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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

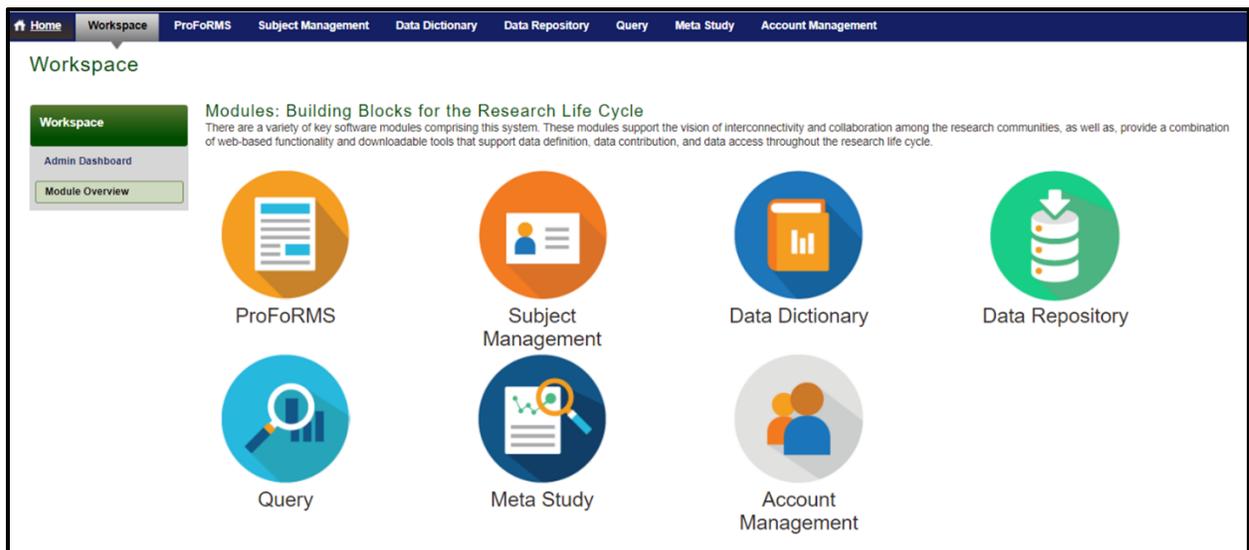
 Important
Information

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

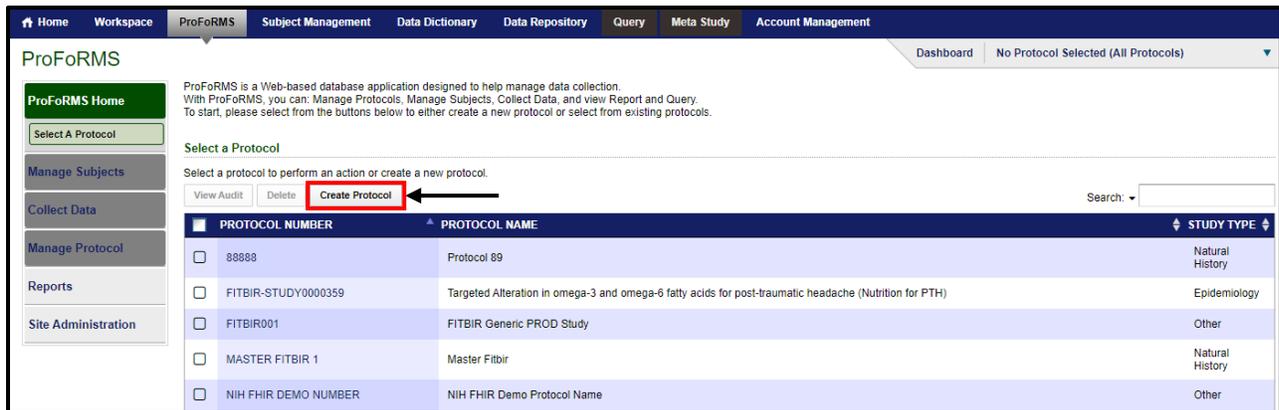
Things to Note:

-  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.

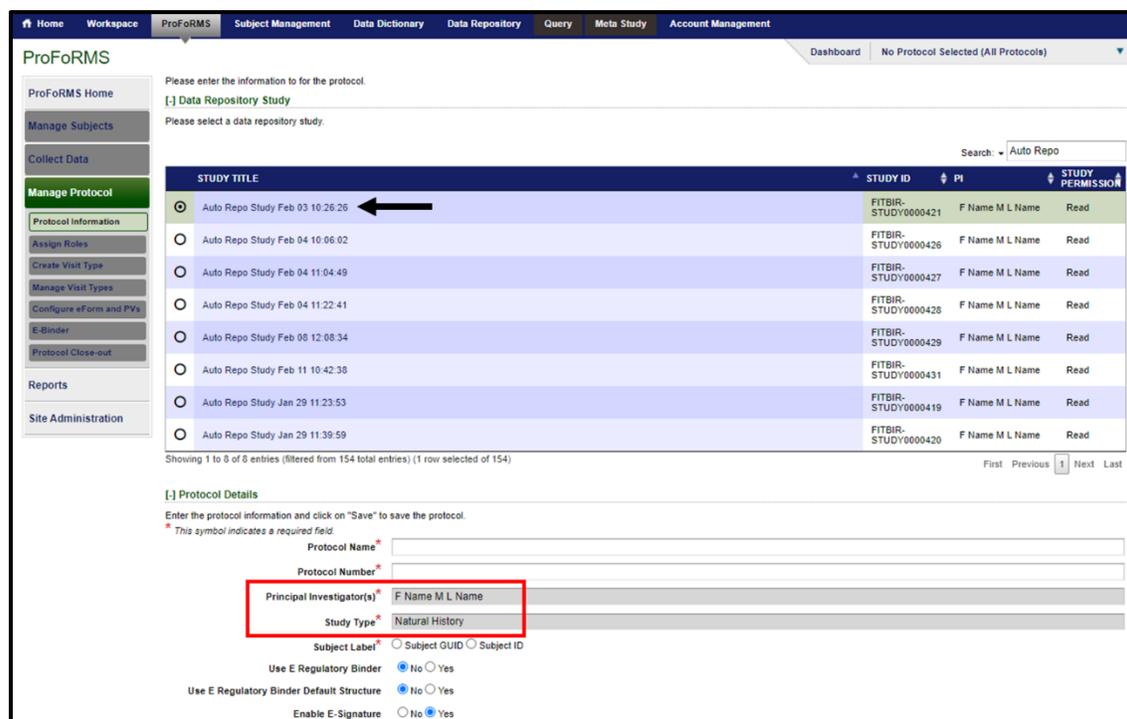
Select a Protocol

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)

[] 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)*

Study Type*

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

Select sites to be associated with this protocol.

Search:

<input type="checkbox"/>	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

3.5.1 Selecting a Protocol

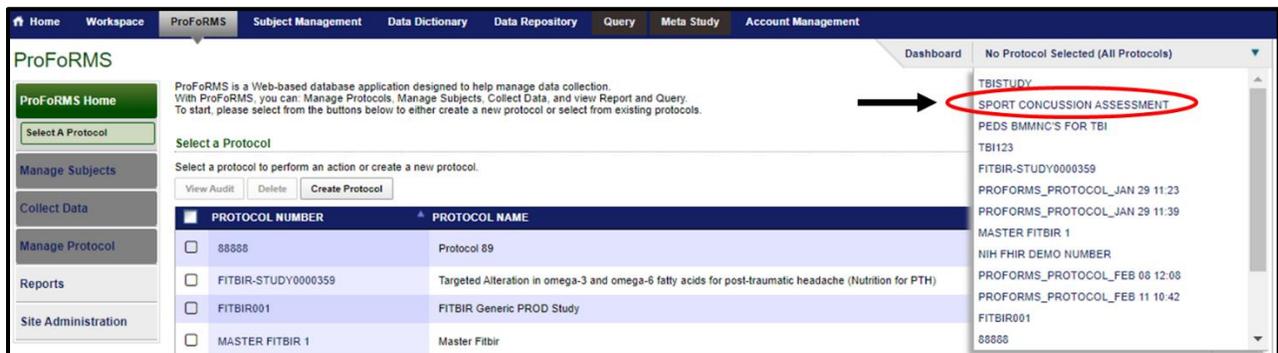
Viewing and selecting a protocol can be done in ProFoRMS via two ways:

- ❖ 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

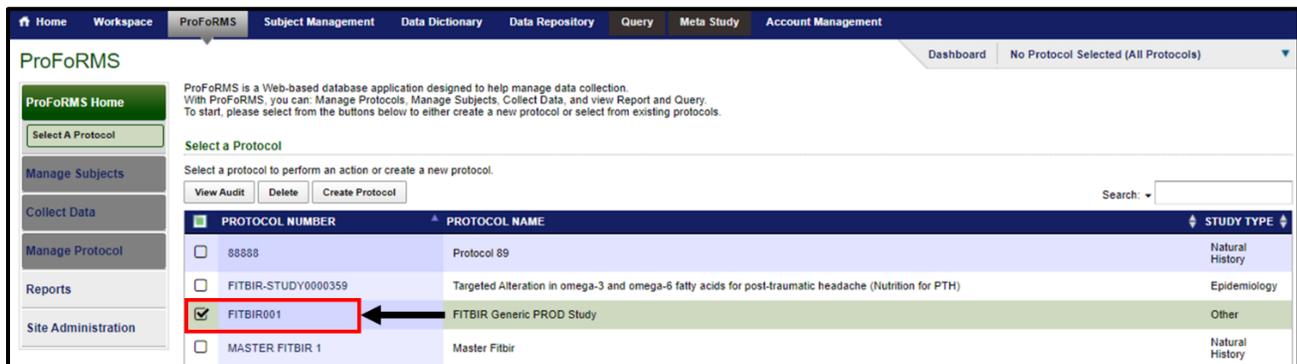


3. **Click** on the desired protocol. The system will load the selected protocol data including the list of subject visits.

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.

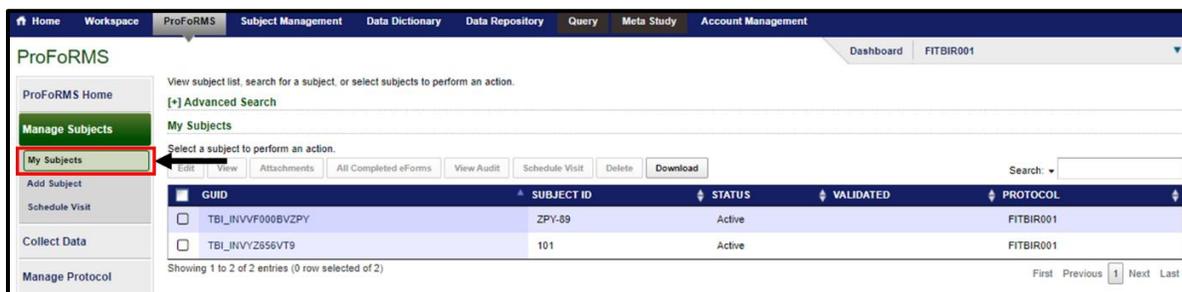
The table menu options allow the user to:

- ❖ 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.



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 has a 'Manage Subjects' section with 'My Subjects' highlighted. The main content area shows a table with the following data:

GUID	SUBJECT ID	STATUS	VALIDATED	PROTOCOL
<input type="checkbox"/> TBI_INVV008VZPY	ZPY-59	Active		FITBIR001
<input type="checkbox"/> TBI_INVV2856VT9	101	Active		FITBIR001

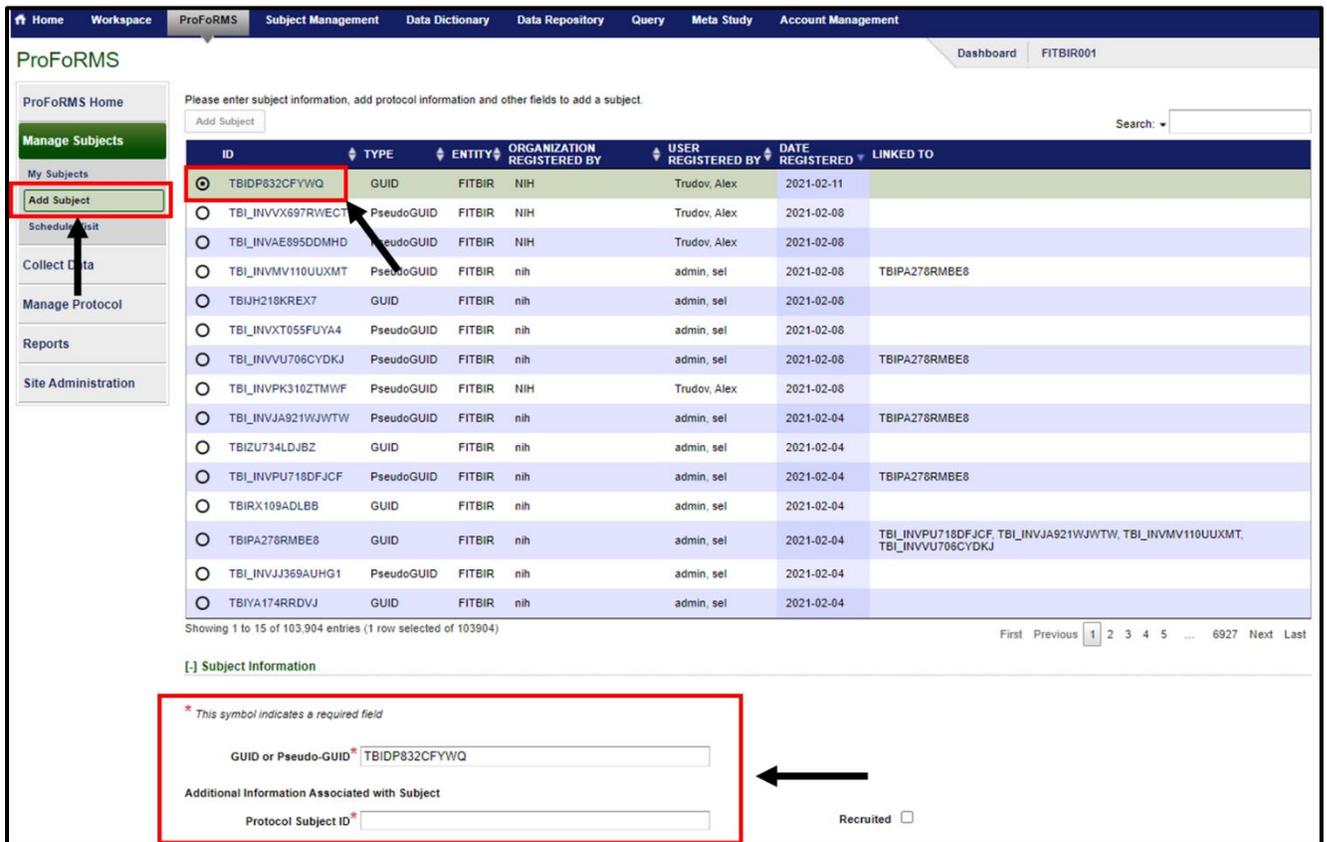
At the bottom of the table, it indicates 'Showing 1 to 2 of 2 entries (0 row selected of 2)'. The page also includes a search bar and navigation controls like 'First', 'Previous', 'Next', and 'Last'.

