



Jackson Heart Study Visit 4

Manual 11

Data Management System

Version 1

October 21, 2020

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## 1 Introduction

The Jackson Heart Study (JHS) Data Management System (DMS) for Visit 4 data collection was developed using REDCap (Research Electronic Data Capture). REDCap is a secure web application for building and managing online surveys and databases. The REDCap server hosting data for JHS Visit 4 is maintained by the JHS Coordinating Center at the University of Mississippi Medical Center. The JHS REDCap database can be accessed at the following URL: <http://jhsredcap.umsmed.edu/>. Access to the REDCap database is controlled via individual user accounts. This manual describes information pertaining to data entry and data management tasks of the JHS DMS.

## 2 Data Entry Guide

### 2.1 Log into REDCap

Open a web browser and enter the following URL in the address line: <http://jhsredcap.umsmed.edu/>. Enter your UMMC username and password to log into the REDCap (*Exhibit 1*). After you have logged into the REDCap the first time, the REDCap Administrator will then assign permissions to the JHS projects that you are authorized to access.

#### Exhibit 1

The screenshot shows a web browser window with the URL <http://jhsredcap.umsmed.edu/index.php?action=myprojects>. The page displays the REDCap logo and a "Log In" section. Below the logo, the text reads "Please log in with your user name and password. If you are having trouble logging in, please contact [REDCap Administrator](#)." The login form includes a "Username:" field, a "Password:" field, and a "Log In" button. At the bottom of the page, there is a "Welcome to REDCap!" message and a "REDCap Feature" box with the text "Build online surveys and databa and securely - Create and design; rapidly using secure web authentic".

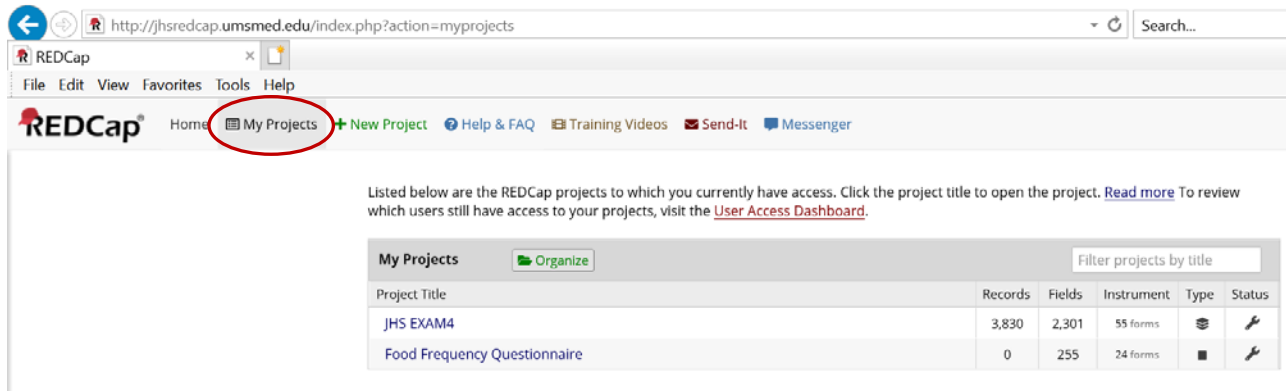
### 2.2 Access JHS Projects

To access JHS projects, click on the My Projects tab at the top of the screen to see a list of projects that you are authorized to access. Then, click on the link to the project for which you will be entering the data.

There are two main JHS projects: "JHS VISIT 4" and "Food Frequency Questionnaire" (*Exhibit 2*). The project "JHS VISIT 4" contains all JHS VISIT 4 data collection forms, except for the food frequency questionnaire, which is a separate project. Additional projects for ancillary studies are added as they become activated.

Note: you will see only the projects for which you have authorization.

