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Chapter

3

ProFoRMS




CHAPTER 3 - PROFORMS

The **Protocol and Form Research Management System (ProFoRMS)** module provides the tools for protocol management, data capture, and is a clinical trial/research module. ProFoRMS is a web-based data collection/research application organized by modules, with a user-friendly interface designed to help researchers to manage individual studies, subjects, eCRFs (electronic Case Report Forms), data collection, define electronic case report forms, schedule, and collect clinical data, and then export, analyze, and report on the data. This module is based on NICHD's Clinical Trial Database (CTDB).





WARNING!

ICON KEY

 Notes

 Important
Information

Things to Note:

-  **Before a protocol can be created, please make sure that the following has been completed:**
 -  A study has been created and approved in the Data Repository;
 -  e-Form(s) has been published in the Data Dictionary; and
 -  Proper permissions are granted to the e-Forms (if the eform is not standardized) for users who are collecting data against the form.

3.1 OBJECTIVE

This chapter provides information for users on how to:

- ❖ Manage Protocol
- ❖ Manage Subjects
- ❖ Collect Data
- ❖ Reports and Data Query

3.2 SYSTEM FUNCTIONS

The main function of ProFoRMS is to provide the tools that help to optimize the clinical study process including the basic functions of managing protocols, subjects as well as data access and account management. Early deployment of ProFoRMS in the study start-up activities, such as site identification, initiation of subject visits, and collection of all the necessary regulatory documents, can save researchers' time and improve the overall process.

As a web-based database application, BRICS provides real-time tools that support:

- ❖ Data Contribution
- ❖ Report and Query Data
- ❖ Collect Data

Once a study is running, ProFoRMS can assist users to keep track of subject visits, data collection and of all the relevant forms and regulatory documents. This provides a strong snapshot of progress in terms of study progress and site activation. The ability to track this information ensures that any potential delays can be identified quickly and addressed.

3.3 ProFORMS ROLES AND PRIVILEGES

The table below describes the specific roles with associated privileges to ProFoRMS module.


Role/Access	Privilege
Associate Investigator	Same as PI, except cannot add/initiate a study
Clinical Research Associate	View studies, visit types, forms, questions, create and manage queries
Clinical Coordinator	View studies, visit types, forms, add/edit schedule visits, data collection and form reassignments
Data Entry	View studies, visit types, forms, data entry and oversight, add/edit schedule visits and data collections
PDBP DMR Administrator	PDBP DMR Operations team members have full access to all ProFoRMS privileges
PDBP Limited User	View-only rights
Principal Investigator	Create, design, and administer forms for prospective collection
Research Associate	View studies, create forms, create visit types, schedule visits, and collect data

3.4 USING ProFoRMS



The **ProFoRMS** module (including sub-modules) are available within the BRICS Workspace.

ICON KEY

 Notes

 Important
Information

Things to Note:

-  The best user experience with navigating through the ProFoRMS module is with the latest Chrome or Firefox browser
-  **Java Runtime Environment (JRE) version 8 or higher is required.** [Check](#) your version of Java.

To access the [ProFoRMS](#) module: Perform the following actions:


1. Login and navigate to the **Workspace** screen where all modules you have access to are displayed
2. Click on the **ProFoRMS** module to enter ProFoRMS




WARNING!

ICON KEY

 Notes

 Important
Information

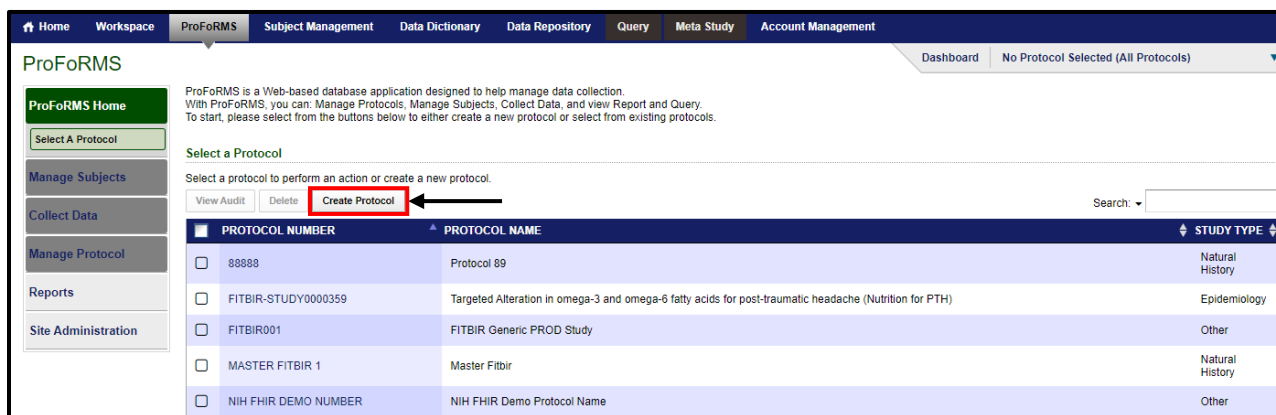
Things to Note:

-  A Protocol must be created first before users can navigate to My Subjects and start adding subjects or managing and/or editing subjects. Refer to [section 3.5.2](#) of this document instruction on creating a protocol.

3.5 CREATE A PROTOCOL

To create a Protocol: perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Click the **Create Protocol** button



ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can: Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

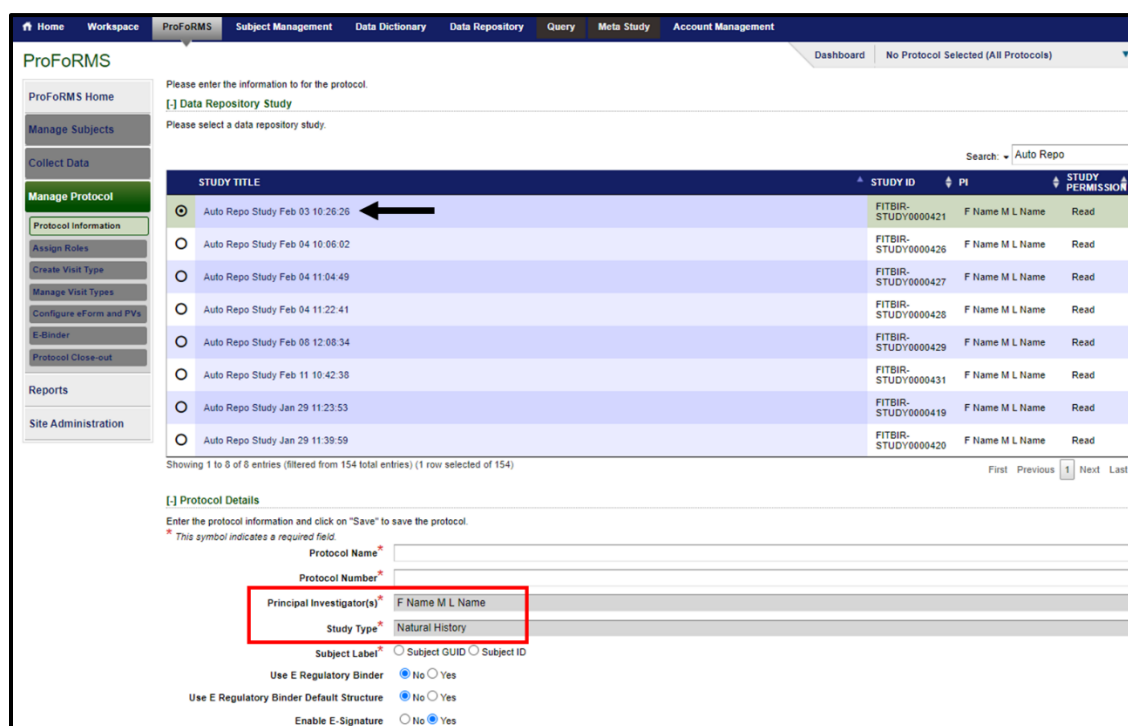
Select a Protocol

Select a protocol to perform an action or create a new protocol.

View Audit Delete **Create Protocol** Search:

PROTOCOL NUMBER	PROTOCOL NAME	STUDY TYPE
<input type="checkbox"/> 88888	Protocol 89	Natural History
<input type="checkbox"/> FITBIR-STUDY0000359	Targeted Alteration in omega-3 and omega-6 fatty acids for post-traumatic headache (Nutrition for PTH)	Epidemiology
<input type="checkbox"/> FITBIR001	FITBIR Generic PROD Study	Other
<input type="checkbox"/> MASTER FITBIR 1	Master Fitbir	Natural History
<input type="checkbox"/> NIH FHIR DEMO NUMBER	NIH FHIR Demo Protocol Name	Other

3. **Select** a study from the Data Repository Study table that the protocol is associated with (doing this will automatically populate the Principal Investigator(s) and Study Type field information)



Please enter the information for the protocol.

[+] Data Repository Study

Please select a data repository study.

Search: Auto Repo

STUDY TITLE	STUDY ID	PI	STUDY PERMISSION
<input checked="" type="radio"/> Auto Repo Study Feb 03 10:26:26	FITBIR-STUDY0000421	F Name M L Name	Read
<input type="radio"/> Auto Repo Study Feb 04 10:06:02	FITBIR-STUDY0000426	F Name M L Name	Read
<input type="radio"/> Auto Repo Study Feb 04 11:04:49	FITBIR-STUDY0000427	F Name M L Name	Read
<input type="radio"/> Auto Repo Study Feb 04 11:22:41	FITBIR-STUDY0000428	F Name M L Name	Read
<input type="radio"/> Auto Repo Study Feb 06 12:08:34	FITBIR-STUDY0000429	F Name M L Name	Read
<input type="radio"/> Auto Repo Study Feb 11 10:42:38	FITBIR-STUDY0000431	F Name M L Name	Read
<input type="radio"/> Auto Repo Study Jan 29 11:23:53	FITBIR-STUDY0000419	F Name M L Name	Read
<input type="radio"/> Auto Repo Study Jan 29 11:39:59	FITBIR-STUDY0000420	F Name M L Name	Read

Showing 1 to 8 of 8 entries (filtered from 154 total entries) (1 row selected of 154)

First Previous 1 Next Last

[+] Protocol Details

Enter the protocol information and click on "Save" to save the protocol.

* This symbol indicates a required field.

Protocol Name*

Protocol Number*

Principal Investigator(s)* F Name M L Name

Study Type* Natural History

Subject Label* ☐ Subject GUID ☐ Subject ID

Use E Regulatory Binder ☒ No ☐ Yes

Use E Regulatory Binder Default Structure ☒ No ☐ Yes

Enable E-Signature ☐ No ☒ Yes

4. **Complete** all of the required fields (fields marked with a red asterisk (*))

- a. **Subject Label** field:
 - i. Depending on which selection you make, you will see this subject identifier displayed as the primary subject identifier in the Collect Data tables
5. **Select** the Protocol Site(s) that will be using this protocol to collect data in, then click **Save**.
The new protocol will appear in the Select a Protocol list.

[-] Protocol Sites
Search:

Select sites to be associated with this protocol.

SITE NAME	CITY	STATE
<input type="checkbox"/> Brooke Army Medical Center (Primary)	San Antonio	Texas
<input type="checkbox"/> UT Health Science Center at San Antonio	San Antonio	Texas

Showing 1 to 2 of 2 entries (0 row selected of 2)
First Previous **1** Next Last

Save
Cancel

3.5.1 Selecting a Protocol

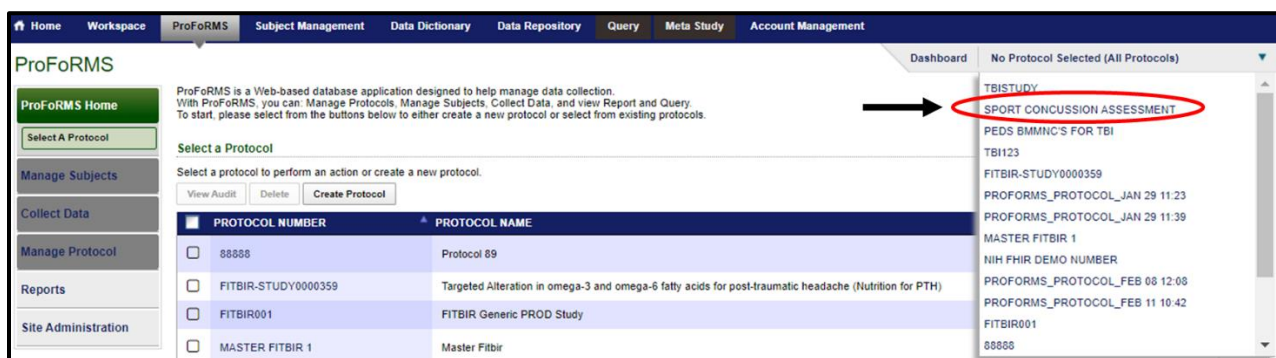
Viewing and selecting a protocol can be done in ProFoRMS via two ways:

- ❖ Using the Dashboard drop-down list; and
- ❖ Using the Select a Protocol table

Using the Dashboard drop-down list:

To select a protocol in ProFoRMS using the drop-down list, perform the following actions:

1. Navigate to the ProFoRMS module
2. Select a protocol by using the drop-down menu located in the top right-hand area of the module. The list of available protocols appears.
 - a. **Note:** Admins have access to all protocols. If you are not an admin and do not see any protocols displayed in the Dashboard drop-down, reach out to your instance admin for assistance so they can grant you access

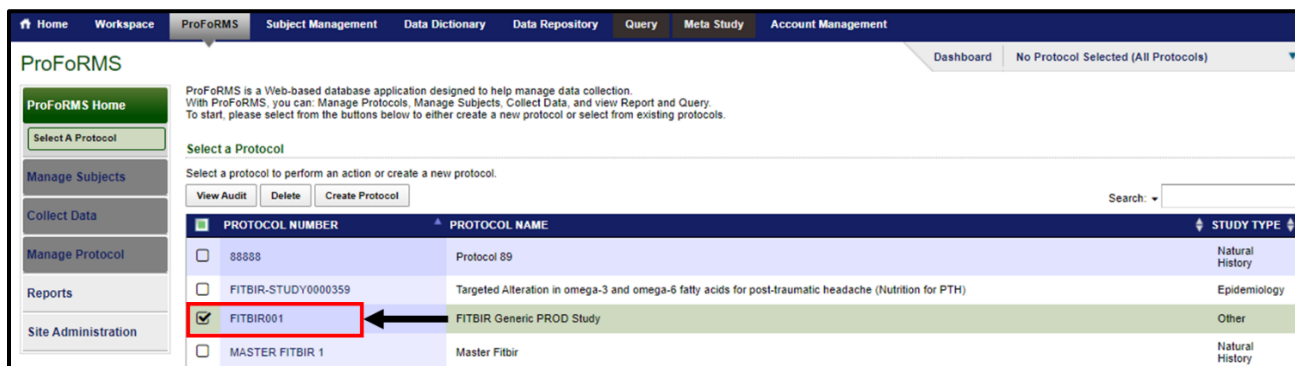


3. Click on the desired protocol. The system will load the selected protocol data including the list of subject visits.

Using the Select a Protocol table:

To select a protocol in ProFoRMS using the Select a Protocol table, perform the following actions:

1. Navigate to the ProFoRMS module
2. Click of the desired protocol in the Select a Protocol table. The system will load the selected protocol data including the list of subject visits



3.6 MANAGE SUBJECTS

This section of ProFoRMS is designed to help you view the subjects in your protocol, add subjects to your protocol and schedule subject visits. The sub-sections available in the Manage Subjects menu are as follows: (**may want to refer back to 3.5 My Subjects section for description**)

- ❖ My Subjects
- ❖ Add Subject
- ❖ Schedule Visit

3.6.1 My Subjects

The **My Subjects** page lists all subjects currently enrolled into the protocol. The user can sort the list of subjects by **GUID**, **Subject ID**, **Status**, **Validation**, and **Protocol**. The table also includes a simple search function.

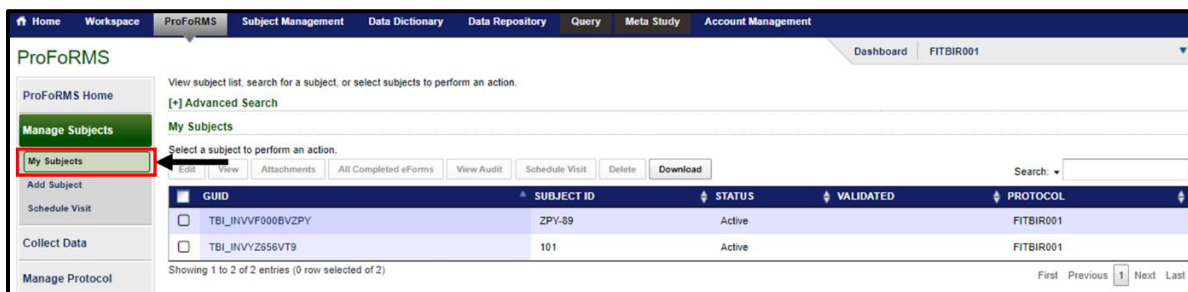
The table menu options allow the user to:

- ❖ View and edit subject's information;
- ❖ View and upload subject related documents;
- ❖ View forms completed for a selected subject;
- ❖ View the audit information;
- ❖ Schedule a visit;
- ❖ Delete selected subjects;
- ❖ Download table information; and
- ❖ Search for information in the table using a keyword

3.6.1.1 Access My Subject

To access **My Subjects** page, perform the following actions:

1. Log into the system
2. Navigate to the **ProFoRMS** module
3. Select a protocol (see section 3.5.1)
 - a. **Note:** Many of the features on the left-hand side will not be active until a protocol is selected. If you are unable to select a protocol, please contact the Operations Team for assistance.
4. The ProFoRMS Dashboard opens. Click the **Manage Subjects** tab on the left-side tool bar.
5. **My Subjects** page appears with a list that can be sorted by clicking on the arrows within each column header.
6. Select a subject to perform any desired action available in the table menu options.