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_INVXT055FU44	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_INVJA921WJVTW	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_INVJA921WJVTW, 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

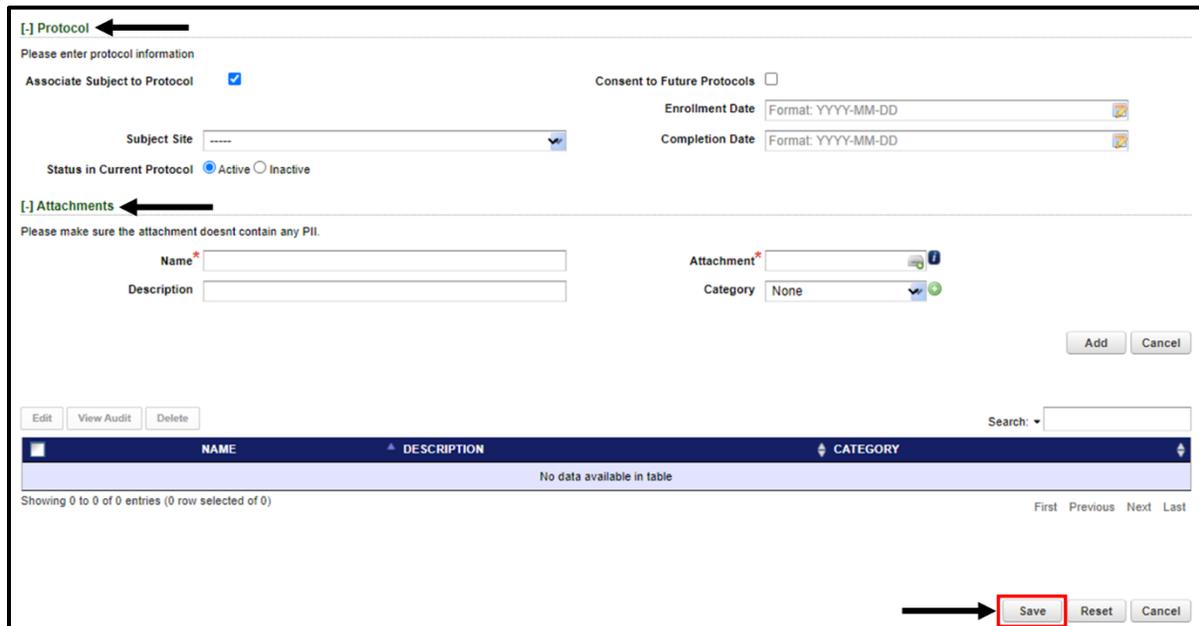
GUID or Pseudo-GUID*

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: [Dropdown] Enrollment Date: [Date Picker] Format: YYYY-MM-DD

Completion Date: [Date Picker] Format: YYYY-MM-DD

Status in Current Protocol: Active Inactive

[+] Attachments

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

Name*: [Text Field] Attachment*: [File Upload]

Description: [Text Field] Category: [Dropdown] None

[Add] [Cancel]

[Edit] [View Audit] [Delete] Search: [Text Field]

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]

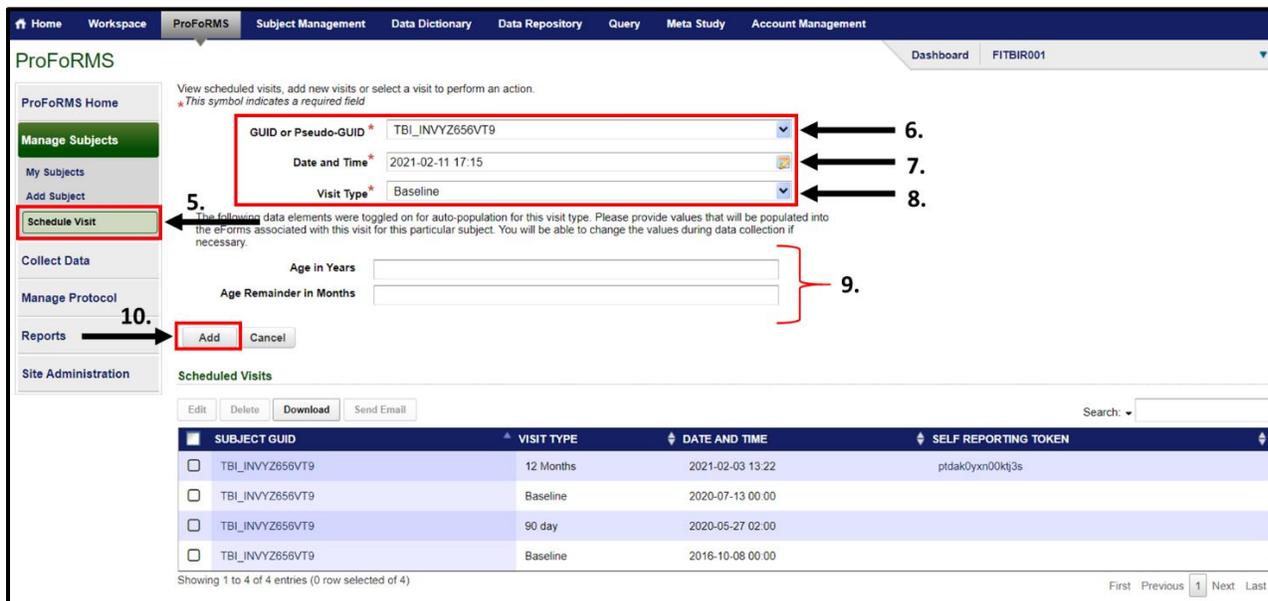
10. After selecting the **Save** button, the platform returns you to the **My Subjects** page where the newly added subject can be viewed.
11. If the subject does not have a **GUID** or **Pseudo-GUID** created in the system, click on the **Add Subject** button to launch the Subject Management tool and 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.



The screenshot shows the ProFoRMS interface with the 'Schedule Visit' form. The form includes the following fields and controls:

- GUID or Pseudo-GUID**: TBI_INVYZ856VT9 (Callout 6)
- Date and Time**: 2021-02-11 17:15 (Callout 7)
- Visit Type**: Baseline (Callout 8)
- Age in Years**: (Callout 9)
- Age Remainder in Months**: (Callout 9)
- Add** button (Callout 10)

The 'Scheduled Visits' table below the form contains the following data:

	SUBJECT GUID	VISIT TYPE	DATE AND TIME	SELF REPORTING TOKEN
<input type="checkbox"/>	TBI_INVYZ856VT9	12 Months	2021-02-03 13:22	pldak0yxn00ktj3s
<input type="checkbox"/>	TBI_INVYZ856VT9	Baseline	2020-07-13 00:00	
<input type="checkbox"/>	TBI_INVYZ856VT9	90 day	2020-05-27 02:00	
<input type="checkbox"/>	TBI_INVYZ856VT9	Baseline	2016-10-08 00:00	

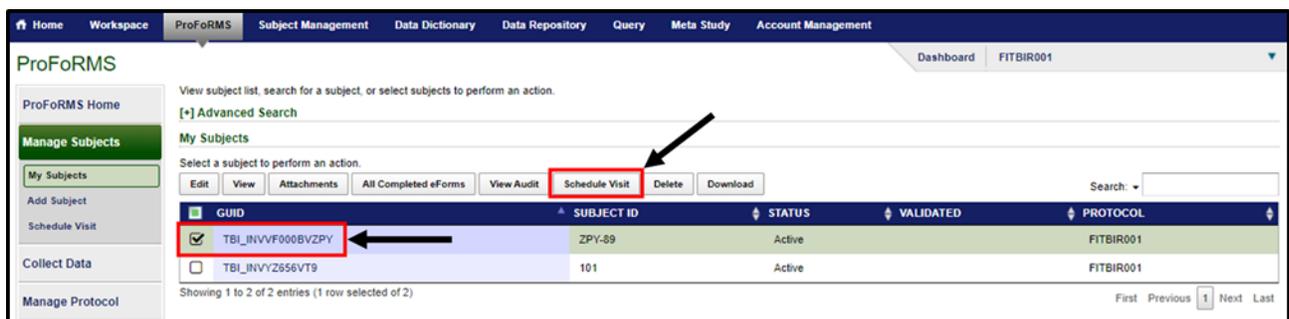
Showing 1 to 4 of 4 entries (0 row selected of 4)

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



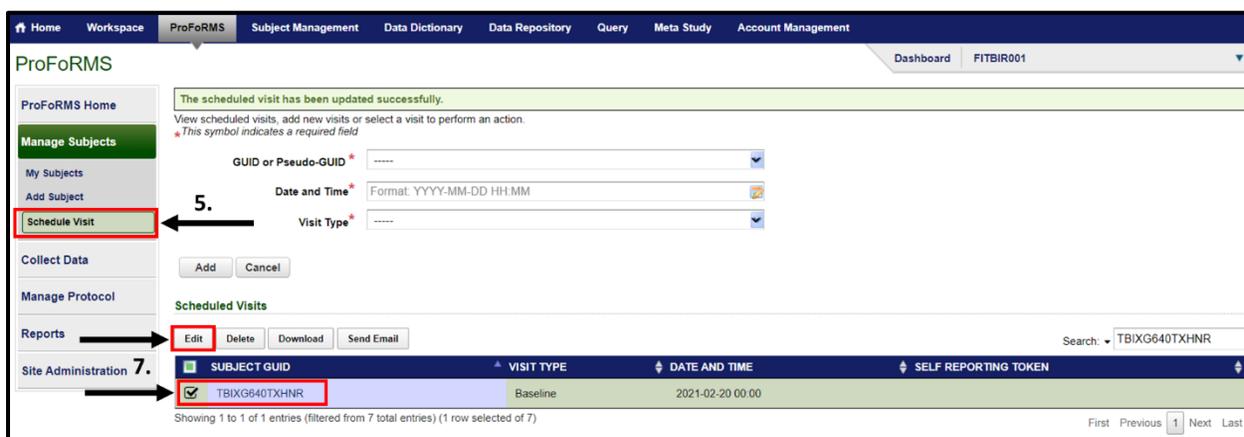
The screenshot shows the ProFoRMS interface. The top navigation bar includes Home, Workpace, ProFoRMS, Subject Management, Data Dictionary, Data Repository, Query, Meta Study, and Account Management. The main content area is titled 'My Subjects' and contains a table of subjects. The 'Schedule Visit' button is highlighted with a red box and an arrow. The first row of the table, with GUID 'TBI_INVVF000BVZPY', is also highlighted with a red box and an arrow.

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

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



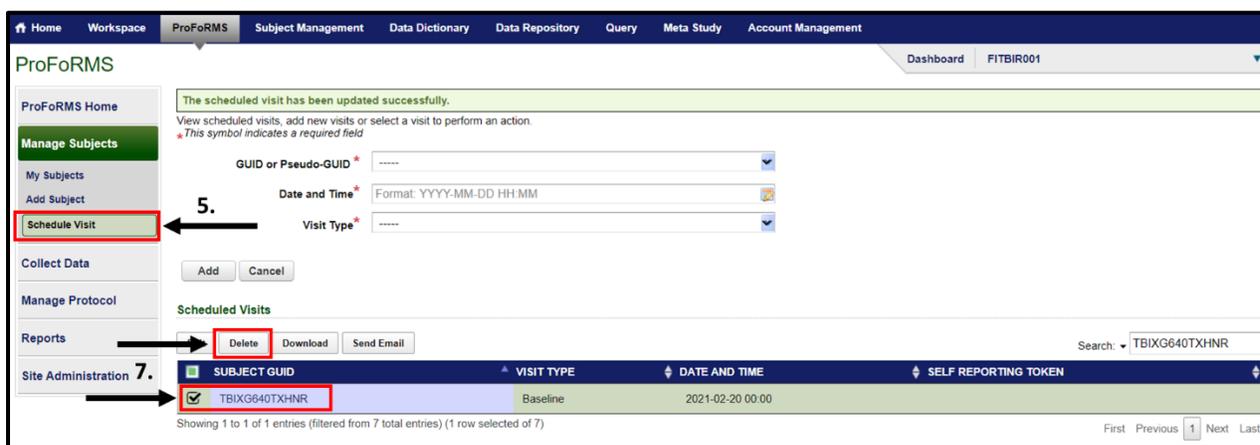
The screenshot displays the ProFoRMS interface. On the left sidebar, the 'Schedule Visit' button is highlighted with a red box and labeled '5.'. The main content area shows a form for adding or editing a scheduled visit, with fields for 'GUID or Pseudo-GUID', 'Date and Time', and 'Visit Type'. Below the form is a table titled 'Scheduled Visits' with columns: SUBJECT GUID, VISIT TYPE, DATE AND TIME, and SELF REPORTING TOKEN. The table contains one row with the following data: TBIXG640TXHNR, Baseline, 2021-02-20 00:00. The 'Edit' button in the table's action bar is highlighted with a red box and labeled '7.'. A success message at the top of the form reads: '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.

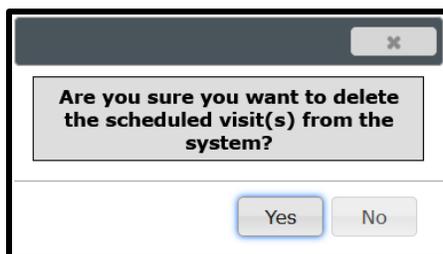
3.6.3.2 Deleting Scheduled Visits

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.