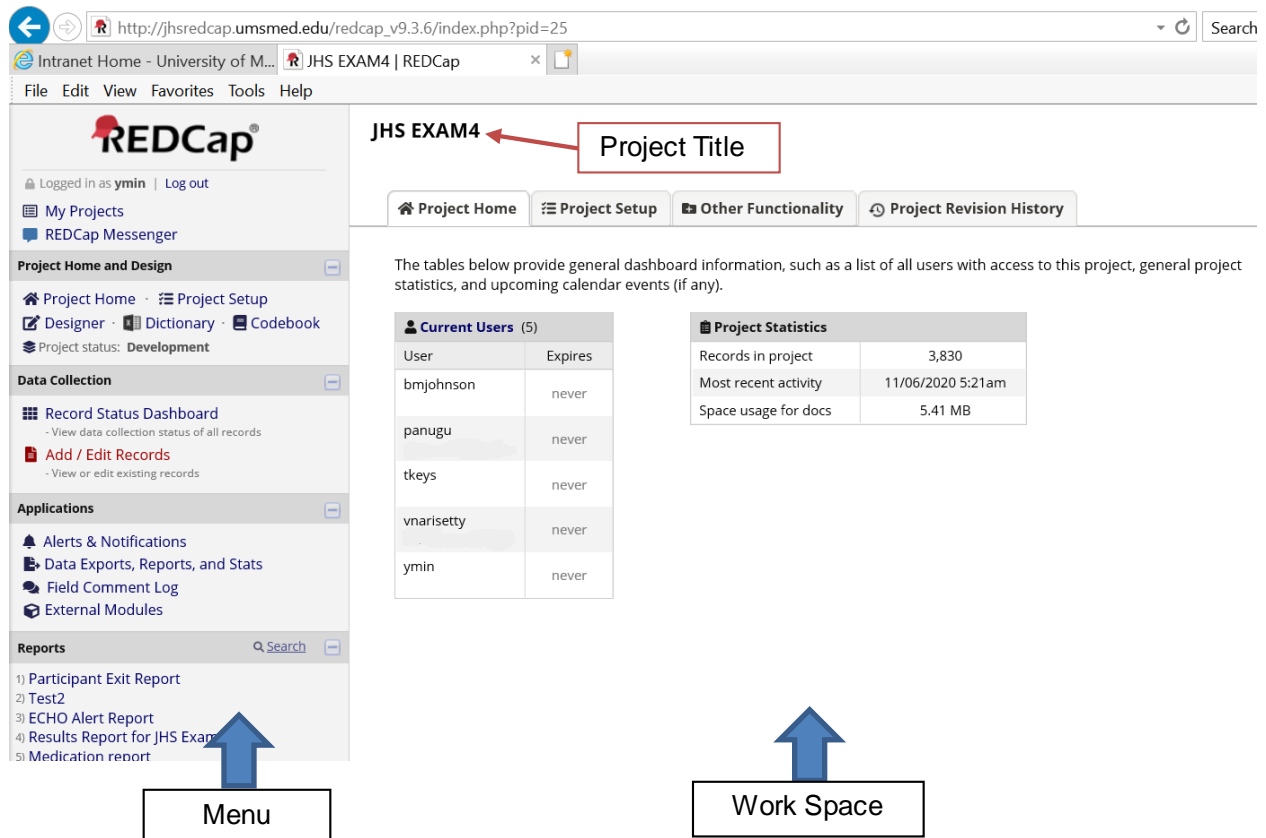
Exhibit 2



### 2.3 Data Entry

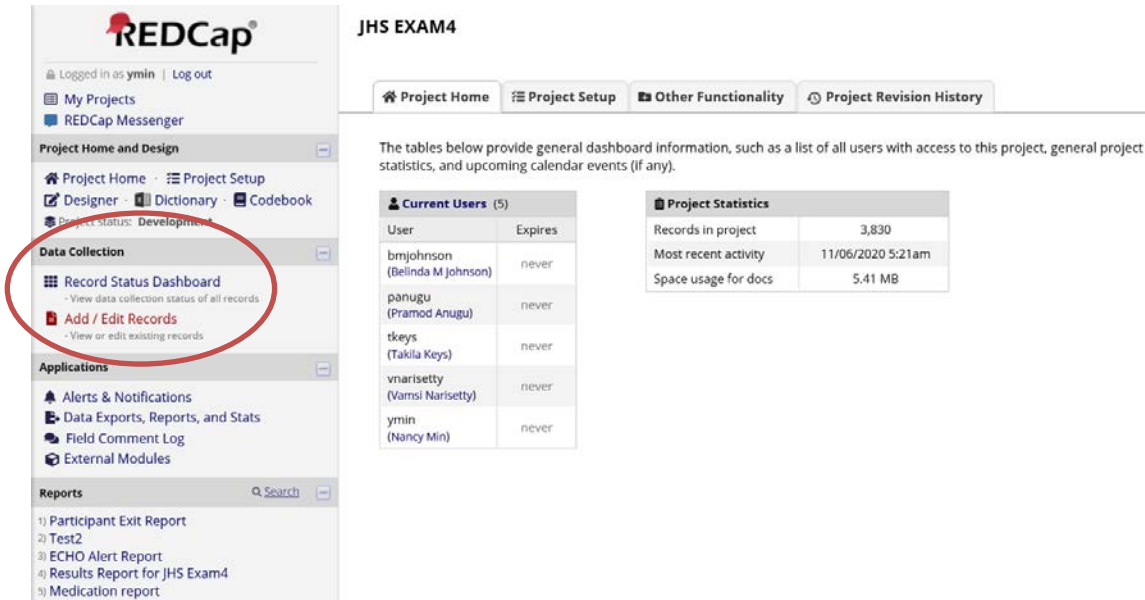
All REDCap projects have the general layout as shown in *Exhibit 3*. On the left is the menu and on the right is the workspace. The project title appears at the top.

