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RePORT International Long TB – User Guide to Frontier Science Utilities

REPORT LONG TB REFGD001

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Contents

About **3**

Registering for Access to Frontier Science Utilities **3**

About the File Exchange Utility (FEU) **4**

About the Data Submission System (DSS) **4**

About REDCap **5**

REDCap Training Acknowledgement **5**

Initial REDCap Access **5**

RePORT International Long TB Project Access **7**

Logging In **8**

Accessing a REDCap Project **8**

Data Collection **9**

Record Status Dashboard 9

View/Edit Records vs. Add/Edit Records 13

Form Status 16

Save Options 16

Repeating Forms 17

Log Forms 17

Obtaining Blank CRFs for Data Collection 18

Resolving Issues/Queries 18

Resolution Metrics 22

REDCap Video Tutorials **23**

Collecting Data Using the REDCap App **23**

Configuring a Tablet for Use with the REDCap App 24

Collecting Data Using the REDCap App 25

About

The RePORT International Long TB project will collect data in a variety of ways.

1. A central REDCap build hosted at Frontier Science. All sites must register for accounts to access this central REDCap build to log participant data.
2. The File Exchange Utility (FEU) hosted at Frontier Science. All sites must register for accounts to access this utility to upload de-identified DIACOM scan files.
3. The Data Submission System (DSS) hosted at Frontier Science. All sites must register for accounts to access this utility to upload information about specimen storage and availability.

This guide includes instructions for registering for accounts and for accessing and using these tools.

Registering for Access to Frontier Science Utilities

All users must first register for a Frontier Science portal account. Begin by navigating to www.frontierscience.org and clicking on the Portal link and then on the Register for a Portal account link.

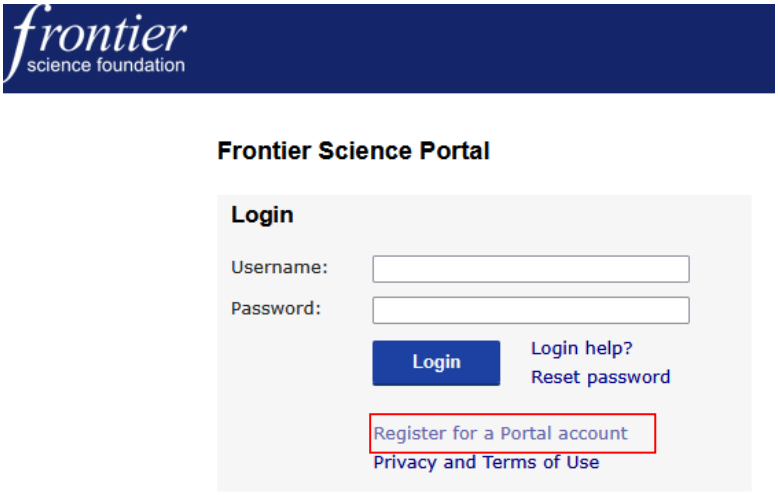

Figure 1: File Exchange Utility link

Complete the Frontier Science portal registration form, including setting your password, and click **Next>.**

On the following page request access for the RePORT project.

- **Site IDs have been assigned as follows. Please be sure to enter the 2-digit ID corresponding to your site:**
  - 12- Christian Medical College (CMC), Vellore
  - 13- Byramjee-Jeejeebhoy Government Medical College (BJGMC), Pune
  - 14- Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Pondicherry
  - 15- University of Cape Town (UCT)
  - 16- Stellenbosch University, Cape Town
  - 17- University of the Philippines, Manila
  - 18- Makerere University, Kampala
- If you require access to the RePORT International central REDCap build for the Long TB project, select REDCap

access.

- If you also require access to the File Exchange Utility, which will be used to transfer the de-identified DIACOM files for CT, X-ray, and other scans, select File Exchange Utility access.

Once you have completed and submitted your registration, Frontier Science User Support will notify you of your account creation and User Name within 2 business days.

NOTE: Your Frontier Science portal account password will automatically be set to the password you chose during account registration.

About the File Exchange Utility (FEU)

The Frontier Science File Exchange Utility is a web based, secure file transfer tool. The RePORT International Long TB project will use this utility to transfer all scan files collected from participants.

NOTE: All scan files must be transferred in DIACOM format.

NOTE: All scan files must be de-identified before they are uploaded to the File Exchange Utility.

To access the File Exchange Utility, first log into the Frontier Science portal. From the TB RICC tab select the File Exchange Utility link found under the Utilities heading.

Figure 2: File Exchange Utility link

Complete the required information regarding the scan you will be uploading**,** including**:**

1. Participant ID – in LTB-01-001 format
2. Scan Type – Choose between MDCT, CXR, Echocardiogram, or Carotid Ultrasound
3. Study Visit – Choose between Baseline 0M, End of Treatment (EOT), 6 Month Post EOT (EOT +6M), Tx Failure/Relapse/Withdrawal.

Each participant scan must be uploaded individually. Do not bulk upload scans. It is recommended scans are de-identified and uploaded to the File Exchange Utility the same day the scan is completed.

About the Data Submission System (DSS)

The Frontier Science DSS is a web based, secure file transfer tool. The RePORT International Long TB project will use this utility to transfer information regarding the storage and availability of specimens.

Each site is responsible for tracking the ongoing storage and availability of specimens collected and processed for the Long TB study. Each site will use the specimen tracking system they are comfortable with, for example FreezerPro or LDMS. Sites must minimally track the storage location of each available specimen within their freezers along with the information needed to link the specimen to the participant it was collected from. This information must be transferred to the Long TB project team and must include key details about each specimen, like:

1. Participant ID in LTB-AAA-001 format
2. Storage location
3. Specimen type
4. Specimen volume

5. A unique identifier used to locate the specimen within the site's specimen tracking tool

Each site must provide line listings of this specimen information to the Long TB project team. These line listing specimen files are transferred using the Frontier Science DSS.

Access to the DSS is granted to individuals who have registered for and received a Frontier Science portal account. First log into the Frontier Science portal. From the TB RICC tab select the Data Submission System link found under the Lab Data Programs heading.

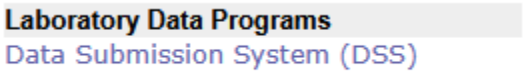

Figure 3: Data Submission System link

Select the TB RePORT project from the project drop down and complete the remaining information about your file upload. When prompted, browse for and select the specimen information data file you will be submitting regarding Long TB project specimen storage and availability at your site.

About REDCap

REDCap Academic (REDCap) is a user-friendly web-based data collection tool that you can access from any browser or through a Mobile App. Built-in prompts and help resources provide guidance at every step. This guide describes how to login to the central REDCap build at Frontier Science for the RePORT Long TB project and how to perform data entry.

REDCap Training Acknowledgement

All users must complete the REDCap Training Acknowledgement before Frontier Science User Support will grant them access to the central REDCap build at Frontier Science for the RePORT International Long TB project. Accessing the link to the REDCap Training Acknowledgement requires a Frontier Science portal account. Begin by signing into the Frontier Science portal and then locating and clicking the REDCap Training Acknowledgement link found on the TB RICC tab. You are then prompted to read and acknowledge the REDCap User Guide. After doing so, enter your Frontier Science portal username and password into the REDCap Academic Training Acknowledgment popup window. Following completion of this process, Frontier Science User Support will issue you an account to access the RePORT Long TB central REDCap.

NOTE: If you need assistance locating the REDCap Training Acknowledgement or have signed the REDCap Training Acknowledgment and received confirmation from User Support, but are experiencing difficulties logging in, contact Frontier Science User Support by email at user.support@frontierscience.org or by phone at (716) 834-0900, x7302. Use the **Forgot your password?** link if your access challenges are related to a forgotten password.

Initial REDCap Access

When your REDCap account is created you will receive an email prompting you to create a username and password.

NOTE: Your Frontier Science portal and REDCap accounts will be different accounts.

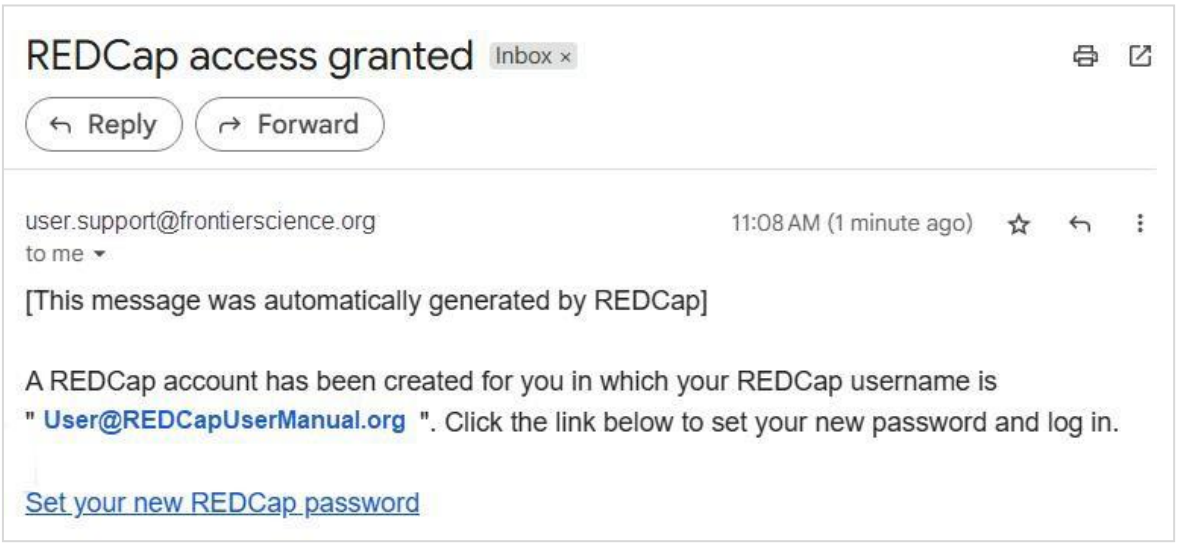

Figure 4: REDCap Access Granted Email

Click **Set your new REDCap password** and enter a password.

