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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 Trail Database (CTDB).

WARNING!

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🕮 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 acount 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.

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📖 Notes

🗁 Important Information

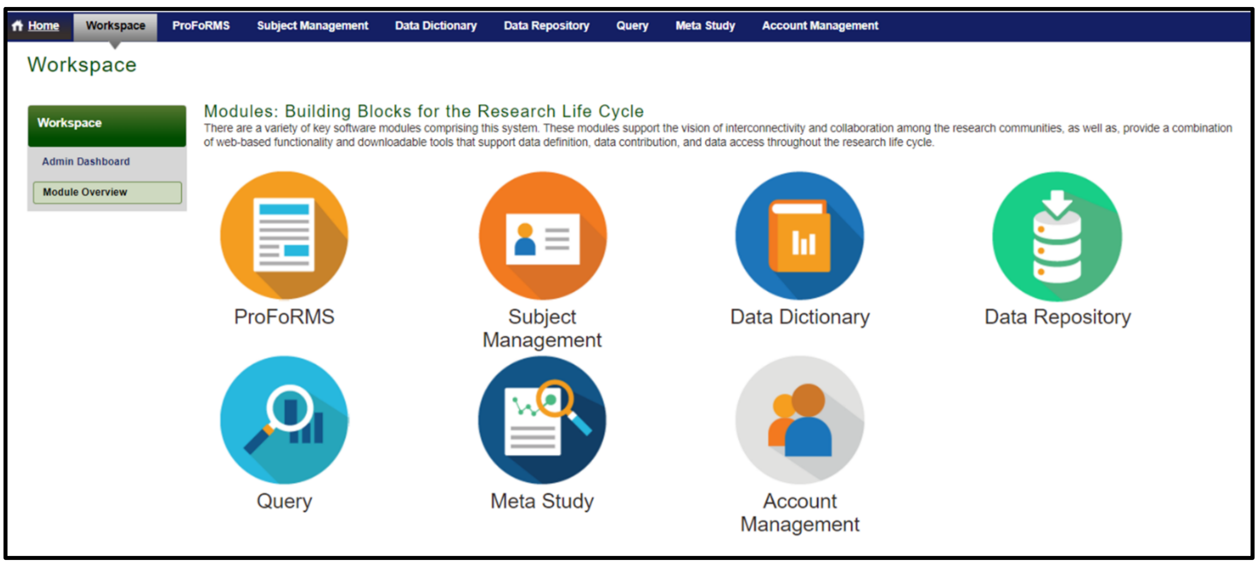
Things to Note:

🗁 **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

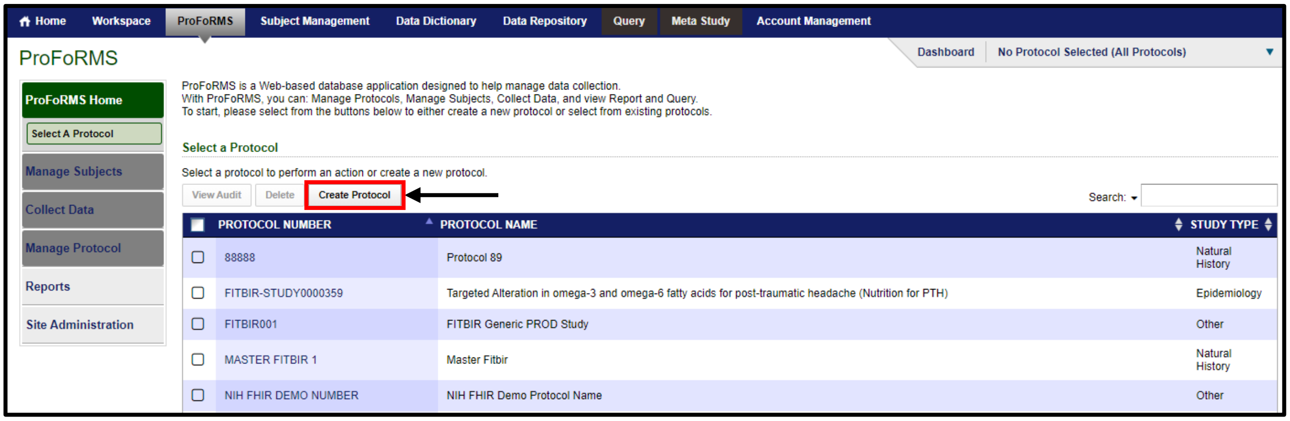
Things to Note:

🗁 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.