Exhibit 3



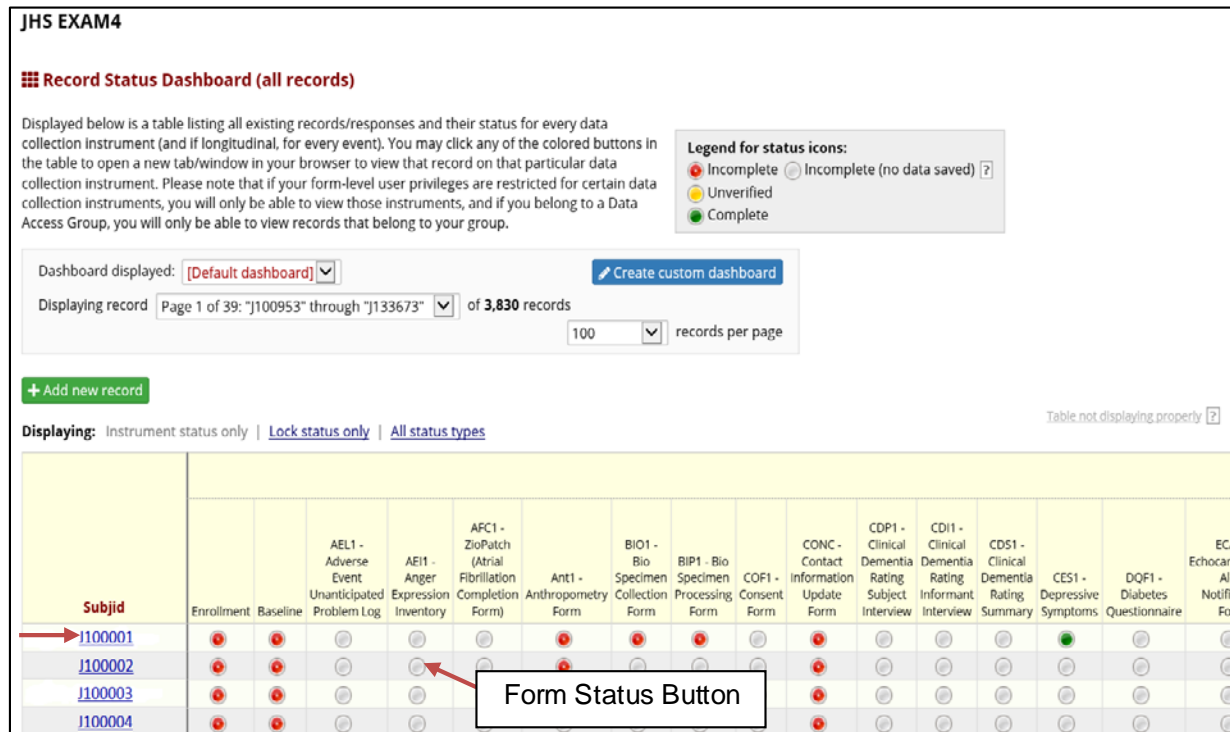
The main area used for data entry is the menu's Data Collection section: Record Status Dashboard and Add /Edit Records (*Exhibit 4*).

*Exhibit 4*



The **Record Status Dashboard** displays the records that have already been created (*Exhibit 5*). Each record or row on the Dashboard corresponds to a different participant in the study. The “Subjid” is a unique ID assigned to each participant in the JHS. This Dashboard page is used to open existing records, by clicking the “Subjid” or the colored Form Status buttons.

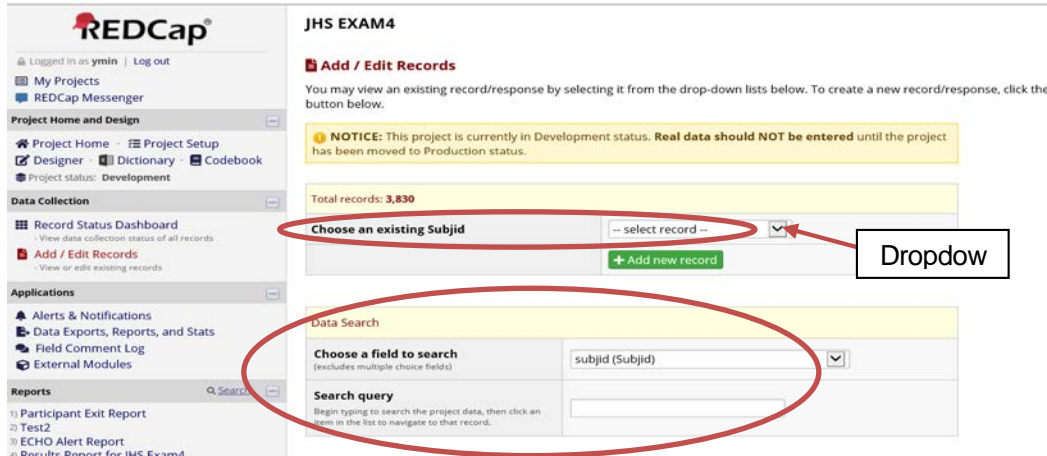
*Exhibit 5*



Records may also be opened by clicking “Add / Edit Records”. Either select records from the dropdown menu or use the search box to find a Subjid (*Exhibit 6*).