Figure 5: Set Your Password

After you create your username and password, you will be logged into REDCap. Click on the **My Projects** link.

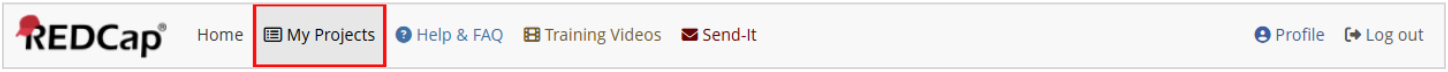

Figure 6: My Projects

If you see a message stating that you do not have access to any projects, it means you have not been invited to a project yet.

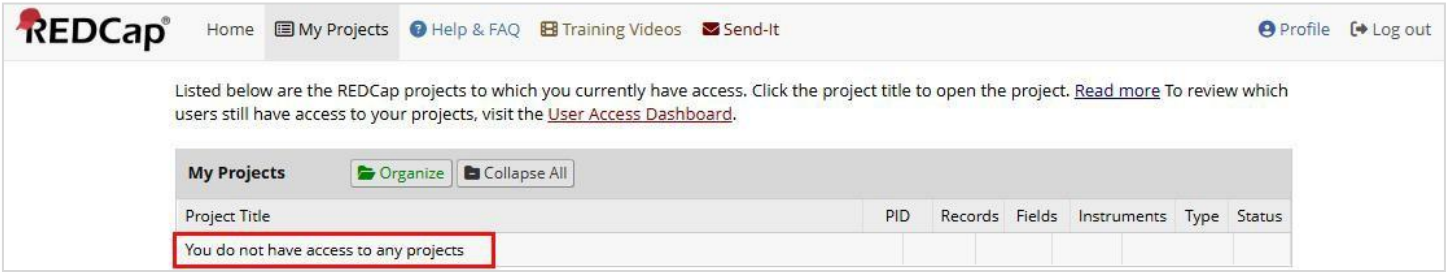

Figure 7: You do not have access to any projects

RePORT International Long TB Project Access

Check your inbox for an email with the subject line **REDCap project access granted**. This typically comes shortly after the REDCap account setup email. The link located at the bottom of the email will take you to the RePORT International Long TB project. Clicking the link will take you to REDCap. (**NOTE:** You may need to login again with your REDCap credentials.)

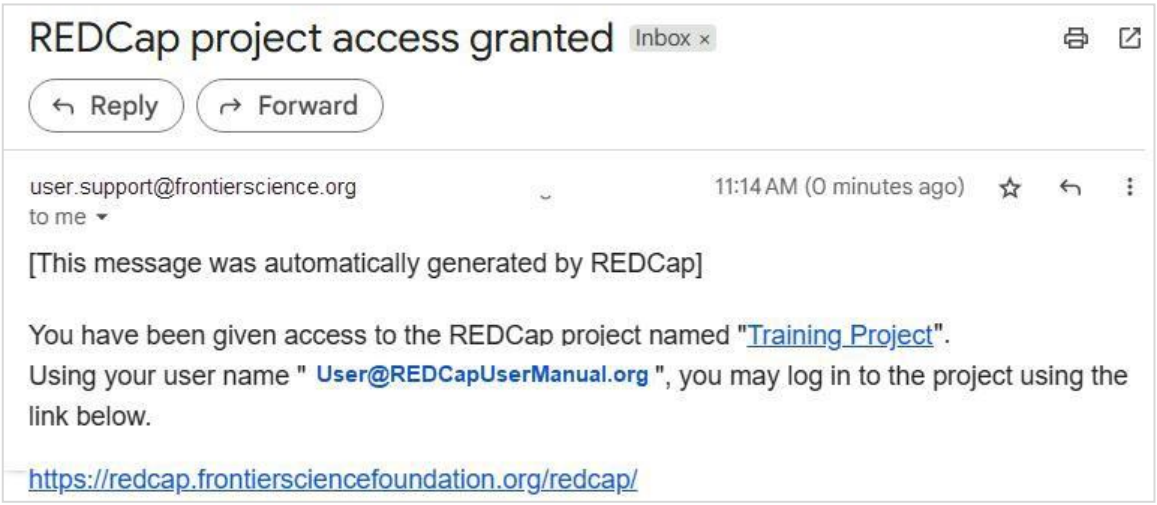

Figure 8: REDCap project access granted

You will then see that you have access to the RePORT International Long TB project when you click on **My Projects**. Click on the link to open the project.

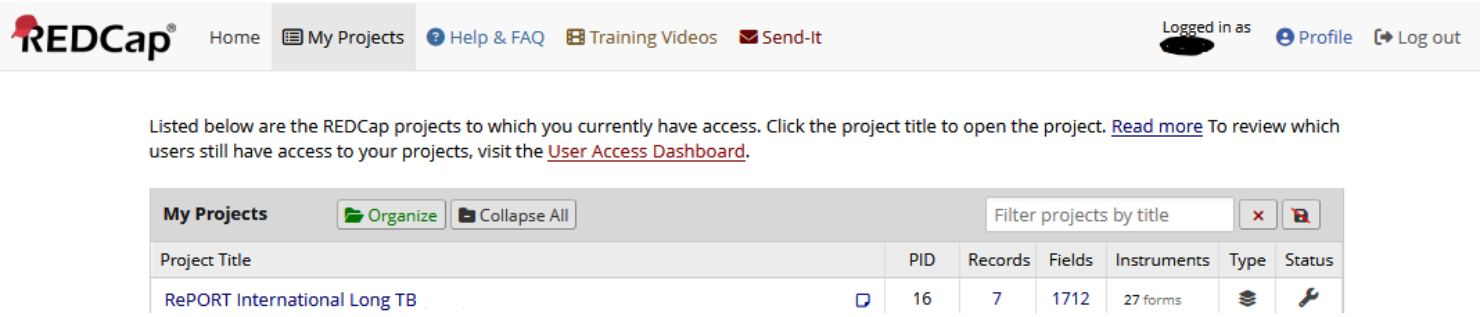

Figure 9: Project Access

Logging In

After your initial REDCap account and project login, moving forward you will access to REDCap by navigating to RePORTInternationalREDCap.org.

Login with your REDCap Username and Password. You will be automatically directed to the **Project Home** page.

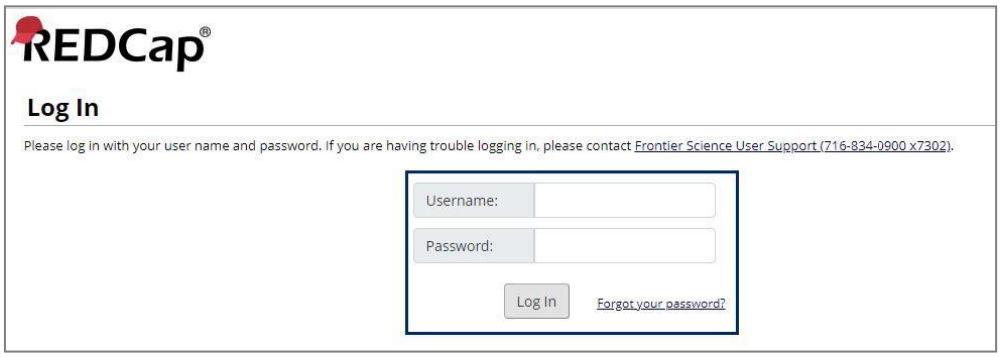

Figure 10: REDCap Academic Login Screen

Accessing a REDCap Project

The **My Projects** page displays a list of REDCap projects to which the user has access. Click the RePORT International Long TB project link to access the **Project Home**.

Figure 11: My Projects

All projects have the same general layout, consisting of the Menu on the left and the workspace on the right.

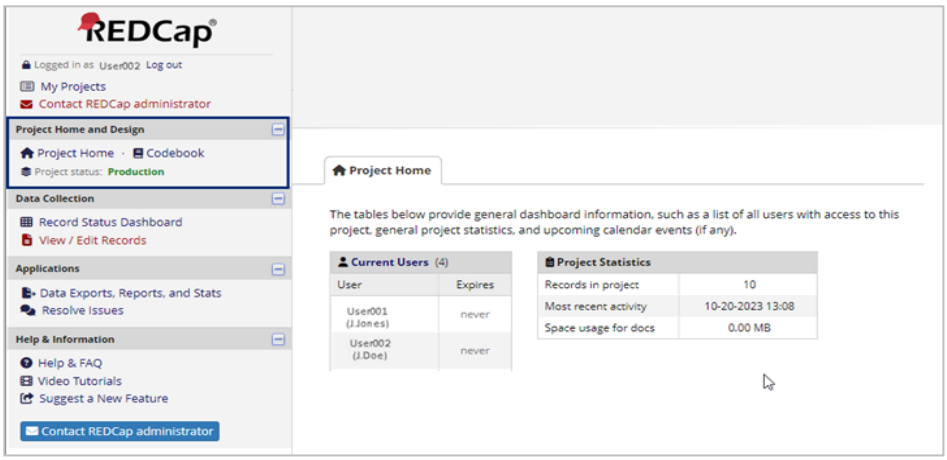

Figure 12: REDCap Menu and Project Home

Data Collection

To enter or view individual records, navigate to the **Data Collection** section of the REDCap menu.