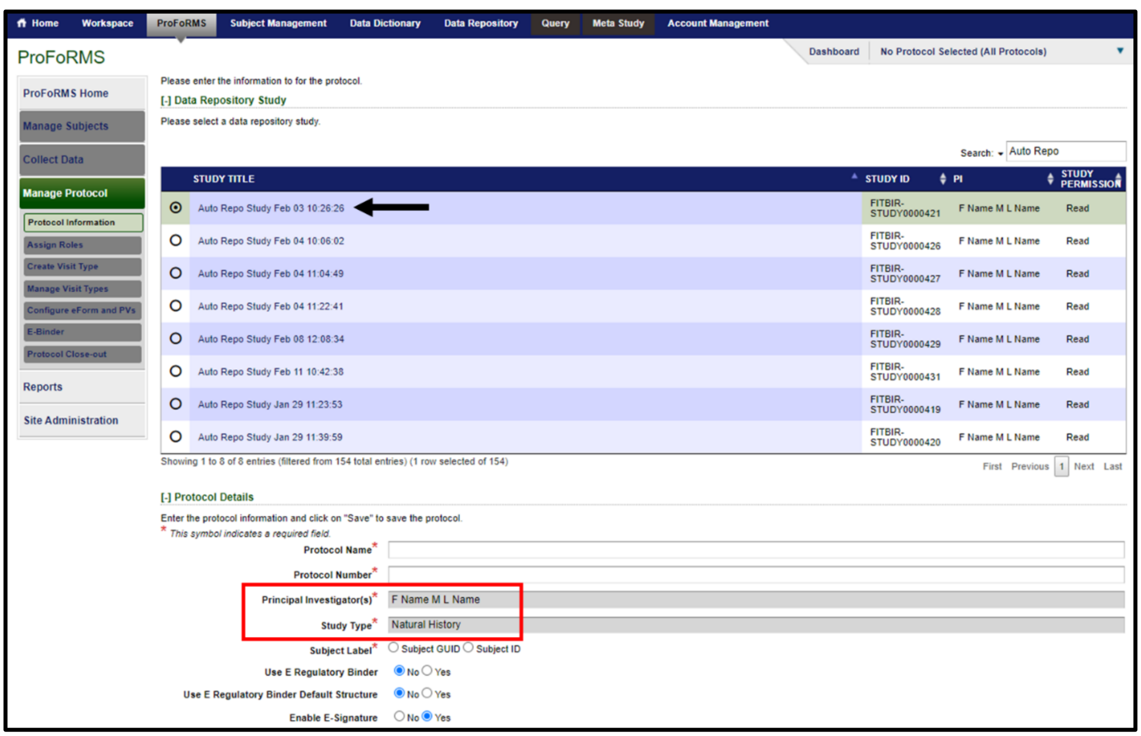
3.5 CREATE A PROTOCOL

To create a Protocol: perform the following actions:

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



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)

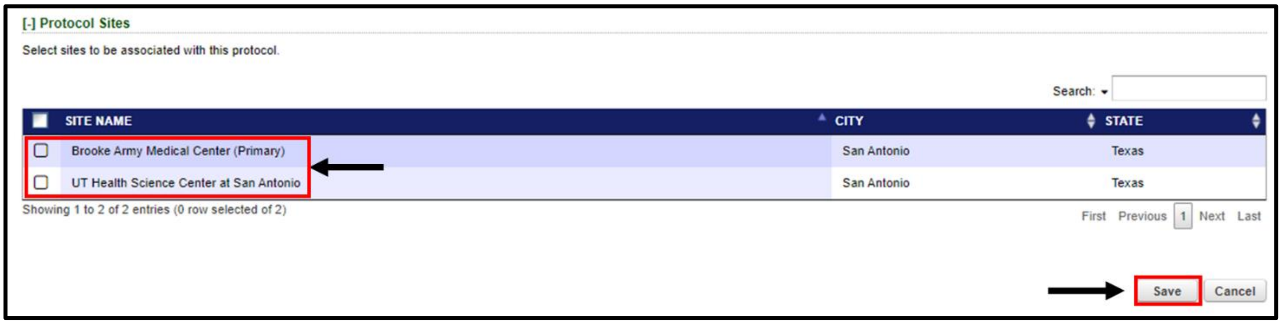


4. **Complete** all of the required fields (fields marked with a red asterisk (*))

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.



3.5.1 Selecting a Protocol

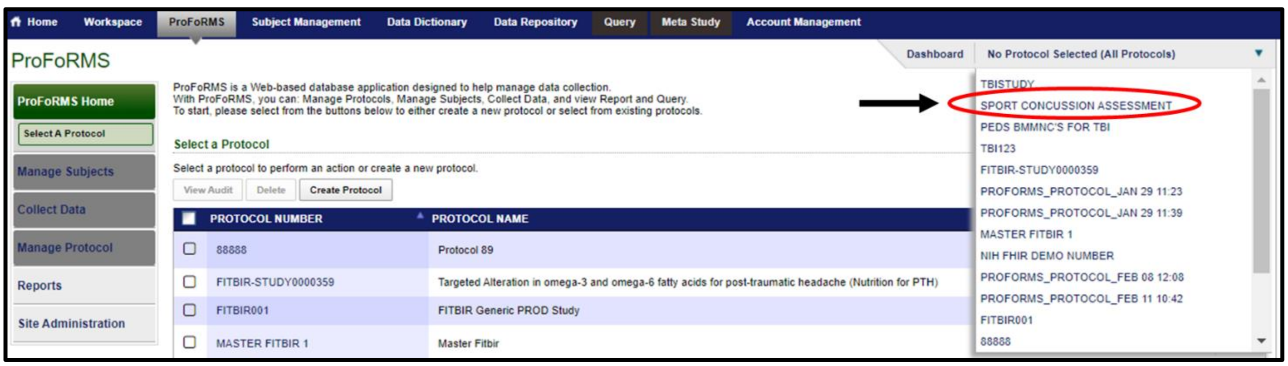
Viewing and selecting a protocol can be done in ProFoRMS via two ways:

- ❖ 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

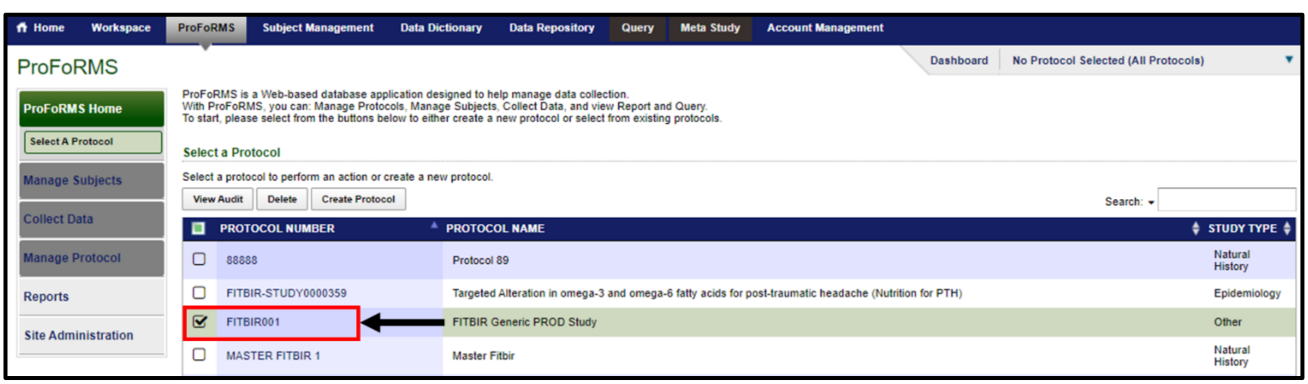


3. **Click** on the desired protocol. The system will load the selected protocol data including the list of subject visits.

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.