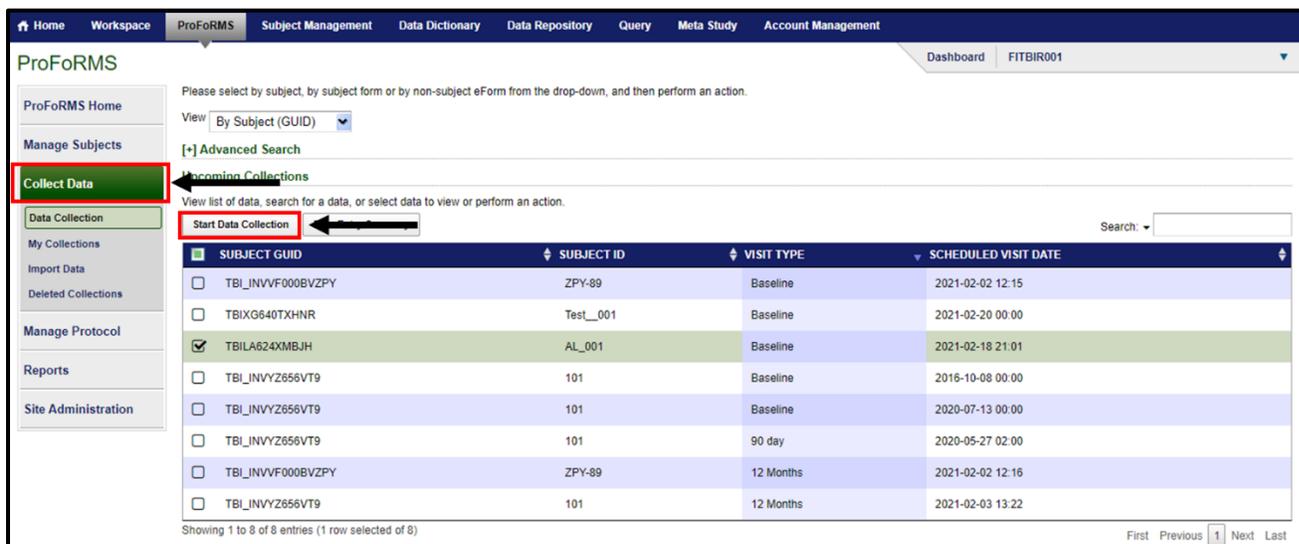
Clinical data may be captured electronically at its source, or in paper form and later transcribed into the system. There are two options for collecting data in ProFoRMS.

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.

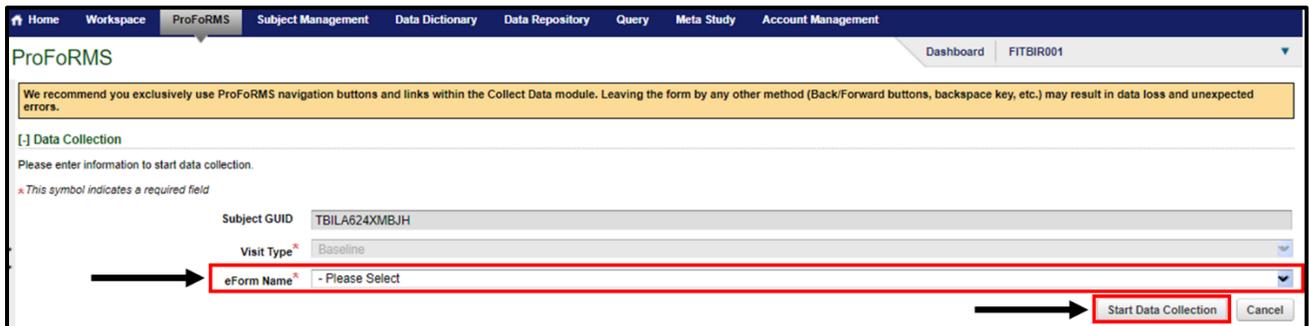


The screenshot shows the ProFoRMS interface with the following elements:

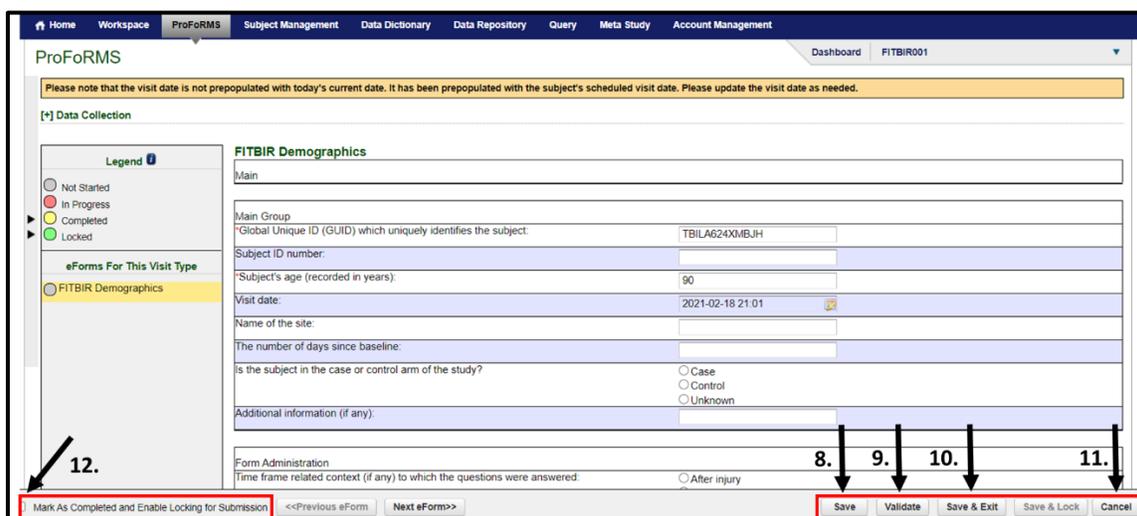
- Navigation Bar:** Home, Workspace, ProFoRMS, Subject Management, Data Dictionary, Data Repository, Query, Meta Study, Account Management.
- Left Sidebar:** ProFoRMS Home, Manage Subjects, **Collect Data** (highlighted), Data Collection, My Collections, Import Data, Deleted Collections, Manage Protocol, Reports, Site Administration.
- Main Content Area:**
 - Instructions: "Please select by subject, by subject form or by non-subject eForm from the drop-down, and then perform an action."
 - View: By Subject (GUID)
 - [+] Advanced Search
 - Incoming Collections
 - View list of data, search for a data, or select data to view or perform an action.
 - Search: [input field]
 - Start Data Collection** button (highlighted with a red box and arrow)
- Table:**

	SUBJECT GUID	SUBJECT ID	VISIT TYPE	SCHEDULED VISIT DATE
<input type="checkbox"/>	TBLINVVF000BVZPY	ZPY-89	Baseline	2021-02-02 12:15
<input type="checkbox"/>	TBIXG640TXHNR	Test_001	Baseline	2021-02-20 00:00
<input checked="" type="checkbox"/>	TBILA624XMBJH	AL_001	Baseline	2021-02-18 21:01
<input type="checkbox"/>	TBLINVY2656VT9	101	Baseline	2016-10-08 00:00
<input type="checkbox"/>	TBLINVY2656VT9	101	Baseline	2020-07-13 00:00
<input type="checkbox"/>	TBLINVY2656VT9	101	90 day	2020-05-27 02:00
<input type="checkbox"/>	TBLINVVF000BVZPY	ZPY-89	12 Months	2021-02-02 12:16
<input type="checkbox"/>	TBLINVY2656VT9	101	12 Months	2021-02-03 13:22
- Footer:** Showing 1 to 8 of 8 entries (1 row selected of 8) | First Previous 1 Next Last

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.



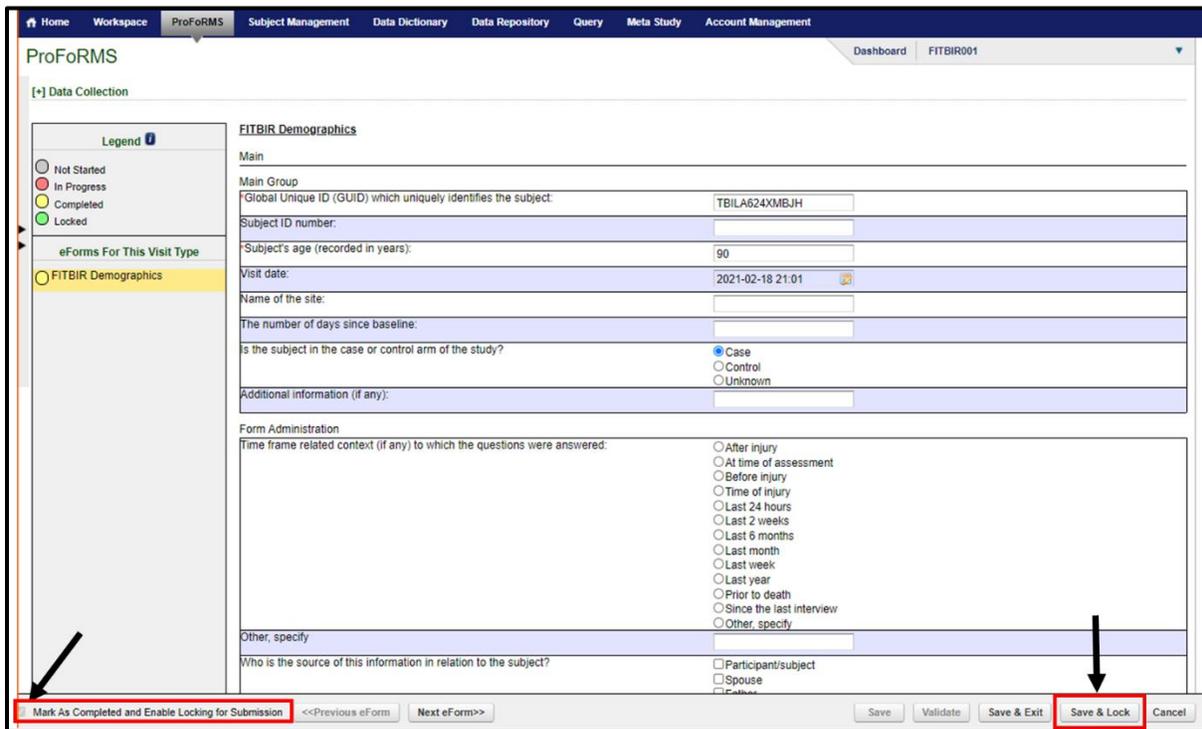
13. Once a form has been marked as completed, three things will happen:
 - a. The Save & Lock button will be enabled;
 - b. The system validation will run;
 - c. An audit trail will start if a user changes their response to an answer
14. If the form failed, you will be notified with a list of errors 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 for the 'FITBIR Demographics' form. The form is titled 'FITBIR Demographics' and is part of a 'Data Collection'. The form includes sections for 'Main', 'Form Administration', and 'Other, specify'. The 'Mark As Completed and Enable Locking for Submission' button is highlighted with a red box and an arrow. The 'Save & Lock' button at the bottom right is also highlighted with a red box and an arrow.

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.

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**

The screenshot shows the ProFoRMS interface. The top navigation bar includes Home, Workspace, ProFoRMS, Subject Management, Data Dictionary, Data Repository, Query, Meta Study, and Account Management. The ProFoRMS dashboard is active, showing a sidebar with 'Collect Data' selected. The main content area displays a table of available forms. A dropdown menu is open, showing 'By eForm (GUID)' selected, with an arrow pointing to it labeled '5.'. Below the table, the 'View' button is highlighted with a red box and an arrow labeled '6.'. The table lists forms such as CISTAR1013, FITBIR Demographics, Glasgow Outcome Scale Extended (GOS-E), Montreal Cognitive Assessment (MoCA), Patient Health Questionnaire (PHQ), and Satisfaction with Life Scale (SWLS).

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

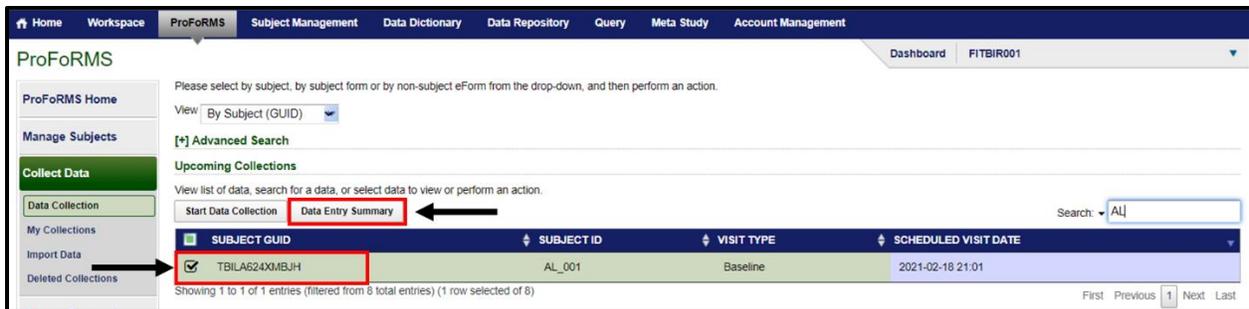
7. A new tab will open in your browser displaying the eForm details in **View Mode**
8. You can view the data **By Subject (GUID)**, or **By eForm (GUID)**. Depending on the view you selected, the table will display either the list of subjects, or the list of eForms.

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:

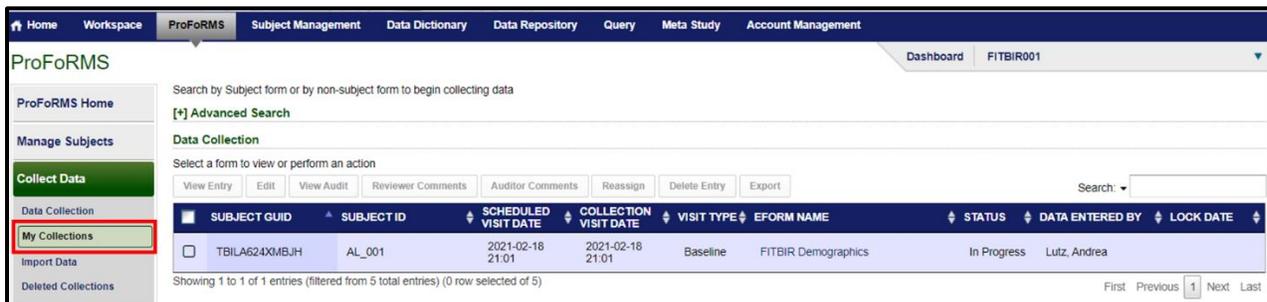
1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Select the **Collect Data** tab on the left-side tool bar.
4. The **Data Collection** page appears.
5. Select the check-box next to the **Subject GUID** that you are interested in viewing 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 a table of upcoming collections. A red box highlights the 'Data Entry Summary' link, and an arrow points to it from the left. Another red box highlights the checkmark next to the subject GUID 'TBILA624XMBJH' in the table. The table has the following columns: SUBJECT GUID, SUBJECT ID, VISIT TYPE, and SCHEDULED VISIT DATE. The row for TBILA624XMBJH has a value of AL_001 for SUBJECT ID, Baseline for VISIT TYPE, and 2021-02-18 21:01 for SCHEDULED VISIT DATE.

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 interface with the 'My Collections' tab selected in the sidebar. The main area displays a table of data collections. A red box highlights the 'My Collections' tab in the sidebar. The table has the following columns: SUBJECT GUID, SUBJECT ID, SCHEDULED VISIT DATE, COLLECTION VISIT DATE, VISIT TYPE, EFORM NAME, STATUS, DATA ENTERED BY, and LOCK DATE. The row for TBILA624XMBJH has a value of AL_001 for SUBJECT ID, 2021-02-18 21:01 for SCHEDULED VISIT DATE, 2021-02-18 21:01 for COLLECTION VISIT DATE, Baseline for VISIT TYPE, FITBIR Demographics for EFORM NAME, In Progress for STATUS, Lutz, Andrea for DATA ENTERED BY, and no lock date.