Record Status Dashboard

Clicking the **Record Status Dashboard** link displays a table listing of all existing records/responses and their status for each record. This dashboard can be used to locate an existing Participant ID and to view, edit, or complete additional data collection instruments.

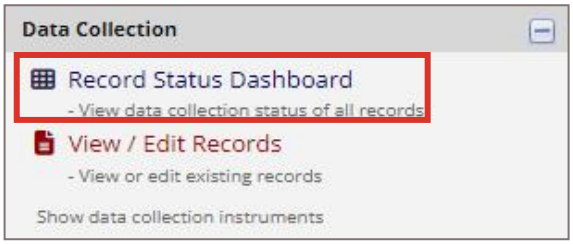

Figure 13: Record Status Dashboard

The **Record Status Dashboard** table is displayed by **Participant ID** (first column) in each row, with data collection **Instruments** organized under **Event** categories.

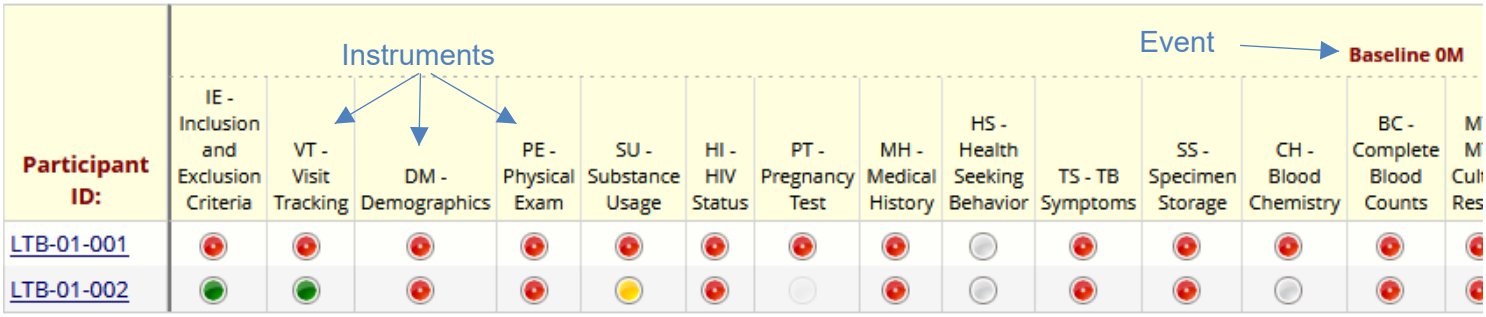

Figure 14: Record Status Dashboard table

The Legend for status icons contains helpful information to assist the user in understanding the status of the record. Click the ? (question mark) icon to learn additional information.

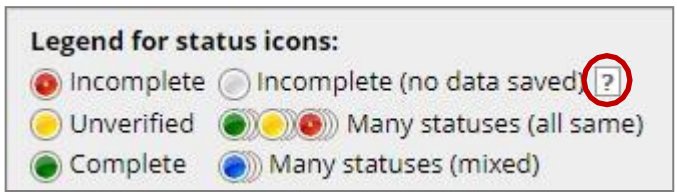

Figure 15: Legend for Status Icons

There are two ways to navigate to the data collection instruments for a participant via the Record Status Dashboard table.

1. Clicking on a single **Participant ID** link (in first column) to open a **Record Home Page** for the selected **Participant ID**. This page includes a table of data collection instruments and their associated statuses for the participant.

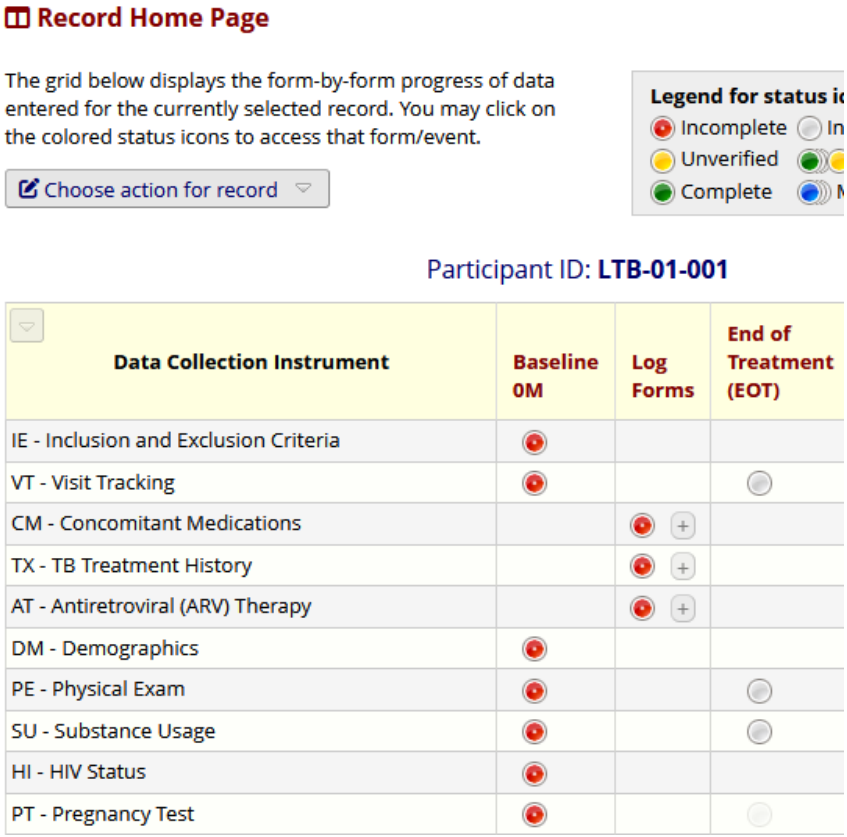

Figure 16: Record Home Page accessed via the Record Status Dashboard table

2. Clicking on a single status icon (radio button) in the cell for the desired PID and data collection instrument to open the corresponding data collection instrument. Users may edit the fields on the data collection instrument, adjust the Form Status field, and choose the desired Save option.

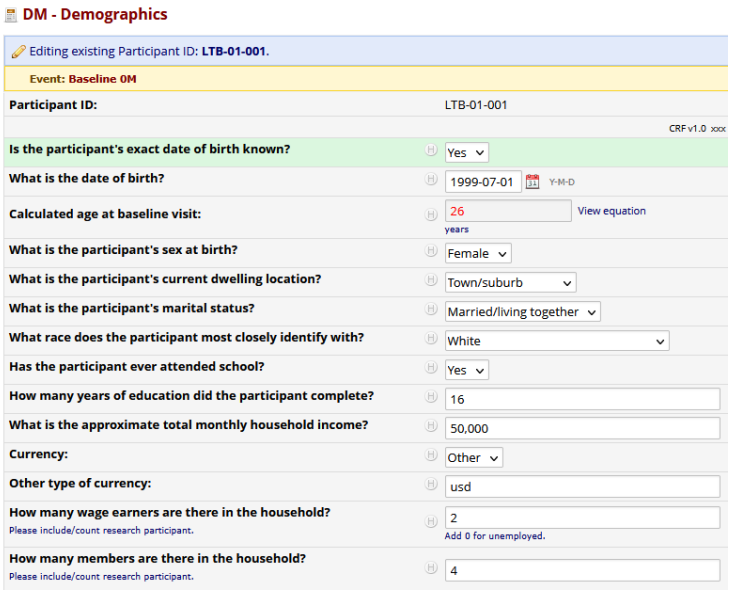

Figure 17: DM- Demographics data collection instrument accessed via the Record Status Dashboard table.

When a data collection instrument is open, the REDCap menu displays a **full listing of selectable data collection instruments** within the same event for the participant. Users can click on the status icons in the REDCap menu display to view/edit other data collection instruments for the participant.

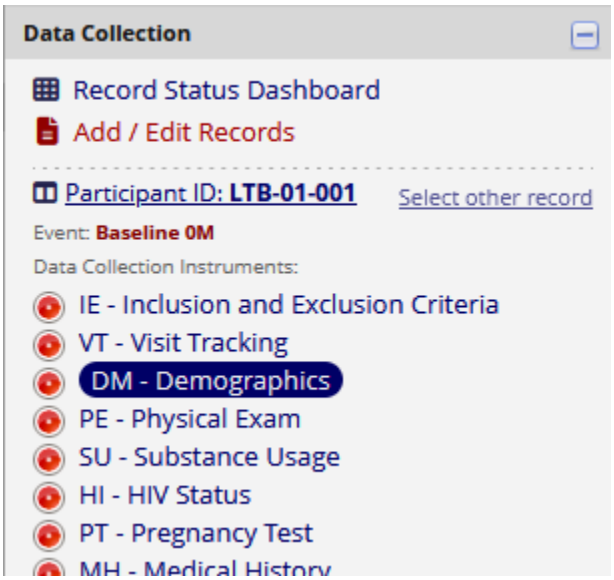

Figure 18: Available Data collection instruments

View/Edit Records vs. Add/Edit Records

Use the **Add/Edit Records** link to create new Participant IDs and view or edit existing data collection instruments for enrolled participants.

