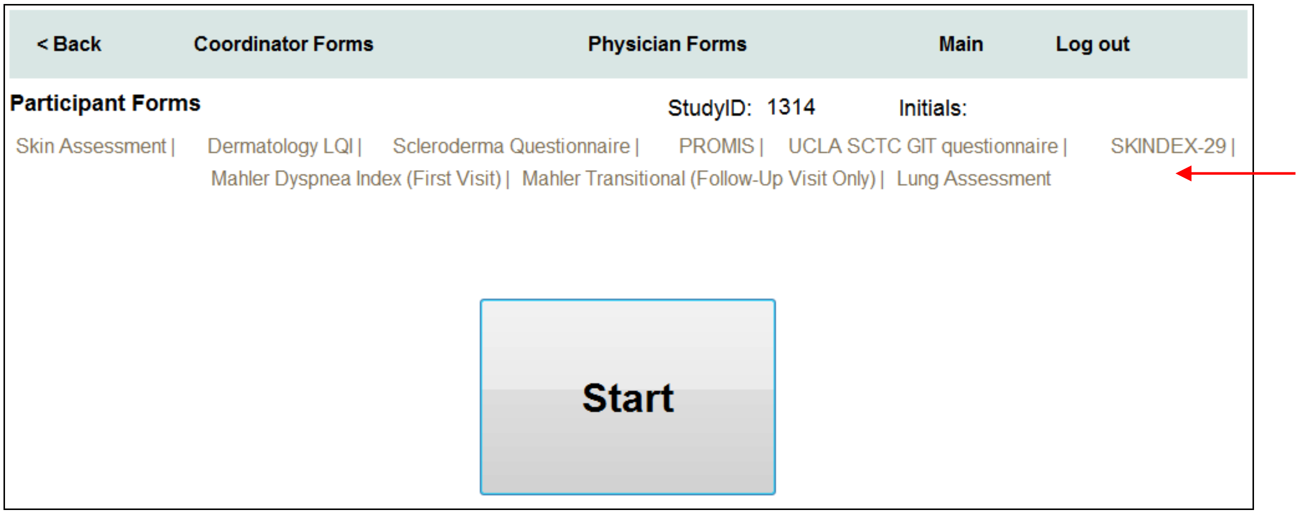


Within the data collection forms, the navigation bar reflects the three categories of forms that will be collected for each participant: Coordinator Forms, Physician Forms, and Participant Forms. Each one of these will have a navigation bar of forms to be entered by that person (coordinator, physician, or participant). Clicking on “< Back” displays the participant’s Diagnosis form again.





Physician forms shown in red font are part of the recommended clinical core forms that are strongly recommended for each participant.



Each visit has associated with it a Diagnosis page and three categories of forms to be entered (coordinator forms, participant forms, and physician forms).

Diagnosis

The Diagnosis form includes information on diagnoses, clinical characteristics, alcohol use, smoking, and BMI. We strongly encourage users to complete the visit date and diagnosis questions before additional forms are completed.

Coordinator Forms

The Coordinator Forms are to be completed by study staff, and include information on concomitant diseases, current medications, and lab assessments.

Participant Forms

The Participant Forms are self-reported questionnaires that each participant should complete. Note that these forms are designed so that answer option selection spaces are optimized for easier participant use on iPads (larger boxes, etc). Unlike the Coordinator Forms and Physician Forms, these webpages automatically move from one page to the next when the “Submit” button is clicked; the specific forms are shown in the navigation bar, but the participant does not need to navigate through forms manually.

Physician Forms

The Physician Forms are for clinical assessments performed by physicians, including various systems (skin, musculoskeletal, etc). The forms shown in red font on the navigation bar are strongly recommended as part of the core clinical data for the repository. All other forms are optional.