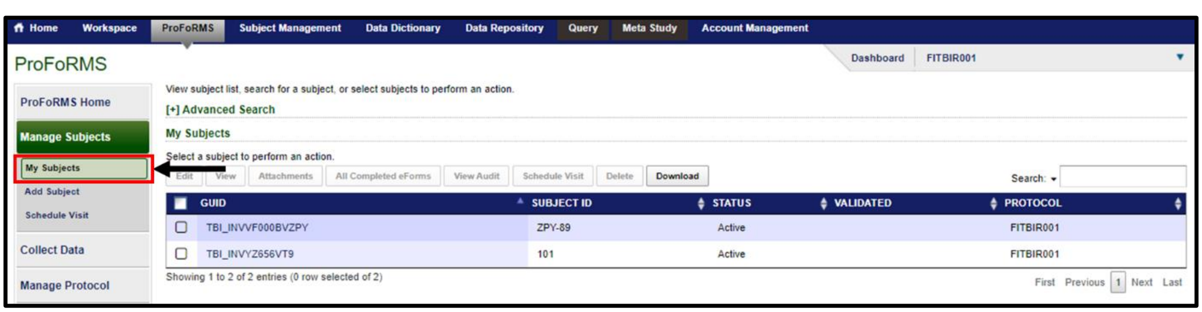
The table menu options allow the user to:

- 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.