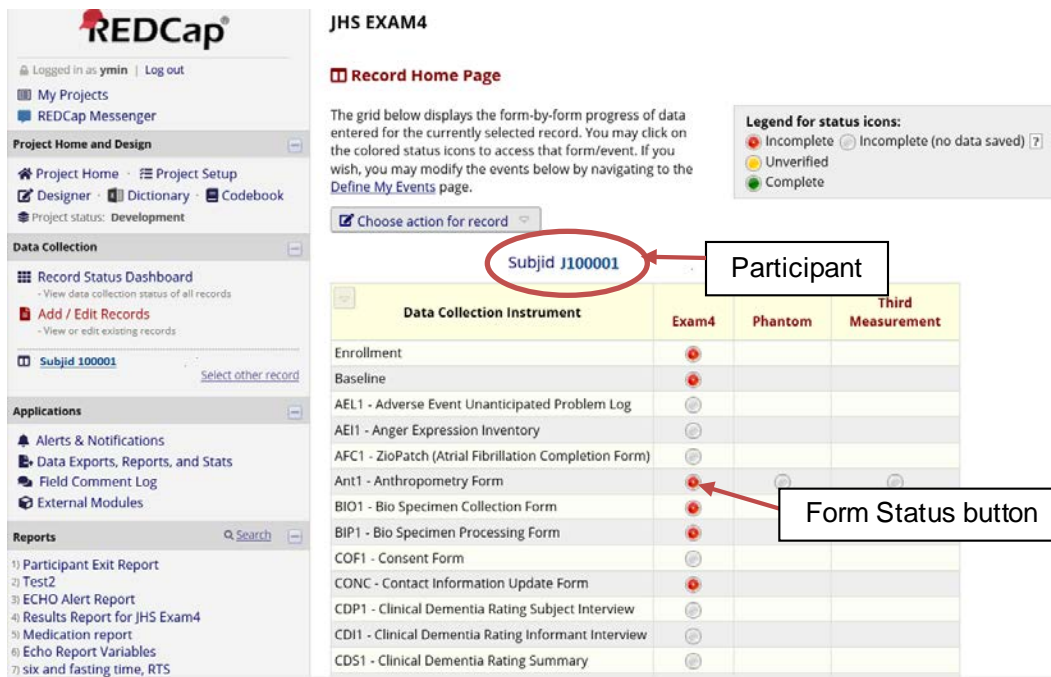
Note: all JHS participant ID’s have been pre-populated in the DMS. Do not create any new record.

*Exhibit 6*



An example of the **Record Home Page** for a selected Subjid is shown in *Exhibit 7*. Participant ID (Subjid) is located at the top of the screen once a participant is selected. The table below the Participant ID displays the form-by-form progress of data entered for the selected participant. Click on the Form Status button next to each form to access individual forms.

*Exhibit 7*



Click on the Form Status button for the Anthropometry Form to retrieve it for data entry (*Exhibit 8*).

Use the [Tab] key or mouse clicks to navigate between fields on a form. If you press [Enter], you will save the form, and exit the current screen.

### Required Field

All fields labeled as **'\* must provide a value'** must be completed in order to save a form. If an item is unknown or missing, use the dropdown menu to select or enter designated values for 'Don't know', 'Missing' or 'Refused' as appropriate. Do not leave any item blank (empty).

### Exhibit 8

**REDCap**

Logged in as ymin | Log out

My Projects  
REDCap Messenger

**Project Home and Design**

Project Home · Project Setup  
Designer · Dictionary · Codebook  
Project status: Development

**Data Collection**

Record Status Dashboard  
- View data collection status of all records

Add / Edit Records  
- View or edit existing records

Subjid 100001  
Select other record

Event: Exam4  
Data Collection Instruments:

- Enrollment
- Baseline
- AEL1 - Adverse Event Unanticipated Problem Log
- AEI1 - Anger Expression Inventory
- AFC1 - ZioPatch (Atrial Fibrillation Completion Form)
- Ant1 - Anthropometry Form**
- BIO1 - Bio Specimen Collection Form
- BIP1 - Bio Specimen Processing Form
- COF1 - Consent Form

**JHS EXAM4**

Actions: Modify instrument Download PDF of instrument(s) VIDEO: Basic data entry

**Ant1 - Anthropometry Form**

Editing existing Subjid J100001

Event Name: Exam4

Subjid J100953

**Administrative Information**

00. Form Start Time: 13:32 H:M  
\* must provide value

0a. Completion Date: 05-22-2020 Today M-D-Y  
\* must provide value

0b. Staff ID: 107  
\* must provide value

**Instructions: In order to measure bioimpedance, the participant must be barefoot. Set the Tanita analyzer to report metric units (cm/kg).**

**A.DETERMINATION OF ABILITY TO STAND**

1. Assessment of ability to stand  
\* must provide value

Can stand erectly on both feet  
 Can stand on both feet, but posture not erect  
 Cannot stand on both feet

**B. SELF REPORT**

2a. Self-reported weight (to the nearest pound) 120.0

### Validation

**Formatting** Some text fields require a specific type of formatting. This is called validation. Validation is a way to ensure that data are saved in a consistent format. REDCap will automatically re-format certain data. If a wrong format was entered, REDCap will display an alert.

**Range Checks** Some numeric fields have range validation. If anything entered was outside of the expected range, REDCap will display an alert (*Exhibit 9*).

Note: Whenever there is a range validation, values outside the expected minimum and maximum can be saved. This value is displayed in bold and highlighted in red to illustrate that it falls outside the expected range, which was pre-defined for the field.

### Exhibit 9

Event Name: **Exam4**

Subjid J100953

**Administrative Information**

00. Form Start Time:  H:M  
\* must provide value

0a. Completion Date:  Today M-D-Y  
\* must provide value

0b. Staff ID:  
\* must provide value

**Instructions:** In order to report metric units (cm/kg).

**A.DETERMINATION OF**

1. Assessment of ability to stand  
\* must provide value

Can stand on both feet, but posture not erect  
 Cannot stand on both feet

reset

**Alert**

The value you provided is outside the suggested range. (50.0 - 400.0). This value is admissible, but you may wish to double check it.

Close

### Calculated Fields

The calculated fields complete automatically when you have entered the other data used in their pre-defined equation. These fields look like text boxes, but they have red font that cannot be changed.