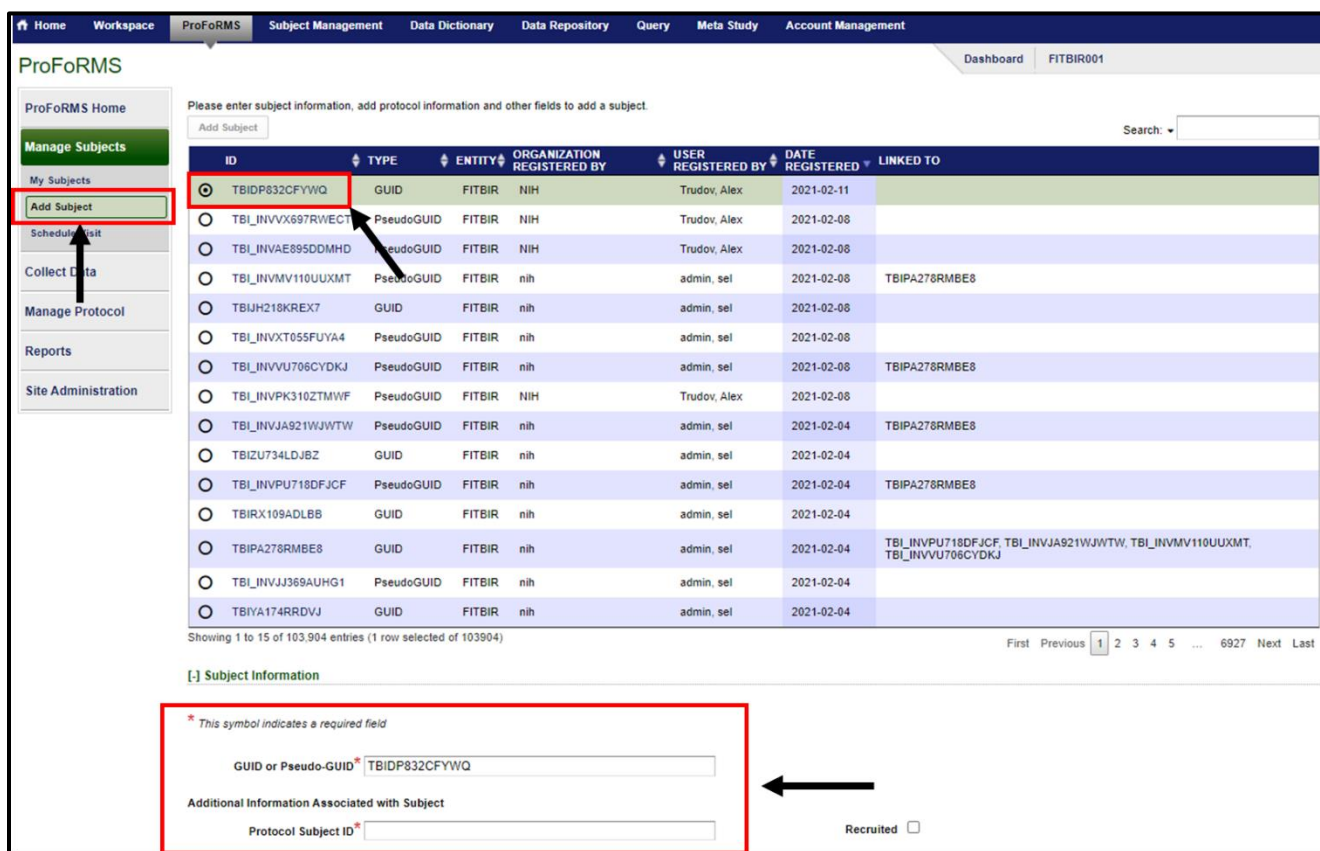


3.6.2 Add Subject

To add a subject (research participant) to a protocol, the subject must be provided with a unique Identification number (ID). This is done by creating a Global Unique Identifier (GUID) in the Subject Management tool. The GUID serves as an ID that allows researchers to associate data with the subject without exposing or transferring the subject's Personally Identifiable Information (PII). For more information about the GUID, please refer to [Chapter 6 Subject Management](#).

To **Add Subject**, perform the following actions:

1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.
4. The **My Subjects** page appears.
5. Click the **Add Subject** tab on the left-side tool bar.
6. Select the subject that you want to add to the protocol from the subject table. Doing so will auto-populate the **GUID or Pseudo-GUID** field in the **Subject Information** section
 - a. If no subjects appear in the subject table, go to step #11
7. Enter the **Protocol Subject ID**. This ID is unique across the system and is determined by the user and clinical site.



Please enter subject information, add protocol information and other fields to add a subject.

Add Subject

Search:

ID	TYPE	ENTITY	ORGANIZATION REGISTERED BY	USER REGISTERED BY	DATE REGISTERED	LINKED TO
<input checked="" type="radio"/> TBIDP832CFYWQ	GUID	FITBIR	NIH	Trudov, Alex	2021-02-11	
<input type="radio"/> TBI_INVVX697RWECT	PseudoGUID	FITBIR	NIH	Trudov, Alex	2021-02-08	
<input type="radio"/> TBI_INVAE895DDMHD	PseudoGUID	FITBIR	NIH	Trudov, Alex	2021-02-08	
<input type="radio"/> TBI_INVMV110UUXMT	PseudoGUID	FITBIR	niH	admin, sel	2021-02-08	TBIPA278RMBE8
<input type="radio"/> TBIJH218KREX7	GUID	FITBIR	niH	admin, sel	2021-02-08	
<input type="radio"/> TBI_INVXT055FUYA4	PseudoGUID	FITBIR	niH	admin, sel	2021-02-08	
<input type="radio"/> TBI_INVVU706CYDKJ	PseudoGUID	FITBIR	niH	admin, sel	2021-02-08	TBIPA278RMBE8
<input type="radio"/> TBI_INVPK310ZTMWF	PseudoGUID	FITBIR	NIH	Trudov, Alex	2021-02-08	
<input type="radio"/> TBI_INVJA921WJWTV	PseudoGUID	FITBIR	niH	admin, sel	2021-02-04	TBIPA278RMBE8
<input type="radio"/> TBIZU734LDJBZ	GUID	FITBIR	niH	admin, sel	2021-02-04	
<input type="radio"/> TBI_INVPU718DFJCF	PseudoGUID	FITBIR	niH	admin, sel	2021-02-04	TBIPA278RMBE8
<input type="radio"/> TBIRX109ADLBB	GUID	FITBIR	niH	admin, sel	2021-02-04	
<input type="radio"/> TBIPA278RMBE8	GUID	FITBIR	niH	admin, sel	2021-02-04	TBI_INVPU718DFJCF, TBI_INVJA921WJWTV, TBI_INVMV110UUXMT, TBI_INVVU706CYDKJ
<input type="radio"/> TBI_INVJJ369AUHG1	PseudoGUID	FITBIR	niH	admin, sel	2021-02-04	
<input type="radio"/> TBIYA174RRDVJ	GUID	FITBIR	niH	admin, sel	2021-02-04	

Showing 1 to 15 of 103,904 entries (1 row selected of 103904)

First Previous 1 2 3 4 5 ... 6927 Next Last

[.] Subject Information

* This symbol indicates a required field

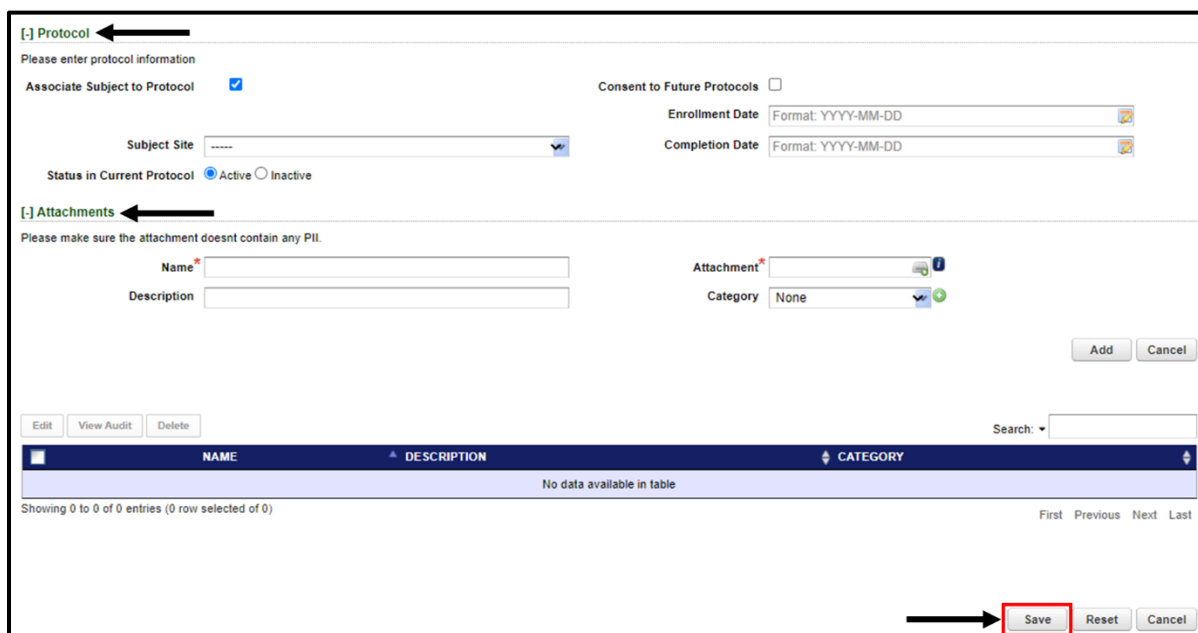
GUID or Pseudo-GUID*

Additional Information Associated with Subject

Protocol Subject ID*

Recruited ☐

8. Expand the **Protocol** and **Attachments** section to add any relevant documents as required, making sure the attachment does not contain any PII.
9. After entering all the required protocol information, click the **Save** button.



[-] Protocol

Please enter protocol information

Associate Subject to Protocol ☒

Consent to Future Protocols ☐

Subject Site -----

Enrollment Date Format: YYYY-MM-DD

Completion Date Format: YYYY-MM-DD

Status in Current Protocol ☒ Active ☐ Inactive

[-] Attachments

Please make sure the attachment doesn't contain any PII.

Name*

Description

Attachment*

Category None

Add Cancel

Edit View Audit Delete

Search:

NAME	DESCRIPTION	CATEGORY
No data available in table		

Showing 0 to 0 of 0 entries (0 row selected of 0)

First Previous Next Last

Save Reset Cancel

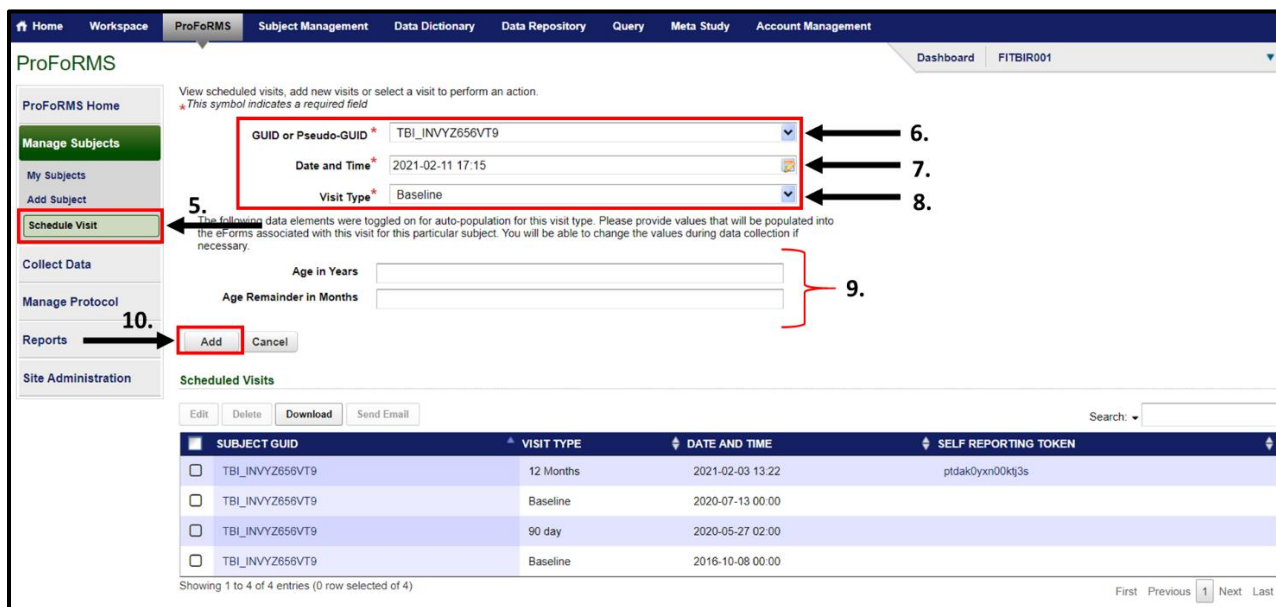
10. After selecting the **Save** button, the platform returns you to the **My Subjects** page where the newly added subject can be viewed.
11. If the subject does not have a **GUID** or **Pseudo-GUID** created in the system, click on the **Add Subject** button to launch the Subject Management tool and refer to the **Chapter 6 Subject Management** user guide for directions on how to create a GUID.
 - a. **Note:** the Subject Management user guide can be found in the following location in the platform; **Subject Management** tab, **Create Subject** tab, navigate to the **Helpful Documentation** section and select the **GUID User Guide (pdf)**.

3.6.3 Schedule Visit

The **Schedule Visit** feature provides you with the ability to schedule visits as well as perform other functions such as **Edit** visits (see section 3.6.3.1) and **Delete** visits (see section 3.6.3.2).

To **Schedule a Visit**, perform the following actions:

1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.
4. The **My Subjects** page appears.
5. Click the **Schedule Visit** tab on the left-side tool bar.
6. Select the GUID or Pseudo-GUID of the subject you would like to schedule a visit for from the **GUID or Pseudo-GUID** drop-down menu.
7. Click the **Calendar** icon to choose the desired **Date and Time** for the visit.
8. Select the **Visit Type** from the drop-down menu.
9. After selecting the Visit Type, the **Age in Years** and **Age Remainder in Months** fields appear. If you enter data into these fields, this data will auto-populate on all data collection eForms for this Visit Type.
10. Click the **Add** button to finish “scheduling” the visit.



ProFoRMS

View scheduled visits, add new visits or select a visit to perform an action.
* This symbol indicates a required field

GUID or Pseudo-GUID * TBI_INVYZ656VT9

Date and Time * 2021-02-11 17:15

Visit Type * Baseline

Age in Years

Age Remainder in Months

Add Cancel

Scheduled Visits

	SUBJECT GUID	VISIT TYPE	DATE AND TIME	SELF REPORTING TOKEN
<input type="checkbox"/>	TBI_INVYZ656VT9	12 Months	2021-02-03 13:22	ptdak0yxn00kt3s
<input type="checkbox"/>	TBI_INVYZ656VT9	Baseline	2020-07-13 00:00	
<input type="checkbox"/>	TBI_INVYZ656VT9	90 day	2020-05-27 02:00	
<input type="checkbox"/>	TBI_INVYZ656VT9	Baseline	2016-10-08 00:00	

Showing 1 to 4 of 4 entries (0 row selected of 4)

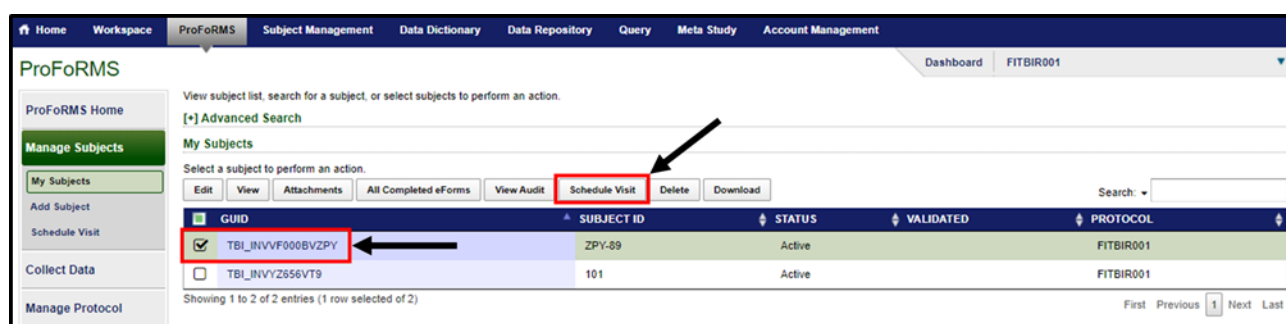
First Previous 1 Next Last

11. The newly scheduled visit will be displayed in the **Schedule Visit** table and will include a list of all visits that have been scheduled for subjects on the protocol.

***NOTE:** you may also schedule a visit for a specific subject by selecting a subject on the **My Subjects** page (which will enable numerous table buttons for use) and selecting the **Schedule Visit** button located at the top of the table.

This will direct you to the **Schedule Visit** page with the **GUID or Pseudo-GUID** field prepopulated with the subject's ID you selected.

This step is recommended as the user can search/filter for a specific GUID through the search bar instead of searching for the GUID using the drop-down menu



ProFoRMS

View subject list, search for a subject, or select subjects to perform an action.

[+] Advanced Search

My Subjects

Select a subject to perform an action.

Edit View Attachments All Completed eForms View Audit **Schedule Visit** Delete Download

Search:

GUID	SUBJECT ID	STATUS	VALIDATED	PROTOCOL
<input checked="" type="checkbox"/> TBI_INVVF000BVZPY	ZPY-89	Active		FITBIR001
<input type="checkbox"/> TBI_INVYZ656VT9	101	Active		FITBIR001

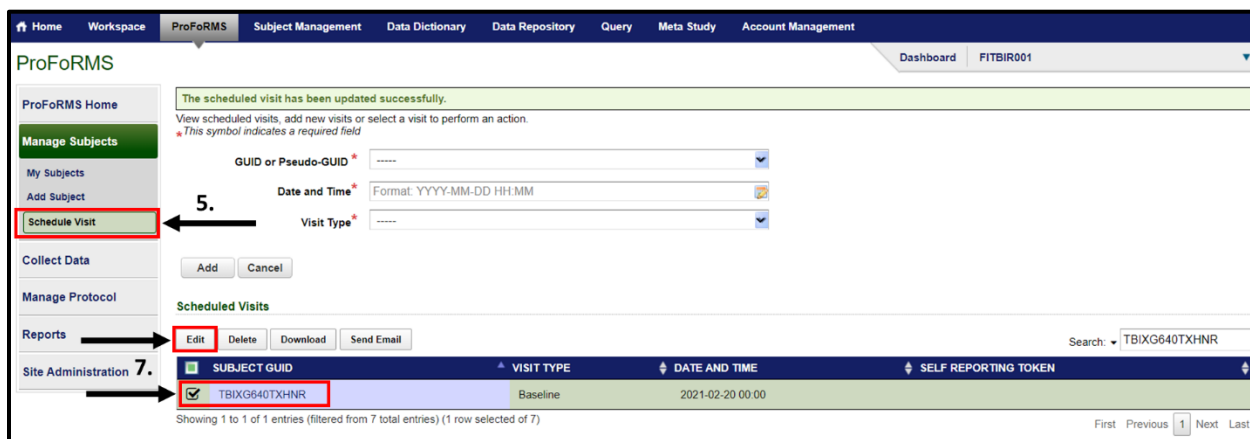
Showing 1 to 2 of 2 entries (1 row selected of 2)

First Previous **1** Next Last

3.6.3.1 Editing Scheduled Visits

To **Edit** scheduled visits, perform the following actions:

1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.
4. The **My Subjects** page appears.
5. Click the **Schedule Visit** tab on the left-side tool bar.
6. The **Schedule Visit** table appears where you can **View Scheduled Visits**, **Add New Visits**, or **Select a Visit** to perform an action.
7. Select the **Subject GUID** and the corresponding **Visit Type** from the table, that you would like to edit, then select the **Edit** button at the top of the table



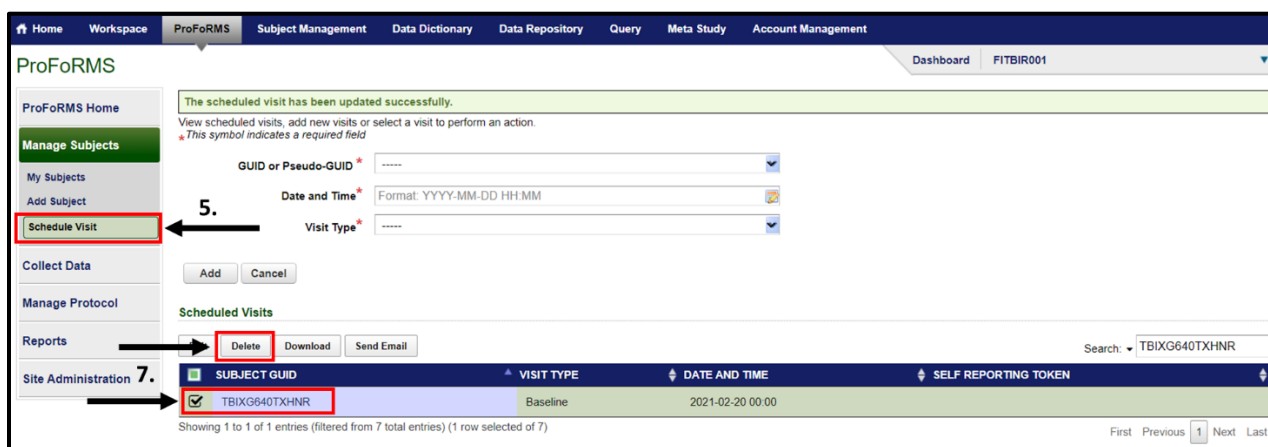
The screenshot shows the ProFoRMS interface. On the left sidebar, the 'Schedule Visit' tab is highlighted with a red box and an arrow labeled '5.'. The main content area shows a form for adding a new visit with fields for 'GUID or Pseudo-GUID', 'Date and Time', and 'Visit Type'. Below the form is a table titled 'Scheduled Visits'. The table has columns: 'SUBJECT GUID', 'VISIT TYPE', 'DATE AND TIME', and 'SELF REPORTING TOKEN'. The first row is selected, and the 'Edit' button in the table's action bar is highlighted with a red box and an arrow labeled '7.'. A success message at the top states: 'The scheduled visit has been updated successfully.'