Figure 19: Add/Edit Records

Type the assigned Participant ID into the **Enter a new or existing Participant ID** field and click **Enter**.

NOTE: To ensure the uniqueness of Participant IDs assigned by each of the RePORT Long TB sites, the RePORT International Coordinating Center (RICC) has established a required Participant ID format. Each site is required to adhere to this format when assigning Long TB Participant IDs and entering records to the Long TB REDCap. All Participant IDs must begin with the LTB prefix, followed by a hyphen (-), followed by a 3-character Site ID, followed by a hyphen (-), followed by a 3-digit participant number. Refer to the RePORT Long TB MOP for further details, including the assigned 3-character Site IDs.

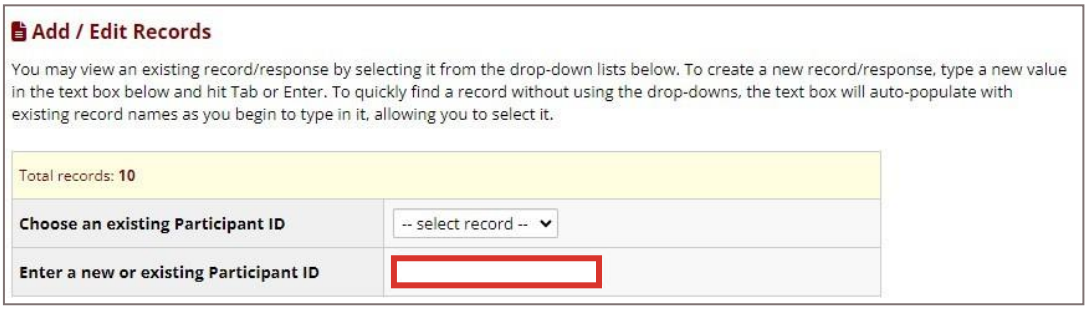

Figure 20: Enter a new or existing Participant ID field, Add/Edit Records

To create the record and begin entering data, click any gray status icon. Once data are entered and the form is saved, the newly-added participant record will display in the Record Status Dashboard.

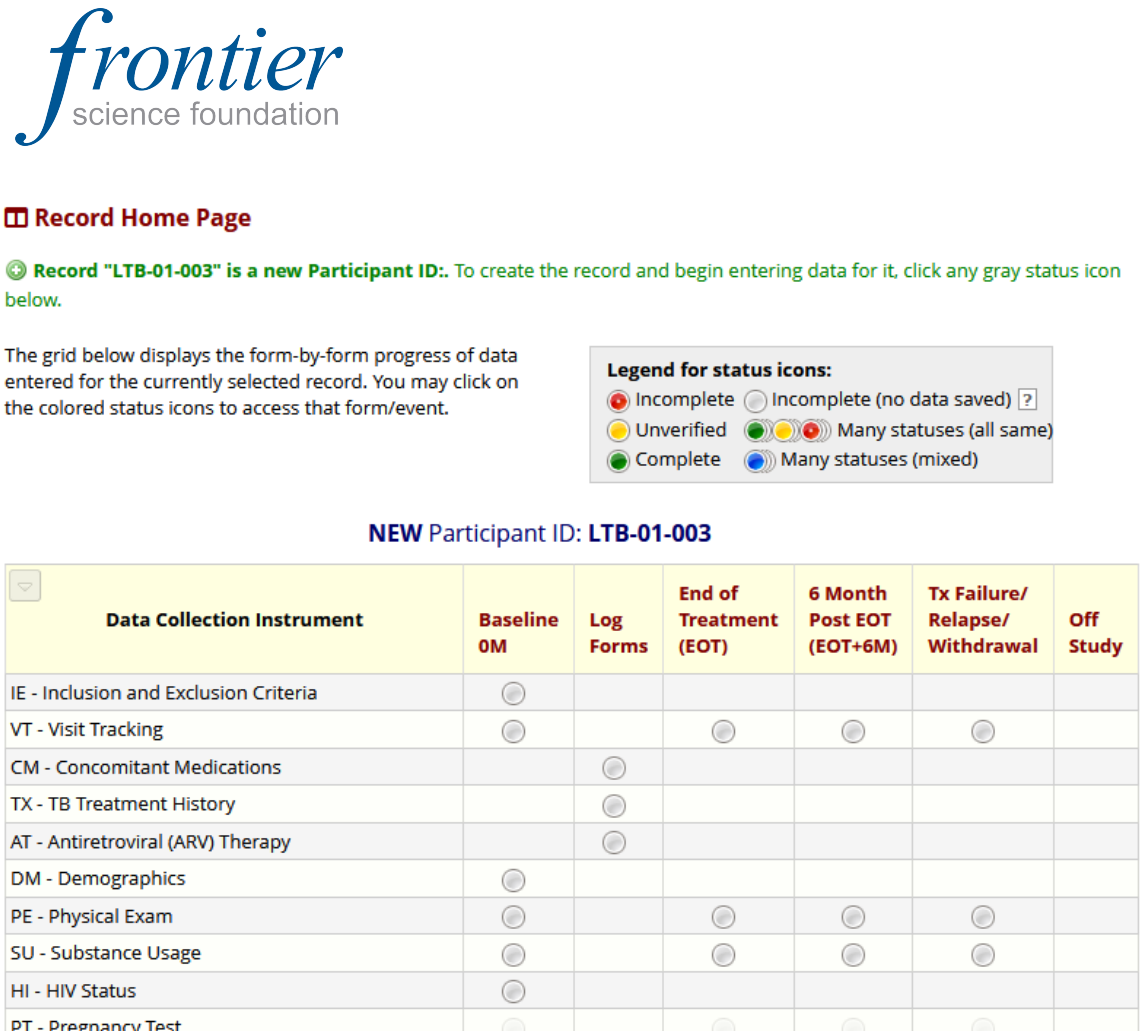

Figure 21: New Participant ID Record Home Page

To view or edit data collection instruments for an existing PID, select a PID from the **Choose an existing Participant ID** list.

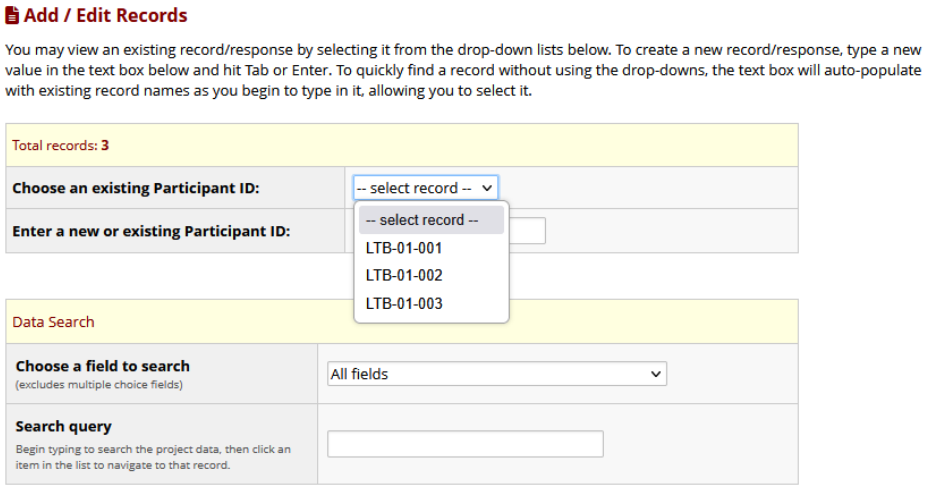

Figure 22: Choose an existing Participant ID dropdown list, Add/Edit Records

On the participant's **Record Home Page**, click a single status icon in the cell for the desired data collection instrument to open the corresponding instrument.

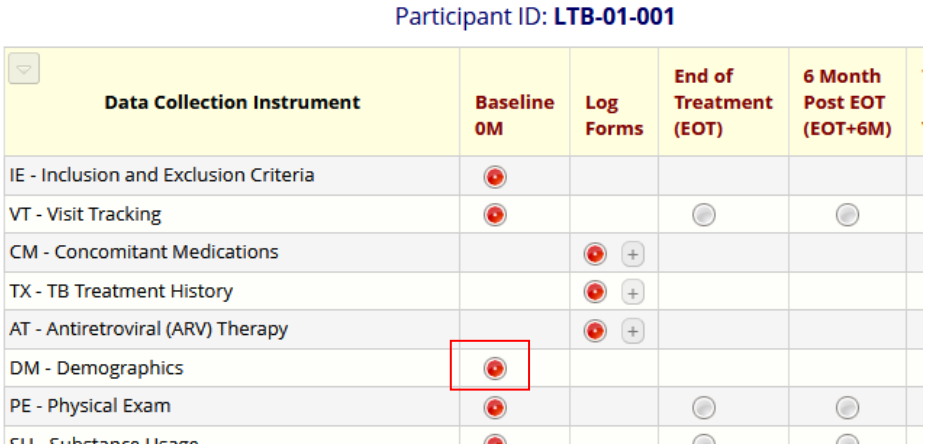

Figure 23: Data collection instrument table on participant's Record Home Page

Note: **Editing existing Participant ID** message displays at the top of the data collection instrument.