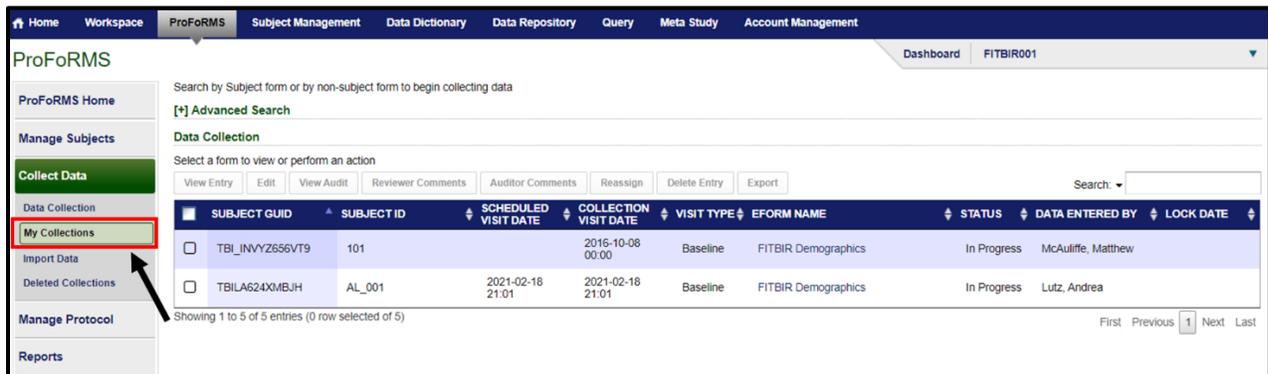
SUBJECT GUID	SUBJECT ID	SCHEDULED VISIT DATE	COLLECTION VISIT DATE	VISIT TYPE	EFORM NAME	STATUS	DATA ENTERED BY	LOCK DATE
<input type="checkbox"/> TBILA624XMBJH	AL_001	2021-02-18 21:01	2021-02-18 21:01	Baseline	FITBIR Demographics	In Progress	Lutz, Andrea	

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



The screenshot shows the ProFoRMS interface. The left sidebar has a 'My Collections' tab highlighted with a red box and an arrow. The main content area displays a table with the following data:

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	

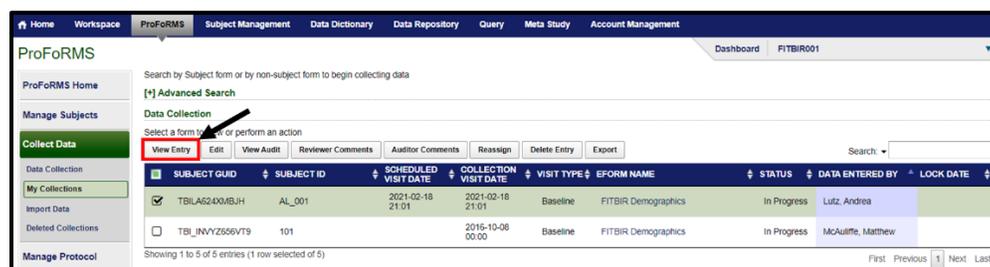
A user can perform the following actions in the **My Collections** table:

- ❖ 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.

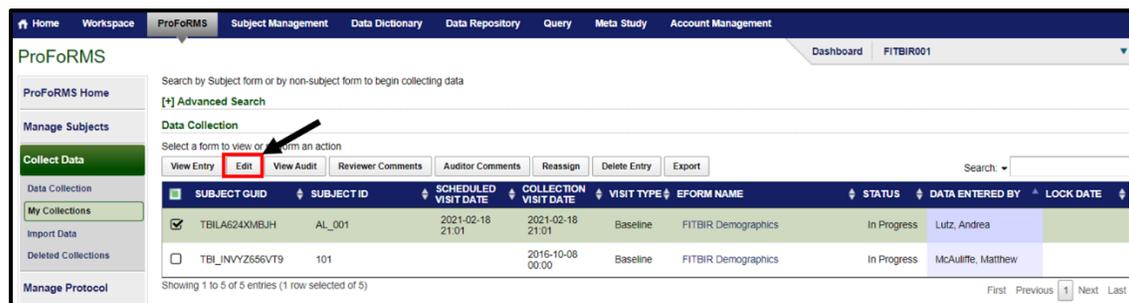


The screenshot shows the ProFoRMS interface with the 'View Entry' button highlighted in the top toolbar. The table data is the same as in the previous screenshot.

3.7.2.2 Edit eForm

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

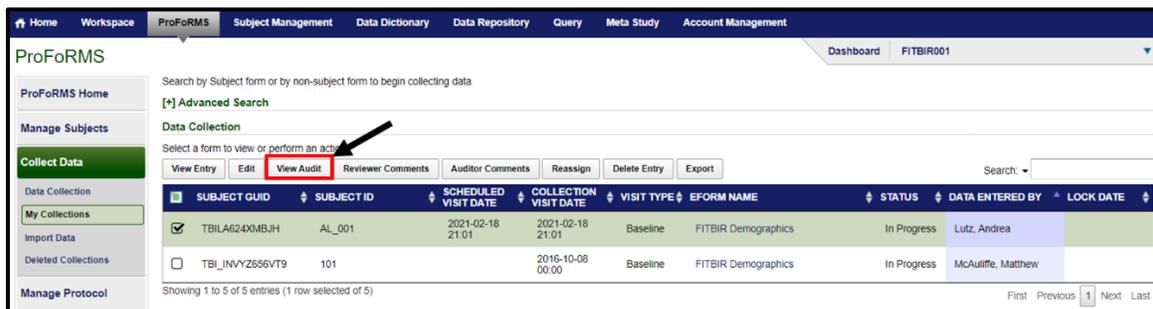
1. Perform steps 1-6 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in editing, then select **Edit**.
 - a. **Note:** non-admin users are only able to edit forms with an **In Progress** or **Completed** status. If your form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

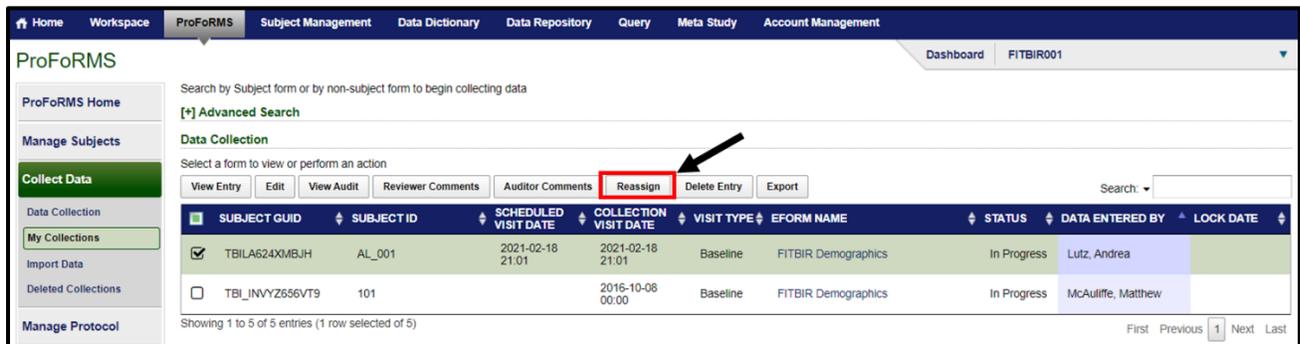
1. Perform steps 1-6 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in viewing, then select **View Audit**.
3. A new browser page will open with the **Data Collection Audit Log** details.



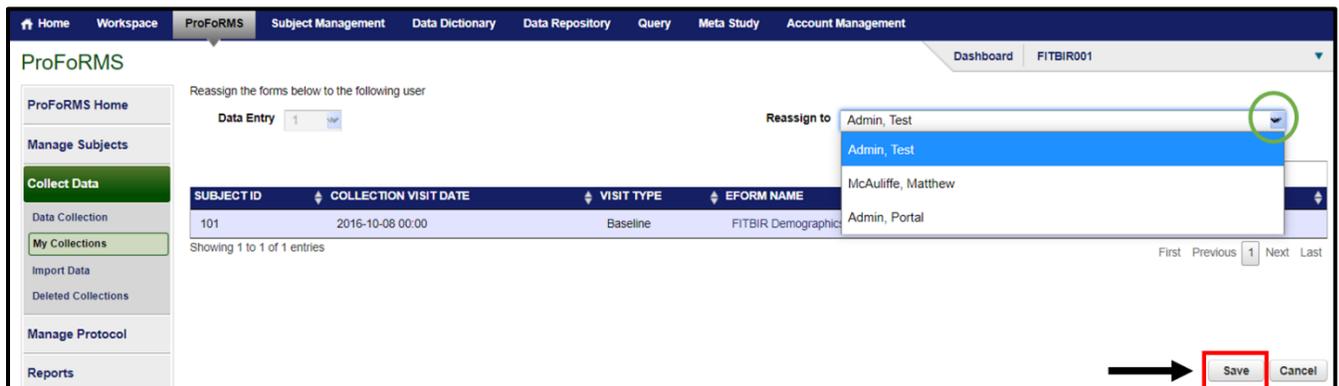
3.7.2.4 Reassign eForm

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*



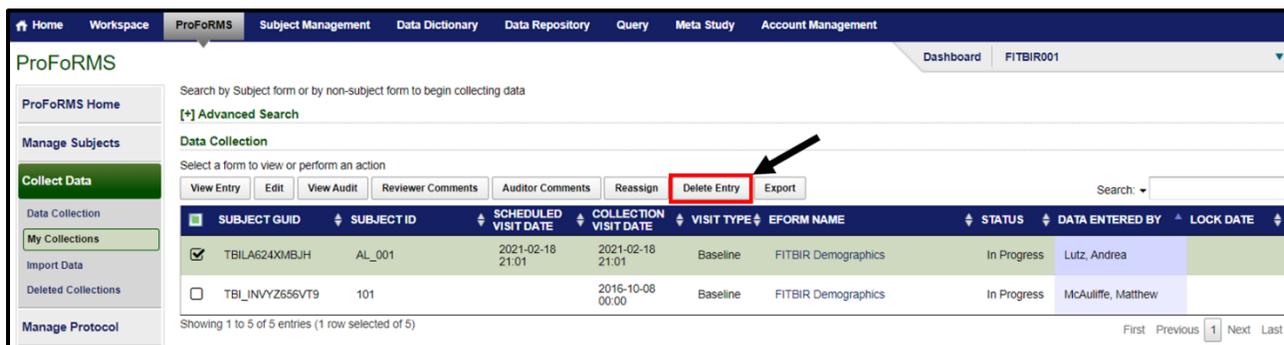
3. The **Reassign** data entry page appears.
4. Using the drop-down menu, select the desired user to reassign the eForm to, then select **Save**.
5. The **My Collections** page appears with the reassigned form update.



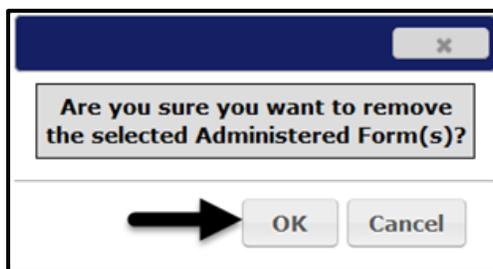
3.7.2.5 Delete Entry

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)?’

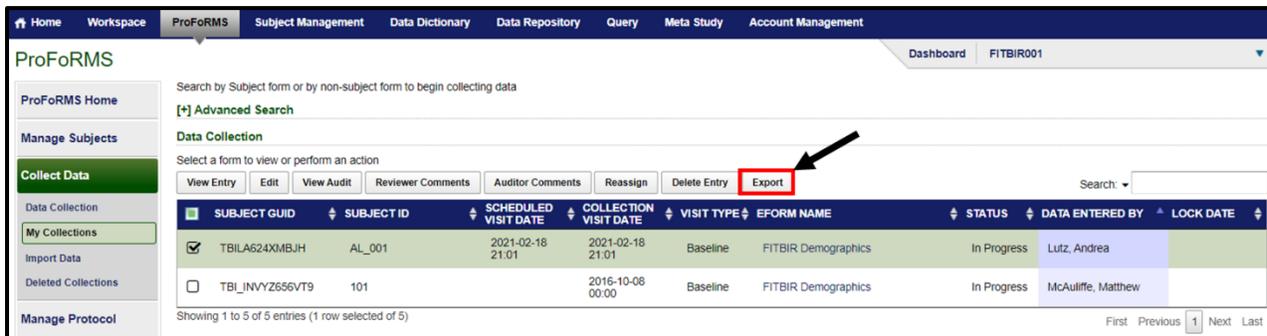


4. The **My Collections** page appears with the confirmation of the deleted eForm.

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.