8. Make desired edits to the **Date and Time** and **Visit Type** fields then select the **Update** button to complete the edit action.
9. The newly updated **Scheduled Visit** will be displayed in the **Schedule Visit** table.

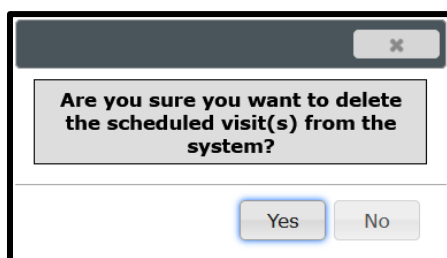
3.6.3.2 Deleting Scheduled Visits

To **Delete** scheduled visits, perform the following actions:

1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.
4. The **My Subjects** page appears.
5. Click the **Schedule Visit** tab on the left-side tool bar.
6. The **Schedule Visit** table appears where you can **View Scheduled Visits**, **Add New Visits**, or **Select a Visit** to perform an action.
7. Select the **Subject GUID** and the corresponding **Visit Type** from the table, that you would like to delete, then select the **Delete** button at the top of the table



8. A pop-up notification appears asking if you would like to delete the scheduled visit(s) from the system:



9. Select the **Yes** button to confirm that you want to delete the scheduled visit(s) from the system. Select the **No** button to cancel the update process.
10. The deleted visit will be removed from the **Schedule Visit** table.

3.7 COLLECT DATA

This feature allows researchers to collect data for subjects and/or specific electronic forms to add data or modify previously collected data entries, to view and resolve data discrepancies if double data entry is specified, perform quality assurance of collected data and monitor subject safety. The module has a functionality that assures that changes are tracked in the system and can be viewed in Audit Logs.

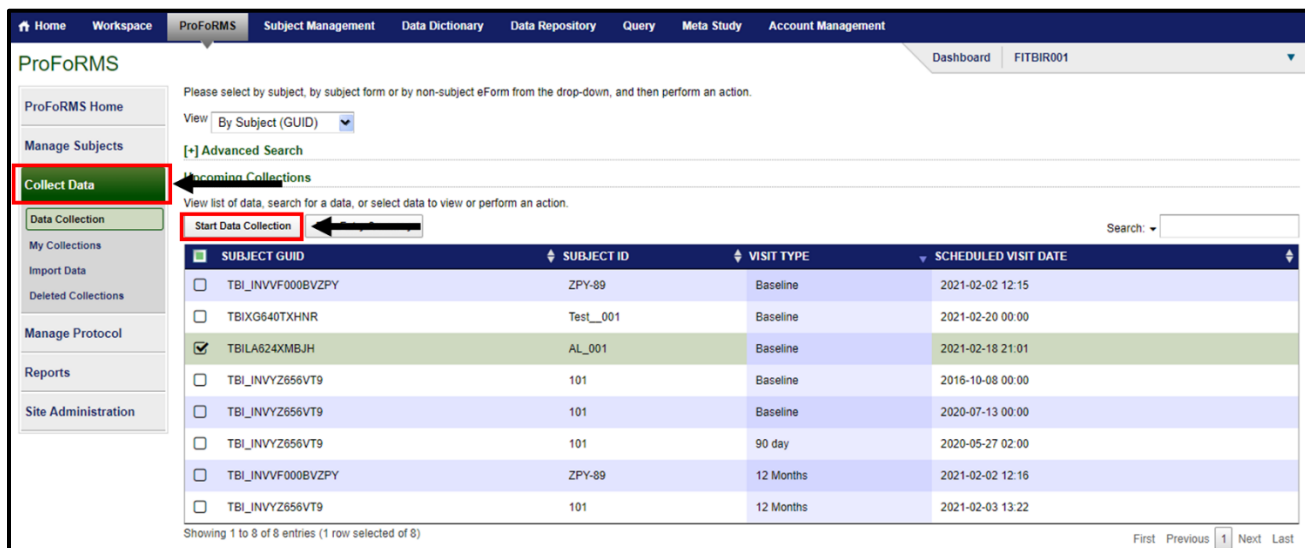
Clinical data may be captured electronically at its source, or in paper form and later transcribed into the system. There are two options for collecting data in ProFoRMS.

1. Real-time data entry method; and
2. Pen and paper method, which is then transcribed into ProFoRMS at a later date

3.7.1 Data Collection

To start **Data Collection**, perform the following actions:

1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Click the **Collect Data** tab on the left-side tool bar.
4. The **Data Collection** page appears.
5. To start data collection, select the check-box beside the Subject GUID/Subject ID then select the **Start Data Collection** button.
 - a. **Note:** we recommend that you exclusively use ProFoRMS navigation buttons and links within the Collect Data tab. Leaving the form by any other method (back/forward buttons, backspace key, etc.) may result in data loss and unexpected errors. We also recommend that you do not open multiple database tabs in your browser when collecting data.

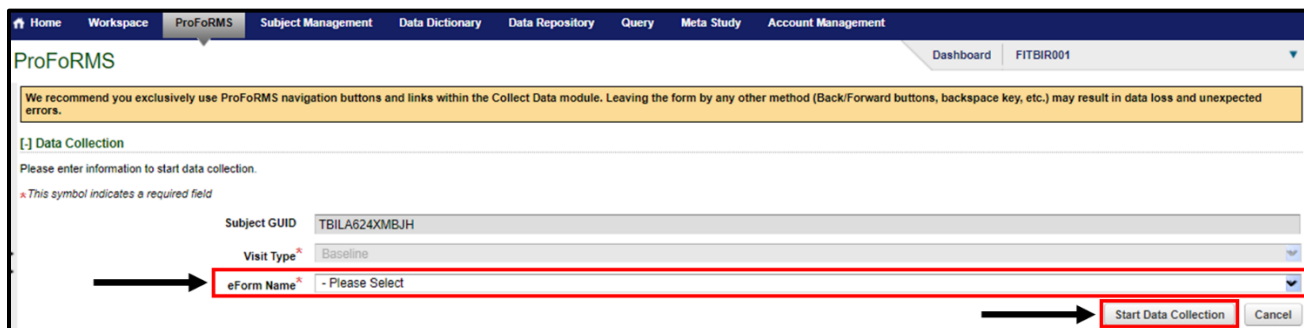


The screenshot shows the ProFoRMS interface. On the left, the 'Collect Data' tab is highlighted in green. The main content area shows a table of data collection entries. The table has the following columns: SUBJECT GUID, SUBJECT ID, VISIT TYPE, and SCHEDULED VISIT DATE. The first row is selected, and the 'Start Data Collection' button is highlighted with a red box and an arrow.

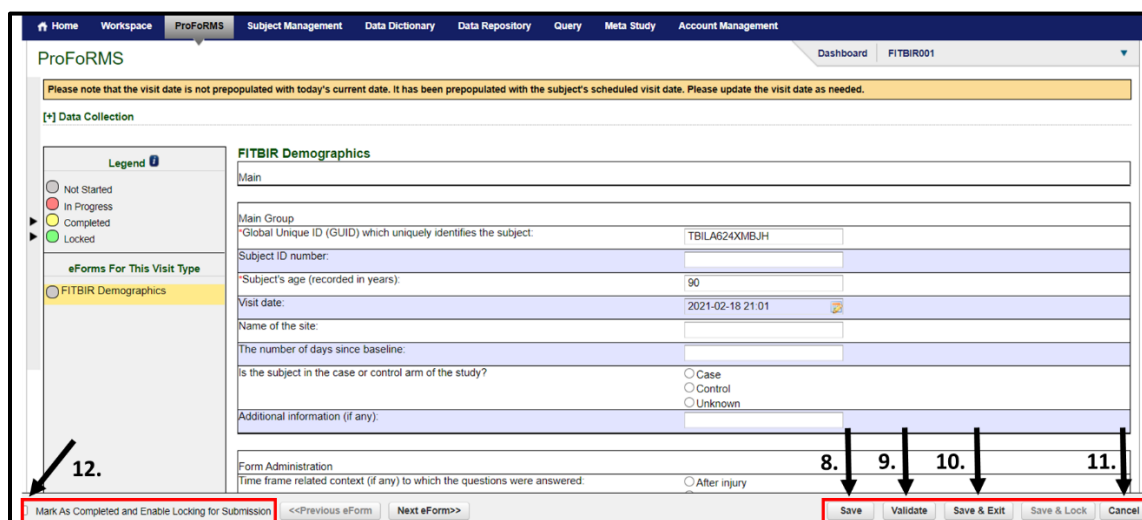
SUBJECT GUID	SUBJECT ID	VISIT TYPE	SCHEDULED VISIT DATE
<input type="checkbox"/> TBI_INVVF000BVZPY	ZPY-89	Baseline	2021-02-02 12:15
<input type="checkbox"/> TBI_XG640TXHNR	Test_001	Baseline	2021-02-20 00:00
<input checked="" type="checkbox"/> TBI_LA624XMBJH	AL_001	Baseline	2021-02-18 21:01
<input type="checkbox"/> TBI_INVYZ656VT9	101	Baseline	2016-10-08 00:00
<input type="checkbox"/> TBI_INVYZ656VT9	101	Baseline	2020-07-13 00:00
<input type="checkbox"/> TBI_INVYZ656VT9	101	90 day	2020-05-27 02:00
<input type="checkbox"/> TBI_INVVF000BVZPY	ZPY-89	12 Months	2021-02-02 12:16
<input type="checkbox"/> TBI_INVYZ656VT9	101	12 Months	2021-02-03 13:22

Showing 1 to 8 of 8 entries (1 row selected of 8)

6. Select the **eForm Name** from the drop-down list that you want to collect data for, then select **Start Data Collection**.
 - a. **Note:** Subject GUID and Visit Type are auto-populated



7. Enter data into the form and make sure all mandatory fields (marked with an asterisk*) are completed.
8. Select **Save** to save your progress on the form.
 - a. **Note:** the system also auto-saves your progress
9. Select **Validate** to validate and confirm you are completing the fields properly.
10. Select **Save & Exit** to save your progress on the form and leave the eForm data collection page. You will then be directed back to the **My Collections** page.
 - a. Your form will show a status of “In Progress” in the My Collections table.
11. Select **Cancel** when you want to leave the form and not save any work.
12. Select **Mark as Completed and Enable Locking for Submission** and **Save & Exit** when you want to mark your form as **Completed** status but are not ready to Save & Lock the data for submission to the database.
 - a. Your form will show a status of “Complete” in the My Collections table.
 - b. **Note:** Some sites use this feature for auditing purposes. For example, a user may mark the form as **Completed** so their internal Quality Assurance (QA) person or Study Monitor can review the data for accuracy and completion prior to the user saving and locking the form.



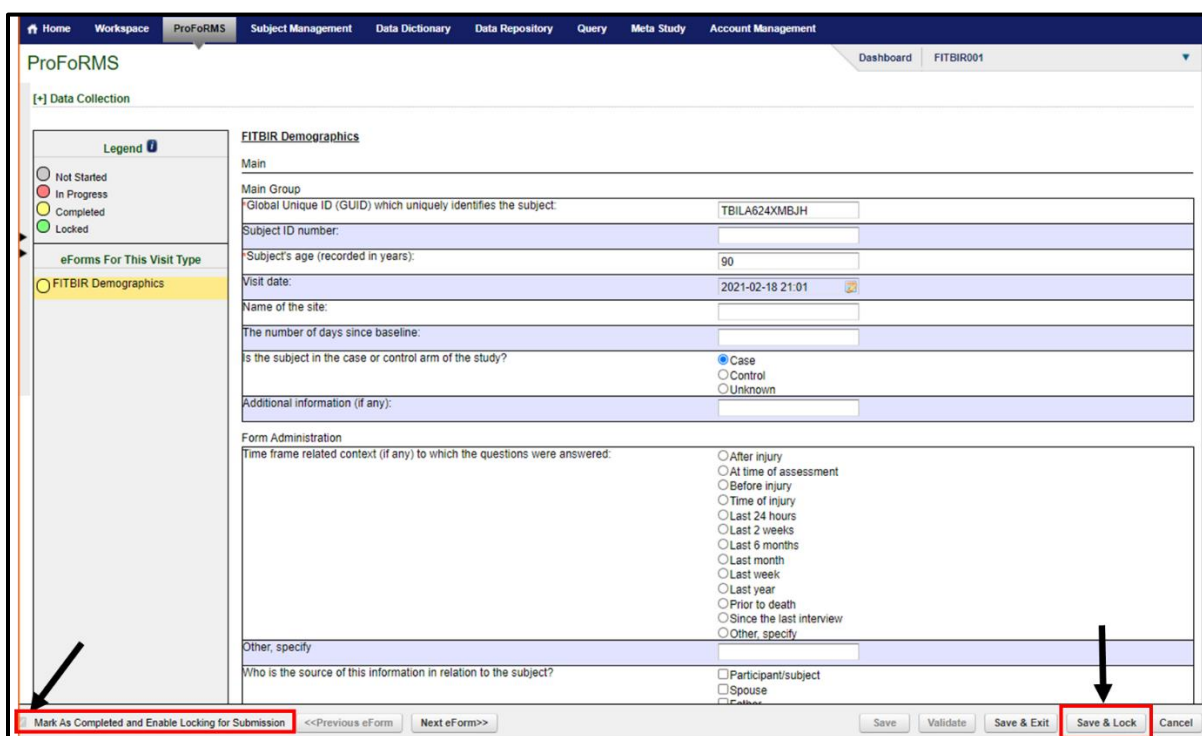
13. Once a form has been marked as completed, three things will happen:
 - a. The Save & Lock button will be enabled;
 - b. The system validation will run;
 - c. An audit trail will start if a user changes their response to an answer
14. If the form failed, you will be notified with a list of errors stating why, along with a link to the question that failed the validation. Once all the errors have been resolved, you will be able to **Save & Lock** the form (see section 3.7.1.1).

3.7.1.1 Locking the eForm

After you have filled out the form and verified that the data is complete and accurate, you can **Save & Lock** the eForm. Forms should not be locked until reviewed and ready for final submission. (should I add information regarding data being sent to Data Repo → Query Tool for other users to view?) – Yes, include this as a note

To **Save & Lock** your form, perform the following actions:

1. Select the GUID and form you want to lock from the My Collections table and make sure the form is complete and accurate.
2. Select the **Mark as Completed and Enable Locking for Submission**. The **Save & Lock** button will then be enabled.



The screenshot shows the ProFoRMS interface with the 'FITBIR Demographics' form. The 'Mark As Completed and Enable Locking for Submission' button is highlighted with a red box and an arrow. The 'Save & Lock' button is also highlighted with a red box and an arrow. The form includes fields for 'Global Unique ID (GUID)', 'Subject ID number', 'Subject's age', 'Visit date', 'Name of the site', 'The number of days since baseline', 'Is the subject in the case or control arm of the study?', 'Additional information (if any)', 'Form Administration', 'Time frame related context (if any)', 'Other, specify', and 'Who is the source of this information in relation to the subject?'. The 'Save & Lock' button is located at the bottom right of the form.

3. A **Collect Data Lock Confirmation** notification will appear asking you to confirm that all data entry for the form is accurate and complete to the best of your knowledge.
4. Select the checkbox to confirm.
 - a. If the e-signature is enabled in the protocol, you will also be asked for your electronic signature by inputting your password.

Collect Data Lock Confirmation - Signature Required

Protocol Name:	FITBIR Generic PROD Study
eForm Name:	FITBIR Demographics
Subject GUID:	TBILA624XMBJH
Collection Visit Date:	2021-02-18 21:01
Scheduled Visit Date:	2021-02-18 21:01
Visit Type:	Baseline
Data Entered By:	amlutz

☐ I hereby confirm that all data entry for this form is accurate and complete to the best of my knowledge.

View Completed Form
Lock & << Previous eForm
Lock & Next eForm >>
Lock & Exit
Cancel

5. Select **Lock & Next eForm** to continue collecting data for the study visit or select **Lock & Exit** to be taken back to the My Collections page.
 - a. Your form will show a status of “Locked” and will have a locked date and time in the My Collections table.










THINGS TO NOTE:

ICON KEY

 Notes

 Important

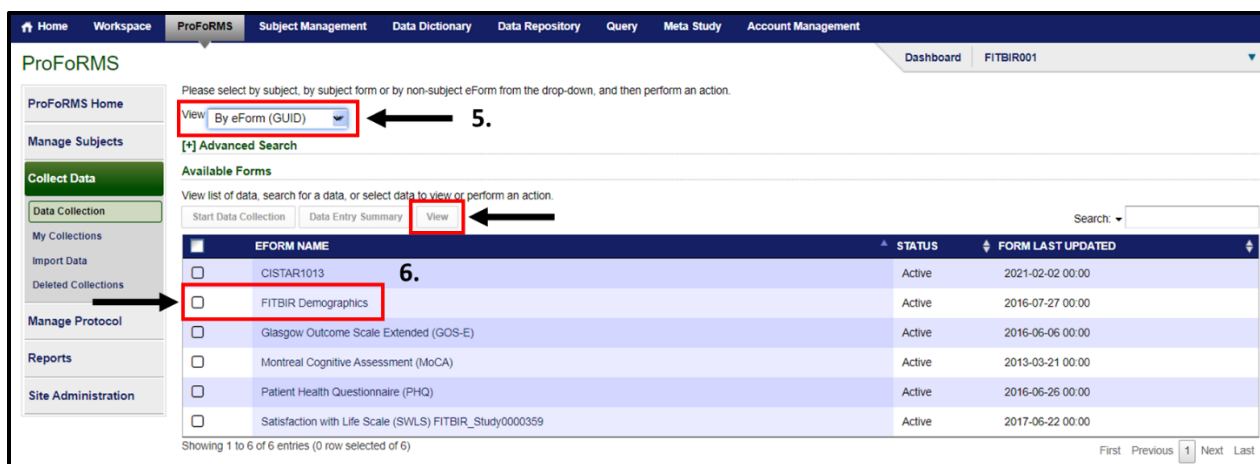
Information

-  To reset the questions on the eform, double-click on the Radio buttons
-  To save the eform, use the **Save** button at the bottom of the eform
-  To cancel the data collection process, simply click on the **Cancel** button
-  The system auto-saves the eform every **8 minutes**
-  All Required fields are marked by **red asterisks**
-  Certain questions are greyed-out by **Skip logic**
-  Auto-calculated fields ~~that~~ appear in several forms. Answers will appear if you click on them, but it is **NOT** necessary to save the eform.
-  Green sections are collapsible. User can expand/hide to read further instructions or view scoring sections.
-  To leave the form and complete it at a later date and time, use the **Save & Exit** button

3.7.1.2 Viewing Data Collection eForms

To view Data Collection eForms, perform the following actions:

1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Select the **Collect Data** tab on the left-side tool bar.
4. The **Data Collection** page appears.
5. Select **By eForm (GUID)** from the View drop-down
6. Select the **eForm Name** link OR select the check-box next to the **eForm Name** you want to view then select **View**



ProFoRMS

Please select by subject, by subject form or by non-subject eForm from the drop-down, and then perform an action.