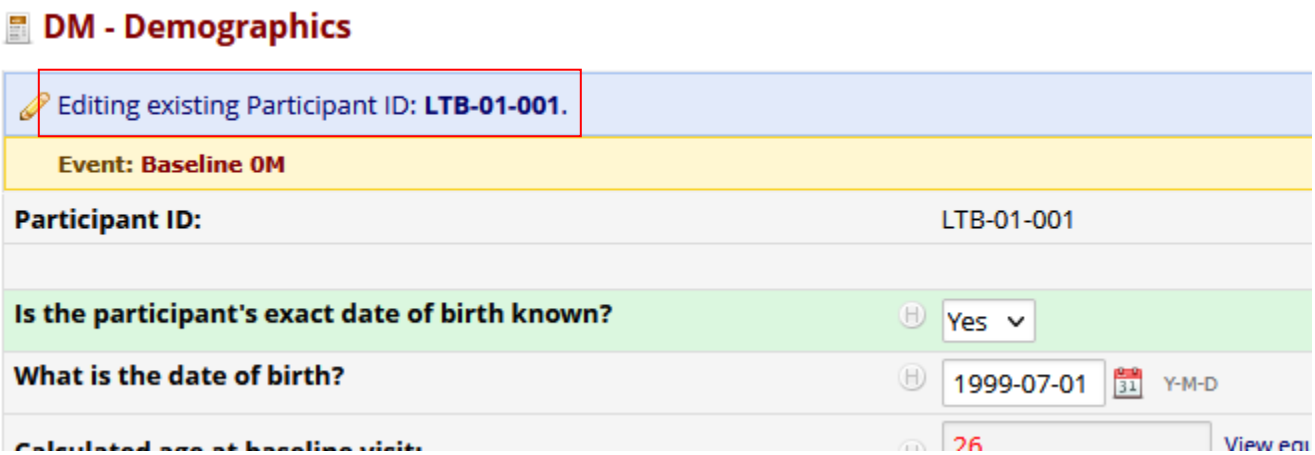

Figure 24: Editing existing Participant ID

Click or Tab on your keyboard to navigate to the desired field(s) and enter data, as required. Required questions are indicated by the * *must provide value* text below each question.

Figure 25: Required question example

NOTE: If responses are not provided to all required questions, an error message displays upon saving the data collection

instrument.

NOTE: Additional questions may dynamically display based on the responses provided to previous questions.

Form Status

After completing data entry, select one of the appropriate options from the **Form Status** dropdown at the bottom of the form to indicate the status of the data collection instrument.

Form Status dropdown options include:

- **Incomplete**: Further data entry is needed.
- **Unverified**: All data have been entered but internal review has not yet occurred (as applicable).
- **Complete**: Data entry is complete, even if values are missing.

Figure 26: Form Status Options

Save Options

After a **Form Status** dropdown option is selected, save the data collection instrument before navigating away from the page.

Select the desired **Save** dropdown option.

- **Save & Exit Form:** Save any progress made on the data collection instrument and go back to the Record Home Page.
- **Save & Stay:** Save any progress made on the data collection instrument and stay on the current data collection instrument.
- **Save & Go To Next Form:** Save any progress made on the data collection instrument and move to the next data collection instrument for the current participant.
- **Save & Exit Record:** Save any progress made on the data collection instrument and go to View/Edit Records.
- **Save & Go To Next Record:** Save any progress made on the data collection instrument and move to the next PID.

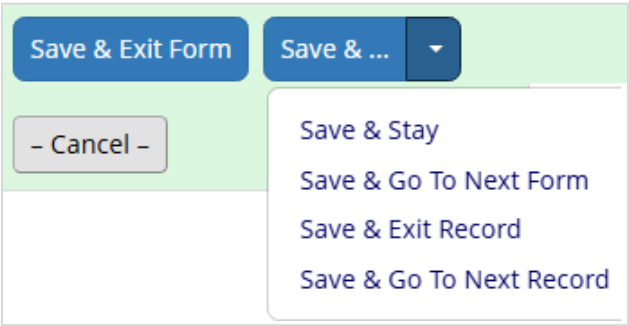

Figure 27: Save Options

Repeating Forms

Repeating forms may be used where a second instance of the form is needed. For example, some test results may need a repeating form if the results initially came back as Indeterminant. If this test is run a second time, a new instance of the form can be added to enter those results. Click the + sign next to the form to add another instance of the form. You can now complete the second form as needed to track the second set of results.

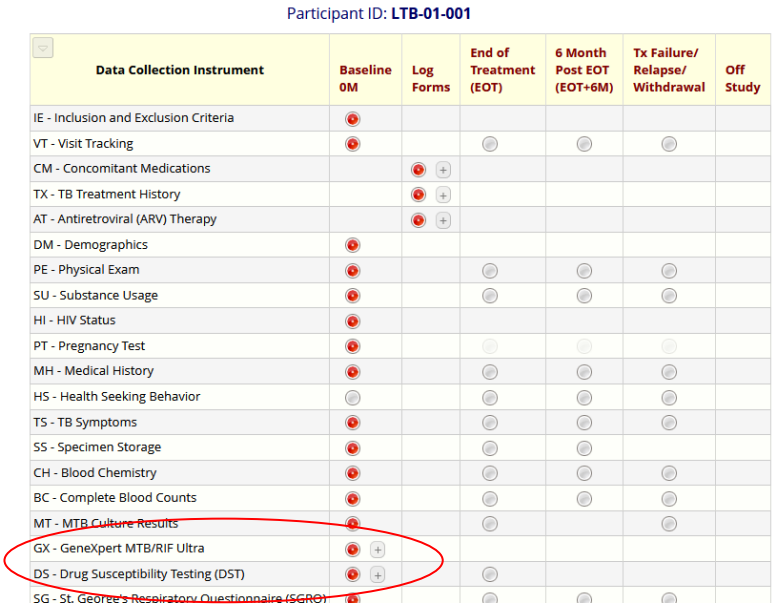

Figure 28: Repeating Forms

Log Forms

The Long TB central build makes use of Log forms to track a participant's medication history over the course of the study. The log forms must be reviewed and maintained at each participant visit, noting any changes to a participant's medication information. Medication information is split into 3 different Log forms: TX- to track a participant's TB medication, AT- to track ARV therapy for participants living with HIV, and CM- to track any other relevant concomitant medications.

At the entry visit, simply enter the participant's TB medications. Enter the name, dose, frequency, expected number of doses, and start date.

At the first visit it would be expected that treatment is Ongoing, and the ongoing field should be set to Yes.

After entering rows for each prescribed TB medication, set the form status to Incomplete and Save & Exit.

At each subsequent visit, you must open the Log forms and enter any changes to these medications or add rows for new medications. For example, at the EOT visit, the participant may no longer be on active TB treatment and medications on the TX form would need to change Ongoing to No and enter a Stop Date and Stop Reason.

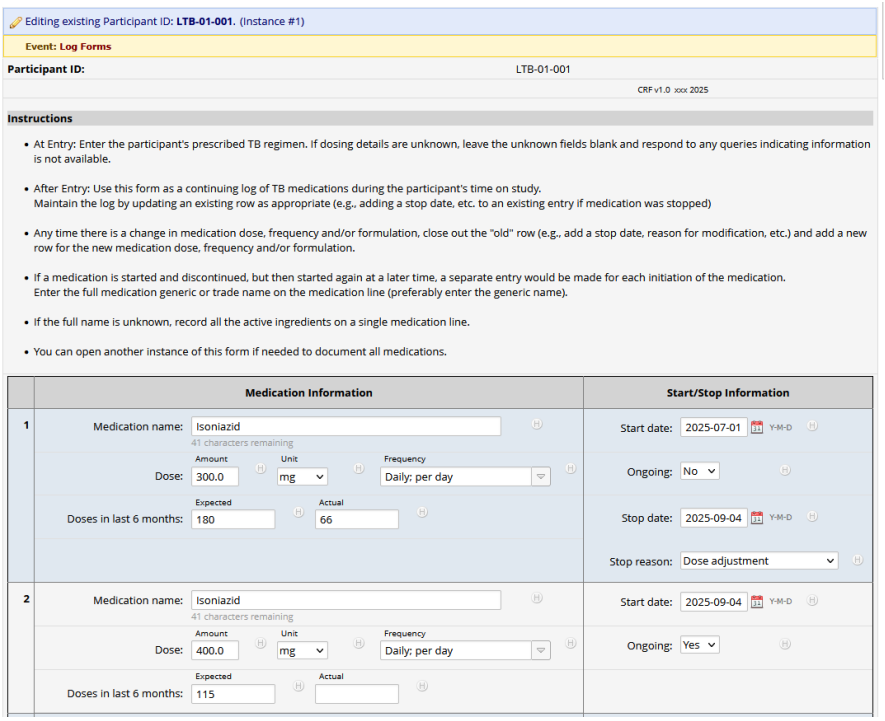

Figure 29: Log Forms

Obtaining Blank CRFs for Data Collection

If blank CRFs are required for data collection which will later be transcribed into the RePORT International central REDcap, do not download the blank data collection instruments directly from REDCap.

The appropriate blank CRFs needed for data collection can be provided to you by the RePORT International Long TB protocol team. Please reach out to request these forms.

Resolving Issues/Queries

The **Resolve Issues** page displays a list of queries and allows users to manage and document the resolution of data issues.

Figure 30: Resolve Issues

Anyone with respond privileges will be able to respond to an open query (even if it is assigned to a specific person). The

responder may select a response type (e.g., typographical error) and provide a descriptive comment with the ability to also attach a file (optional). Once a query has been responded to, a data manager will review the response and either ask for further clarification or close the query, after which it will be considered resolved.