Study Conclusion Form

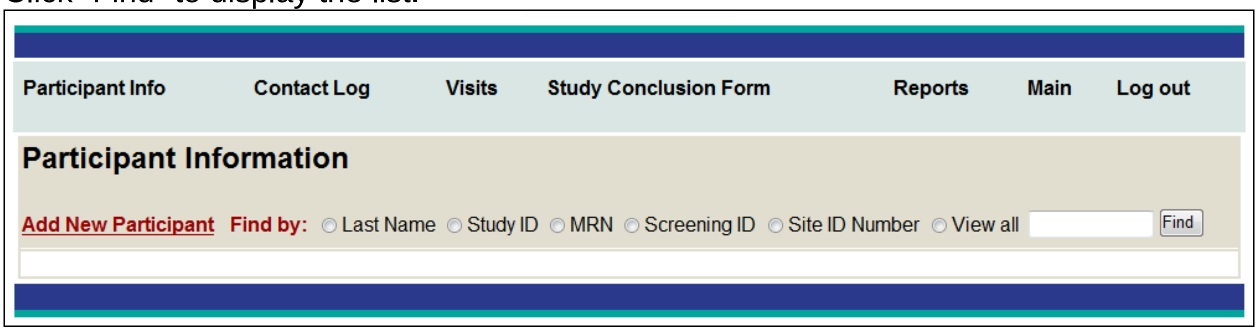
This form should be completed whenever a participant completes, withdraws from, or is terminated from the study. This includes participants who pass away or are lost to follow-up.

V. Website Subject Tracking

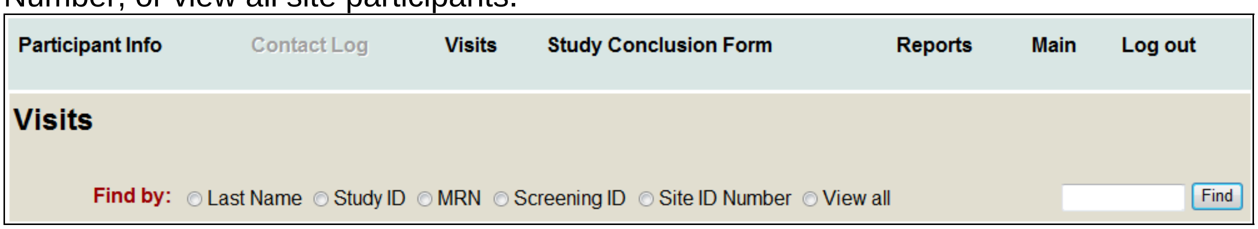
Searching For a Subject

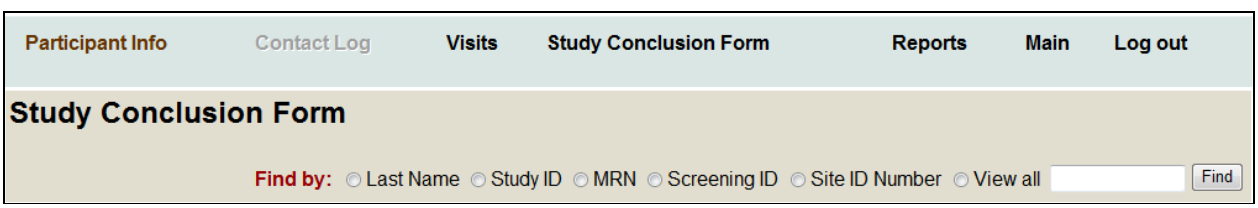
There are several ways to search for a subject. Clicking on any of the Data Entry Forms listed on the study-specific page displays a search option.

For the Participant Info, one may display a list of all IDs at the user's site, or specify one of the search options and a text field to narrow the search results. Click "Find" to display the list.



For the Visits and Study Conclusion Form, one may search by participant's last name (Boston site only), study ID, MRN (Boston site only), Screening ID, Site ID Number, or view all site participants.





In either case, the displayed list of participants looks like this, and clicking on the "Open Record" hyperlink displays that participant's data.

Find by: ○ Last Name ○ Study ID ○ MRN ○ Screening ID ○ Site ID Number ◉ View all [Find]

Study ID	Last Name	First Name	MRN	Screening ID	Site ID Number	
1310				70359	999ZZZ	Open Record
1313				70362	ABC123	Open Record
1314				70363	SantaClaus	Open Record

Contact Log (Boston Site Only)

The Contact Log allows study staff to document phone, mail, email, and in-person contacts with each participant. One must first select the participant whose contact log one wishes to view or update; see the section *Searching for a Subject* for more details. Scheduling for follow-up appointments can be tracked this way, and the date and time of scheduled appointments are used to populate the reports on upcoming appointments and follow-up schedules.