View By eForm (GUID) 5.

[+] Advanced Search

Available Forms

View list of data, search for a data, or select data to view or perform an action.

Start Data Collection Data Entry Summary View

	EFORM NAME	STATUS	FORM LAST UPDATED
<input type="checkbox"/>	CISTAR1013	Active	2021-02-02 00:00
<input type="checkbox"/>	FITBIR Demographics	Active	2016-07-27 00:00
<input type="checkbox"/>	Glasgow Outcome Scale Extended (GOS-E)	Active	2016-06-06 00:00
<input type="checkbox"/>	Montreal Cognitive Assessment (MoCA)	Active	2013-03-21 00:00
<input type="checkbox"/>	Patient Health Questionnaire (PHQ)	Active	2016-06-26 00:00
<input type="checkbox"/>	Satisfaction with Life Scale (SWLS) FITBIR_Study0000359	Active	2017-06-22 00:00

Showing 1 to 6 of 6 entries (0 row selected of 6)

First Previous 1 Next Last

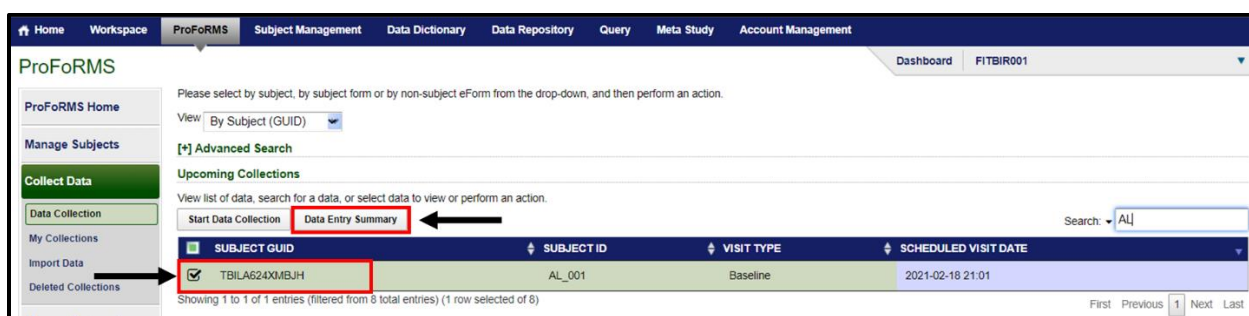
7. A new tab will open in your browser displaying the eForm details in **View Mode**
8. You can view the data **By Subject (GUID)**, or **By eForm (GUID)**. Depending on the view you selected, the table will display either the list of subjects, or the list of eForms.

3.7.1.3 Viewing Data Entry Summary

Data Entry Summary allows the user to view all data collected for a subject at one time in the My Collections table.

To view the **Data Entry Summary**, perform the following actions:

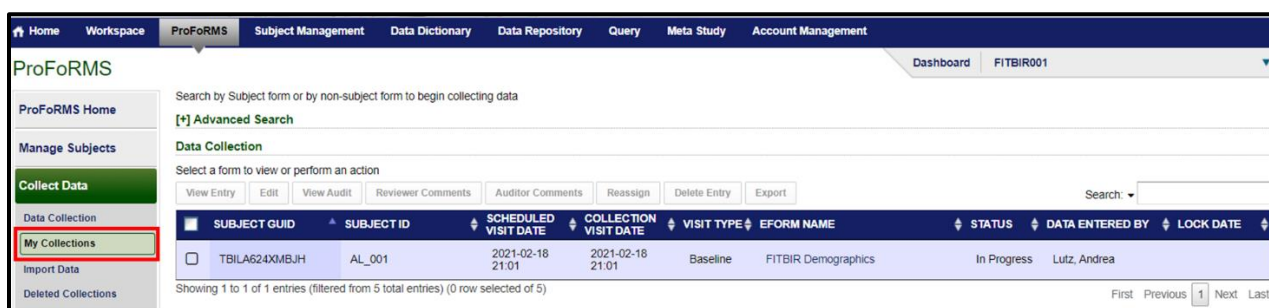
1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Select the **Collect Data** tab on the left-side tool bar.
4. The **Data Collection** page appears.
5. Select the check-box next to the **Subject GUID** that you are interested in viewing then select **Data Entry Summary**



The screenshot shows the ProFoRMS interface. On the left sidebar, the 'Collect Data' tab is selected. The main area displays 'Upcoming Collections'. A table lists data collection entries. The first entry is selected (checkbox checked). A red box highlights the 'Data Entry Summary' button next to the selected entry. A black arrow points from the text 'select Data Entry Summary' in the instructions to this button.

SUBJECT GUID	SUBJECT ID	VISIT TYPE	SCHEDULED VISIT DATE
<input checked="" type="checkbox"/> TBILA624XMBJH	AL_001	Baseline	2021-02-18 21:01

6. You will then be brought to the **My Collections** table where all of the started and completed data collections will appear.



The screenshot shows the ProFoRMS 'My Collections' table. The left sidebar has 'My Collections' selected. The table lists data collection entries with columns for Subject GUID, Subject ID, Scheduled Visit Date, Collection Visit Date, Visit Type, EForm Name, Status, Data Entered By, and Lock Date.

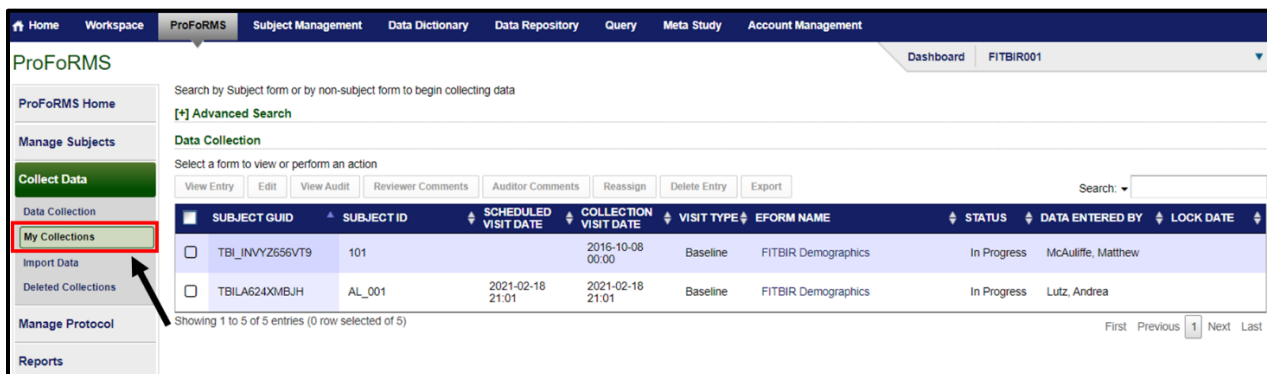
SUBJECT GUID	SUBJECT ID	SCHEDULED VISIT DATE	COLLECTION VISIT DATE	VISIT TYPE	EFORM NAME	STATUS	DATA ENTERED BY	LOCK DATE
<input type="checkbox"/> TBILA624XMBJH	AL_001	2021-02-18 21:01	2021-02-18 21:01	Baseline	FITBIR Demographics	In Progress	Lutz, Andrea	

3.7.2 My Collections

The **My Collections** page displays a table with all of the clinical assessments or eForms that were collected for a subject in the selected Protocol.

To view the **My Collections** page, perform the following actions:

1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Select the **Collect Data** tab on the left-side tool bar.
4. The **Data Collection** page appears.
5. Select the **My Collections** tab



SUBJECT GUID	SUBJECT ID	SCHEDULED VISIT DATE	COLLECTION VISIT DATE	VISIT TYPE	EFORM NAME	STATUS	DATA ENTERED BY	LOCK DATE
<input type="checkbox"/> TBI_INVYZ656VT9	101		2016-10-08 00:00	Baseline	FITBIR Demographics	In Progress	McAuliffe, Matthew	
<input type="checkbox"/> TBI_LA624XMBJH	AL_001	2021-02-18 21:01	2021-02-18 21:01	Baseline	FITBIR Demographics	In Progress	Lutz, Andrea	

Showing 1 to 5 of 5 entries (0 row selected of 5)

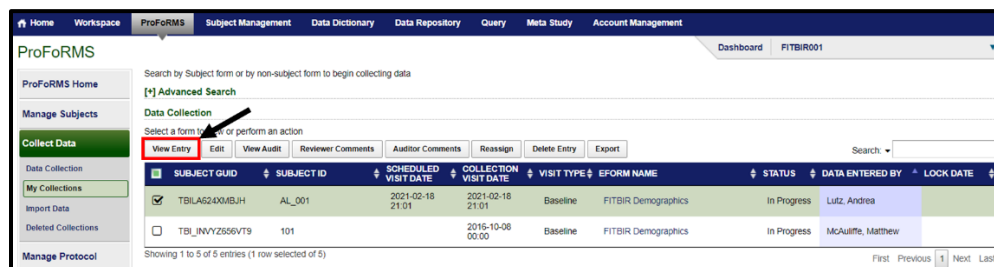
A user can perform the following actions in the **My Collections** table:

- ❖ View Entry ([section 3.7.2.1](#));
- ❖ Edit (section 3.7.2.2);
- ❖ View Audit (section 3.7.2.3);
- ❖ Reassign (section 3.7.2.4);
- ❖ Delete Entry (section 3.7.2.5); and
- ❖ Export (section 3.7.2.6)

3.7.2.1 View Entry

To **View Entry** or eForm information, perform the following actions:

1. Perform steps 1-6 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in viewing, then select **View Entry**.
3. The **eForm View Mode** will open, displaying the data that has been entered on the eForm.



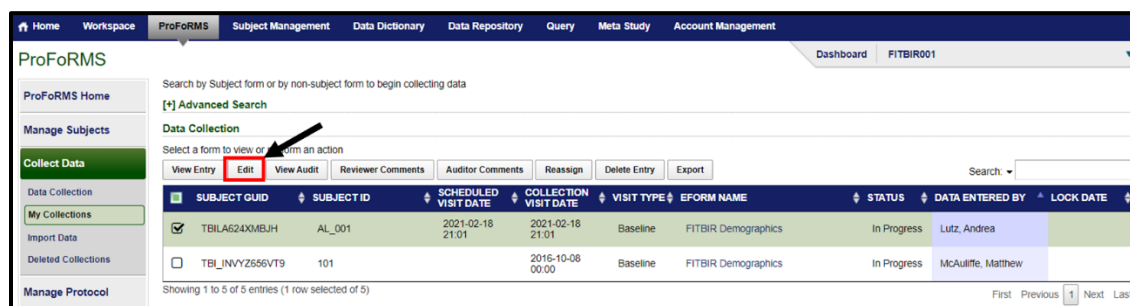
SUBJECT GUID	SUBJECT ID	SCHEDULED VISIT DATE	COLLECTION VISIT DATE	VISIT TYPE	EFORM NAME	STATUS	DATA ENTERED BY	LOCK DATE
<input checked="" type="checkbox"/> TBI_LA624XMBJH	AL_001	2021-02-18 21:01	2021-02-18 21:01	Baseline	FITBIR Demographics	In Progress	Lutz, Andrea	
<input type="checkbox"/> TBI_INVYZ656VT9	101		2016-10-08 00:00	Baseline	FITBIR Demographics	In Progress	McAuliffe, Matthew	

Showing 1 to 5 of 5 entries (1 row selected of 5)

3.7.2.2 Edit eForm

To **Edit eForm**, perform the following actions:

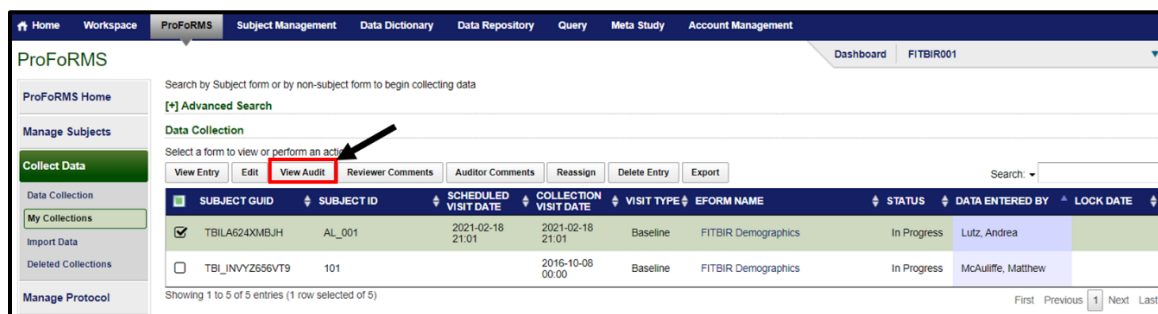
1. Perform steps 1-6 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in editing, then select **Edit**.
 - a. **Note:** non-admin users are only able to edit forms with an **In Progress** or **Completed** status. If your form is showing a **Locked** status and you need to make edits, reach out to the Operations Team for assistance.



3.7.2.3 View Audit

To **View Audit**, perform the following actions:

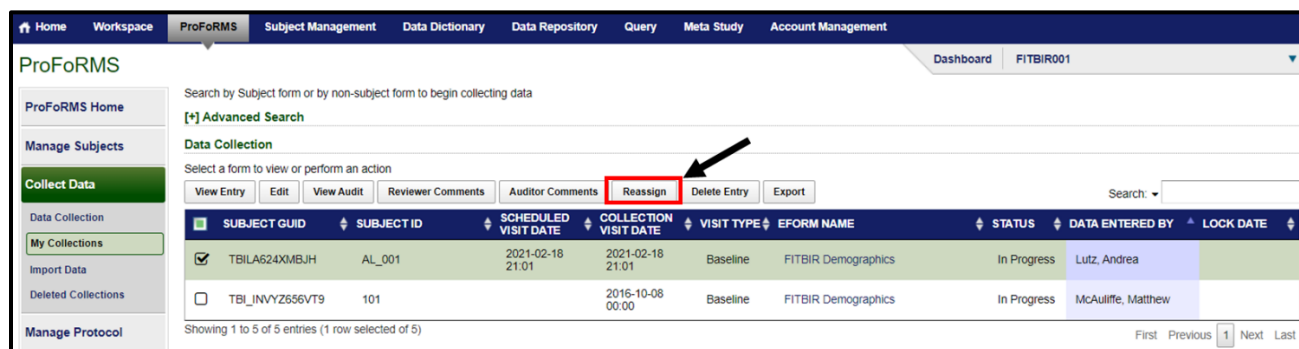
1. Perform steps 1-6 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in viewing, then select **View Audit**.
3. A new browser page will open with the **Data Collection Audit Log** details.



3.7.2.4 Reassign eForm

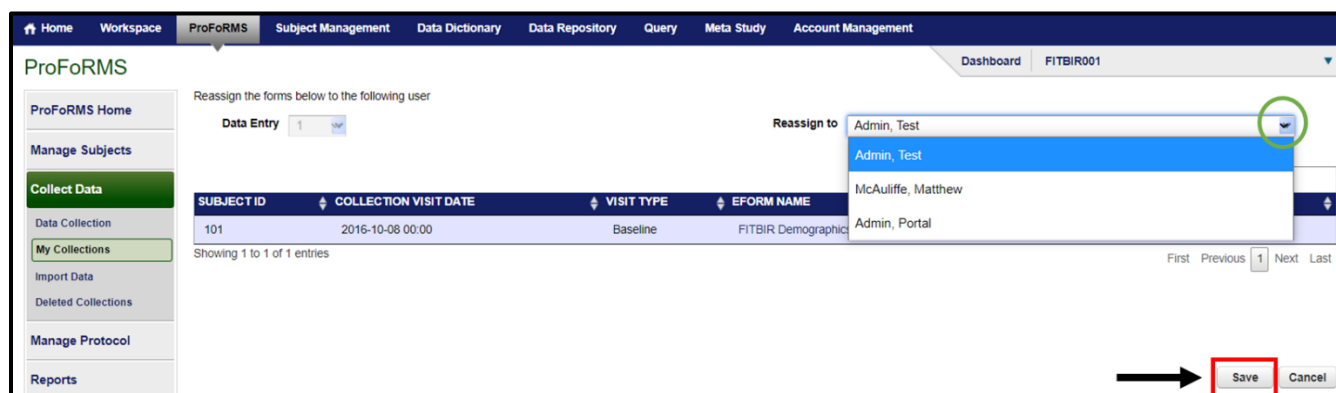
To **Reassign** an eForm, perform the following actions:

1. Perform steps 1-6 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in reassigning, then select **Reassign**.
 - a. **Note:** the ability to assign the form to another user for editing are limited to:
 - i. *Global Admin Users;*
 - ii. *Non-Admin Users with Primary Investigator (PI) Role;*
 - iii. *Non-Admin Users with Clinical Coordinators Role;*
 - iv. *Non-Admin Users with Study QA Role; and*
 - v. *Non-Admin Users with a role that has the privileges to Reassign Data Entry*



SUBJECT GUID	SUBJECT ID	SCHEDULED VISIT DATE	COLLECTION VISIT DATE	VISIT TYPE	EFORM NAME	STATUS	DATA ENTERED BY	LOCK DATE
<input checked="" type="checkbox"/>	TBILA624XMBJH	AL_001	2021-02-18 21:01	2021-02-18 21:01	Baseline	FITBIR Demographics	In Progress	Lutz, Andrea
<input type="checkbox"/>	TBI_INVYZ656VT9	101	2016-10-08 00:00	2016-10-08 00:00	Baseline	FITBIR Demographics	In Progress	McAuliffe, Matthew

3. The **Reassign** data entry page appears.
4. Using the drop-down menu, select the desired user to reassign the eForm to, then select **Save**.
5. The **My Collections** page appears with the reassigned form update.