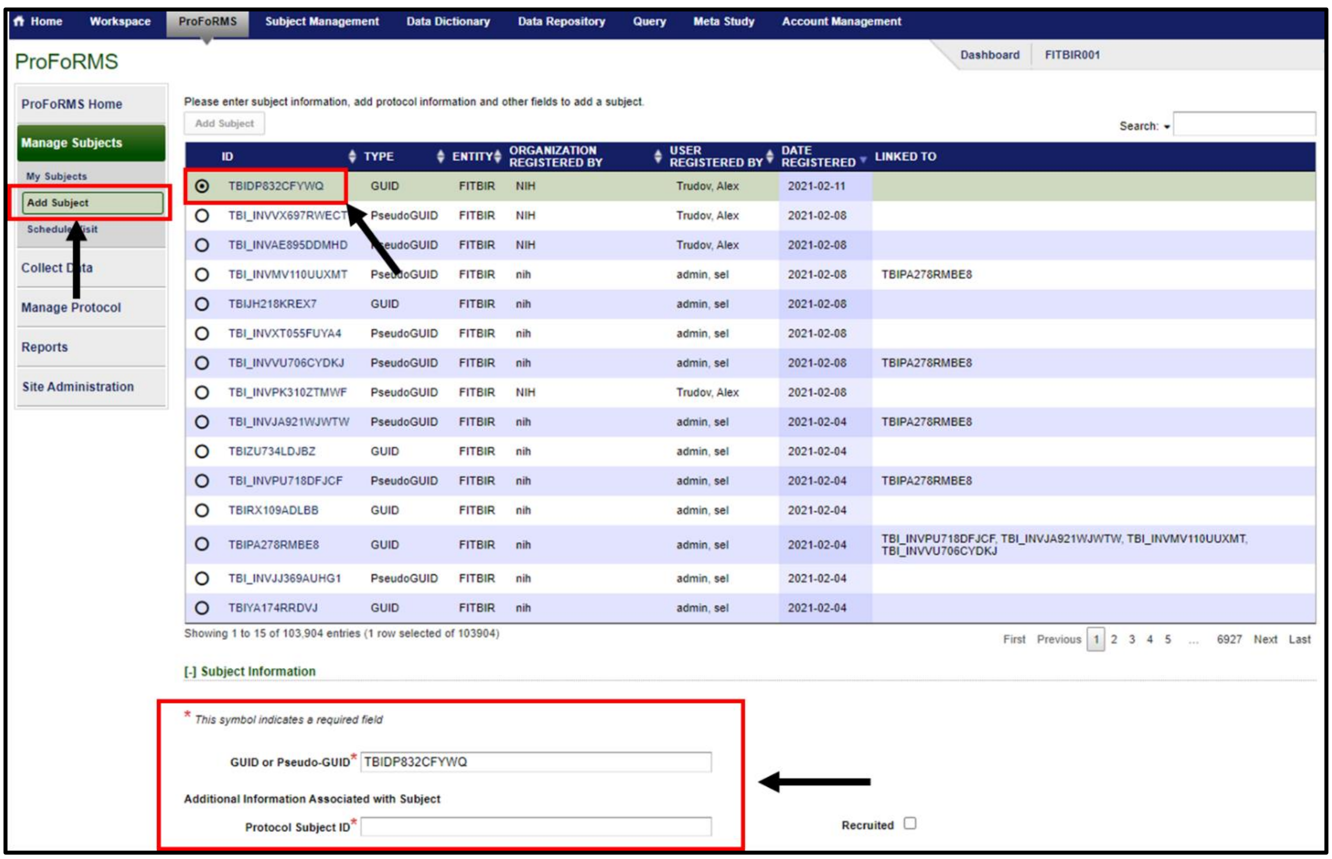


3.6.2 Add Subject

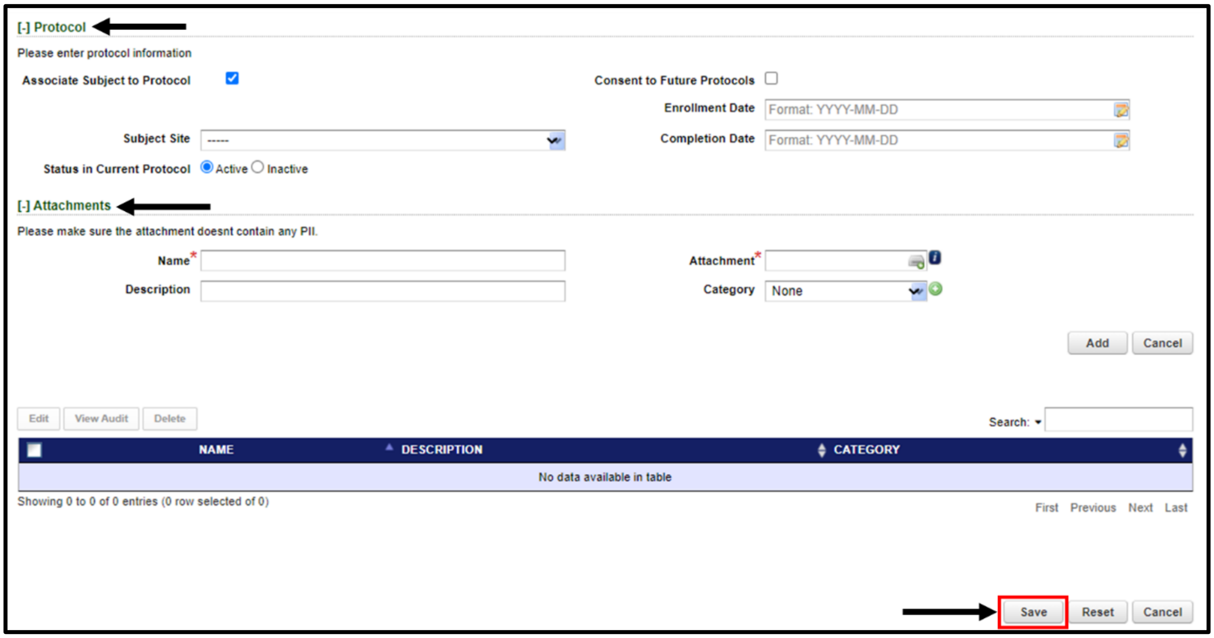
To add a subject (research participant) to a protocol, the subject must be provided with a unique Identification number (ID). This is done by creating a Global Unique Identifier (GUID) in the Subject Management tool. The GUID serves as an ID that allows researchers to associate data with the subject 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 Dasboard 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.



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.



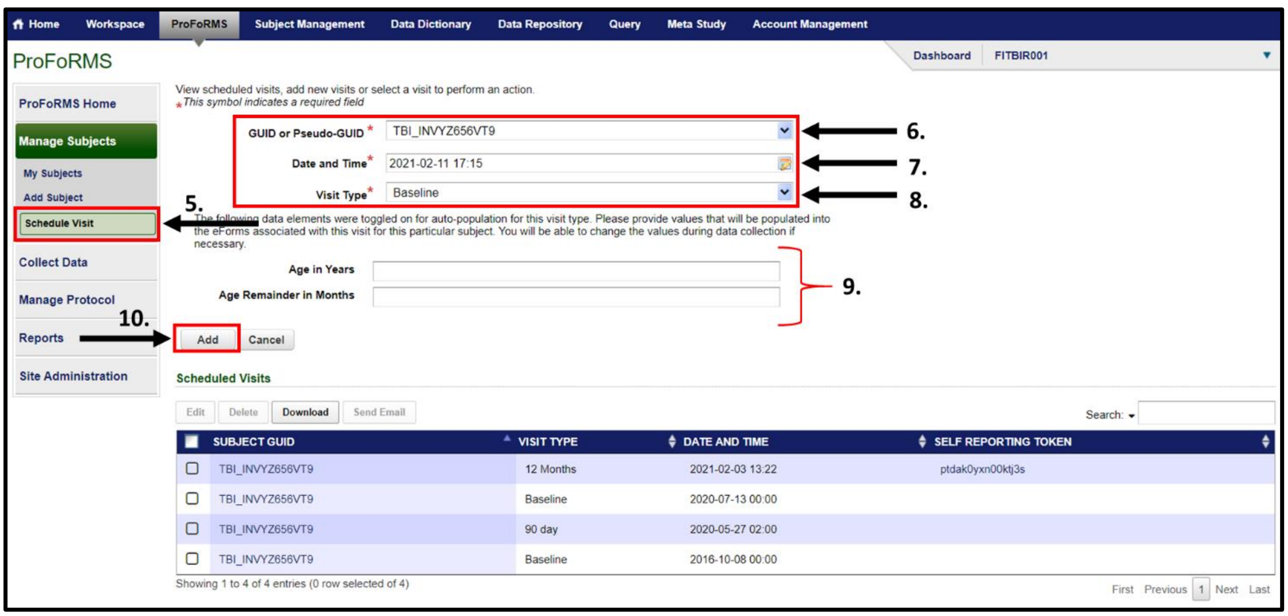
10. After selecting the **Save** button, the platform returns you to the **My Subjects** page where the newly added subject can be viewed.
11. If the subject does not have a **GUID** or **Pseudo-GUID** created in the system, click on the **Add Subject** button to launch the Subject Management tool and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

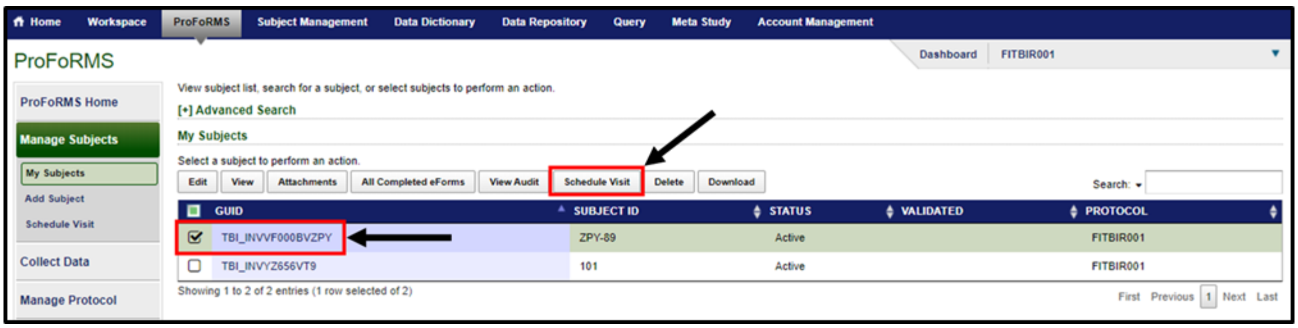


11. The newly scheduled visit will be displayed in the **Schedule Visit** table and will include a list of all visits that have been scheduled for subjects on the protocol.