The page also displays the results of previous contacts at the bottom of the webpage, in the Contact History section. If no previous contacts have been made, the Contact History displays the message "No contact was entered for this subject." Previous contacts can be edited or deleted, using the hyperlinks in the Contact History displayed at the bottom of the webpage.

To Enter a New Contact

1. Select the participant whose contact log should be updated; see the section *Searching for a Subject* for more details.
2. Enter information in the appropriate fields of the Contact Log.

Contact Log

Find by: ○ Last Name ○ Study ID ○ MRN ◉ View all [Find]

Study ID: **1031** Last Name: **Claus** First Name: **Santa** MRN:

Date:	Time:	Method:	Answer:	Left message:	Phone #:	Other:
mm/dd/yyyy	hh:mm PM/AM	Please Select	Please Selec	Please Sel	Please Select	(xxx)xxx-xxxx

Appointment Details: Type: Please Select; Date: mm/dd/yyyy; Time: hh:mm PM/AM

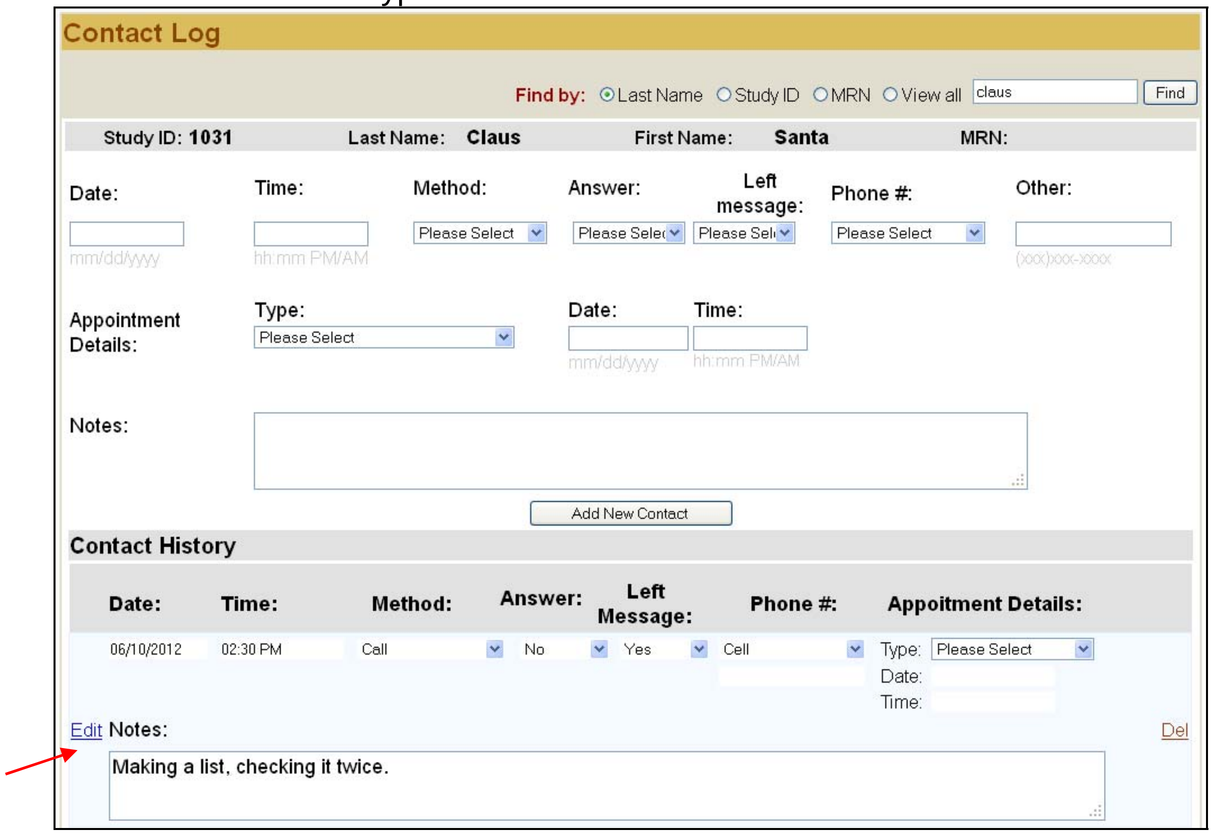
Notes:

[Add New Contact]

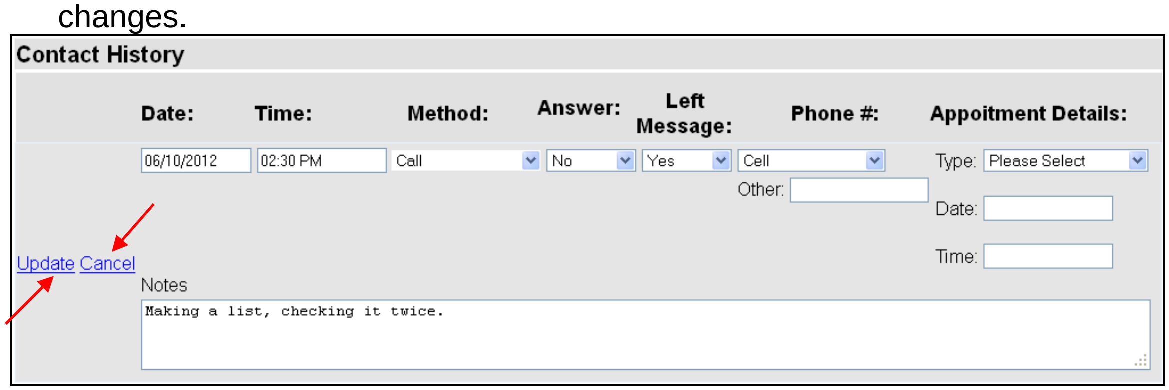
3. Click "Add New Contact" to save the contact.