Reassign the forms below to the following user

Data Entry: 1

SUBJECT ID	COLLECTION VISIT DATE	VISIT TYPE	EFORM NAME
101	2016-10-08 00:00	Baseline	FITBIR Demographic

Showing 1 to 1 of 1 entries

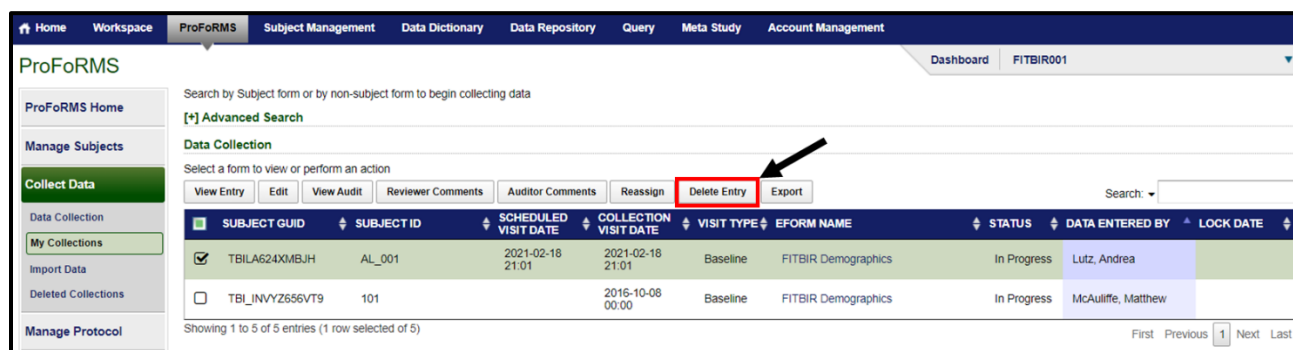
Reassign to: Admin, Test; Admin, Test; McAuliffe, Matthew; Admin, Portal

Save Cancel

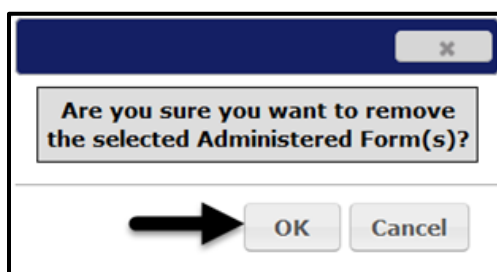
3.7.2.5 Delete Entry

To **Delete** an eForm entry, perform the following actions:

1. Perform steps 1-6 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in deleting, then select **Delete Entry**.
 - a. **Note:** non-admin users are only able to delete forms with an **In Progress** or **Completed** status. If your form is showing a **Locked** status and you need to delete the form, reach out to the Operations Team for assistance.



3. Select the **OK** button when prompted ‘Are you sure you want to remove the selected Administered Form(s)?’

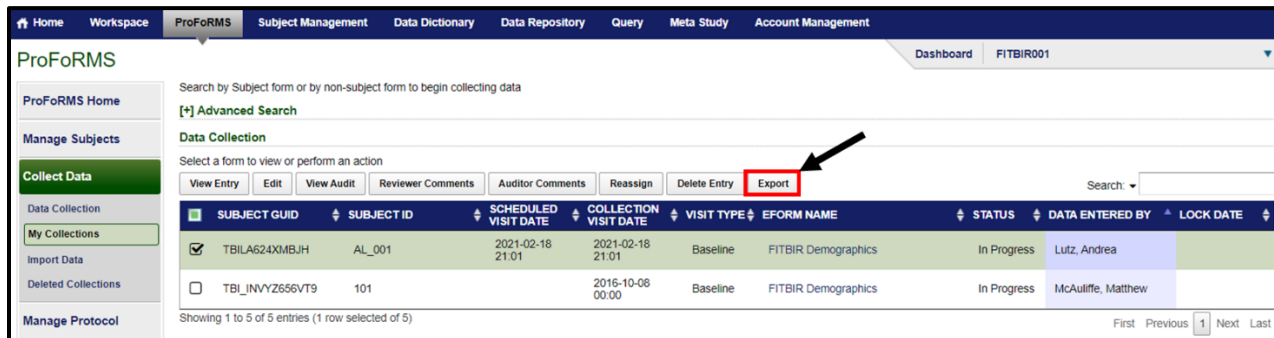


4. The **My Collections** page appears with the confirmation of the deleted eForm.

3.7.2.6 Export Data

To **Export** data, perform the following actions:

1. Perform steps 1-6 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in deleting, then select **Export**.
 - a. **Note:** only forms with a **Locked** status can be exported
3. When prompted, select **OK** to open the CSV file.



The screenshot shows the ProFoRMS interface. On the left sidebar, the 'Collect Data' tab is selected. The main area displays a table of data collections. The 'Export' button in the top action bar is highlighted with a red box and an arrow. The table has columns: SUBJECT GUID, SUBJECT ID, SCHEDULED VISIT DATE, COLLECTION VISIT DATE, VISIT TYPE, EFORM NAME, STATUS, DATA ENTERED BY, and LOCK DATE. Two rows are visible, both with a status of 'In Progress'.

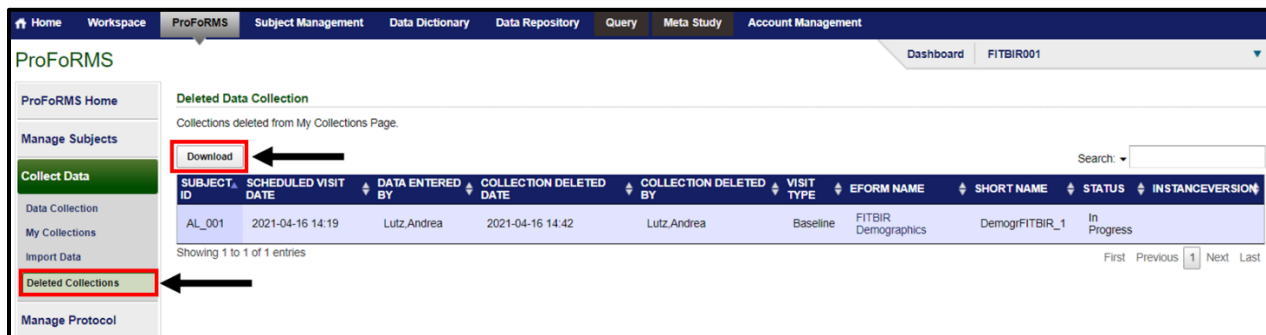
SUBJECT GUID	SUBJECT ID	SCHEDULED VISIT DATE	COLLECTION VISIT DATE	VISIT TYPE	EFORM NAME	STATUS	DATA ENTERED BY	LOCK DATE
<input checked="" type="checkbox"/>	TBILA624XMBJH	AL_001	2021-02-18 21:01	2021-02-18 21:01	Baseline	FITBIR Demographics	In Progress	Lutz, Andrea
<input type="checkbox"/>	TBI_INVYZ656VT9	101	2016-10-08 00:00	Baseline	FITBIR Demographics	In Progress	McAuliffe, Matthew	

3.7.3 Deleted Collections

The **Deleted Collections** page displays a table with any eForm data collections that were deleted from the **My Collections** table.

To view the **Deleted Collections** page, perform the following actions:

1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Select the **Collect Data** tab on the left-side tool bar.
4. The **Data Collection** page appears.
5. Select the **Deleted Collections** tab
6. Select the **Download** button to download an Excel or CSV file of the **Deleted Data Collection** table



The screenshot shows the ProFoRMS interface with the 'Deleted Data Collection' page. On the left sidebar, the 'Deleted Collections' tab is highlighted. The main area displays a table of deleted data collections. The 'Download' button in the top action bar is highlighted with a red box and an arrow. The table has columns: SUBJECT ID, SCHEDULED VISIT DATE, DATA ENTERED BY, COLLECTION DELETED DATE, COLLECTION DELETED BY, VISIT TYPE, EFORM NAME, SHORT NAME, STATUS, and INSTANCEVERSION. One row is visible with a status of 'In Progress'.

SUBJECT ID	SCHEDULED VISIT DATE	DATA ENTERED BY	COLLECTION DELETED DATE	COLLECTION DELETED BY	VISIT TYPE	EFORM NAME	SHORT NAME	STATUS	INSTANCEVERSION
AL_001	2021-04-16 14:19	Lutz, Andrea	2021-04-16 14:42	Lutz, Andrea	Baseline	FITBIR Demographics	DemogrFITBIR_1	In Progress	

3.8 MANAGE PROTOCOL

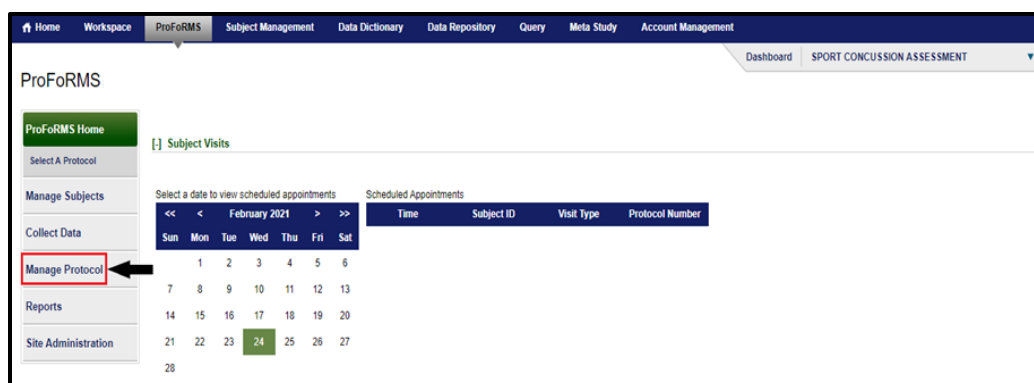
This feature is designed to help the researchers to add and edit study information, schedule create study visits, manage visit types individual subjects across multiple studies within the system, upload subject related document. The sub-sections available in the Manage Subjects menu are as follows:

- ❖ Protocol Information
- ❖ Assign Roles
- ❖ Create Visit Type
- ❖ Manage Visit Types
- ❖ Configure eForm and PVs
- ❖ Patient Self Reporting
- ❖ E-Binder
- ❖ Protocol Close-out

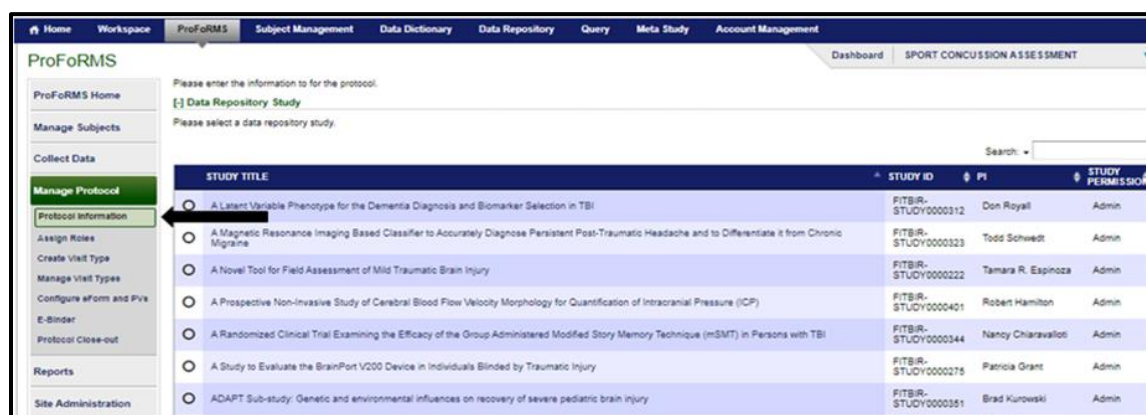
3.8.1 Viewing Protocol Information

To view **Protocol Information**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar.



4. Click the **Protocol Information** on the left-side tool bar. The Study Information page appears.



5. Click on the **Study Title** to open the Protocol.

Home
Workspace
ProFoRMS
Subject Management
Data Dictionary
Data Repository
Query
Meta Study
Account Management

Dashboard
SPORT CONCUSSION ASSESSMENT

ProFoRMS Home
Manage Subjects
Collect Data
Manage Protocol
Protocol Information
Assign Roles
Create Visit Type
Manage Visit Types
Configure eForm and PIVs
E-Binder
Protocol Close-out
Reports
Site Administration

Please enter the information for the protocol.
[-] Data Repository Study
Please select a data repository study.

Search:

STUDY TITLE	STUDY ID	PI	STUDY PERMISSION
<input type="radio"/> A Latent Variable Phenotype for the Dementia Diagnosis and Biomarker Selection in TBI	FITBIR-STUDY0000312	Don Royall	Admin
<input type="radio"/> A Magnetic Resonance Imaging Based Classifier to Accurately Diagnose Persistent Post-Traumatic Headache and to Differentiate it from Chronic Migraine	FITBIR-STUDY0000323	Todd Schwedt	Admin
<input type="radio"/> A Novel Tool for Field Assessment of Mild Traumatic Brain Injury	FITBIR-STUDY0000222	Tamara R. Espinoza	Admin
<input type="radio"/> A Prospective Non-Invasive Study of Cerebral Blood Flow Velocity Morphology for Quantification of Intracranial Pressure (ICP)	FITBIR-STUDY0000401	Robert Hamilton	Admin
<input type="radio"/> A Randomized Clinical Trial Examining the Efficacy of the Group Administered Modified Story Memory Technique (mSMT) in Persons with TBI	FITBIR-STUDY0000344	Nancy Chiaravalloti	Admin
<input type="radio"/> A Study to Evaluate the BrainPort V200 Device in Individuals Blinded by Traumatic Injury	FITBIR-STUDY0000275	Patricia Grant	Admin
<input type="radio"/> ADAPT Sub-study: Genetic and environmental influences on recovery of severe pediatric brain injury	FITBIR-STUDY0000351	Brad Kurowski	Admin
<input type="radio"/> ADAPT Sub-study: MRI Markers of Functional Outcome after Severe Pediatric Traumatic Brain Injury	FITBIR-STUDY0000340	Peter A Ferrazzano, MD	Admin
<input type="radio"/> AIM: TBI Impact of Aging on the Immune Response to Traumatic Brain Injury	FITBIR-STUDY0000288	Hilare J Thompson	Admin
<input type="radio"/> Accumulated white matter fiber strain from repetitive head impacts in contact sports	FITBIR-STUDY0000278	Songbai Ji	Admin
<input type="radio"/> Acute Low-Level Laser Therapy for the Treatment of Moderate Traumatic Brain Injury	FITBIR-STUDY0000262	Benjamin Vakoc	Admin
<input type="radio"/> Adding Legacy Clinical Data to the Federal Interagency Traumatic Brain Injury: Citalopram Brain Injury Treatment Trial (COBRIT)	FITBIR-STUDY0000240	Ross Zafonte, DO	Admin
<input type="radio"/> Addition of Pediatric TBI Data to FITBIR: Child Health After Injury (CHAI) study	FITBIR-STUDY0000230	Frederick P Rivara, MD, MPH	Admin
<input type="radio"/> Administration of Recombinant Erythropoietin to Improve Neovascularization and Decrease Neuroinflammation after TBI (CNRM)	FITBIR-STUDY0000290	Ramon Diaz-Arastia	Admin
<input type="radio"/> Advanced Imaging Acquisition and Data Analysis for a Military TBI Neuroimaging Database at NCoE	FITBIR-STUDY0000234	John Ollinger	Admin

Showing 1 to 15 of 200 entries (0 row selected of 200)

First Previous 1 2 3 4 5 ... 14 Next Last

[-] Protocol Details
Enter the protocol information and click on "Save" to save the protocol.
* This symbol indicates a required field.

Protocol Name* Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment - Test Stability and Effect of Concussion

Protocol Number* SPORT CONCUSSION ASSESSMENT

Principal Investigator(s)*

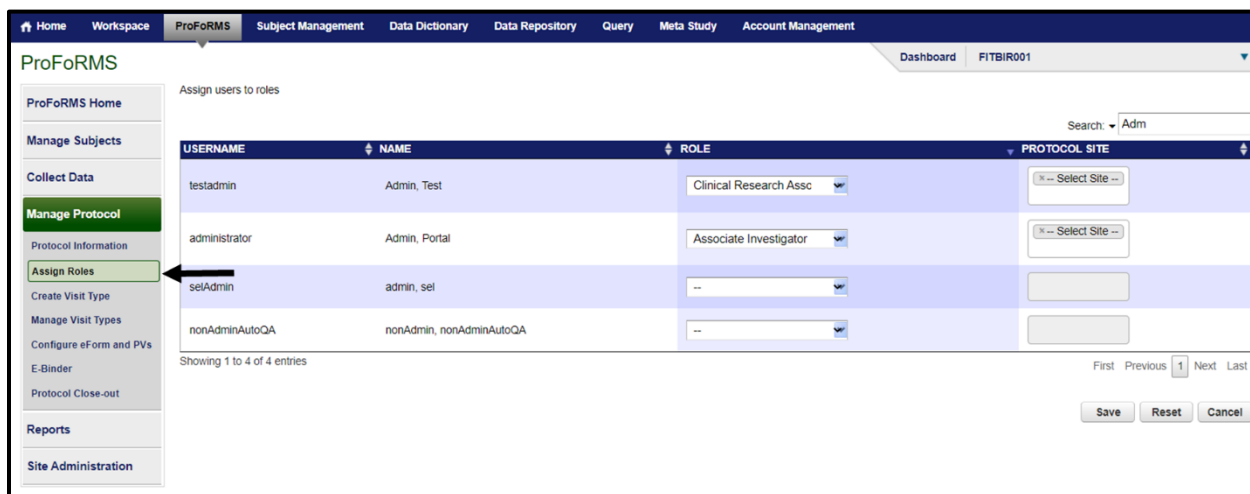
Study Type*

Subject Label* ☐ Subject GUID ☐ Subject ID

3.8.2 Assign Roles

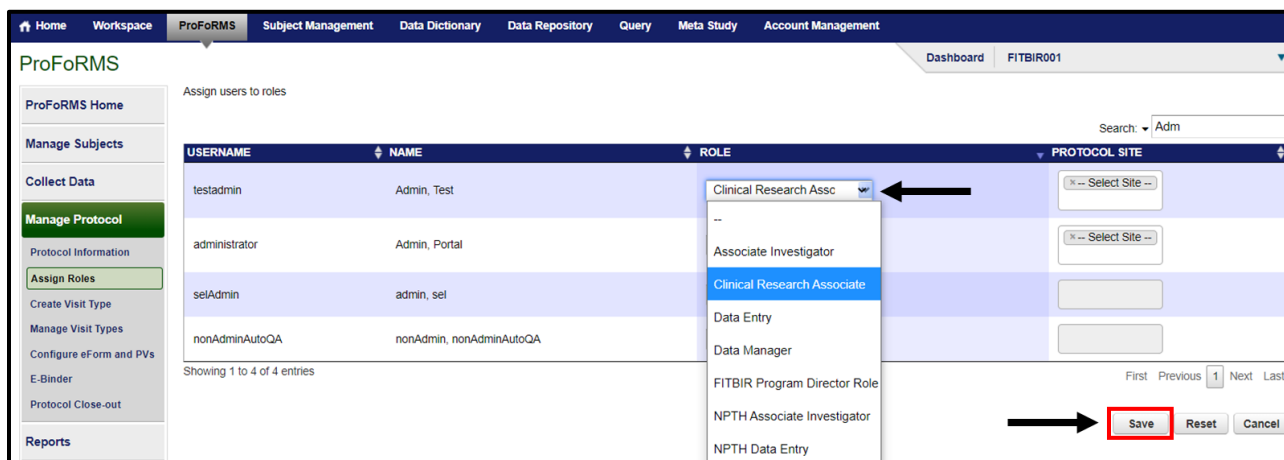
To **Assign Roles** within a study, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar then select the **Assign Roles** tab.



USERNAME	NAME	ROLE	PROTOCOL SITE
testadmin	Admin, Test	Clinical Research Assc	Select Site
administrator	Admin, Portal	Associate Investigator	Select Site
selAdmin	admin, sel	--	
nonAdminAutoQA	nonAdmin, nonAdminAutoQA	--	

4. In the **Assign Roles** page, find a user from the list of users. Use the drop-down menu to select and assign roles for a user in that study. The user roles depend on the study set up and can be as follows: Principal Investigator (max privileges), Clinical Coordinator, Study QA, Data Entry, etc.