### Multiple Choice

Multiple choice fields are commonly used on data collection instruments. Depending on how the project was created, you might be able to type a word or phrase into the field to select your answer from a long list. You might also have checkboxes, where more than one answer can be selected.

### Branching Logic

Branching logic or skip logic hides or reveals questions based on how other questions are answered. Follow the built-in prompts and read through the instrument's instructions to complete the form.

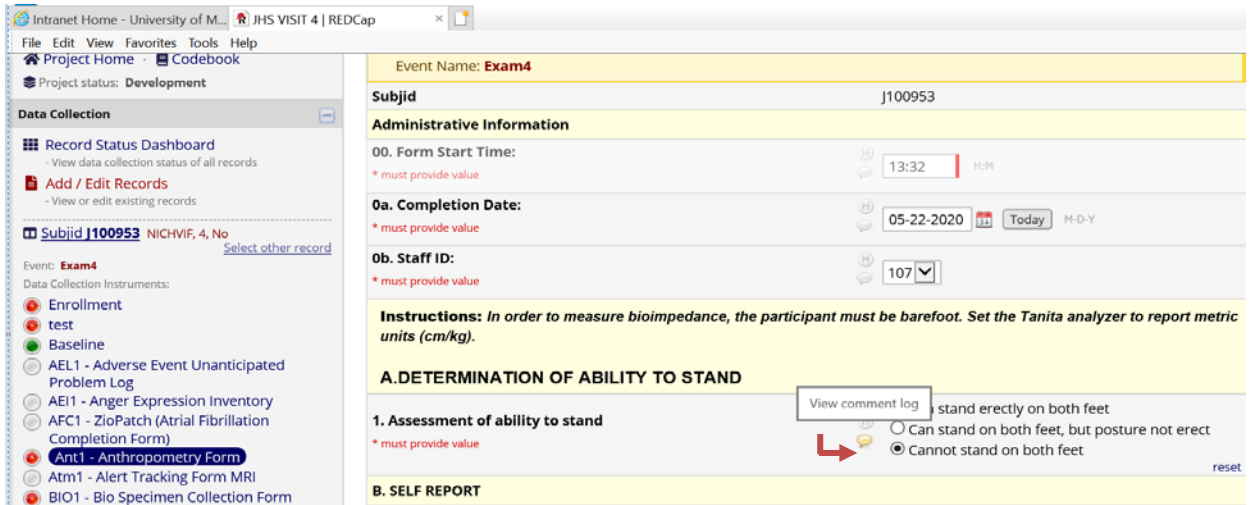
Note: Changing the answer to a question that determines the branching logic may affect answers to subsequent questions. In this case, REDCap displays a warning asking whether to erase all answers to other questions, which have already been answered previously. It is crucial to read through all such warnings and understand them fully before proceeding. If you are not sure what to do, choose to leave the field and data alone, and contact your supervisor for guidance.

### Comment Log

The Field Comment Log is used to enter comments or caveats concerning specific fields (*Exhibit 10*). To create your comment, click the speech bubble next to the field in the record you are working on. Enter your comment and click "Save." You will notice that the speech bubble icon is now lit, indicating that a comment exists for that field.