***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.

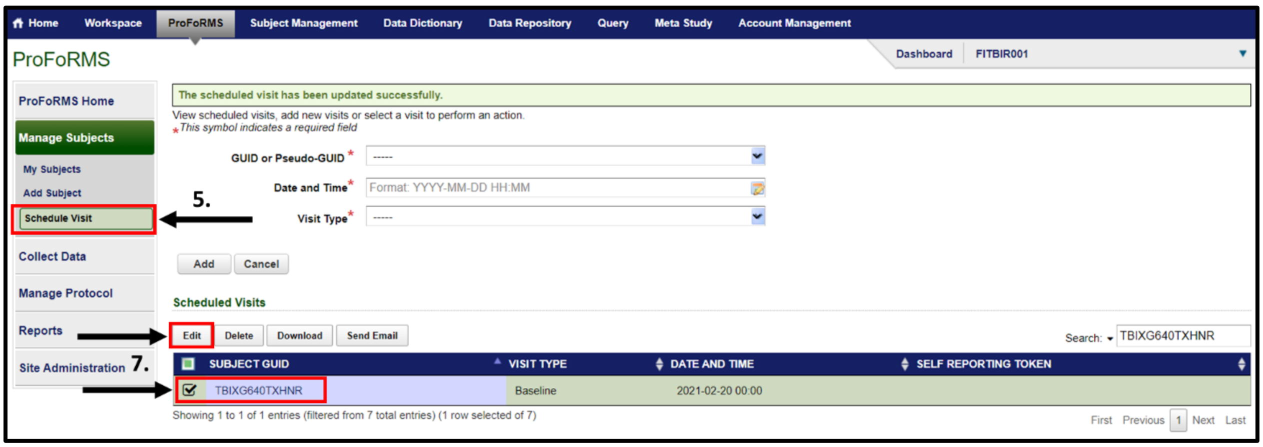
This step is recommended as the user can search/filter for a specific GUID through the search bar instead of searching for the GUID using the drop-down menu



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 Dasboard 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

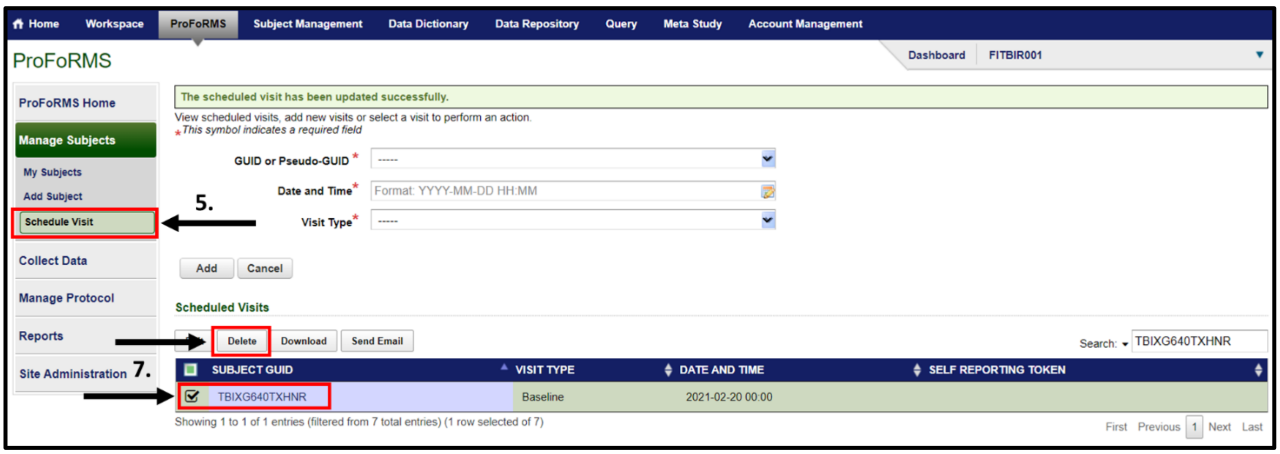


8. Make desired edits to the **Date and Time** and **Visit Type** fields then select the **Update** button to complete the edit action.
9. The newly updated **Scheduled Visit** will be displayed in the **Schedule Visit** table.

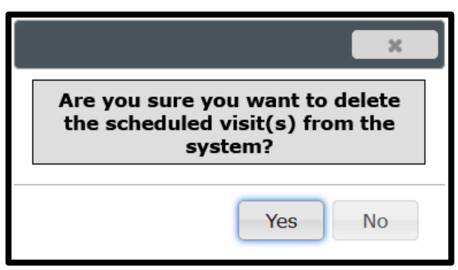
3.6.3.2 Deleting Scheduled Visits

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 Dasboard 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.

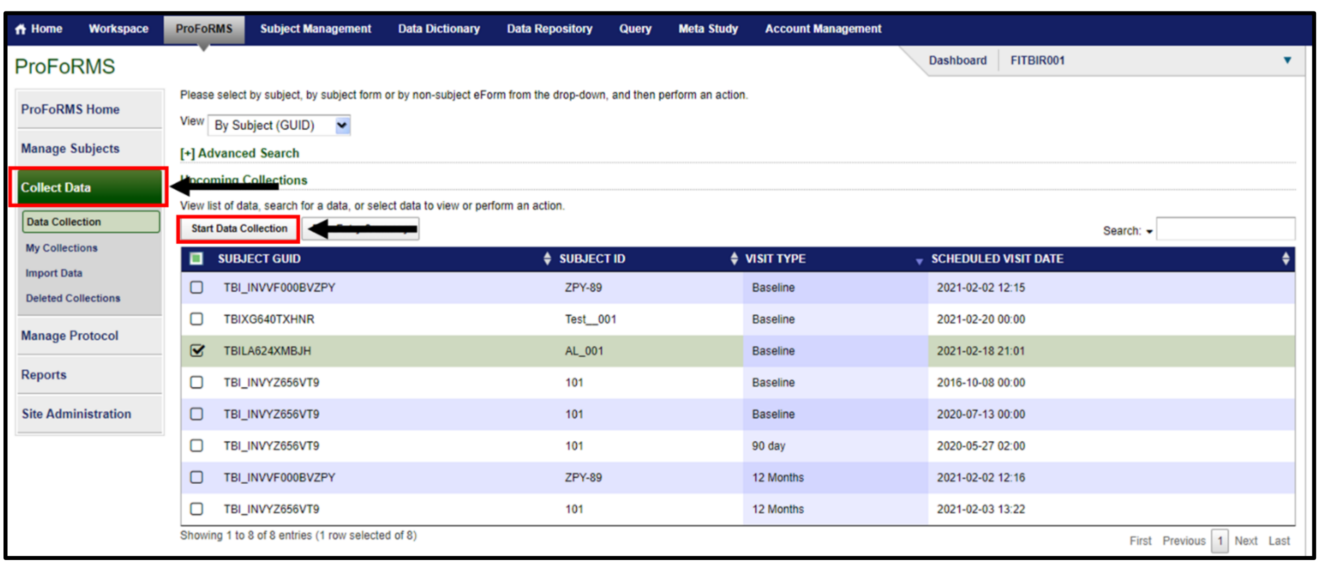
Clinical data may be captured electronically at its source, or in paper form and later transcribed into the system. There are two options for collecting data in ProFoRMS.