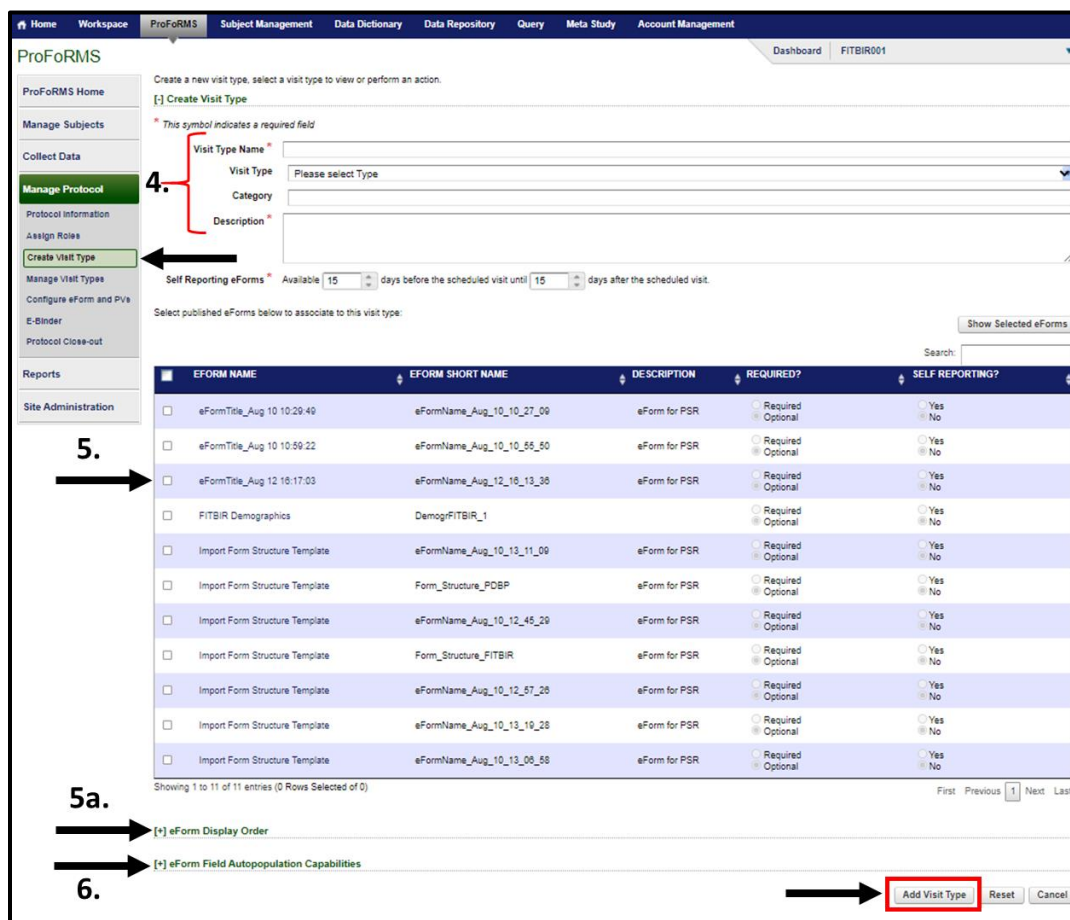
USERNAME	NAME	ROLE	PROTOCOL SITE
testadmin	Admin, Test	Clinical Research Assc	Select Site
administrator	Admin, Portal	Associate Investigator	Select Site
selAdmin	admin, sel	Clinical Research Associate	
nonAdminAutoQA	nonAdmin, nonAdminAutoQA	--	

5. Click the **Save** button. The new user role(s) appear in the protocol setup.

3.8.3 Create Visit Types

To **Create Visit Types**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar then select the **Create Visit Type** tab.
4. Create a new Visit Type by entering the **Visit Type Name**, **Visit Type**, and a **Short Description**
5. Select the check-boxes beside the **eForm Name** to associate published eForms to that Visit Type. Then, use the up and down button to change the order under **[-] eForm Display Order**
6. Finally, the fields within the eForms associated with this visit type have the ability to be autopopulated during data collection. Select the fields under **[-] eForm Field Autopopulation Capabilities** to enable autopopulation within this Visit Type.
 - a. The list only contains the eForms that are selected within the visit type
 - a. You may have to provide additional information when scheduling a visit for a particular subject.
7. Click the **Add Visit Type** button. The new Visit Type(s) appear in the **Manage Visit Types** page.



ProFoRMS

Create a new visit type, select a visit type to view or perform an action.

[+] Create Visit Type

* This symbol indicates a required field

Visit Type Name *

Visit Type Please select Type

Category

Description *

Self Reporting eForms * Available 15 days before the scheduled visit until 15 days after the scheduled visit.

Select published eForms below to associate to this visit type:

Show Selected eForms

EFORM NAME	EFORM SHORT NAME	DESCRIPTION	REQUIRED?	SELF REPORTING?
<input type="checkbox"/> eFormTitle_Aug 10 10:29:49	eFormName_Aug_10_10_27_09	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> eFormTitle_Aug 10 10:59:22	eFormName_Aug_10_10_55_50	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> eFormTitle_Aug 12 16:17:03	eFormName_Aug_12_16_13_38	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> FITBIR Demographics	Demog/FITBIR_1		<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Import Form Structure Template	eFormName_Aug_10_13_11_09	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Import Form Structure Template	Form_Structure_PDBP	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Import Form Structure Template	eFormName_Aug_10_12_45_29	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Import Form Structure Template	Form_Structure_FITBIR	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Import Form Structure Template	eFormName_Aug_10_12_57_28	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Import Form Structure Template	eFormName_Aug_10_13_19_28	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Import Form Structure Template	eFormName_Aug_10_13_06_58	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No

Showing 1 to 11 of 11 entries (0 Rows Selected of 0)

First Previous 1 Next Last

[-] eForm Display Order

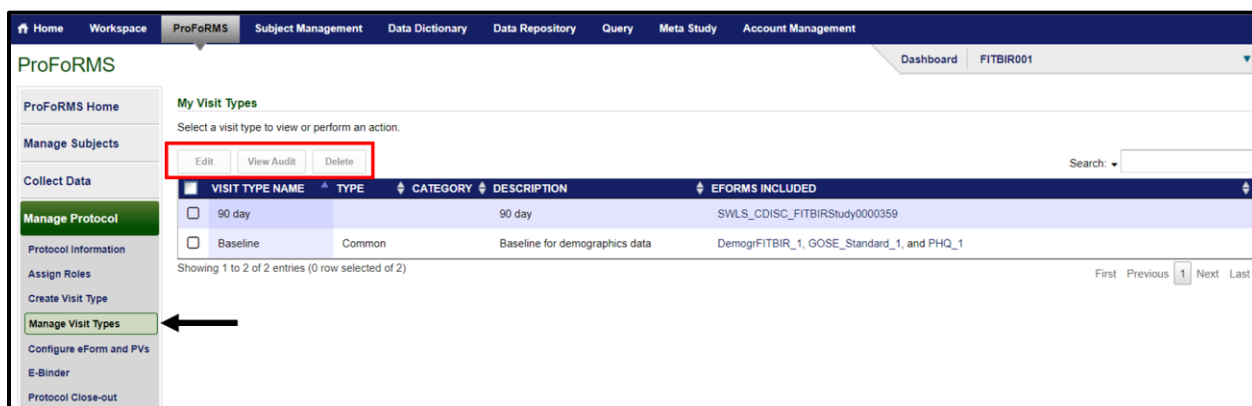
[-] eForm Field Autopopulation Capabilities

Add Visit Type Reset Cancel

3.8.4 Manage Visit Types

To **Manage Visit Types**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar then select the **Manage Visit Types** tab.
4. Select the check-box beside the **Visit Type Name** to perform an action: **Edit**, **View Audit**, and **Delete** functions.



ProFoRMS

My Visit Types

Select a visit type to view or perform an action.

Edit View Audit Delete

VISIT TYPE NAME	TYPE	CATEGORY	DESCRIPTION	EFORMS INCLUDED
<input type="checkbox"/> 90 day			90 day	SWLS_CDISC_FITBIRStudy0000359
<input type="checkbox"/> Baseline	Common		Baseline for demographics data	DemogFITBIR_1, GOSE_Standard_1, and PHQ_1

Showing 1 to 2 of 2 entries (0 row selected of 2)

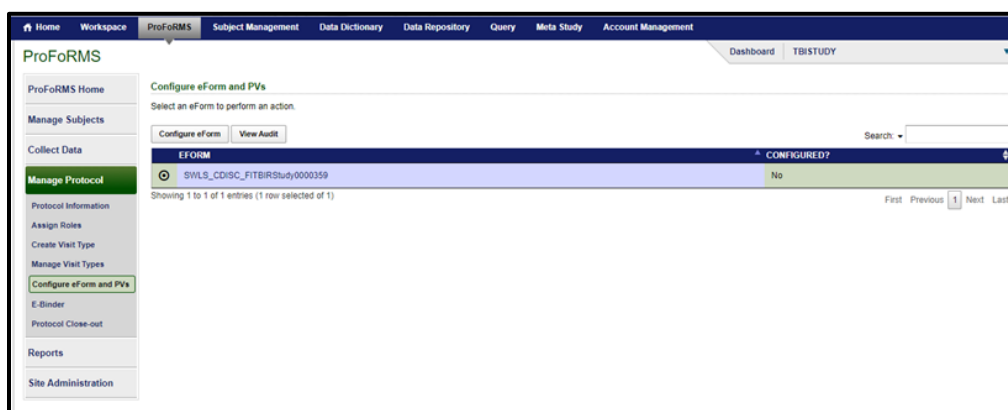
First Previous 1 Next Last

3.8.5 Configure eForm and PVs

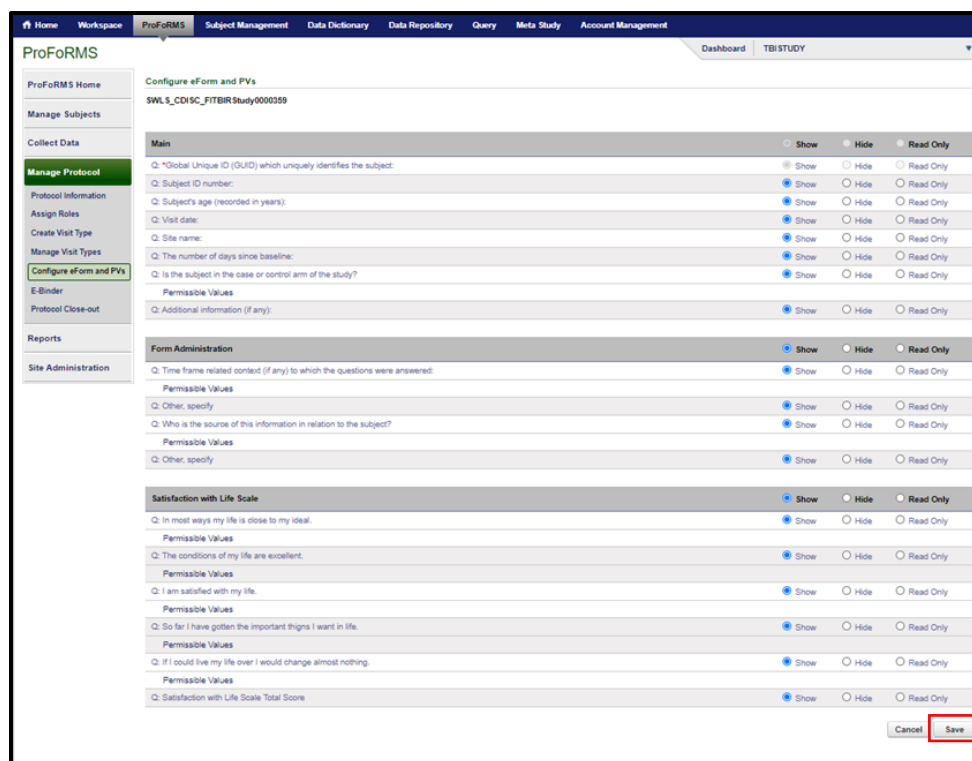
There is a feature where you are able to choose which fields of the eForm and PVs to either **Show**, **Hide**, or **Read Only**.

To **Configure eForm and PVs**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar then select the **Configure eForm and PVs** tab.



4. Choose which fields of the eForm and PVs you want to **Show**, **Hide**, or **Read Only**, then select **Save**.

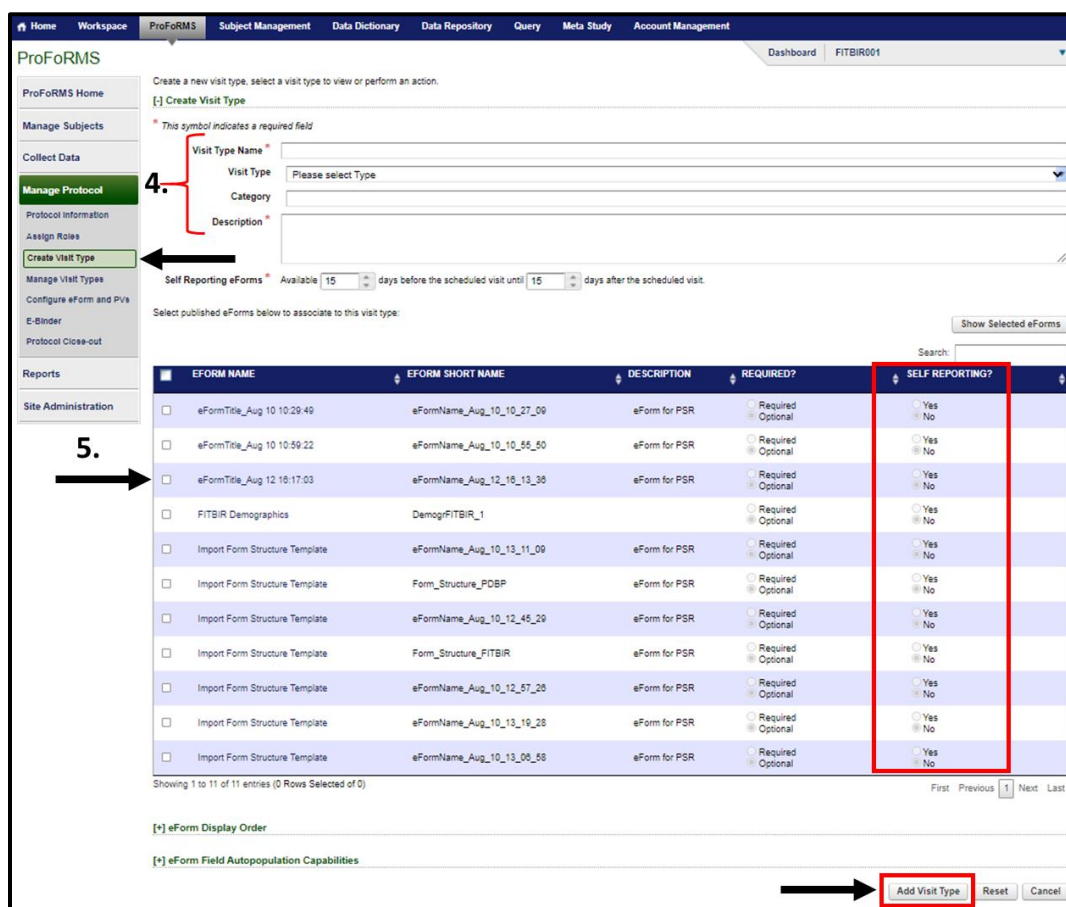


3.8.6 Patient Self-Reporting

Patient Self-Reporting is an Admin-enabled function. You must have an administrative privilege in order to use this feature. Ensure you have Administrative privileges enabled before attempting to set up patient self-reporting in ProFoRMS.

To use **Patient Self-Reporting**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar then select **Create Visit Type**.
4. Create a new Visit Type by entering the **Visit Type Name**, **Visit Type**, and a **Short Description**
5. Select the check-boxes beside the **eForm Name** to associate published eForms to that Visit Type.
6. Under the **Self Reporting** column, select “Yes” next to the eForms that you want to have self-reporting capabilities.
7. Refer back to section 3.8.3 for **[+] eForm Display Order** and **[+] eForm Field Autopopulation Capabilities** information.
8. Select **Add Visit Type** once you are finished.



ProFoRMS

Create a new visit type, select a visit type to view or perform an action.

[+] Create Visit Type

* This symbol indicates a required field

Visit Type Name *

Visit Type Please select Type

Category

Description *

Self Reporting eForms * Available 15 days before the scheduled visit until 15 days after the scheduled visit.

Select published eForms below to associate to this visit type:

Show Selected eForms

eForm Name	eForm Short Name	Description	Required?	Self Reporting?
<input type="checkbox"/> eFormTitle_Aug 10 10:29:49	eFormName_Aug_10_10_27_09	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> eFormTitle_Aug 10 10:59:22	eFormName_Aug_10_10_55_50	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> eFormTitle_Aug 12 16:17:03	eFormName_Aug_12_16_13_36	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> FITBIR Demographics	DemogFITBIR_1		<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Import Form Structure Template	eFormName_Aug_10_13_11_09	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Import Form Structure Template	Form_Structure_PDSP	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Import Form Structure Template	eFormName_Aug_10_12_45_29	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Import Form Structure Template	Form_Structure_FITBIR	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Import Form Structure Template	eFormName_Aug_10_12_57_26	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Import Form Structure Template	eFormName_Aug_10_13_19_28	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Import Form Structure Template	eFormName_Aug_10_13_09_56	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No

Showing 1 to 11 of 11 entries (0 Rows Selected of 0)

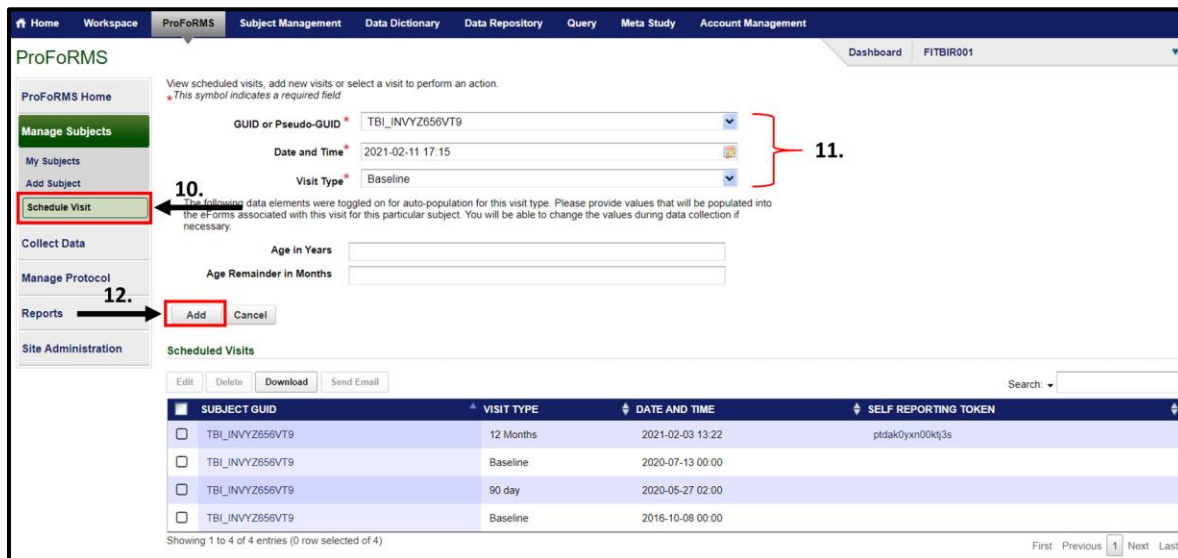
First Previous 1 Next Last

[+] eForm Display Order

[+] eForm Field Autopopulation Capabilities

Add Visit Type Reset Cancel

9. The new Visit Type(s) appear in the **Manage Visit Types** page.
10. Select **Manage Subjects** on the left-side tool bar then select **Schedule Visit**.
11. Add new visit or select a visit from the drop-down menu. * This symbol indicates a required field. Select the desired visit date by clicking on the calendar icon then select a Visit Type from the drop-down.
12. Select the **Add** button.
13. The scheduled visit will be updated successfully.