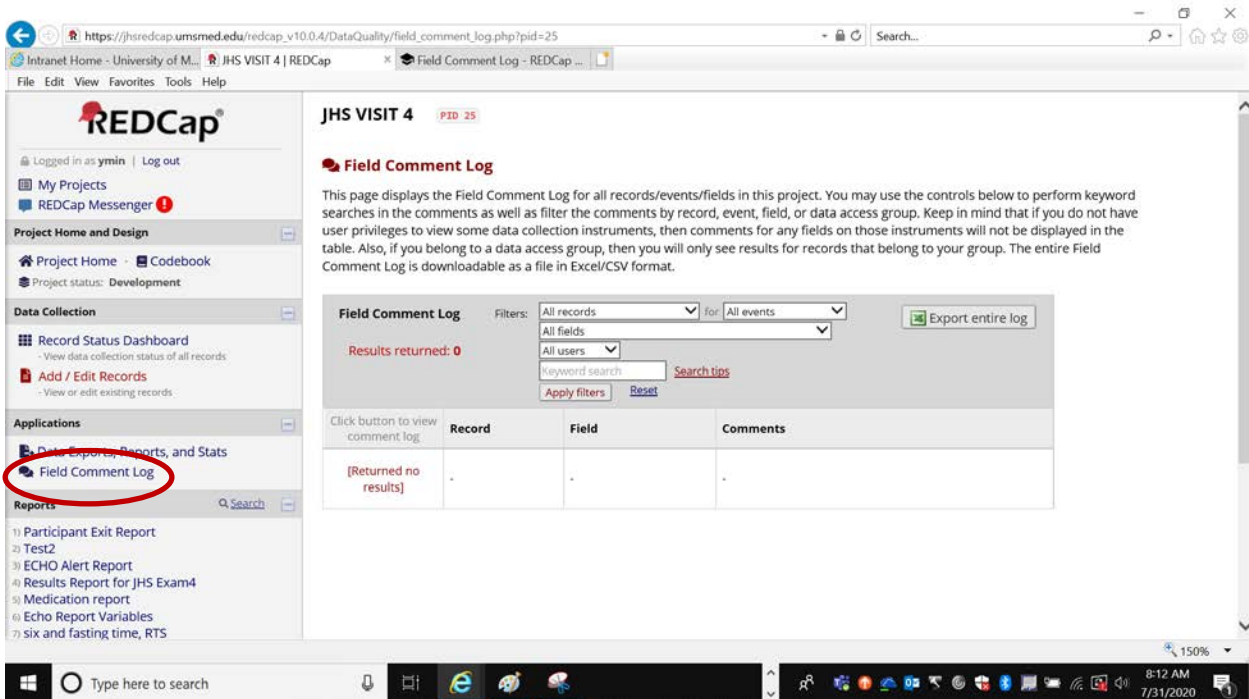
Exhibit 10



To view the collective comments for all records, click the Field Comment Log module in the left-side toolbar (*Exhibit 11*). Comments are linked to their corresponding records, along with the user who made the comment, and the date/time at which the comment was made.

**Note:** If there are any comments for the entire visit, that information can be entered in the Comments form.

Exhibit 11



## 2.4 Form Status

After completing all items on a form, change the form status to complete, before saving the form. If you were not able to complete all items on a form due to participant refusal, rescheduled visit or other reasons, leave the form status as incomplete. Change the form status to unverified if a form is completed but awaiting review (*Exhibit 12*).

*Exhibit 12*

The screenshot shows a portion of a REDCap form. At the top, there is a radio button for 'Cannot stand on both feet' and a 'reset' link. Below this is a section titled 'B. SELF REPORT' with a yellow background. It contains three items: '2a. Self-reported weight (to the nearest pound)' with a text input containing '120.0' and a unit dropdown set to 'lbs (1 decimal places)'; '2b1. Self-reported height (feet and inches)' with a unit dropdown set to 'Feet'; and '2b2. Inches' with a unit dropdown set to 'Inches'. Below this is a section titled 'WEIGHT' with a yellow background, containing '2c. Weight using wheelchair scale' with a text input and a unit dropdown set to 'lbs (1 decimal places)'. The next section is 'D. MEASURED HEIGHT, WEIGHT, and BIOIMPEDANCE (Tanita Scale)' with a yellow background, containing 'Form Completion Time:' with a time input and a 'Now' button. The final section is 'Form Status' with a green background, containing a 'Complete?' label and a dropdown menu. The dropdown menu is open, showing the following options: 'Incomplete', 'Unverified', 'Complete', and 'Save & exit form'. A red arrow points from the 'Form Status' label to the 'Incomplete' option in the dropdown. Below the dropdown are 'Save & ...' and '-- Cancel --' buttons.

## 2.5 Saving Data and Exiting a Form

If you navigate off the form without pressing [Enter] or clicking on one of the five save options (*Exhibit 13*), your work will be lost.

Note: There is no auto-save in REDCap. So save early in the process and save often.

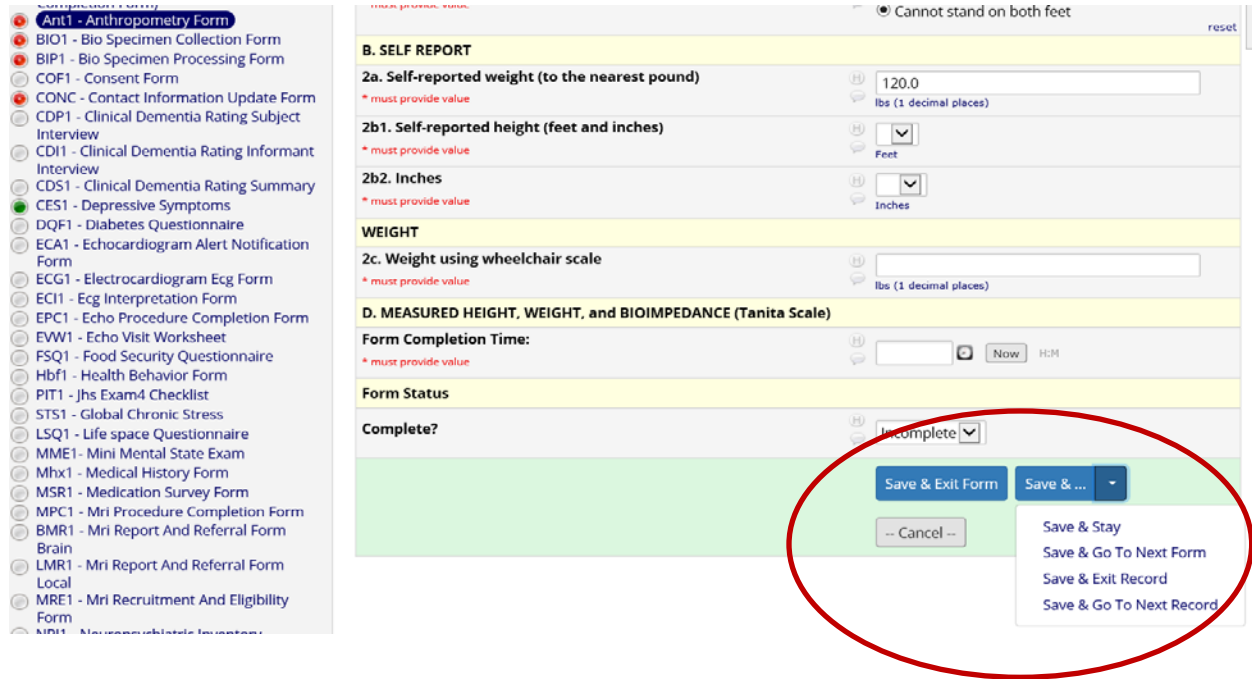
Save options:

1. Save & Stay – save the form and remains on the same form
2. Save & Go To Next Form – save the form and go to the next form on the list
3. Save & Exit Form – save the form and return to the record home page of the same participant
4. Save & Go To Next Record – save the form and go to the record home page of the next participant
5. Save & Exit Record – save the form and return to the record selection page

Cancel option:

Return to the record home page without saving the changes made.