To Edit a Previous Contact

1. Click on the "Edit" hyperlink for the contact to be edited.

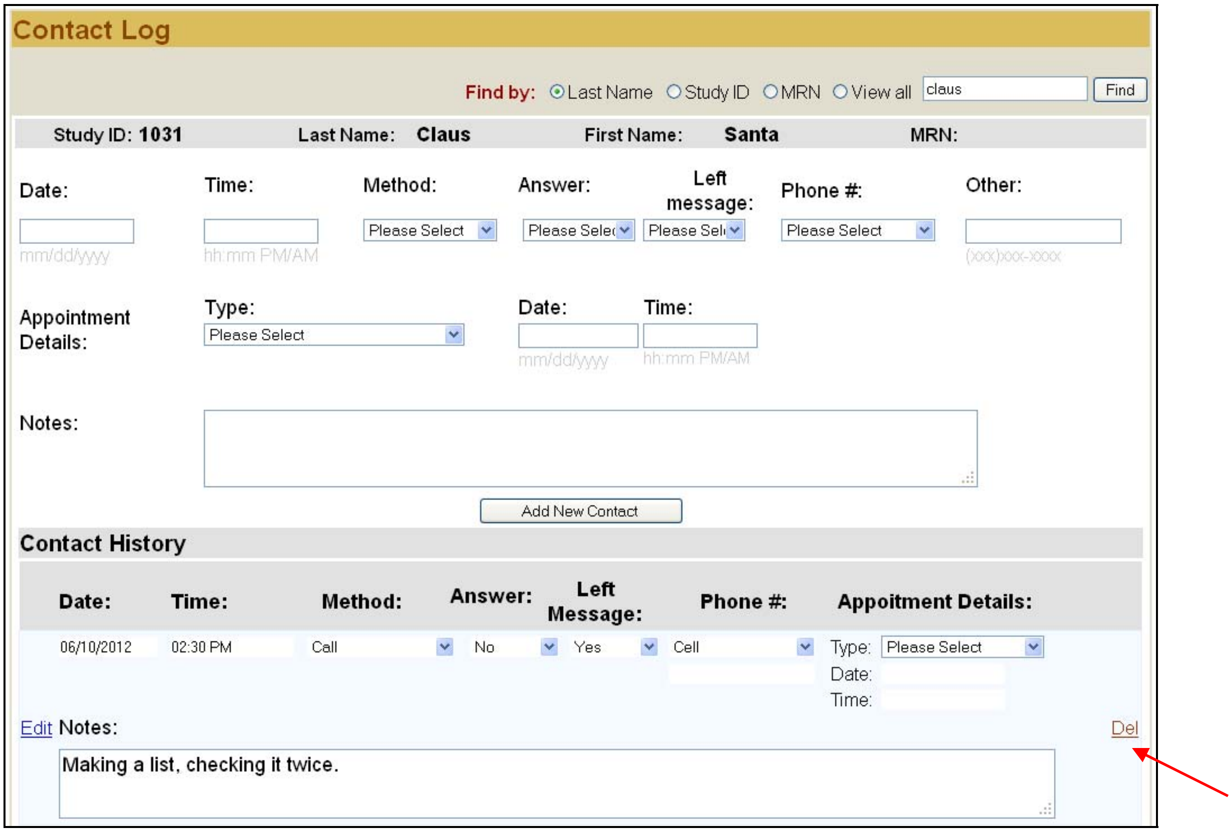


2. Edit the contact.
3. Click on "Update" to save the changes, or "Cancel" to not save any changes.



To Delete a Previous Contact

1. Click on the "Del" hyperlink for the appropriate contact.


Contact Log
Find by: Last Name Study ID MRN View all claus Find
Study ID: 1031 Last Name: Claus First Name: Santa MRN:
Date: Time: Method: Answer: Left message: Phone #: Other:
Please Select
mm/dd/yyyy hh:mm PM/AM (xxx)xxx-xxxx
Appointment Details: Type: Date: Time:
Notes:
Add New Contact
Contact History
Date: Time: Method: Answer: Left Message: Phone #: Appoitment Details:
06/10/2012 02:30 PM Call No Yes Cell
Type: Please Select
Date:
Time:
Edit Notes:
Del
Making a list, checking it twice.

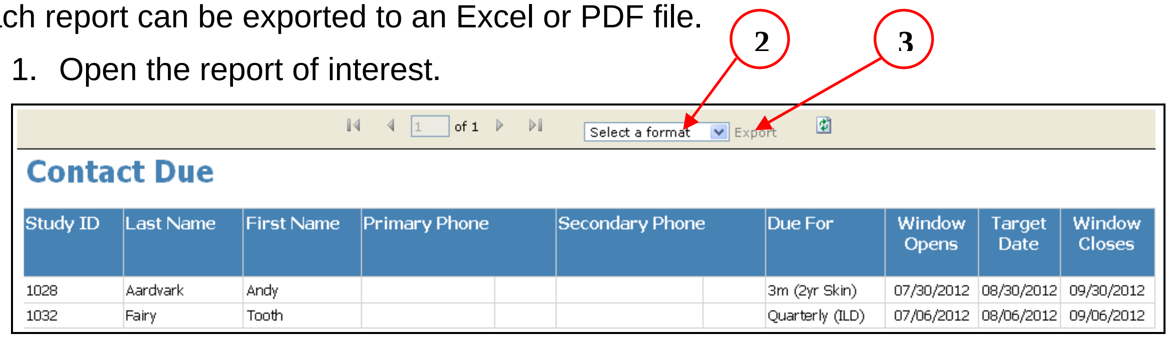
Reports

There are currently three reports to help study staff with scheduling and participant tracking: Contact Due, Weekly Scheduling, and Study Status. Note that the Clinical Summary Report is accessed from the Visits page, as it is specific to a single participant; these reports summarize information for all the participants at one site.

How to Export a Report to Excel or PDF

Each report can be exported to an Excel or PDF file.