View scheduled visits, add new visits or select a visit to perform an action.
* This symbol indicates a required field

GUID or Pseudo-GUID * TBI_INVYZ656VT9

Date and Time * 2021-02-11 17:15

Visit Type * Baseline

Age in Years

Age Remainder in Months

10. **Schedule Visit**

12. **Add** **Cancel**

11.

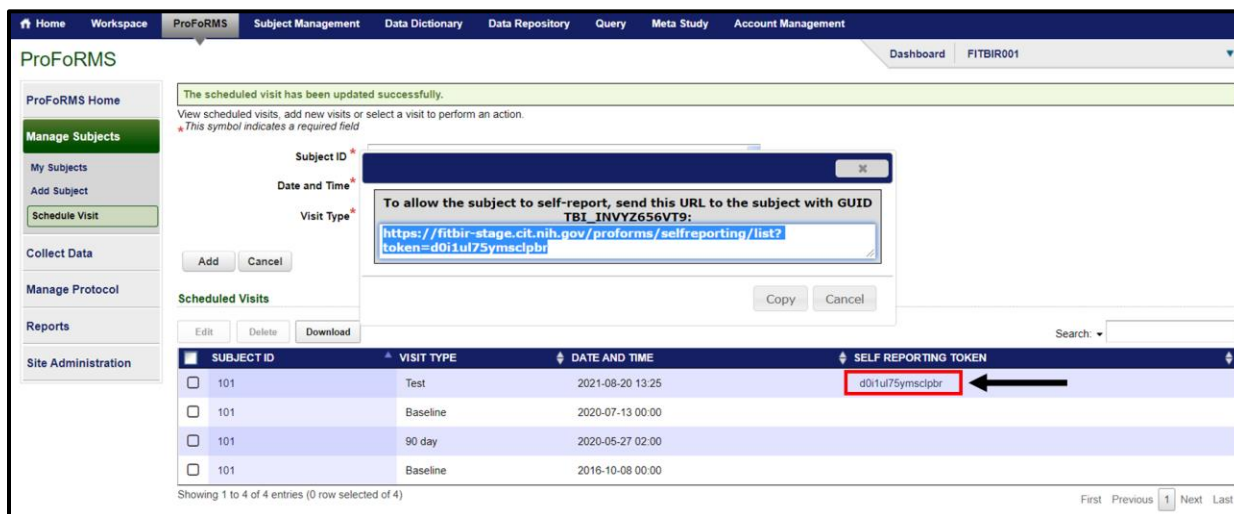
The following data elements were toggled on for auto-population for this visit type. Please provide values that will be populated into the e-forms associated with this visit for this particular subject. You will be able to change the values during data collection if necessary.

Scheduled Visits

SUBJECT GUID	VISIT TYPE	DATE AND TIME	SELF REPORTING TOKEN
TBI_INVYZ656VT9	12 Months	2021-02-03 13:22	ptdak0ym00k3s
TBI_INVYZ656VT9	Baseline	2020-07-13 00:00	
TBI_INVYZ656VT9	90 day	2020-05-27 02:00	
TBI_INVYZ656VT9	Baseline	2016-10-08 00:00	

Showing 1 to 4 of 4 entries (0 row selected of 4)

14. To allow the subject to self-report, select the **Self-Reporting Token** link and send it to the subject with the GUID.



The scheduled visit has been updated successfully.

View scheduled visits, add new visits or select a visit to perform an action.
* This symbol indicates a required field

Subject ID *

Date and Time *

Visit Type *

To allow the subject to self-report, send this URL to the subject with GUID TBI_INVYZ656VT9:
<https://fitbir-stage.cit.nih.gov/proforms/selfreporting/list?token=d0i1ul75ymscipbr>

Scheduled Visits

SUBJECT ID	VISIT TYPE	DATE AND TIME	SELF REPORTING TOKEN
101	Test	2021-08-20 13:25	d0i1ul75ymscipbr
101	Baseline	2020-07-13 00:00	
101	90 day	2020-05-27 02:00	
101	Baseline	2016-10-08 00:00	

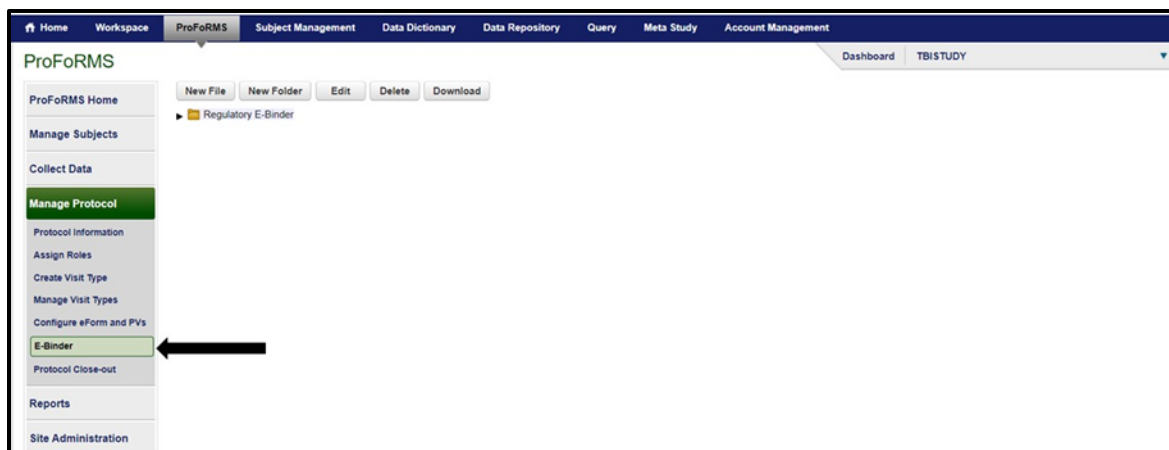
Showing 1 to 4 of 4 entries (0 row selected of 4)

3.8.7 E-Binder

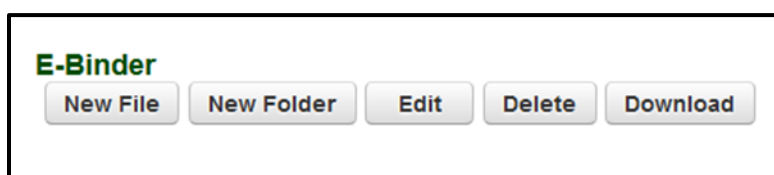
The E-Binder is used to Add/Edit documents or view existing documents.

To access the **E-Binder**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar then select **E-Binder**.



4. Use the **New File** option to upload a new document
5. Use the **New Folder** to create a new folder
6. Use the **Edit** option to edit your uploaded document
7. Use the **Delete** option to delete a document
8. Use the **Download** option to download documents



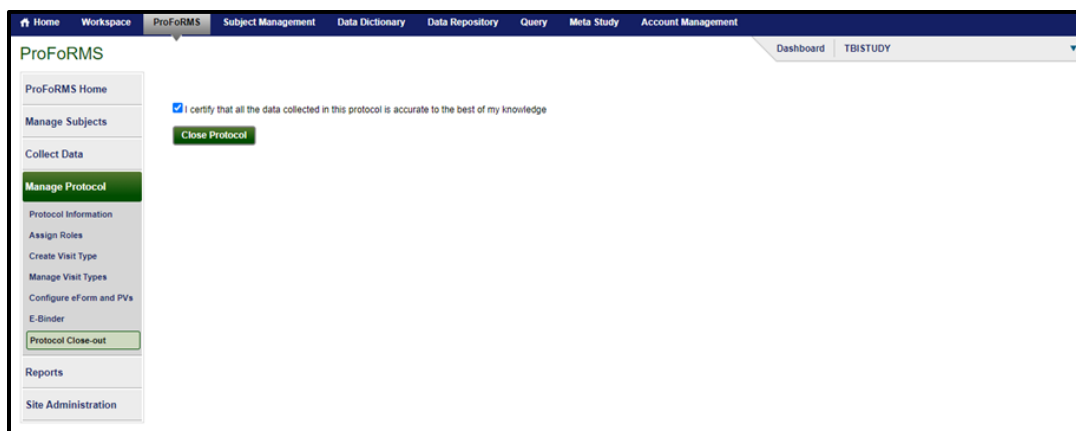
3.8.8 Protocol Closeout

At the end of the study, there needs to be a record that the PI or all investigators acknowledge that the data collected and entered in the repository are clean and accurate.

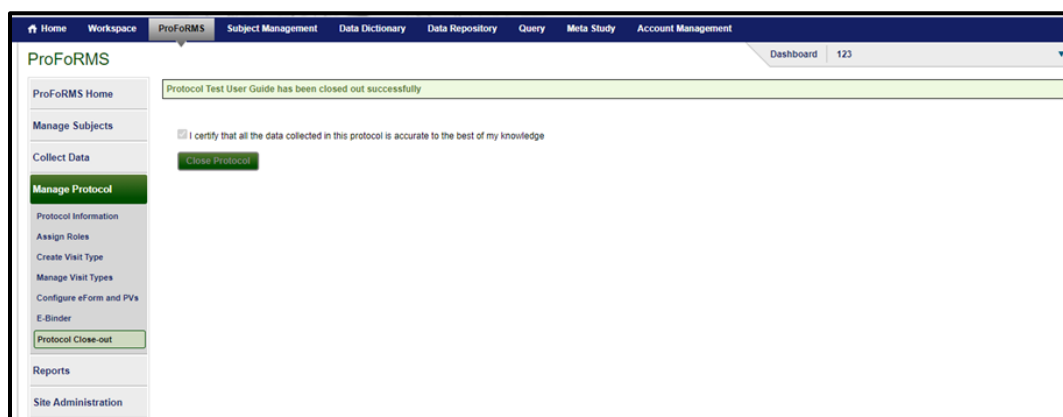
- ❖ The e-form will state that the PI acknowledges that the data collected is accurate to the best of their knowledge
- ❖ The e-form will capture the signature of the PI
- ❖ The e-form will capture the full legal name of the PI
- ❖ The e-form will capture the date and time that the form was signed
- ❖ The PI will be required to lock this e-form
- ❖ This e-form will be sent to the data repository and will be part of the study's data set

To access the **Protocol Closeout**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar then select **Protocol Close-out**.
4. Select the box next to “I certify that all the data collected in this protocol is accurate to the best of my knowledge” then select **Close Protocol**.



5. A confirmation will appear notifying you that the Protocol has been successfully closed out.



3.9 REPORTS

The ProFoRMS reporting feature provides the following report outputs:

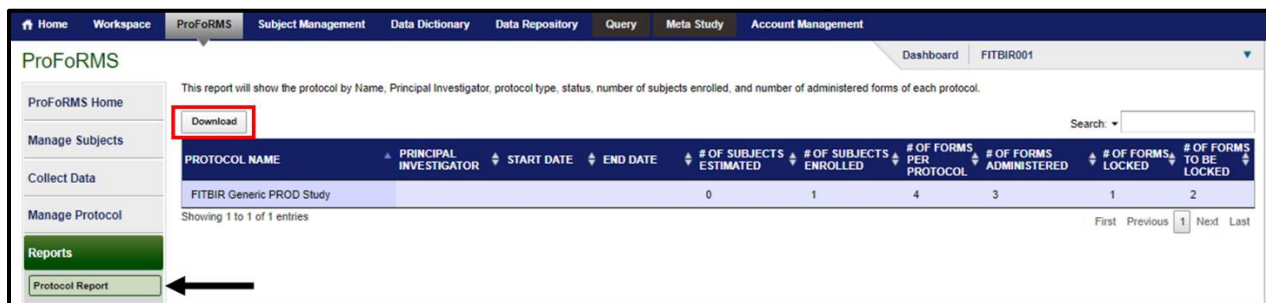
- ❖ Protocol Reports
- ❖ Detailed Protocol Report
- ❖ Without Collections
- ❖ Forms Requiring Completion & Lock
- ❖ Locked Forms
- ❖ Submission Summary
- ❖ Form Status
- ❖ View Auditor Comments
- ❖ View Reviewer Comments

3.9.1 Protocol Report

This report will show the Protocol Name, Principal Investigator, Start Date, End Date, Number of Subjects Estimated, Number of Subjects Enrolled, Number of Forms per Protocol, Number of Forms Administered, Number of Forms Locked, and Number of Forms to be Locked.

To view the **Protocol Report**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar. The **Protocol Report** information page appears.
4. The **Protocol Report** appears. You may use the export feature to export the report to either CSV or Excel formats.



This report will show the protocol by Name, Principal Investigator, protocol type, status, number of subjects enrolled, and number of administered forms of each protocol.

Download

PROTOCOL NAME	PRINCIPAL INVESTIGATOR	START DATE	END DATE	# OF SUBJECTS ESTIMATED	# OF SUBJECTS ENROLLED	# OF FORMS PER PROTOCOL	# OF FORMS ADMINISTERED	# OF FORMS LOCKED	# OF FORMS TO BE LOCKED
FITBIR Generic PROD Study				0	1	4	3	1	2

Showing 1 to 1 of 1 entries

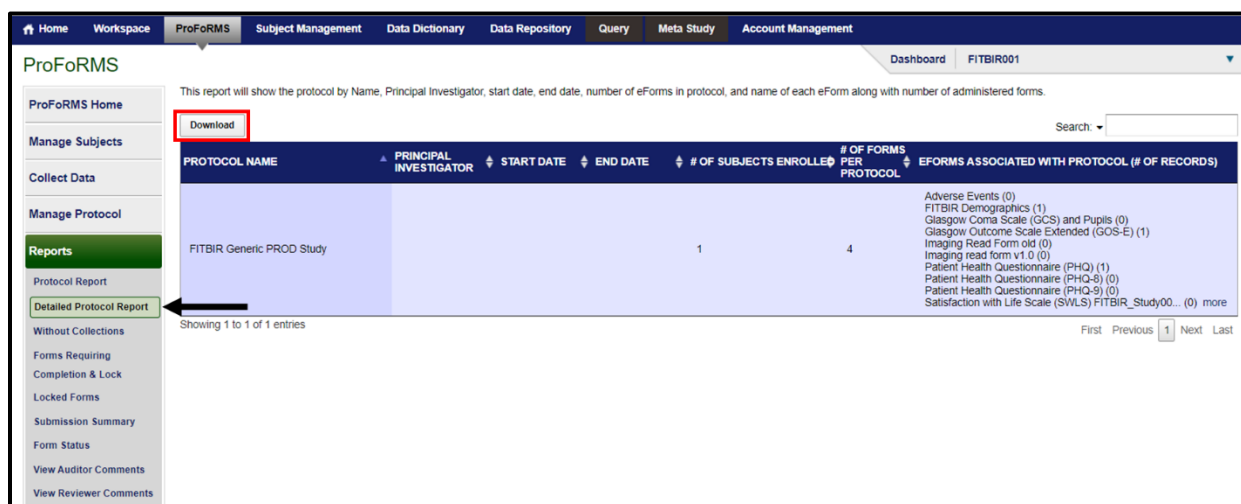
First Previous 1 Next Last

3.9.2 Detailed Protocol Report

This report will show the Protocol Name, Principal Investigator, Start Date, End Date, Number of Subjects Enrolled, Number of Forms per Protocol, and eForms Associated with Protocol (Number of Records).

To view the **Detailed Protocol Report**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar then select the **Detailed Protocol Report** tab.
4. The **Detailed Protocol Report** appears. You may use the export feature to export the report to either CSV or Excel formats.



This report will show the protocol by Name, Principal Investigator, start date, end date, number of eForms in protocol, and name of each eForm along with number of administered forms.

Search:

PROTOCOL NAME	PRINCIPAL INVESTIGATOR	START DATE	END DATE	# OF SUBJECTS ENROLLED	# OF FORMS PER PROTOCOL	EFORMS ASSOCIATED WITH PROTOCOL (# OF RECORDS)
FITBIR Generic PROO Study				1	4	Adverse Events (0) FITBIR Demographics (1) Glasgow Coma Scale (GCS) and Pupils (0) Glasgow Outcome Scale Extended (GOS-E) (1) Imaging Read Form old (0) Imaging read form v1.0 (0) Patient Health Questionnaire (PHQ) (1) Patient Health Questionnaire (PHQ-8) (0) Patient Health Questionnaire (PHQ-9) (0) Satisfaction with Life Scale (SWLS) FITBIR_Study00... (0) more

Showing 1 to 1 of 1 entries

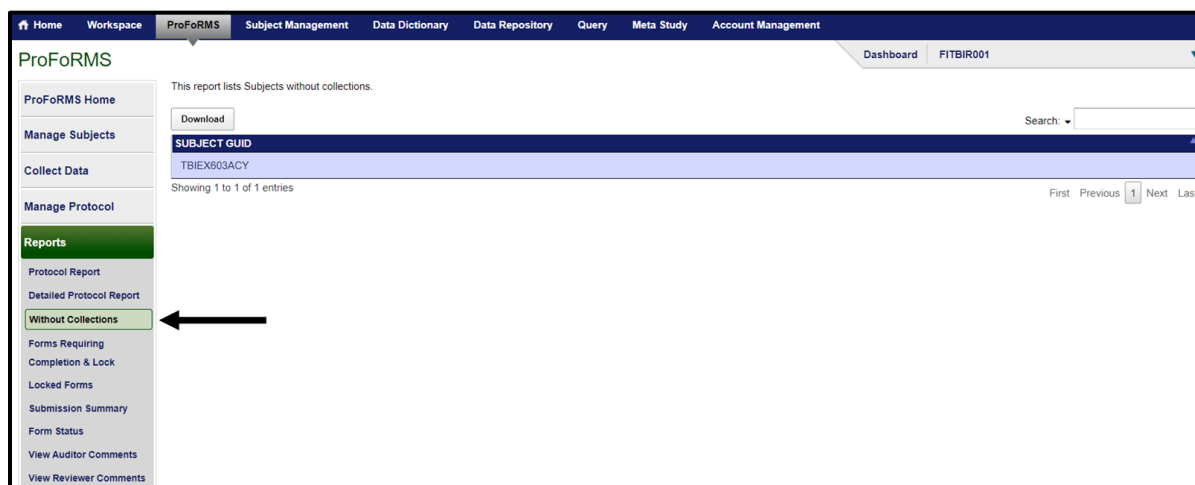
First Previous 1 Next Last

3.9.3 Without Collections

This report lists the GUIDs (including Pseudo-GUIDs) without collections.

To view GUIDs **Without Collections** Report, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar then select the **Without Collections** tab.
4. The **Without Collections** Report appears. You may use the export feature to export the report to Excel.