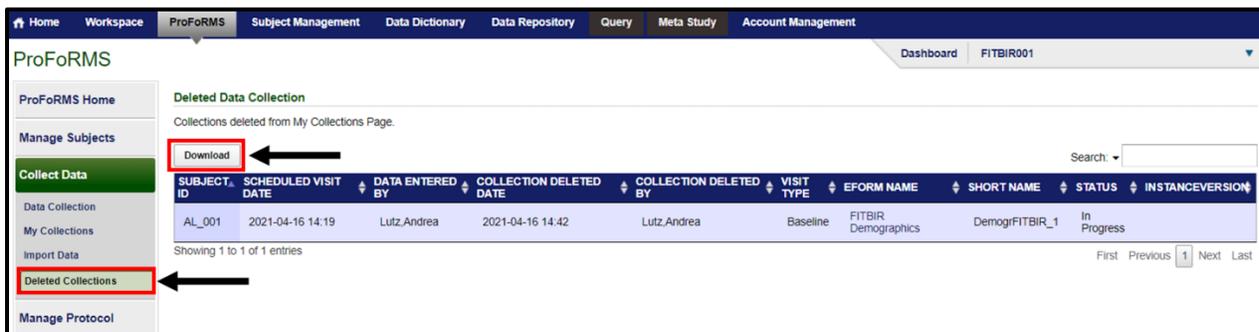


3.7.3 Deleted Collections

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



3.8 MANAGE PROTOCOL

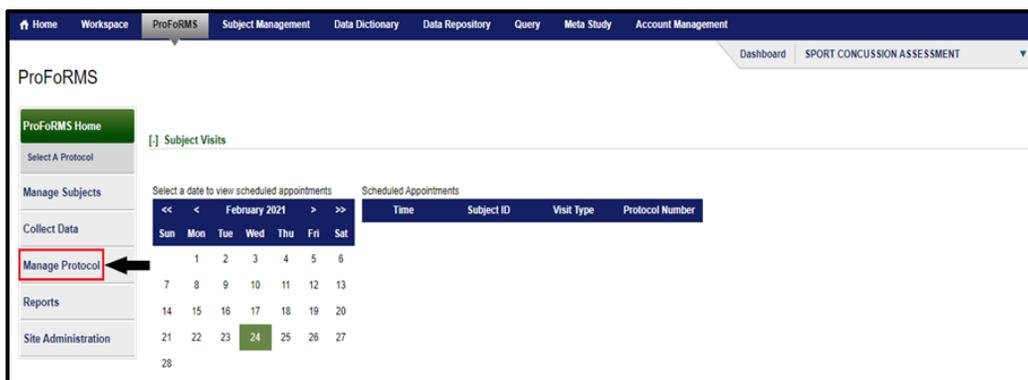
This feature is designed to help the researchers to add and edit study information, schedule create study visits, manage visit types individual subjects across multiple studies within the system, upload subject related document. The sub-sections available in the Manage Subjects menu are as follows:

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

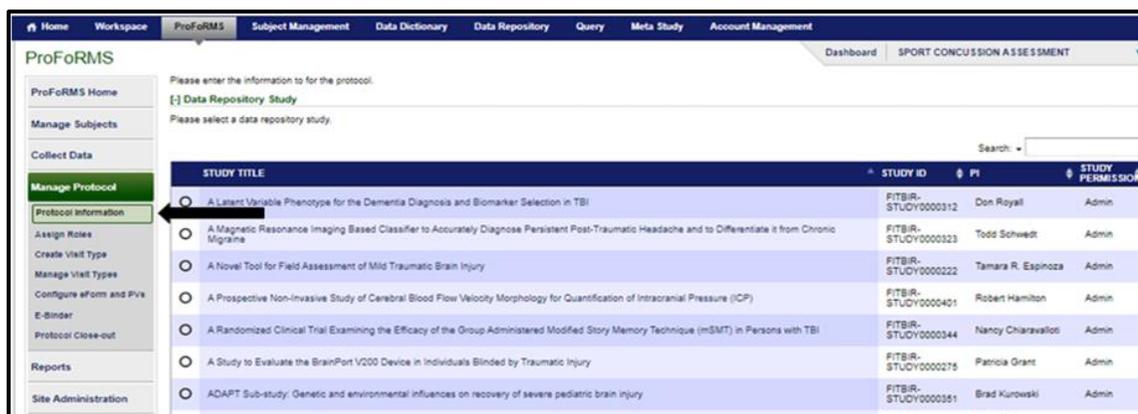
3.8.1 Viewing Protocol Information

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

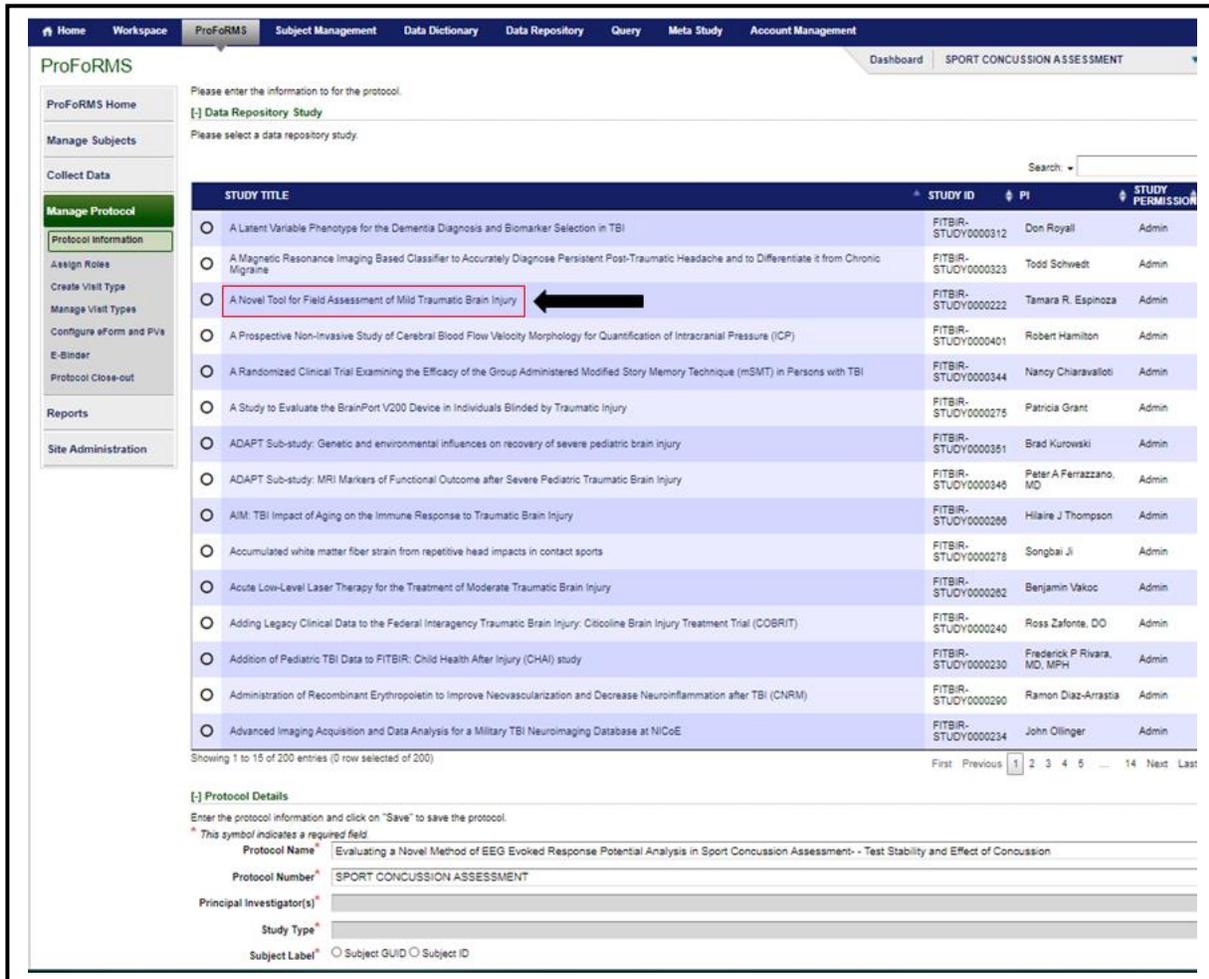
1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar.



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.



The screenshot displays the ProFoRMS web application interface. At the top, there is a navigation bar with tabs for Home, Workspace, ProFoRMS, Subject Management, Data Dictionary, Data Repository, Query, Meta Study, and Account Management. Below this, a breadcrumb trail shows Dashboard > SPORT CONCUSSION ASSESSMENT.

The main content area is divided into a left sidebar and a main panel. The sidebar contains navigation options: ProFoRMS Home, Manage Subjects, Collect Data, Manage Protocol (highlighted in green), Protocol Information, Assign Roles, Create Visit Type, Manage Visit Types, Configure eForm and Pivs E-Binder, Protocol Close-out, Reports, and Site Administration.

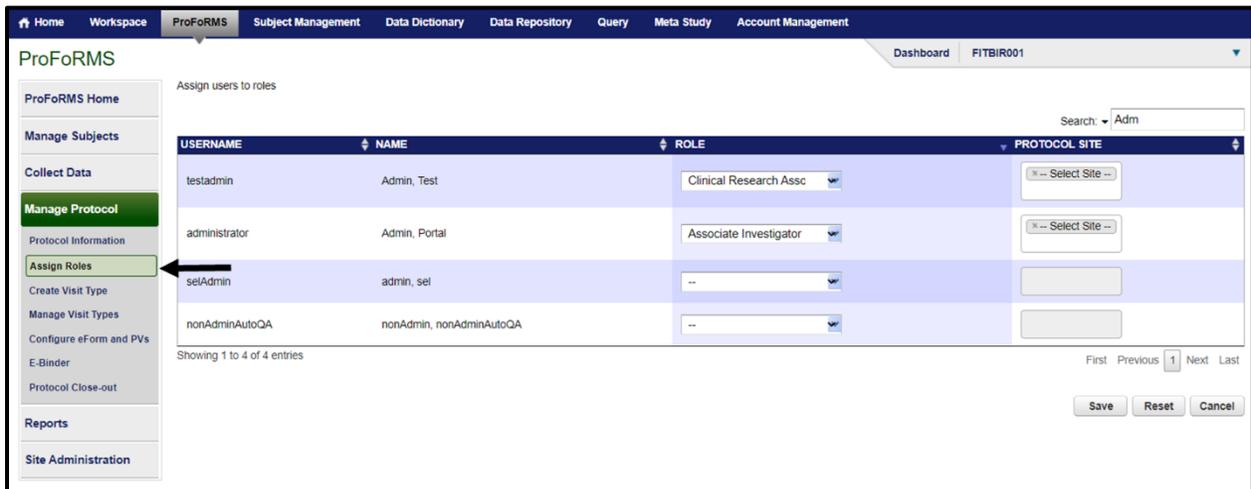
The main panel features a search bar and a table of studies. The table has columns for STUDY TITLE, STUDY ID, PI, and STUDY PERMISSION. The third row, "A Novel Tool for Field Assessment of Mild Traumatic Brain Injury", is highlighted in blue and has a red box around its title with a black arrow pointing to it. Below the table, it indicates "Showing 1 to 15 of 200 entries (0 row selected of 200)" and a pagination control showing "1" selected.

Below the table is the "[-] Protocol Details" section. It contains a form for entering protocol information, with fields for Protocol Name, Protocol Number, Principal Investigator(s), Study Type, and Subject Label. The Protocol Name field is populated with "Evaluating a Novel Method of EEG Evoked Response Potential Analysis in Sport Concussion Assessment - Test Stability and Effect of Concussion".

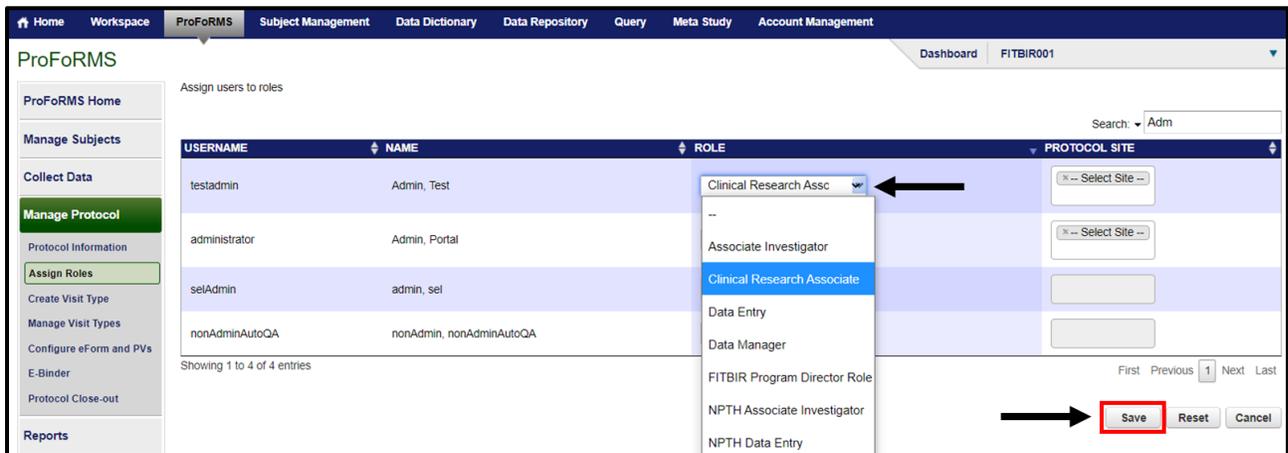
3.8.2 Assign Roles

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.



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.

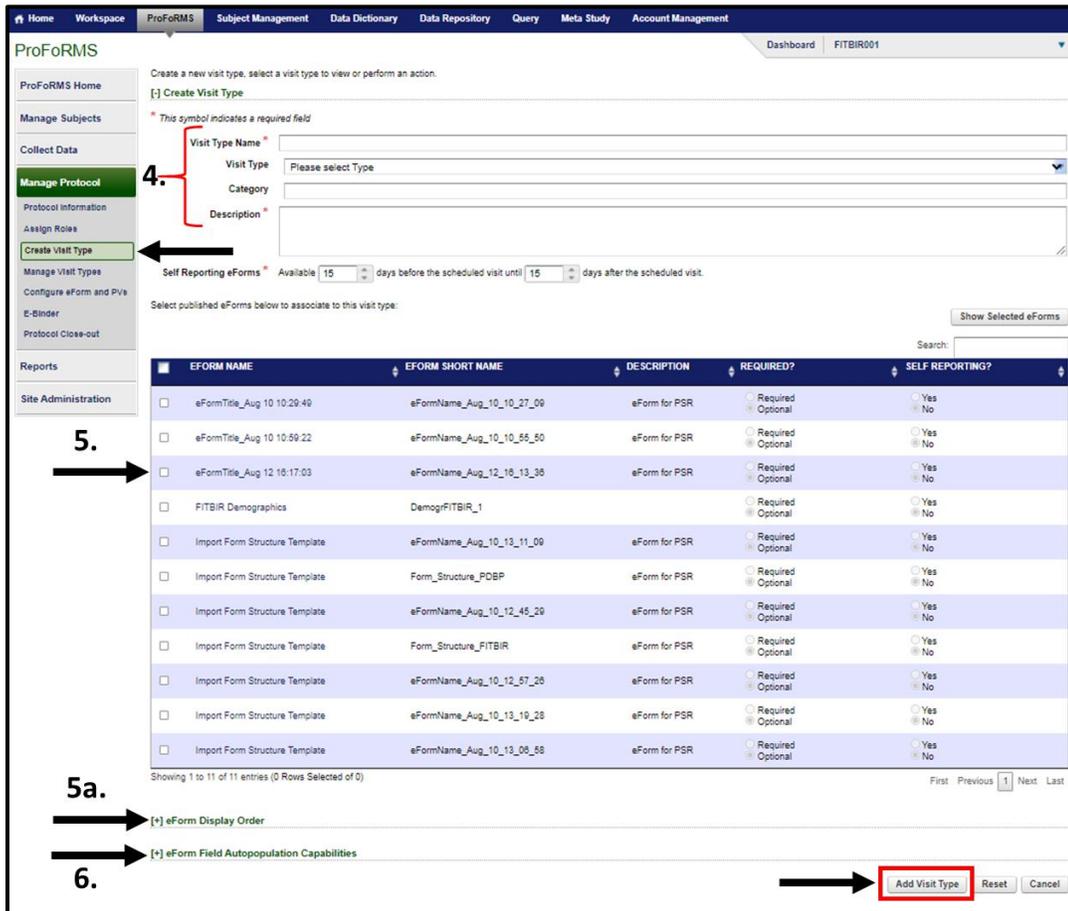


5. Click the **Save** button. The new user role(s) appear in the protocol setup.

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**
- a. The list only contains the eForms that are selected within the visit type
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. 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.