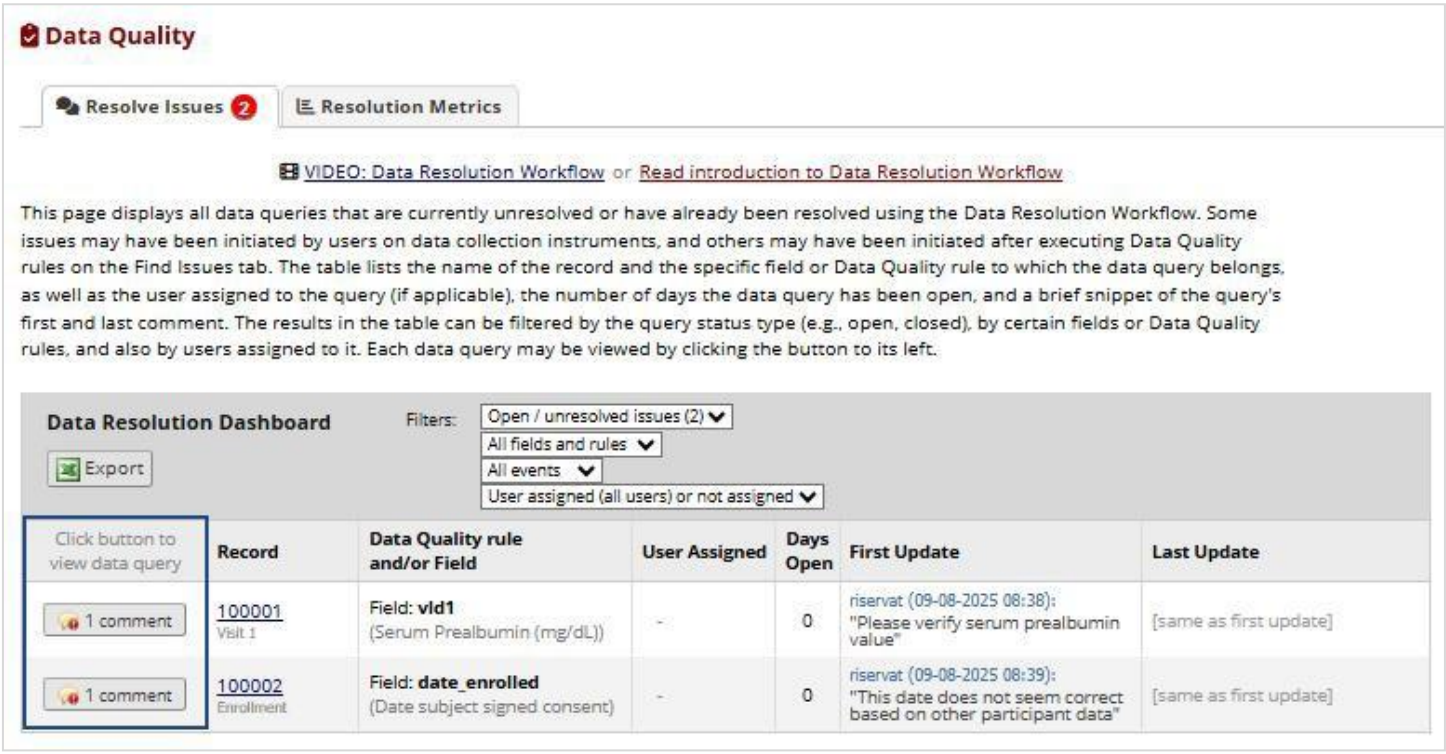

Figure 31: Resolve Issues

This page serves as a dashboard that neatly organizes all queries (both open and closed) so that they may be reviewed and so that any open queries may be easily responded to and closed. That page can serve as a nice to-do list for addressing all open queries.

A table lists the name of the record and the specific field or Data Quality rule to which the data query belongs, as well as the user assigned to the query (if applicable), the number of days the data query has been open, and a brief snippet of the query's first and last comment. The results in the table can be filtered by the following:

- Query status type (e.g., open, closed)
- Certain fields or Data Quality rules
- Event
- Users assigned

Click the button in the first column to view details of the data query. The **Data Resolution Workflow** displays for the specified record for a given field and/or Data Quality rule. Note the query **Status** of **Open / Unresolved (unresponded)**.

Opened data queries may be responded to by users with appropriate privileges, and then they may be closed once the issue has been resolved. All data queries can also be viewed on the **Resolve Issues** page in this project.

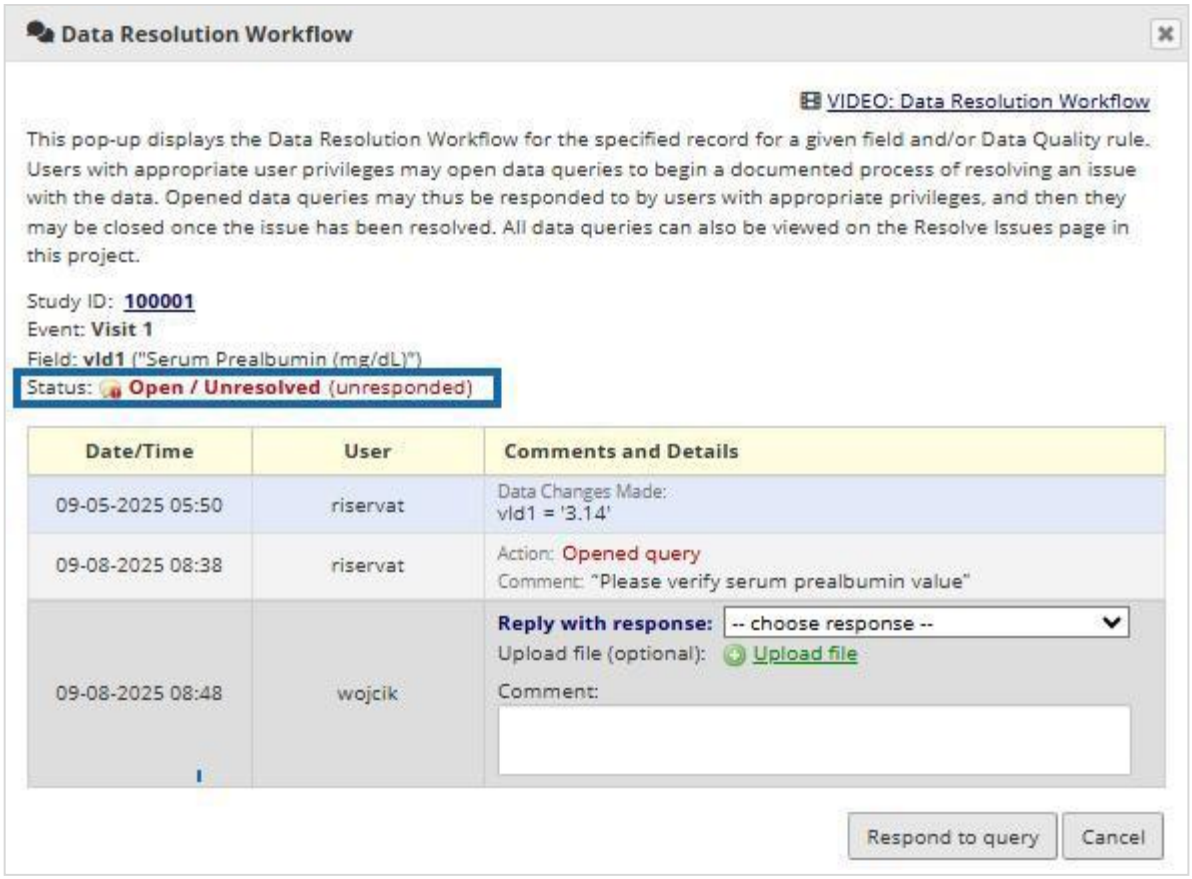

Figure 32: Data Resolution Workflow

1. Select the most appropriate query response from the **Reply with response** listing.
2. The **Upload file** option may be available.
3. Complete the **Comment** field. If data are not corrected, indicate why.
4. Click **Respond to query**. The query Status changes to Open / Unresolved (responded). The DataResolution Dashboard will reflect the updates.

A data manager will be able to view the query response and ask for further clarification or close the query.