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

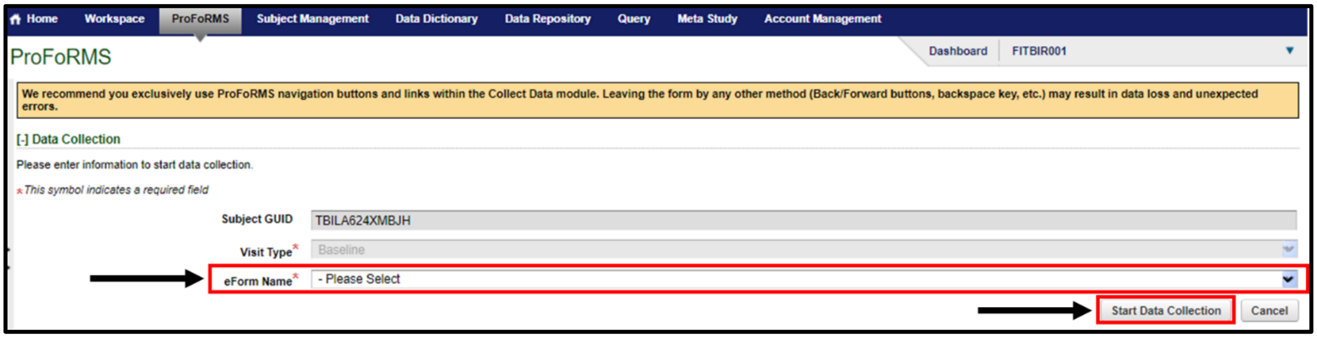
3.7.1 Data Collection

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

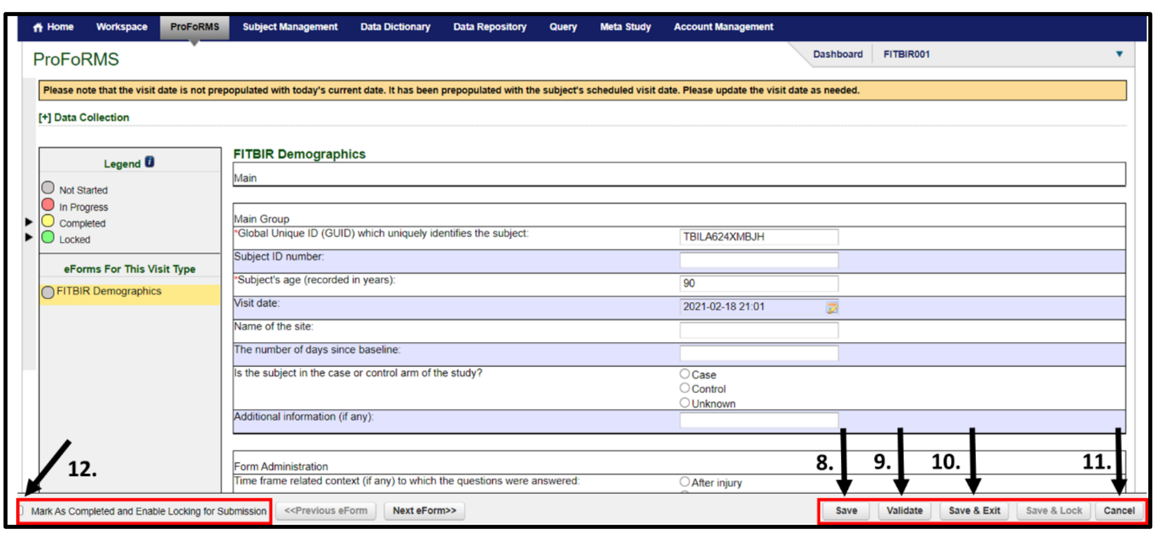
1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dasboard opens. Click the **Collect Data** tab on the left-side tool bar.
4. The **Data Collection** page appears.
5. To start data collection, select the check-box beside the Subject GUID/Subject ID 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.



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.



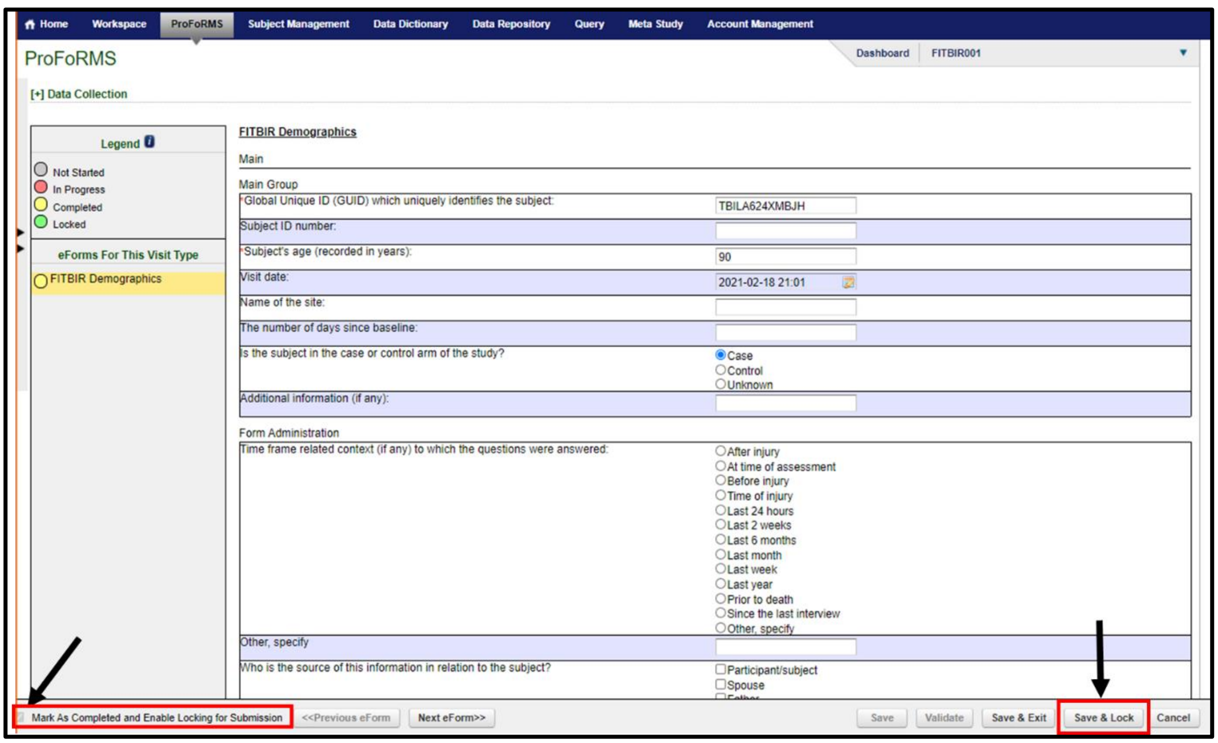
13. Once a form has been marked as completed, three things will happen:
    a. The Save & Lock button will be enabled;
    b. The system validation will run;
    c. An audit trail will start if a user changes their response to an answer
14. If the form failed, you will be notified with a list of errors 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