The screenshot shows the 'Create Visit Type' form in the ProFoRMS system. The form includes the following fields:

- Visit Type Name ***: A text input field.
- Visit Type**: A dropdown menu with 'Please select Type'.
- Category**: A dropdown menu.
- Description ***: A text area.
- Self Reporting eForms ***: A section with two dropdowns: 'Available' (set to 15) and 'days before the scheduled visit until' (set to 15), and 'days after the scheduled visit'.

Below the form is a table of eForms to be associated with the visit type. The table has the following columns:

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	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_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

At the bottom of the interface, there are two sections for configuration:

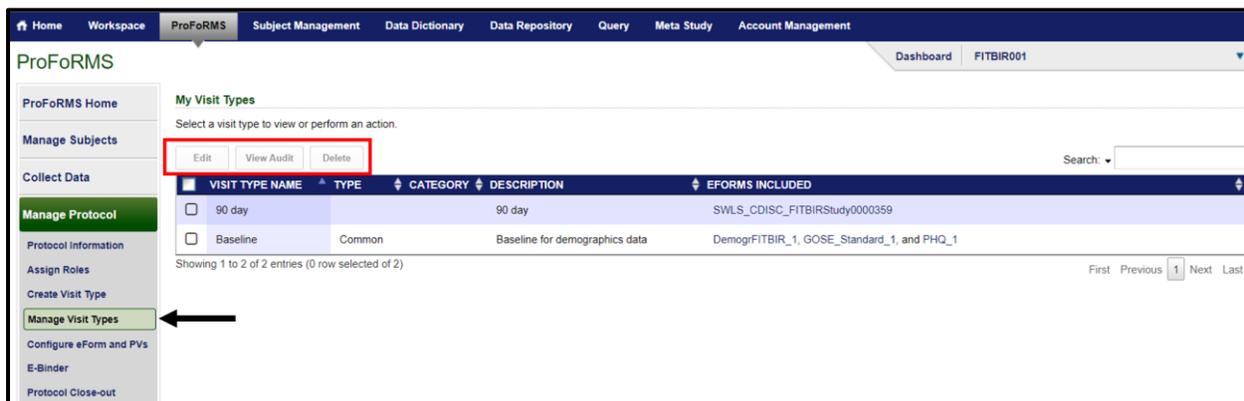
- [-] eForm Display Order**: A section with a plus sign and a list of eForm names.
- [-] eForm Field Autopopulation Capabilities**: A section with a plus sign and a list of eForm names.

The **Add Visit Type** button is highlighted with a red box.

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.



My Visit Types
Select a visit type to view or perform an action.

Edit View Audit Delete

<input type="checkbox"/>	VISIT TYPE NAME	TYPE	CATEGORY	DESCRIPTION	EFORMS INCLUDED
<input checked="" 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

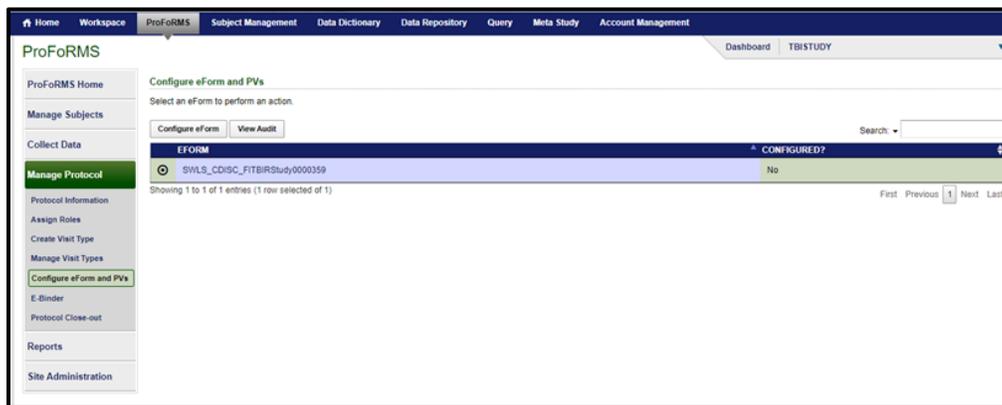
Showing 1 to 2 of 2 entries (0 row selected of 2) First Previous 1 Next Last

3.8.5 Configure eForm and PVs

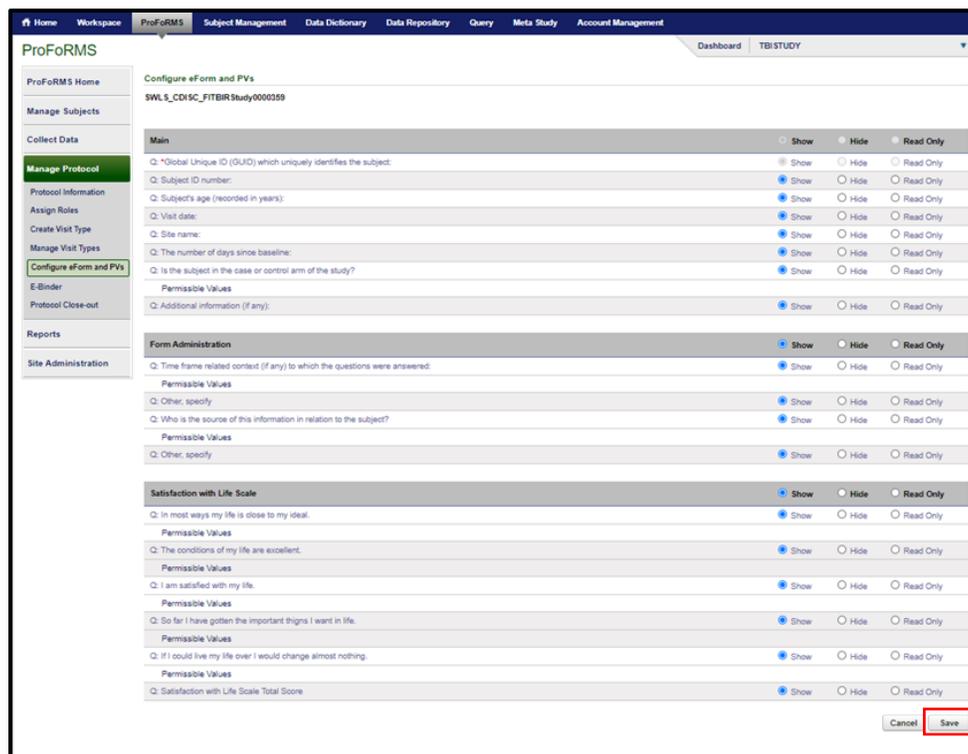
There is a feature where you are able to choose which fields of the eForm and PVs to either **Show**, **Hide**, or **Read Only**.

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**.

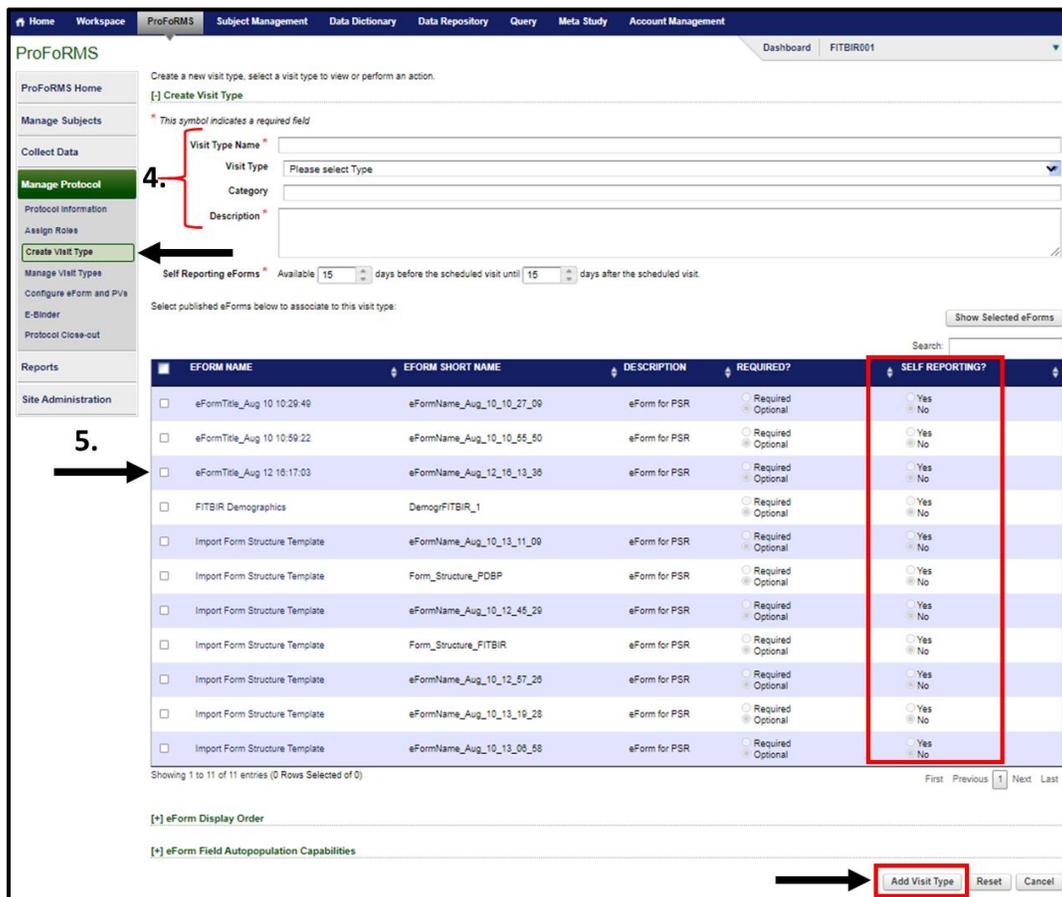


3.8.6 Patient Self-Reporting

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:

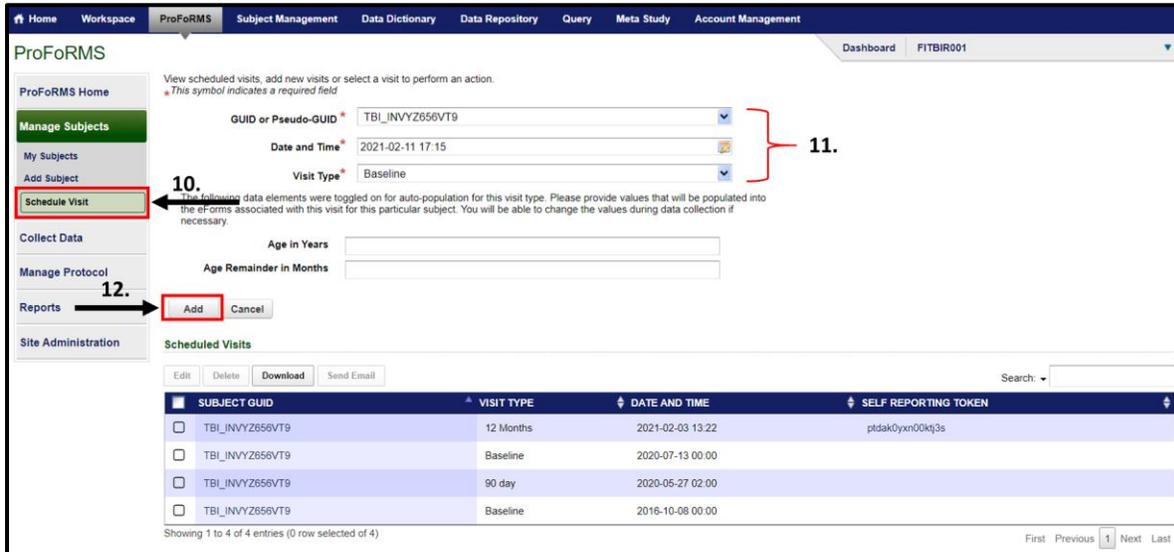
1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar then select **Create Visit Type**.
4. Create a new Visit Type by entering the **Visit Type Name**, **Visit Type**, and a **Short 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.



The screenshot shows the ProFoRMS interface for creating a new visit type. The top navigation bar includes Home, Workspace, ProFoRMS, Subject Management, Data Dictionary, Data Repository, Query, Meta Study, and Account Management. The left sidebar has a 'Manage Protocol' section with a 'Create Visit Type' button highlighted. The main content area has a 'Create Visit Type' form with fields for 'Visit Type Name', 'Visit Type', and 'Description'. Below the form is a table of eForms with columns for 'EFORM NAME', 'EFORM SHORT NAME', 'DESCRIPTION', 'REQUIRED?', and 'SELF REPORTING?'. The 'SELF REPORTING?' column contains radio buttons for 'Yes' and 'No'. A red box highlights this column. At the bottom right, there is an 'Add Visit Type' button, also highlighted with a red box. Arrows and numbers 4 and 5 point to the 'Create Visit Type' button and the 'Add Visit Type' button respectively.

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"/> FITBR Demographics	DemogFITBR_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_FITBR	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_58	eForm for PSR	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No

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.