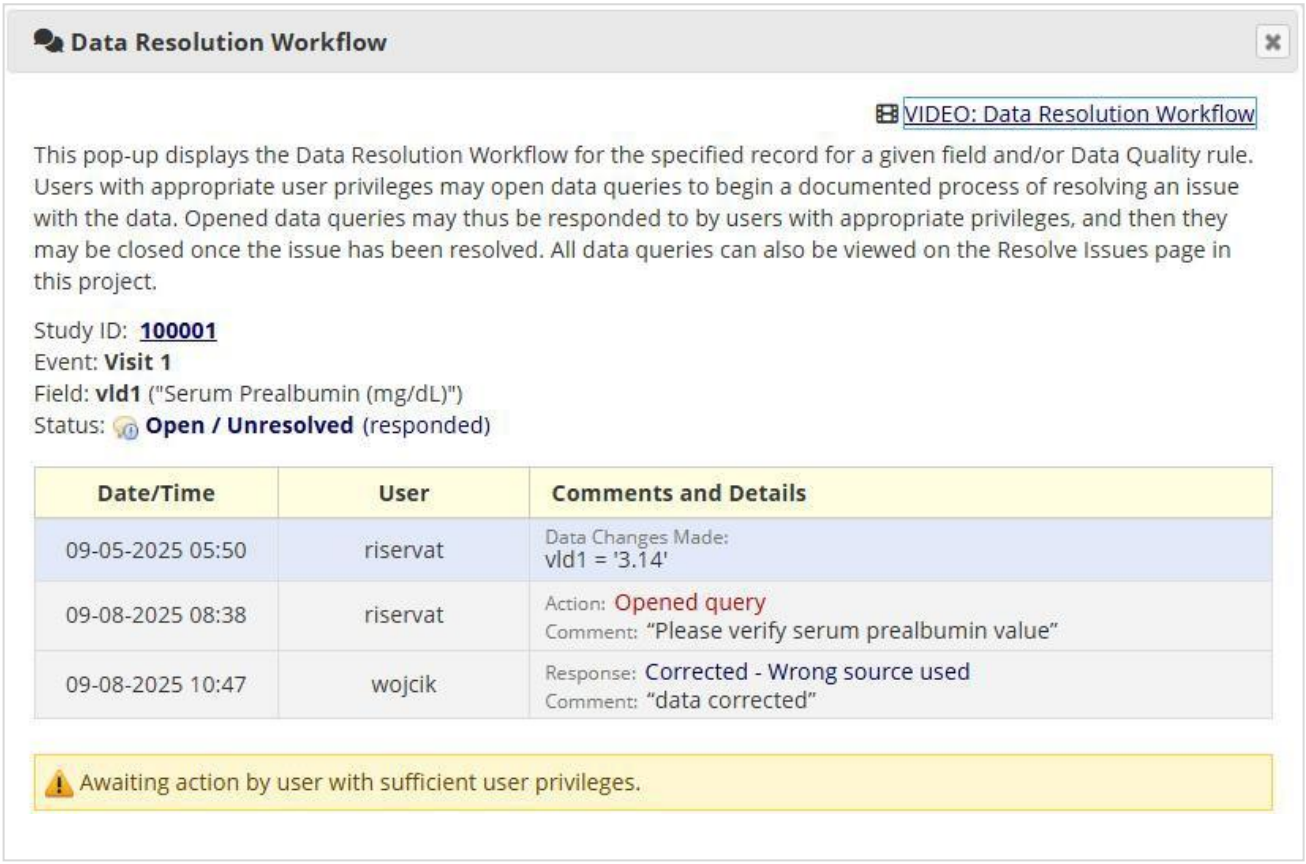

Figure 33: Open / Unresolved (responded) Query

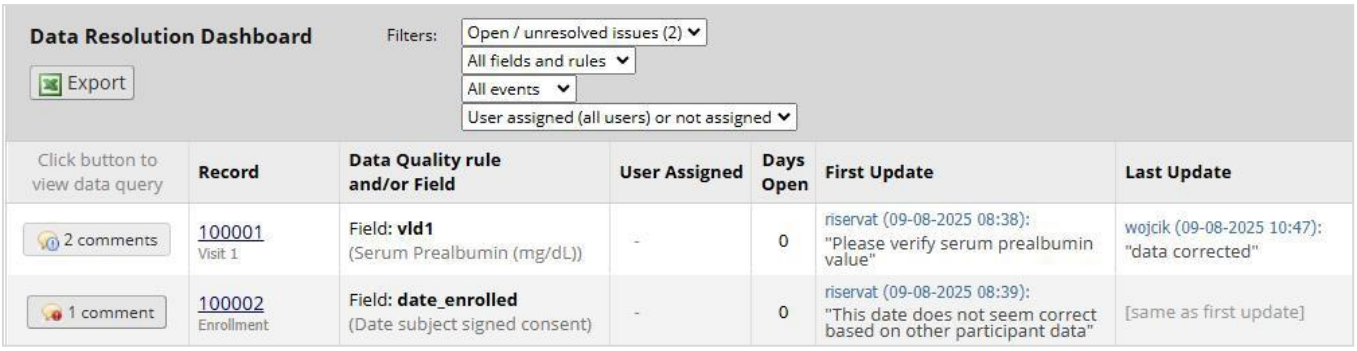

Figure 34: Updated Data Resolution Dashboard

Resolution Metrics

It can sometimes be useful to view metrics with regard to your data queries, such as a count of how many queries are open or closed, the average response time, or the average time to query resolution. The **Resolution Metrics** page provides some useful statistics and some helpful bar charts for viewing progress and activity.

Resolution Metrics displays **General Statistics** regarding query management at each site. These include:

- **Number of open/unresolved queries**
- **Number of closed/resolved queries**
- **Average time for query response**
- **Average time to query resolution**

Charts are provided for each metric as you scroll down the page.

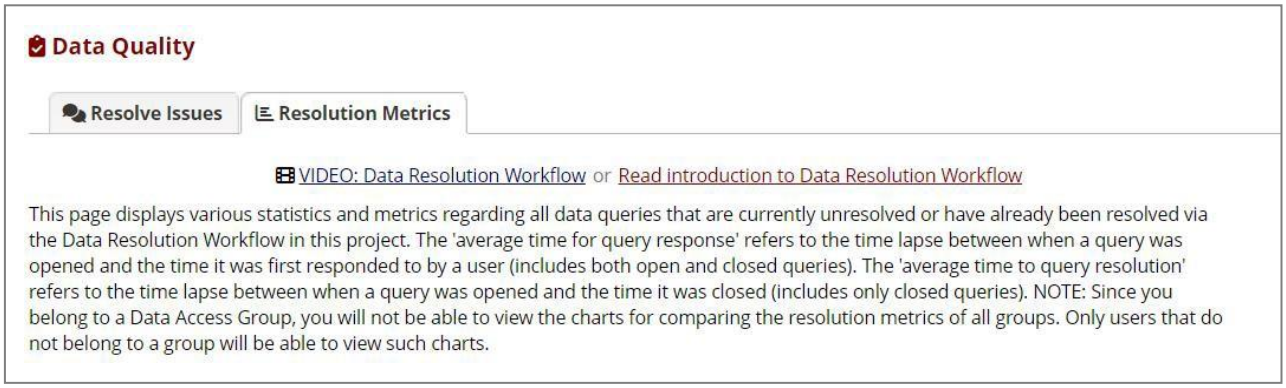

Figure 35: Resolution Metrics

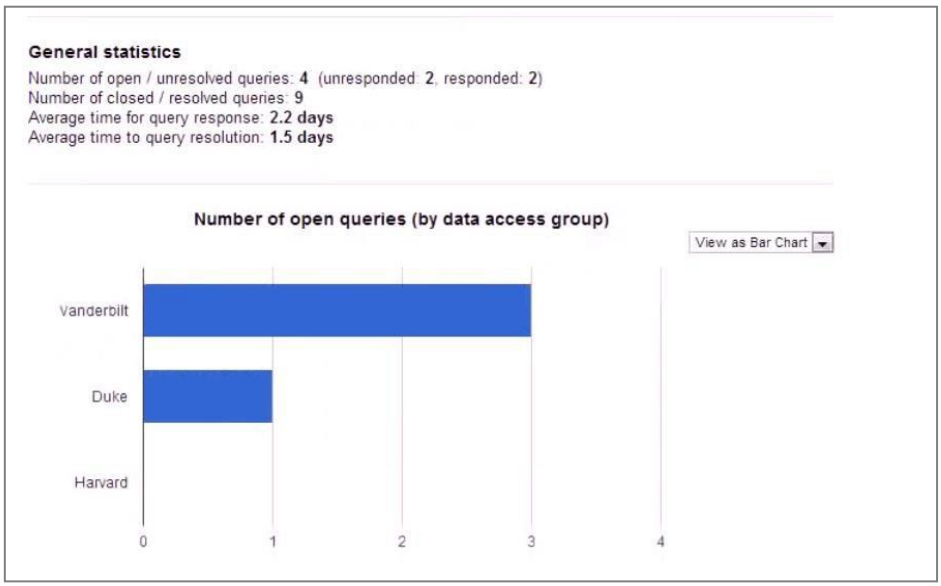

Figure 36: General Statistics

REDCap Video Tutorials

In addition to video tutorials available within the REDCap system, there are a few listed in the **Help and FAQ** section of the menu that you may find helpful as you enter data and utilize the available applications:

- **Data Entry Overview**
- **Applications Overview**

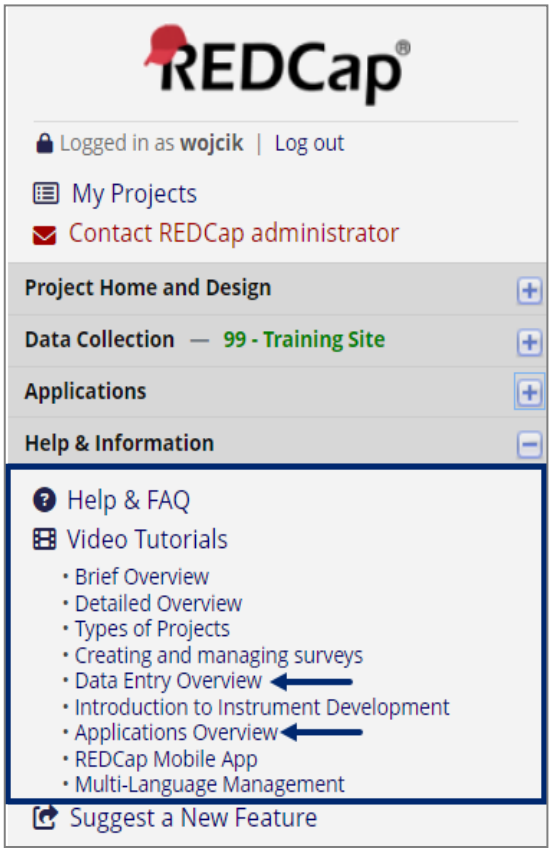

Figure 37: REDCap Overview materials

Collecting Data Using the REDCap App

In addition to the standard web-based data collection tool, REDCap also allows for data to be collected within the REDCap App. The App can be downloaded and installed on various devices, including tablets, and allows for offline data collection.