Exhibit 13



2.6 Logging

All data modifications made to the databases are logged. To view the data history, click on the **H** (History) button located next to each data field (Exhibit 14). An example of the data history is shown in Exhibit 15.

Exhibit 14

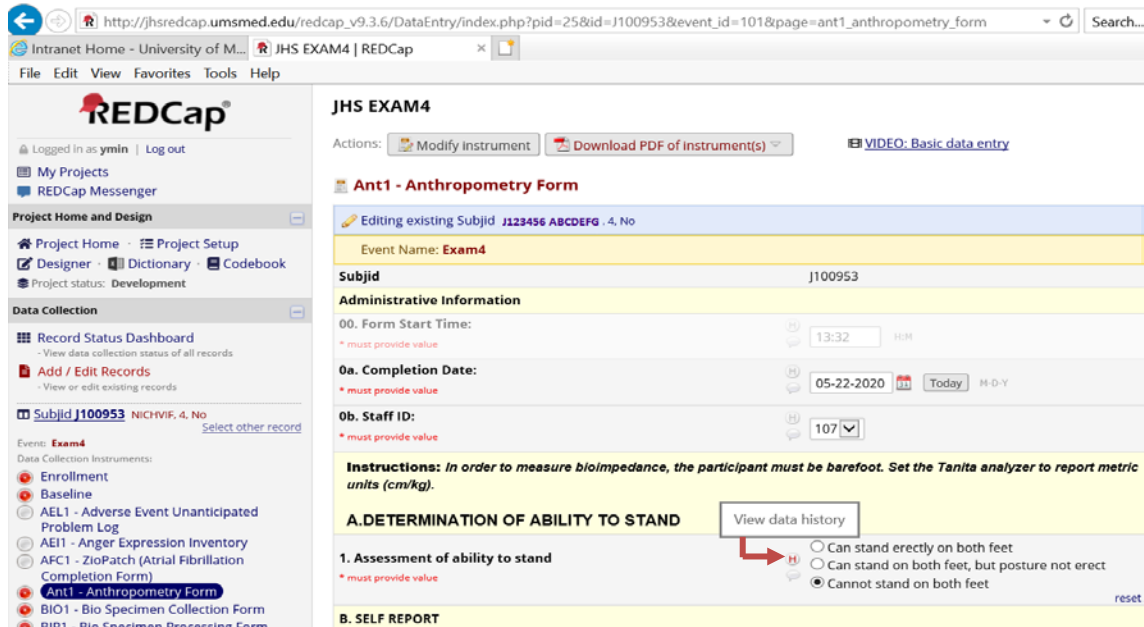


Exhibit 15

**Data History for variable "ant101" for record "J123456"**

Listed below is the history of all data entered for the variable "ant101" for Subjid "J123456". The data history results are sorted from earliest to most recent.

Date/Time of Change	User	Data Changes Made
16/03/2020 15:27:45	panugu	Can stand erectly on both feet (1)
08/04/2020 09:11:09	vnarisetty	
22/05/2020 13:33:31 (most recent data change)	ymin	Cannot stand on both feet (3)

## 2.7 Quality Control Samples

For quality control purposes, a random sample of participants is selected to have anthropometry performed twice by two different technicians. A second Anthropometry Form ("QC") is completed if a participant is selected as a quality control sample. Whether or not a participant is a quality control sample is indicated at the end of the Subjid string (Yes/No) (*Exhibit 16*).

Note: A third Anthropometry Form is completed only if the differences between the first two measures were larger than the pre-specified amounts.

Exhibit 16

**REDCap**  
 Logged in as ymin | Log out  
 My Projects  
 REDCap Messenger  
 Project Home and Design  
 Project Home · Project Setup  
 Designer · Dictionary · Codebook  
 Project status: Development  
 Data Collection  
 Record Status Dashboard  
 Add / Edit Records  
 Subjid J100001 ABCDEFG, 4, Yes  
 Applications  
 Alerts & Notifications  
 Data Exports, Reports, and Stats  
 Field Comment Log  
 External Modules  
 Reports  
 Participant Exit Report  
 Test2

**JHS EXAM4**  
 Record Home Page  
 The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the Define My Events page.  
 Choose action for record

**Legend for status icons:**  
 Incomplete (red circle with white center)  
 Incomplete (no data saved) (grey circle with white center)  
 Unverified (yellow circle with white center)  
 Complete (green circle with white center)