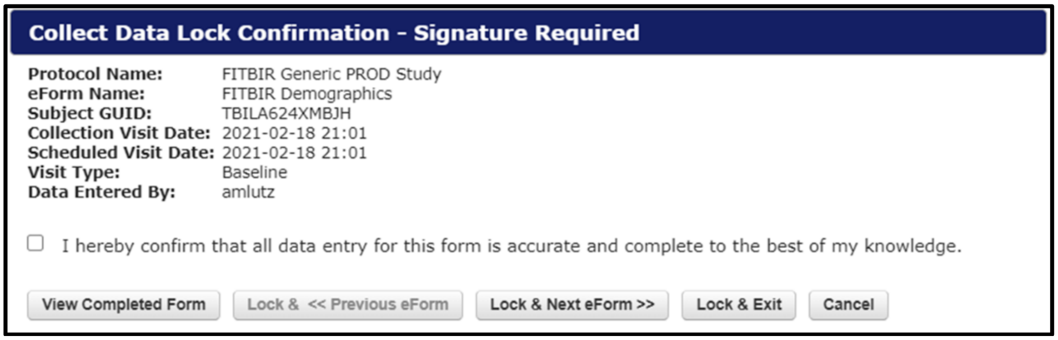
After you have filled out the form and verified that the data is complete and accurate, you can **Save & Lock** the eForm. Forms should not be locked until reviewed and ready for final submission. (should I add information regarding data being sent to Data Repo → Query Tool for other users to view?)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



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.



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.

ICON KEY

📖 Notes

🗁 Important Information

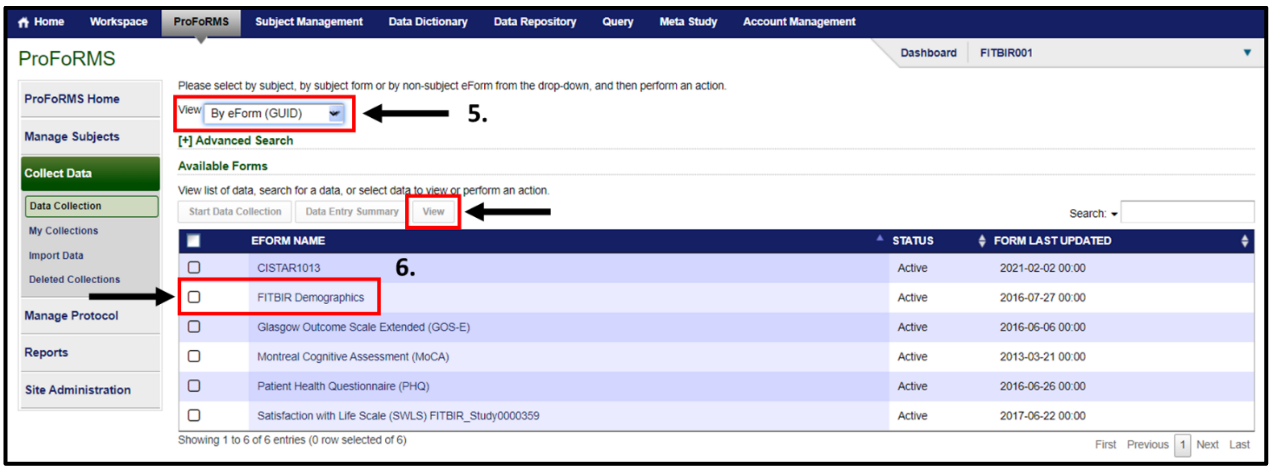
THINGS TO NOTE:

🗁 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 Dasboard 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**



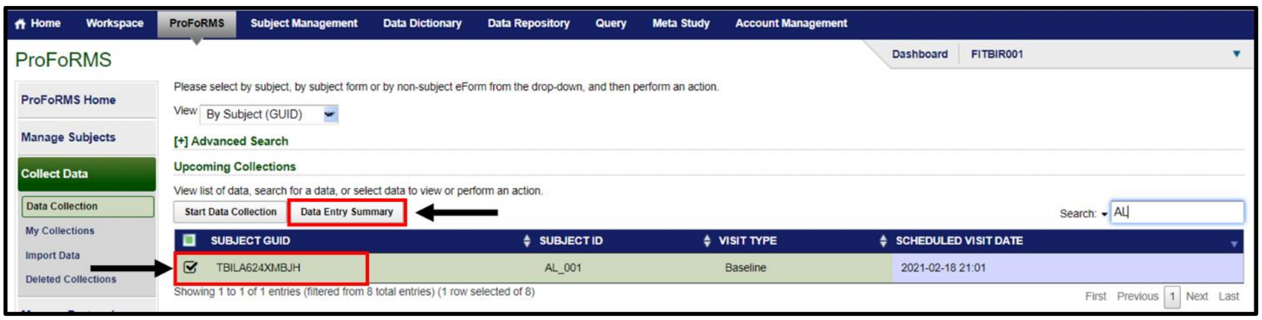
7. A new tab will open in your browser displaying the eForm details in **View Mode**
8. You can view the data **By Subject (GUID)**, or **By eForm (GUID)**. Depending on the view you selected, the table will display either the list of subjects, or the list of eForms.