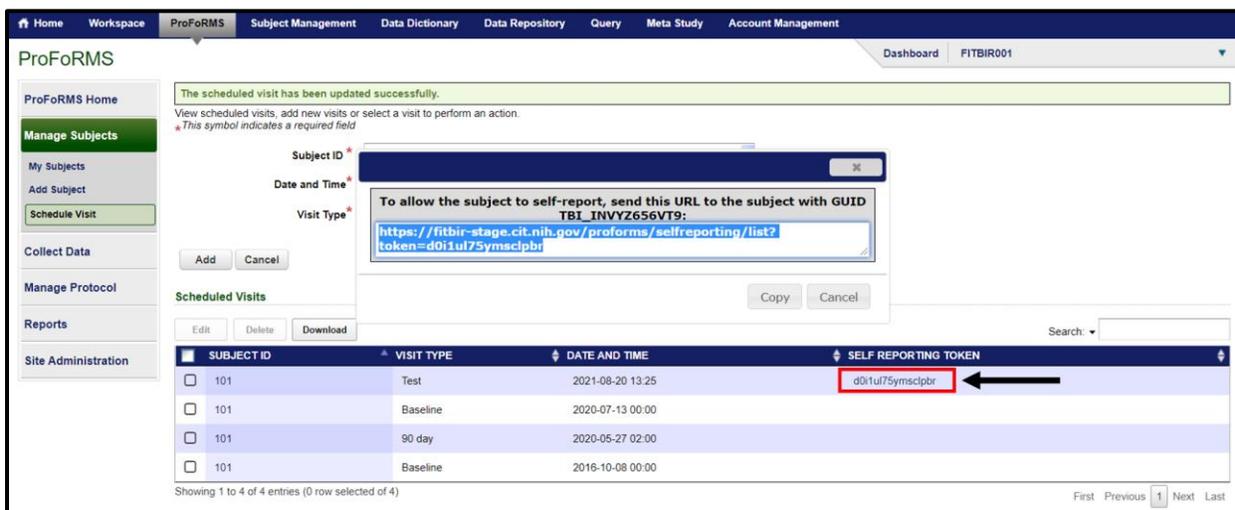
The screenshot shows the ProFoRMS interface for scheduling a visit. The left sidebar has 'Schedule Visit' highlighted. The main form has the following fields:

- GUID or Pseudo-GUID: TBI_INVYZ656VT9
- Date and Time: 2021-02-11 17:15
- Visit Type: Baseline
- Age in Years: [empty]
- Age Remainder in Months: [empty]

 The 'Add' button is highlighted with a red box and labeled '12.'. A red bracket groups the GUID, Date and Time, and Visit Type fields, labeled '11.'. A red box around the 'Schedule Visit' menu item is labeled '10.'. Below the form is a table of 'Scheduled Visits':

SUBJECT GUID	VISIT TYPE	DATE AND TIME	SELF REPORTING TOKEN
<input type="checkbox"/> TBI_INVYZ656VT9	12 Months	2021-02-03 13:22	ptdak0yxrn00k3s
<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	

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



The screenshot shows the ProFoRMS interface after a successful update. A green message bar at the top says 'The scheduled visit has been updated successfully.' A modal dialog is open with the following text:

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=d0i1ul75ymsclpbr>

 Below the modal is a table of 'Scheduled Visits':

SUBJECT ID	VISIT TYPE	DATE AND TIME	SELF REPORTING TOKEN
<input type="checkbox"/> 101	Test	2021-08-20 13:25	d0i1ul75ymsclpbr
<input type="checkbox"/> 101	Baseline	2020-07-13 00:00	
<input type="checkbox"/> 101	90 day	2020-05-27 02:00	
<input type="checkbox"/> 101	Baseline	2016-10-08 00:00	

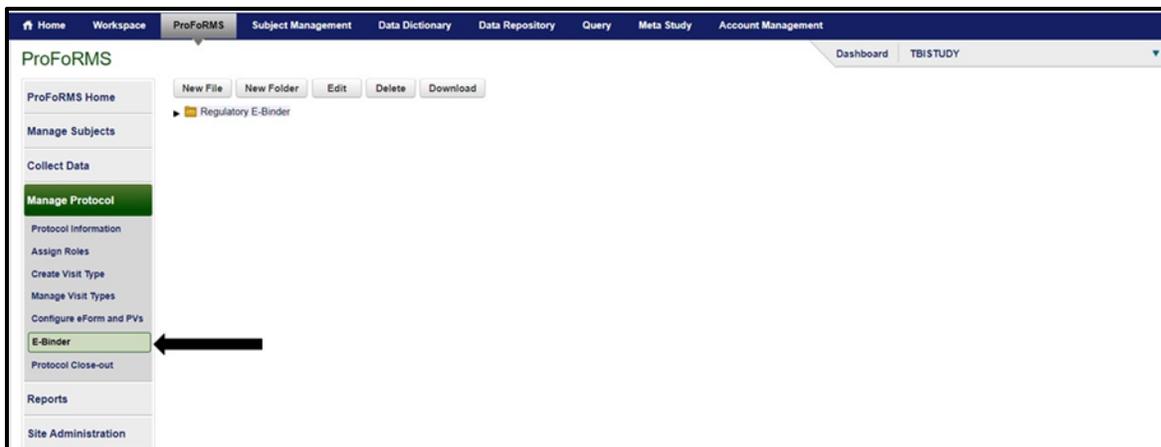
 The 'Self-Reporting Token' column in the first row is highlighted with a red box and labeled with an arrow.

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



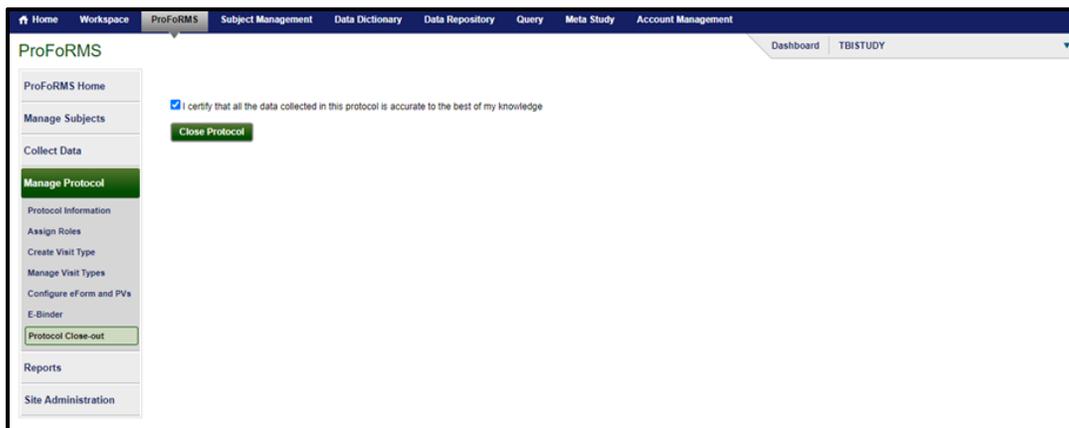
3.8.8 Protocol Closeout

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.

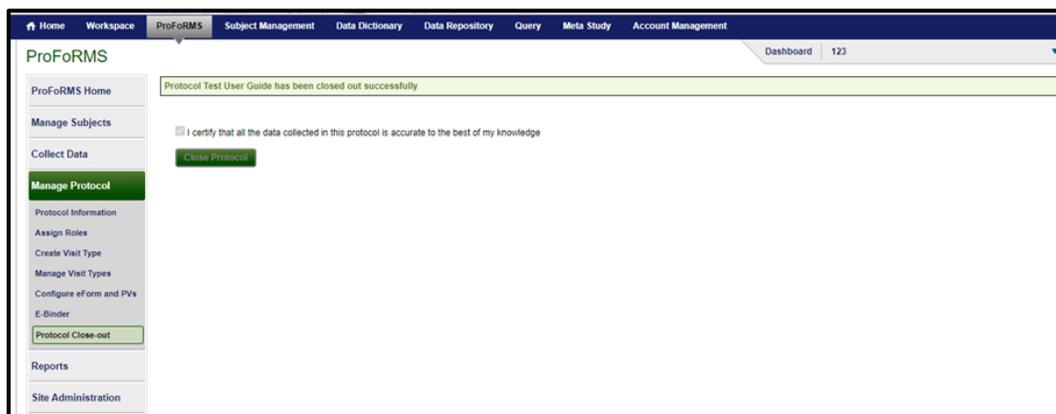
- ❖ The e-form will state that the PI acknowledges that the data collected is accurate to the best of their knowledge
- ❖ The e-form will capture the signature of the PI
- ❖ The e-form will capture the full legal name of the PI
- ❖ The e-form will capture the date and time that the form was signed
- ❖ 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:

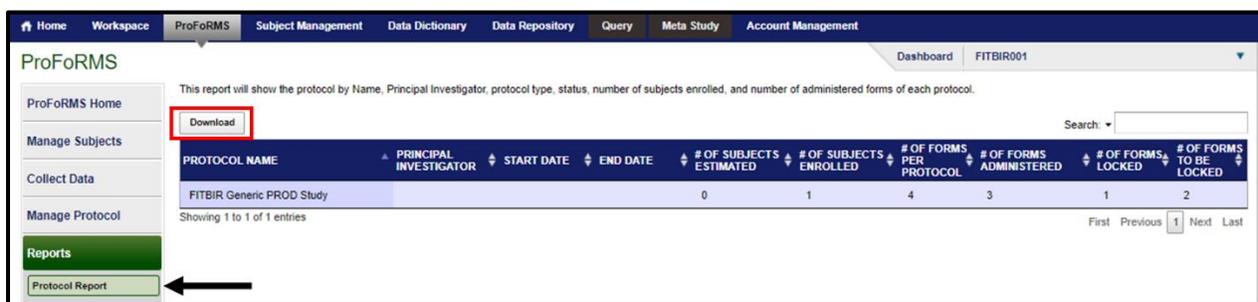
- ❖ Protocol Reports
- ❖ Detailed Protocol Report
- ❖ Without Collections
- ❖ Forms Requiring Completion & Lock
- ❖ Locked Forms
- ❖ Submission Summary
- ❖ Form Status
- ❖ View Auditor Comments
- ❖ View Reviewer Comments

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.



The screenshot shows the ProFoRMS interface with the following elements:

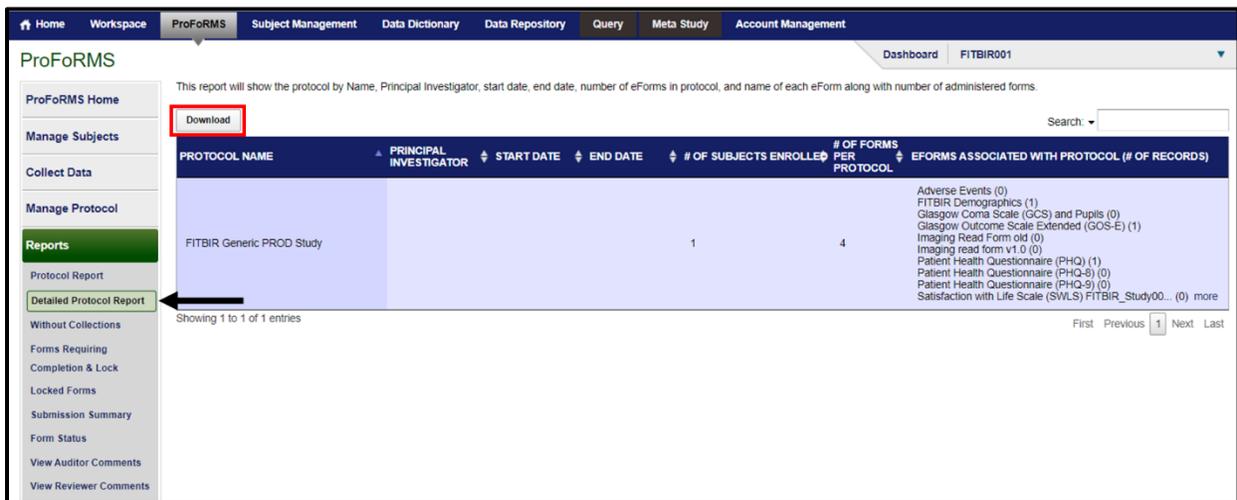
- Navigation tabs: Home, Workspace, ProFoRMS, Subject Management, Data Dictionary, Data Repository, Query, Meta Study, Account Management.
- Dashboard: FITBIR001
- Left sidebar: ProFoRMS Home, Manage Subjects, Collect Data, Manage Protocol, Reports (highlighted with a black arrow), Protocol Report (highlighted with a black arrow).
- Main content area:
 - Text: "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."
 - Table with columns: 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.
 - Table data row: FITBIR Generic PROD Study, [blank], [blank], [blank], 0, 1, 4, 3, 1, 2.
 - Footer: 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.



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 'Detailed Protocol Report' selected. The main content area shows a table with the following data:

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

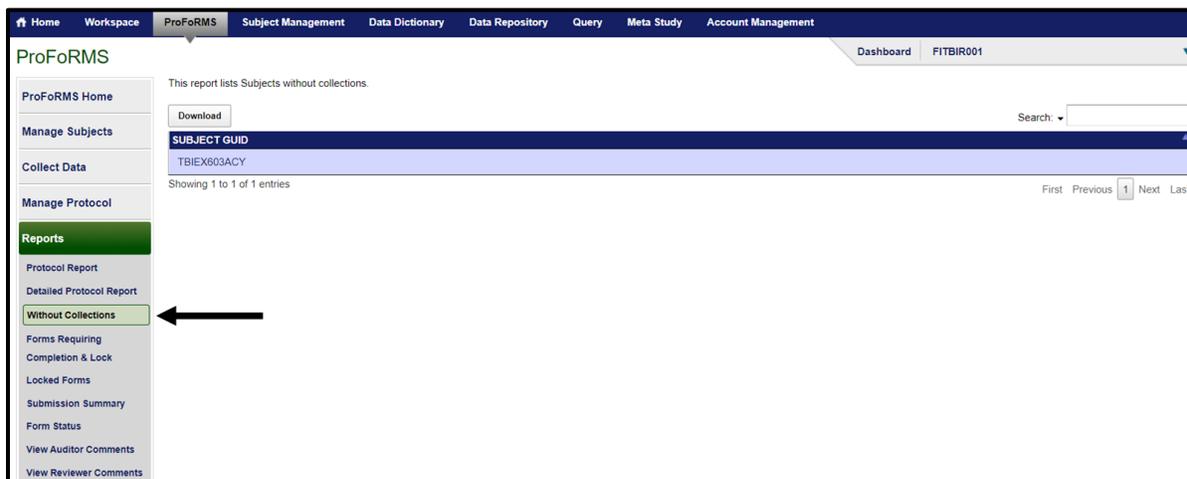
A 'Download' button is highlighted in the top right of the report area. The interface also shows 'Showing 1 to 1 of 1 entries' and pagination controls (First, Previous, 1, Next, Last).

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.

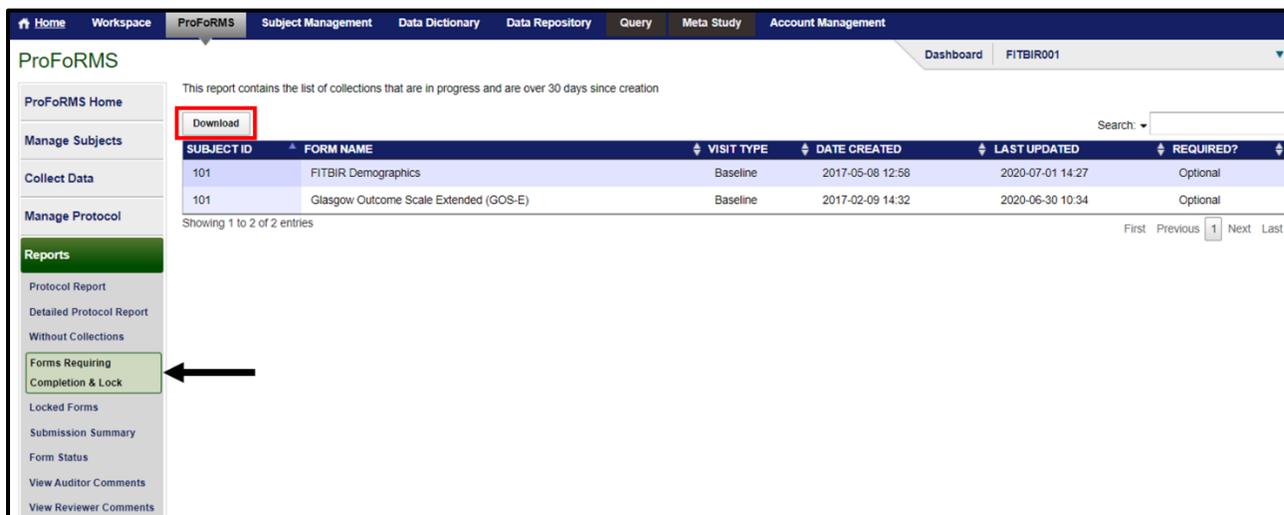


3.9.4 Forms Requiring Completion & Lock

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.