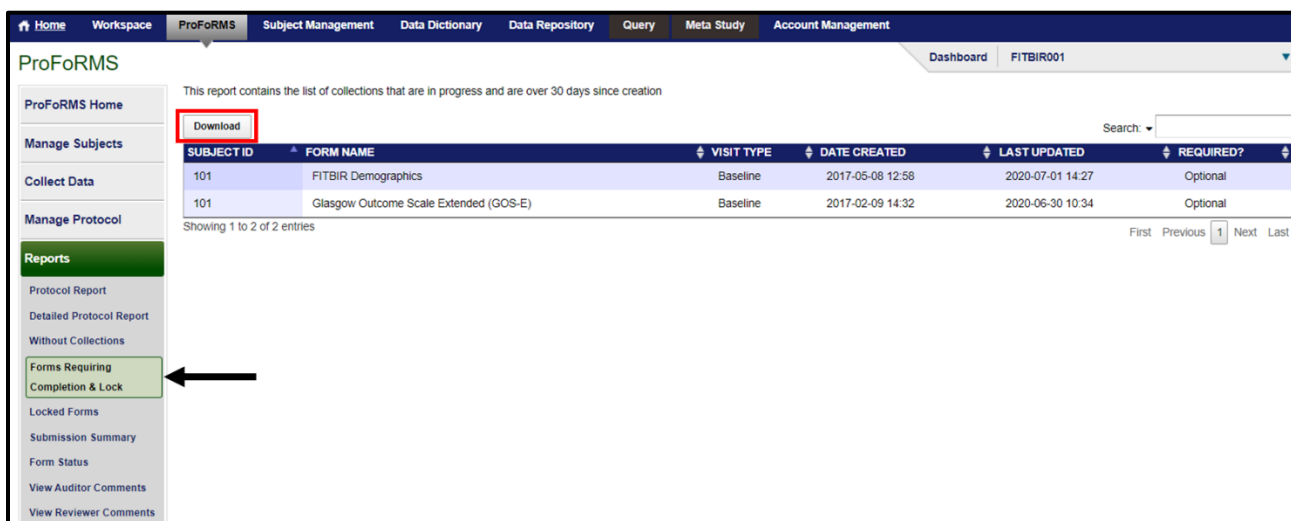


3.9.4 Forms Requiring Completion & Lock

This report contains the list of collections that are in progress and are over 30 days since creation. In addition, this table also provides collections that have been completed, but not locked.

To view **Forms Requiring Completion & Lock**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar then select the **Forms Requiring Completion & Lock** tab.
4. The **Forms Requiring Completion & Lock** Report appears. You may use the export feature to export the report to either CSV or Excel formats.



This report contains the list of collections that are in progress and are over 30 days since creation

Download

SUBJECT ID	FORM NAME	VISIT TYPE	DATE CREATED	LAST UPDATED	REQUIRED?
101	FITBIR Demographics	Baseline	2017-05-08 12:58	2020-07-01 14:27	Optional
101	Glasgow Outcome Scale Extended (GOS-E)	Baseline	2017-02-09 14:32	2020-06-30 10:34	Optional

Showing 1 to 2 of 2 entries

First Previous 1 Next Last

ProFoRMS Home

Manage Subjects

Collect Data

Manage Protocol

Reports

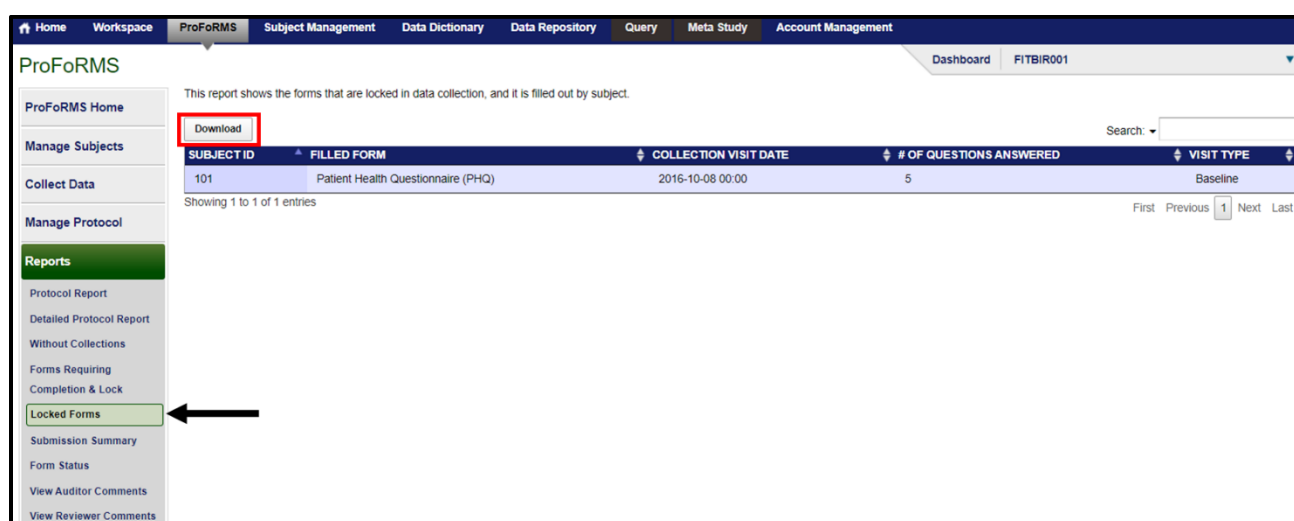
- Protocol Report
- Detailed Protocol Report
- Without Collections
- Forms Requiring Completion & Lock**
- Locked Forms
- Submission Summary
- Form Status
- View Auditor Comments
- View Reviewer Comments

3.9.5 Locked Forms

This report shows the forms that are locked in data collection, and it is filled out by subject.

To view **Locked Forms**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar then select the **Locked Forms** tab.
4. The **Locked Forms** Report appears. You may use the export feature to export the report to either CSV or Excel formats.



This report shows the forms that are locked in data collection, and it is filled out by subject.

Download

SUBJECT ID	FILLED FORM	COLLECTION VISIT DATE	# OF QUESTIONS ANSWERED	VISIT TYPE
101	Patient Health Questionnaire (PHQ)	2016-10-08 00:00	5	Baseline

Showing 1 to 1 of 1 entries

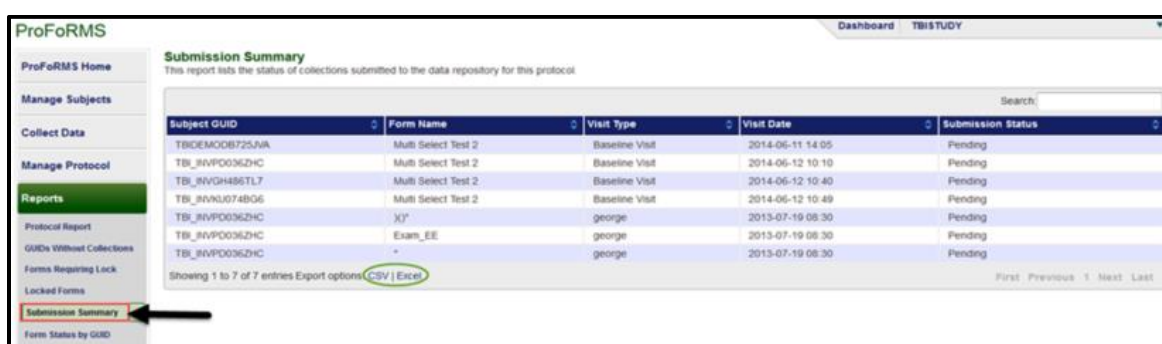
First Previous 1 Next Last

3.9.6 Submission Summary

This report lists the status of collections submitted to the data repository for this protocol.

To view **Submission Summary**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar then select the **Submission Summary** tab.
4. The **Submission Summary** Report appears. You may use the export feature to export the report to either CSV or Excel formats.



Submission Summary
This report lists the status of collections submitted to the data repository for this protocol

Subject GUID	Form Name	Visit Type	Visit Date	Submission Status
TBDEM00B725JVA	Multi Select Test 2	Baseline Visit	2014-06-11 14:05	Pending
TBI_RVPO036ZHC	Multi Select Test 2	Baseline Visit	2014-06-12 10:10	Pending
TBI_RVGH486TL7	Multi Select Test 2	Baseline Visit	2014-06-12 10:40	Pending
TBI_RVNU074BQ6	Multi Select Test 2	Baseline Visit	2014-06-12 10:49	Pending
TBI_RVPO036ZHC	XI*	george	2013-07-19 08:30	Pending
TBI_RVPO036ZHC	Exam_EE	george	2013-07-19 08:30	Pending
TBI_RVPO036ZHC	*	george	2013-07-19 08:30	Pending

Showing 1 to 7 of 7 entries Export options: [CSV](#) | [Excel](#)

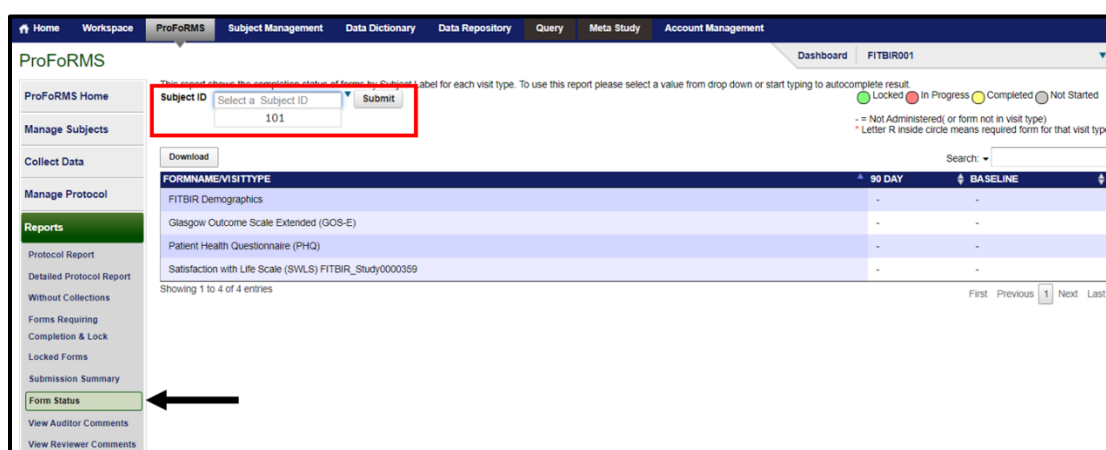
First Previous 1 Next Last

3.9.7 Form Status

This report shows the completion status of forms by Subject Label for each visit type.

To view **Form Status**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar then select the **Form Status** tab.
4. To use this report, you must select a GUID or Subject ID from the drop-down menu or start typing to autocomplete the result in search field then select **Submit** to generate the report.



This report shows the completion status of forms by Subject Label for each visit type. To use this report please select a value from drop down or start typing to autocomplete result.

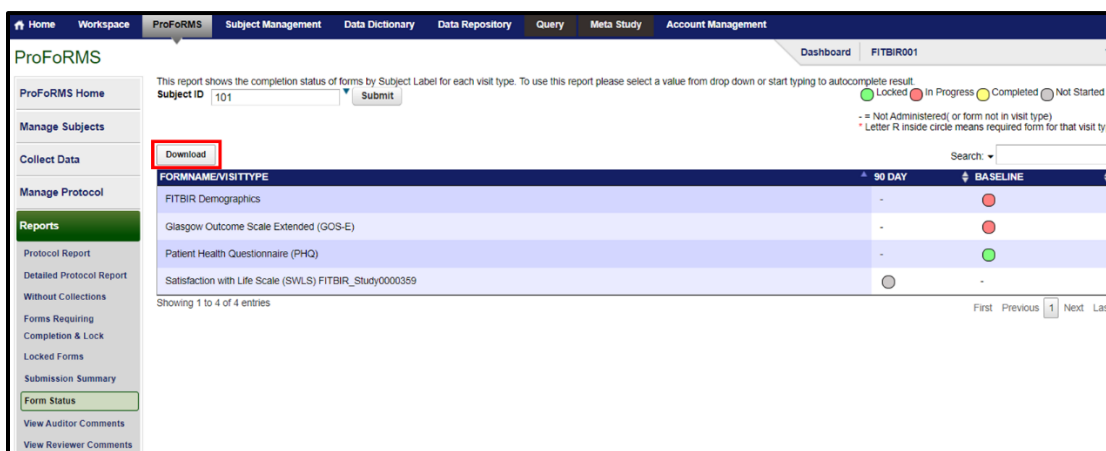
Legend: ● Locked ● In Progress ● Completed ● Not Started
 - = Not Administered, or form not in visit type
 * Letter R inside circle means required form for that visit type

FORMNAME/VISITTYPE	90 DAY	BASELINE
FITBIR Demographics	-	-
Glasgow Outcome Scale Extended (GOS-E)	-	-
Patient Health Questionnaire (PHQ)	-	-
Satisfaction with Life Scale (SWLS) FITBIR_Study0000359	-	-

Showing 1 to 4 of 4 entries

First Previous 1 Next Last

5. You may use the export feature to export the report to either CSV or Excel formats.



This report shows the completion status of forms by Subject Label for each visit type. To use this report please select a value from drop down or start typing to autocomplete result.

Legend: ● Locked ● In Progress ● Completed ● Not Started
 - = Not Administered, or form not in visit type
 * Letter R inside circle means required form for that visit type

FORMNAME/VISITTYPE	90 DAY	BASELINE
FITBIR Demographics	-	●
Glasgow Outcome Scale Extended (GOS-E)	-	●
Patient Health Questionnaire (PHQ)	-	●
Satisfaction with Life Scale (SWLS) FITBIR_Study0000359	●	-

Showing 1 to 4 of 4 entries

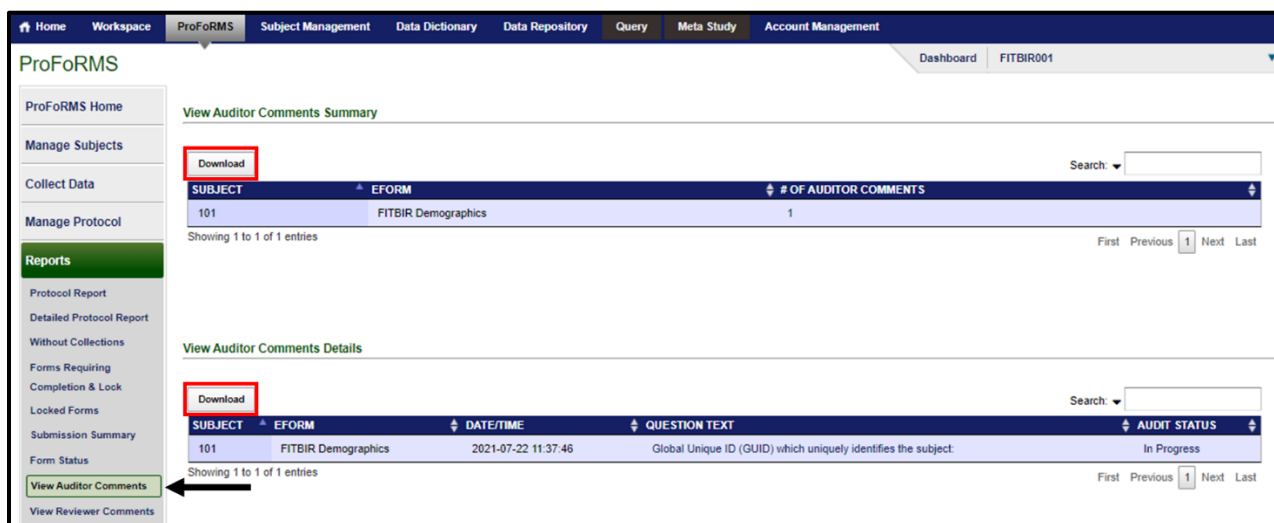
First Previous 1 Next Last

3.9.8 View Auditor Comments

This report shows a summary of auditor comments that are made in the data collections.

To **View Auditor Comments**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar then select the **View Auditor Comments** tab.
4. This report shows the GUID or Subject, eForm, and Number of Auditor Comments that have been made as well as the Date/Time, Question Text, and Audit Status of a collection.
5. You may use the export feature to export the report to either CSV, Excel, or PDF formats.



The screenshot displays the ProFoRMS interface. The top navigation bar includes Home, Workspace, ProFoRMS, Subject Management, Data Dictionary, Data Repository, Query, Meta Study, and Account Management. The left sidebar shows the Reports section with various options, and 'View Auditor Comments' is highlighted with an arrow. The main content area is divided into two sections: 'View Auditor Comments Summary' and 'View Auditor Comments Details'. Both sections feature a 'Download' button (highlighted in red) and a table of data. The summary table has columns for SUBJECT, EFORM, and # OF AUDITOR COMMENTS. The details table has columns for SUBJECT, EFORM, DATE/TIME, QUESTION TEXT, and AUDIT STATUS.

SUBJECT	EFORM	# OF AUDITOR COMMENTS
101	FITBIR Demographics	1

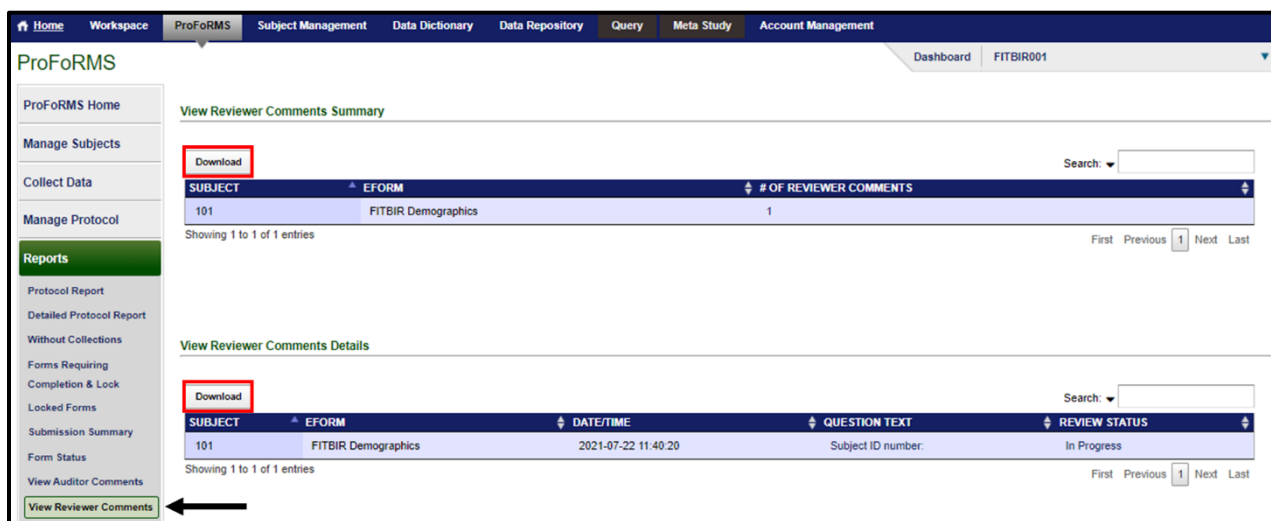
SUBJECT	EFORM	DATE/TIME	QUESTION TEXT	AUDIT STATUS
101	FITBIR Demographics	2021-07-22 11:37:46	Global Unique ID (GUID) which uniquely identifies the subject.	In Progress

3.9.9 View Reviewer Comments

This report shows a summary of reviewer comments that are made in the data collections.

To **View Reviewer Comments**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar then select the **View Reviewer Comments** tab.
4. This report shows the GUID or Subject, eForm, and Number of Reviewer Comments that have been made as well as the Date/Time, Question Text, and Review Status of a collection.
5. You may use the export feature to export the report to either CSV, Excel, or PDF formats.



View Reviewer Comments Summary

SUBJECT	EFORM	# OF REVIEWER COMMENTS
101	FITBIR Demographics	1

Showing 1 to 1 of 1 entries

View Reviewer Comments Details

SUBJECT	EFORM	DATE/TIME	QUESTION TEXT	REVIEW STATUS
101	FITBIR Demographics	2021-07-22 11:40:20	Subject ID number:	In Progress

Showing 1 to 1 of 1 entries