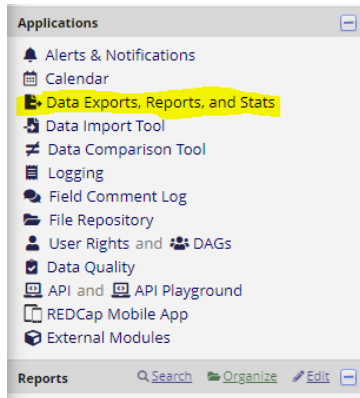
Subjid **J100001 ABCDEFG, 4, Yes** ← Participant selected

Data Collection Instrument	Exam4	Phantom	Third Measurement
Enrollment	Incomplete		
Baseline	Incomplete		
AEL1 - Adverse Event Unanticipated Problem Log	Incomplete		
AEI1 - Anger Expression Inventory	Incomplete		
AFC1 - ZioPatch (Atrial Fibrillation Completion Form)	Incomplete		
<b>Ant1 - Anthropometry Form</b>	Incomplete	Incomplete	Incomplete
BIO1 - Bio Specimen Collection Form	Incomplete		
BIP1 - Bio Specimen Processing Form	Incomplete		
COF1 - Consent Form	Incomplete		
CONC - Contact Information Update Form	Incomplete		

### 3 Data Management

#### 3.1 Export Data from REDCap

1. Click on the “Data Exports, Reports, and the Stats” Tab in the application section.



2. Click on Export Data and select option SAS Statistical Software.

My Reports & Exports				
	Report name	View/Export Options	Management Options	Report ID <small>(auto-generated)</small>
A	All data (all records and fields)	<a href="#">View Report</a> <a href="#">Export Data</a> <a href="#">Stats &amp; Charts</a>		

**Exporting "All data (all records and fields)"**

Select your export settings, which includes the export format (Excel/CSV, SAS, SPSS, R, Stata) and if you wish to perform de-identification on the data set.

**Choose export format**

- CSV / Microsoft Excel (raw data)
- CSV / Microsoft Excel (labels)
- SPSS Statistical Software
- SAS Statistical Software
- R Statistical Software
- Stata Statistical Software
- CDISC ODM (XML)

**De-identification options (optional)**

The options below allow you to limit the amount of sensitive information that you are exporting out of the project. Check all that apply.

**Known Identifiers:**

- Remove all tagged Identifier fields (tagged in Data Dictionary)
- Hash the Record ID field (converts record name to an unrecognizable value)

**Free-form text:**

- Remove unvalidated Text fields (i.e. Text fields other than dates, numbers, etc.)
- Remove Notes/Essay box fields

**Date and datetime fields:**

- Remove all date and datetime fields
- OR
- Shift all dates by value between 0 and 364 days (shifted amount determined by algorithm for each record) [What is date shifting?](#)

[Deselect all options](#)

**Advanced data formatting options**

**Set CSV delimiter character**  
Set the delimiter used to separate values in the CSV data file (only valid for CSV Raw Data and CSV Labels export formats):

**Force all numbers into a specified decimal format?**  
You may choose to force all data values containing a decimal to have a specified decimal character (comma or period/full stop). This will be applied to all calculations and number-validated text values in the export file.

NOTE: Your data formatting selections above will be remembered in the future and will be pre-selected upon your next export.


3. When exporting data to SAS, REDCap will generate 3 files: Pathway Mapper file (.bat), SAS program file and data file. Download and save all 3 files to the folder \StudyData\Visit4\Redcap\JHS SAS V4\1-Data\Raw data. There should not be other program or data files from previous export in this folder.
4. First, double click on the pathway mapper file, which will run quickly and invisibly. This step will add codes to the SAS program file about the location of the data file.
5. Then, open the SAS program file and run the codes to import the data to SAS. The SAS program will automatically read in all data and add variable labels and formats. This step creates a temporary dataset ("REDCAP") in the work library.

✔ Data export was successful!
✕

The data export was successful, and your data is now ready to be downloaded. Click the download icon(s) below on the right to download your data file. If exporting to a specific statistical analysis package, you will additionally need to download the syntax file that is provided for that stats package. For more details, follow the instructions in the box below.

**Citation Notice**


Please **cite the REDCap project when publishing manuscripts** (citation information and template methods language are [available here](#)).

 **SAS Statistical Software**

Download and save all 3 files on the right to a common location. First, double-click on the Pathway Mapper (.bat) file, which will run quickly and invisibly. (If you are not using a Windows operating system, such as Mac or Linux, please see the *Additional Instructions*.) Now double-click on the \*.sas file, which will open SAS. When the file is loaded and displayed, choose Run (or Run-->Submit) from the top menu options. This action will launch the script that will automatically read in all data and manipulate data fields with labels, option values, etc.

[Additional instructions](#)

Click icon(s) to download:



Send file?

Close

### 3.2 Create Visit 4 Raw Datasets and Analysis Datasets

1. Run the SAS program 'Raw data sets program' (\StudyData\Visit4\Redcap\JHS SAS V4\2-programs) to create raw datasets for each data collection form that includes identifiers, open ended responses in \StudyData\Visit4\Redcap\JHS SAS V4\1- Data\Raw data folder.
2. Run the SAS program 'Analysis program' (\StudyData\Visit4\Redcap\JHS SAS V4\2-program"). This program drops all the identifiers from the raw dataset and creates all the individual analysis datasets in \StudyData\Visit4\Redcap\JHS SAS V4\1- Data\Analysis data folder.