1. Open the report of interest.

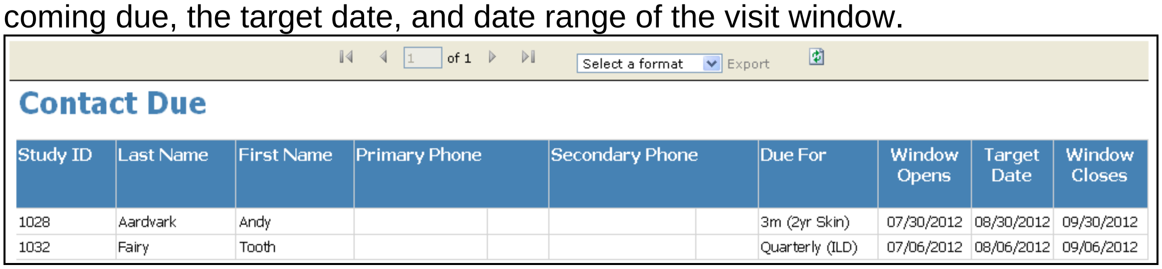


Study ID	Last Name	First Name	Primary Phone	Secondary Phone	Due For	Window Opens	Target Date	Window Closes
1028	Aardvark	Andy			3m (2yr Skin)	07/30/2012	08/30/2012	09/30/2012
1032	Fairy	Tooth			Quarterly (ILD)	07/06/2012	08/06/2012	09/06/2012

2. Select an export format (Excel file or PDF) from the dropdown menu.
3. Click on the “Export” hyperlink.
4. Save the file.

Contact Due

The Contact Due report displays a list of participants who are due to be scheduled for a follow-up visit. The report includes some participant contact information as well as information on which is the next follow-up visit that is coming due, the target date, and date range of the visit window.



Study ID	Last Name	First Name	Primary Phone	Secondary Phone	Due For	Window Opens	Target Date	Window Closes
1028	Aardvark	Andy			3m (2yr Skin)	07/30/2012	08/30/2012	09/30/2012
1032	Fairy	Tooth			Quarterly (ILD)	07/06/2012	08/06/2012	09/06/2012

Weekly Scheduling

The Weekly Scheduling report displays a list of upcoming scheduled visits. The report defaults to a date range from the system date to a week from the system date, but this can be changed.

Start Date: 08/30/2012 End Date: 09/07/2012

After entering new dates click on the refresh button below to requery.

1 of 1 Select a format Export

Weekly Scheduling

Study ID	Last Name	First Name	Schedule For	Date	Time
1001	DCC	Dcctest	Quarterly (ILD)	09/02/2012	02:00 PM

To change the date range, simply type in the new start date and end date, and click on the Refresh icon.

Study Status

The Study Status report displays the status of both active and terminated participants.

Study status

Study Status:	Active							
	Study ID	Last Name	First Name	Baseline	Study Status	Study Participation	Termination Reason	Details
	1000	TEST	Test	05/31/2012	Active	P50		
	1001	DCC	Dcctest	05/30/2012	Active	P50		
	1026	Aardvark	Aaron		Active	P50		
	1028	Aardvark	Andy	05/30/2012	Active	P50		
	1031	Claus	Santa	05/30/2012	Active	P50		
	1032	Fairy	Tooth	05/06/2012	Active	P50		
Study Status:	**Terminated**							
	Study ID	Last Name	First Name	Baseline	Study Status	Study Participation	Termination Reason	Details
	1027		New Subject		Terminated	P50	Withdrew	Pt no longer wanted to travel to clinic, refused further participation in study.

VI. Document and Data Downloads

Study Documents

The Study Documents link opens a folder that contains general study documents such as user manuals. These are not site-specific. These documents may be downloaded by right clicking on the filename of interest, selecting “Save As”, and entering the file location of your choice. Note that the files available through this link on the website will always be the most up-to-date versions.

Download Data

This link is restricted and only users who have permission to view and download the data in this folder will see the link on the Main page. This folder includes site-specific data dumps and possibly other site-specific summaries as requested by site PIs. These data may be downloaded by right clicking on the filename of interest, selecting “Save As”, and entering the file location of your choice.