When using the App, please keep in mind that any records you enter must be synced to the main project build server when internet connectivity allows.

NOTE: It is critical that each RePORT International Long TB participating site assigns Participant IDs following the format established in the Long TB MOP. When using the REDCap App, if a duplicate Participant ID is entered that will conflict with a previously existing Participant ID, the data will be unable to sync. It is critical that each site maintain a proper log of assigned Participant IDs to prevent duplicate assignment and conflicts when multiple users are entering data in offline situations.

Configuring a Tablet for Use with the REDCap App

To configure a tablet for use with the REDCap App, you must be logged in to REDCap on both the App and on a desktop/laptop.

On the desktop/laptop:

- On the left-hand side menu bar, under ‘Applications’, click on ‘REDCap Mobile App’ and the ‘Set Up Project’ tab and locate the QR Code.

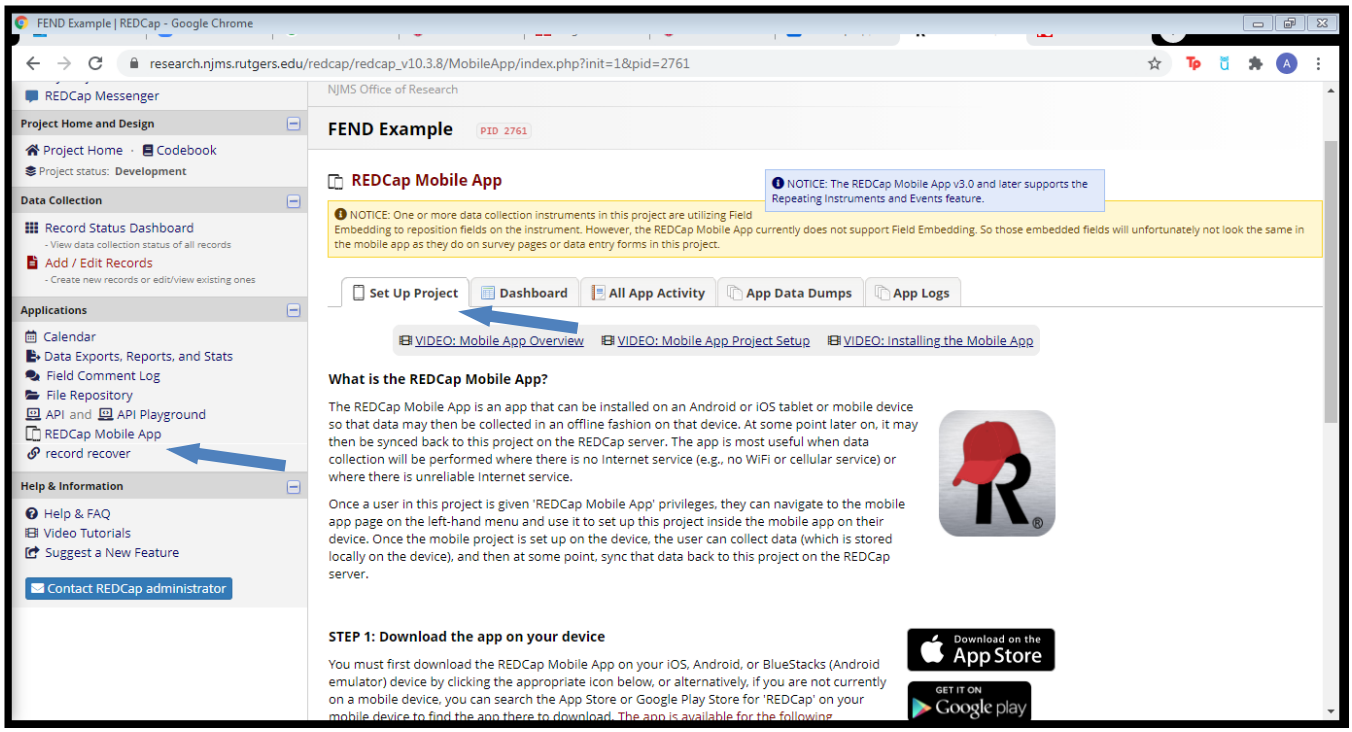

Figure 38: REDCap Mobile App page

On the tablet / device in the REDCap App:

- Click ‘Set Up Mobile Project’ and then ‘Scan QR Code’ to scan the QR Code from the laptop/desktop to begin downloading the RePORT International Long TB project to the App.

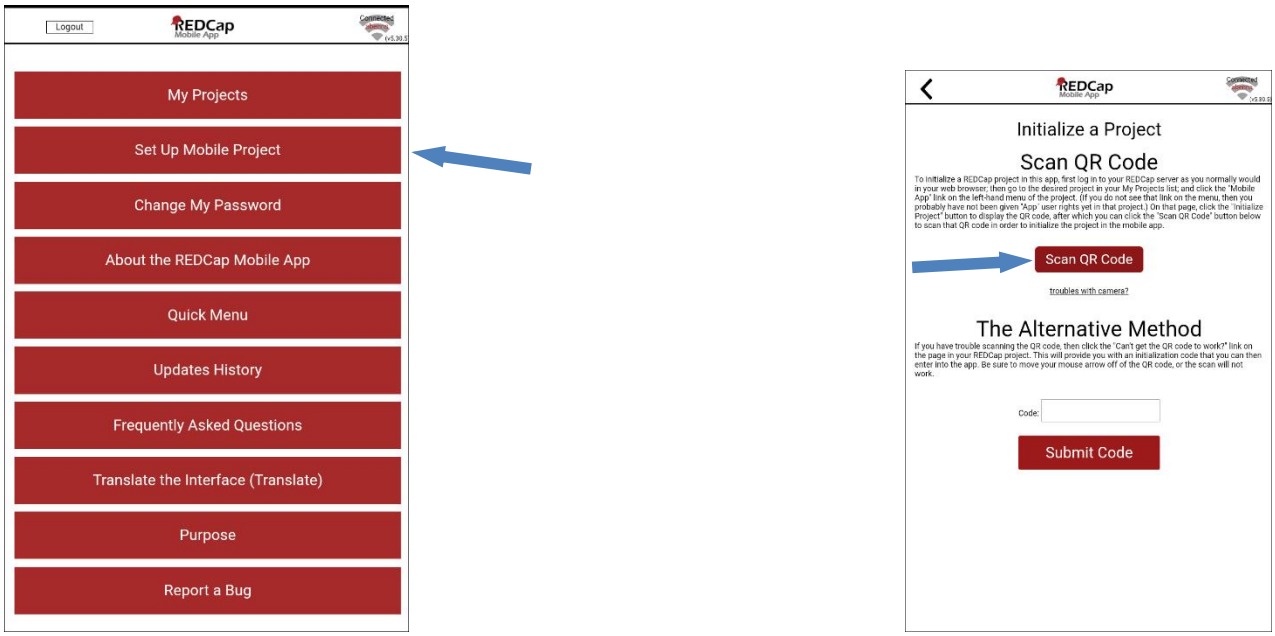

Figure 39: REDCap Mobile App Configuration

Collecting Data Using the REDCap App

After downloading the RePORT International Long TB project to the App, be sure to click ‘Download All Records’ to properly initialize any existing data to the device.

To enter new data to the REDCap App for project, first locate and select the RePORT International Long TB project from ‘My Projects’. Once selected, the project will have the following options:

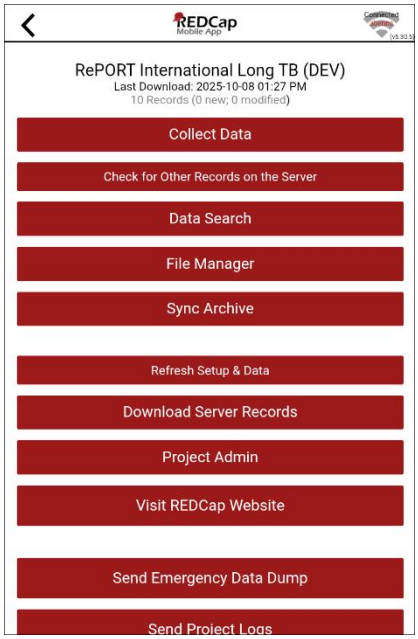

Figure 40: REDCap Mobile App Data Collection

- Collect Data
    - Allows for entry of new records and updates to existing records.
- Send Data to Server (note: this will only appear once Records are created on the app)
    - At the end of each day that the REDCap App is used, make sure to ‘Send Data to Server’
        - When online, send the data to the project’s REDCap server. This will coordinate the mobile device’s data with the main REDCap project
        - If record names or data values conflict, you will be given the opportunity to adjust before completing the upload
        - If the instruments have been modified significantly in the main REDCap project since REDCap Mobile App project set up, you will not be able to complete the upload
    - After the data was sent to the server, verify the data is on the web browser (RePORTInternationalREDCap.org) in the Record Status Dashboard