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 contains a 'Reports' section with the following options: Protocol Report, Detailed Protocol Report, Without Collections, **Forms Requiring Completion & Lock** (highlighted with an arrow), Locked Forms, Submission Summary, Form Status, View Auditor Comments, and View Reviewer Comments. The main content area shows a table with the following data:

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

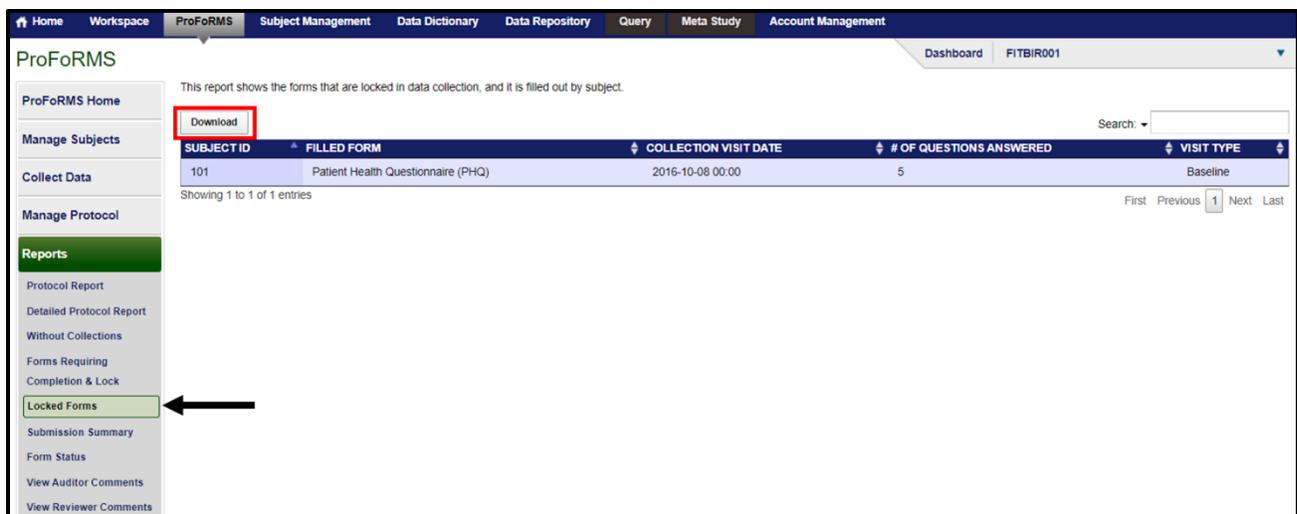
A red box highlights the 'Download' button above the table. The table also includes a search bar and pagination controls (First, Previous, 1, Next, Last).

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.



The screenshot shows 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 has a 'Reports' section with 'Locked Forms' selected. The main content area displays a table with the following data:

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

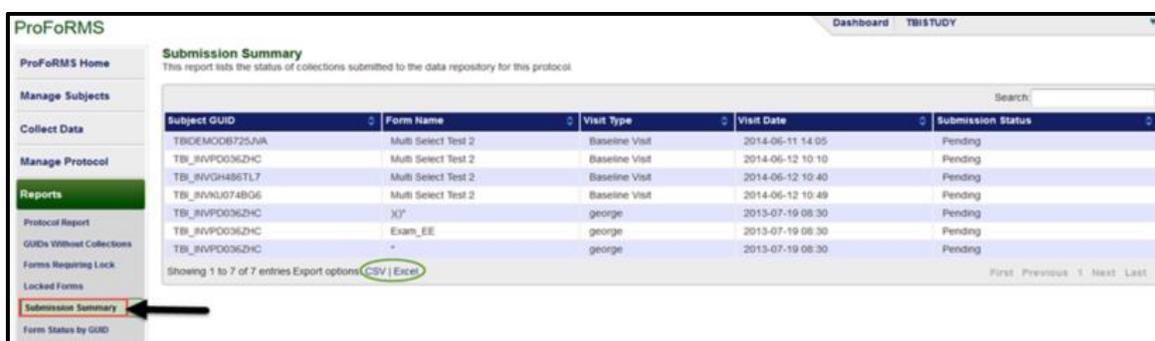
A 'Download' button is highlighted with a red box in the top left of the report area. The table shows 'Showing 1 to 1 of 1 entries' and navigation controls for 'First', 'Previous', '1', 'Next', and 'Last'.

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.



ProFoRMS 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
TBDEMCOB725JVA	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](#)

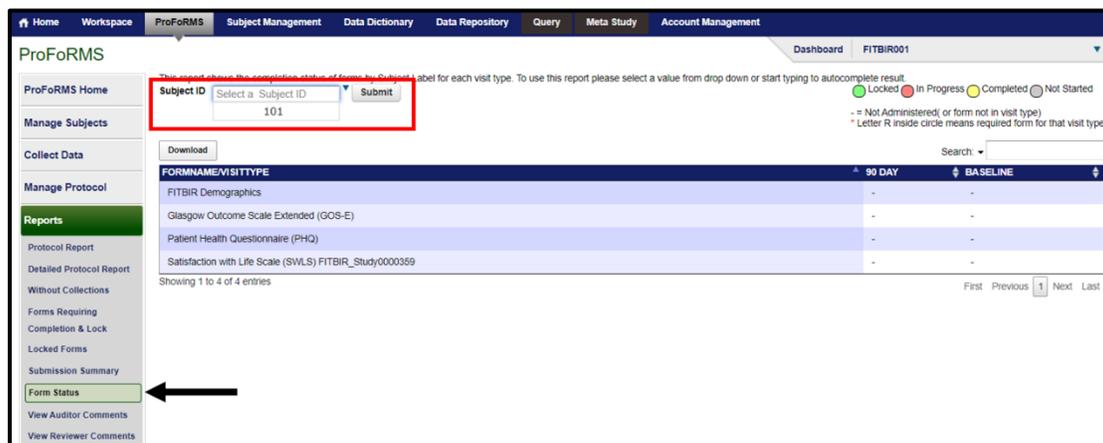
First Previous 1 Next Last

3.9.7 Form Status

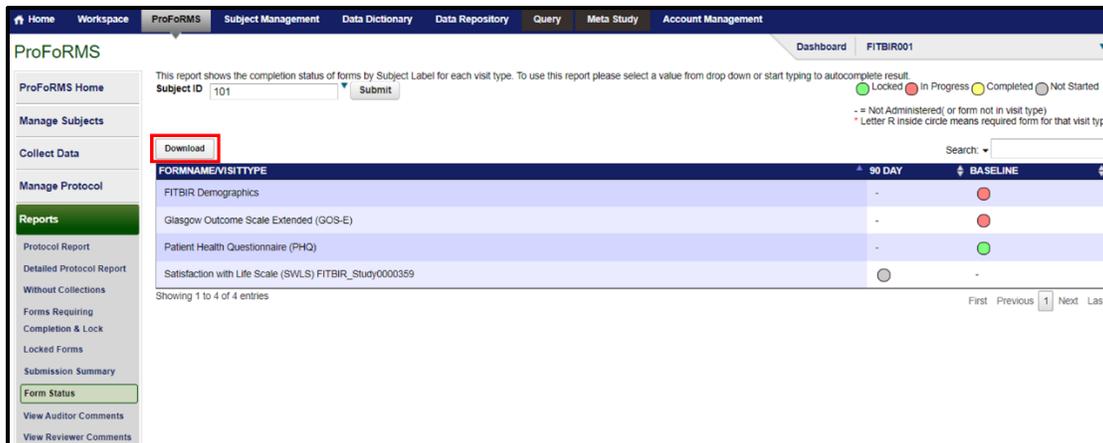
This report shows the completion status of forms by Subject Label for each visit type.

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.



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

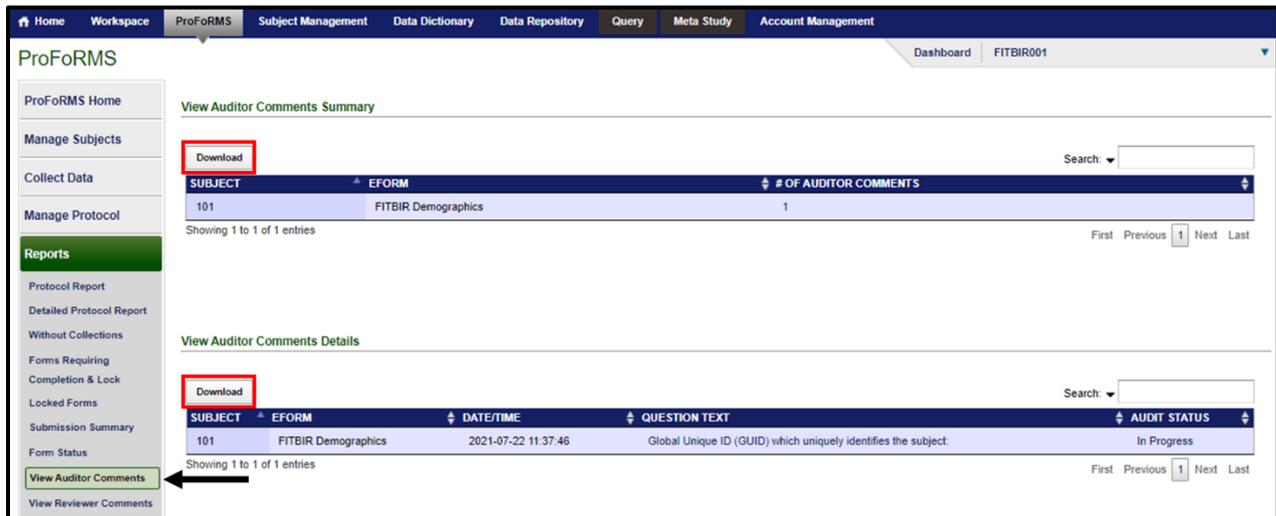


3.9.8 View Auditor Comments

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 with the following components:

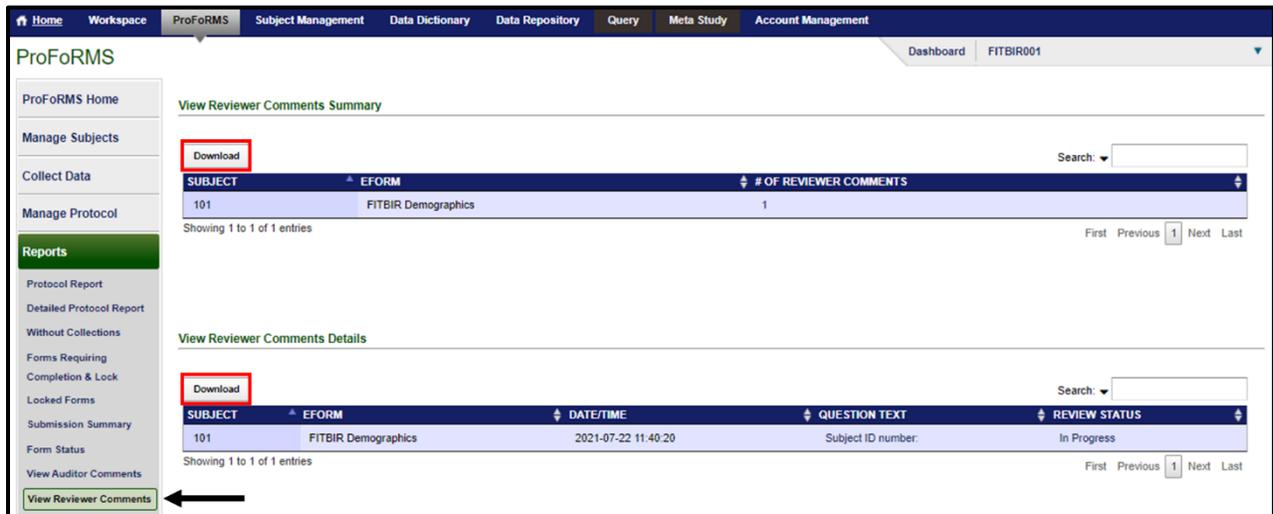
- Navigation Bar:** Home, Workspace, ProFoRMS, Subject Management, Data Dictionary, Data Repository, Query, Meta Study, Account Management.
- Dashboard:** Dashboard, FITBIR001
- Left Sidebar:** ProFoRMS Home, Manage Subjects, Collect Data, Manage Protocol, Reports (highlighted), Protocol Report, Detailed Protocol Report, Without Collections, Forms Requiring Completion & Lock, Locked Forms, Submission Summary, Form Status, View Auditor Comments (highlighted with a green box and arrow), View Reviewer Comments.
- View Auditor Comments Summary:**
 - Download button (highlighted in red)
 - Search:
 - Table with columns: SUBJECT, EFORM, # OF AUDITOR COMMENTS
 - Table Row: 101, FITBIR Demographics, 1
 - Showing 1 to 1 of 1 entries
 - Navigation: First, Previous, 1, Next, Last
- View Auditor Comments Details:**
 - Download button (highlighted in red)
 - Search:
 - Table with columns: SUBJECT, EFORM, DATE/TIME, QUESTION TEXT, AUDIT STATUS
 - Table Row: 101, FITBIR Demographics, 2021-07-22 11:37:46, Global Unique ID (GUID) which uniquely identifies the subject., In Progress
 - Showing 1 to 1 of 1 entries
 - Navigation: First, Previous, 1, Next, Last

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.



The screenshot displays the ProFoRMS interface with the following components:

- Navigation Bar:** Home, Workspace, ProFoRMS, Subject Management, Data Dictionary, Data Repository, Query, Meta Study, Account Management.
- Dashboard:** Dashboard | FITBIR001
- Left Sidebar (Reports):**
 - Protocol Report
 - Detailed Protocol Report
 - Without Collections
 - Forms Requiring Completion & Lock
 - Locked Forms
 - Submission Summary
 - Form Status
 - View Auditor Comments
 - View Reviewer Comments** (highlighted with a black arrow)
- View Reviewer Comments Summary:**
 - Download button (highlighted with a red box)
 - Table with columns: SUBJECT, EFORM, # OF REVIEWER COMMENTS
 - Table Row: 101, FITBIR Demographics, 1
 - Showing 1 to 1 of 1 entries
 - Navigation: First, Previous, 1, Next, Last
- View Reviewer Comments Details:**
 - Download button (highlighted with a red box)
 - Table with columns: SUBJECT, EFORM, DATE/TIME, QUESTION TEXT, REVIEW STATUS
 - Table Row: 101, FITBIR Demographics, 2021-07-22 11:40:20, Subject ID number:, In Progress
 - Showing 1 to 1 of 1 entries
 - Navigation: First, Previous, 1, Next, Last