3.7.1.3 Viewing Data Entry Summary

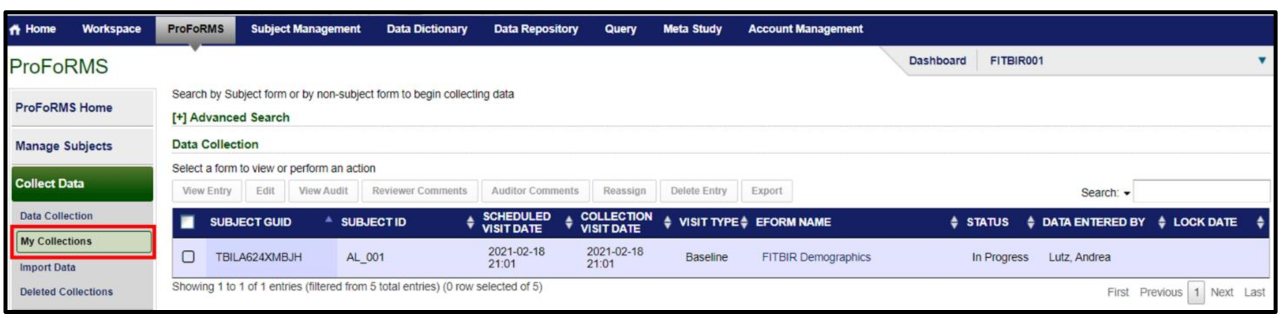
Data Entry Summary allows the user to view all data collected for a subject at one time in the My Collections table.

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**



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

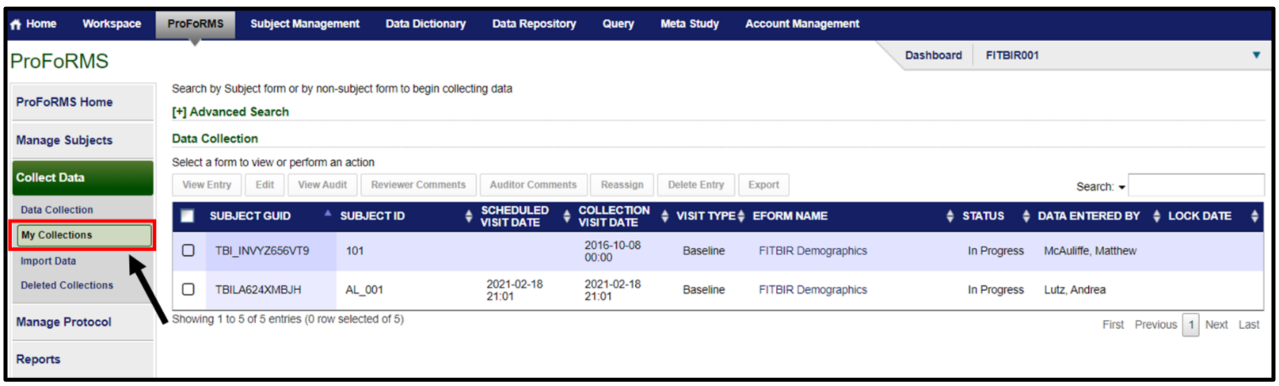


3.7.2 My Collections

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



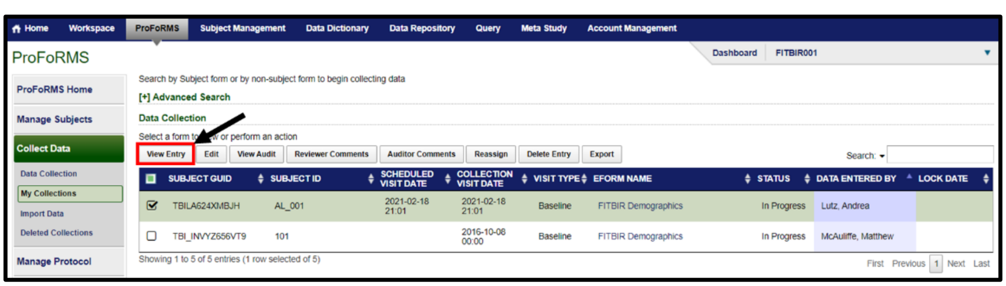
A user can perform the following actions in the **My Collections** table:

- 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:

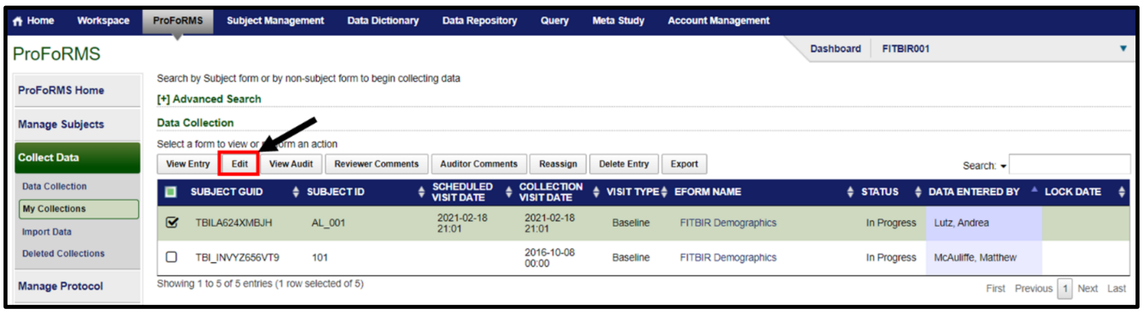
1. Perform steps 1-6 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in viewing, then select **View Entry**.
3. The **eForm** View Mode will open, displaying the data that has been entered on the eForm.



3.7.2.2 Edit eForm

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

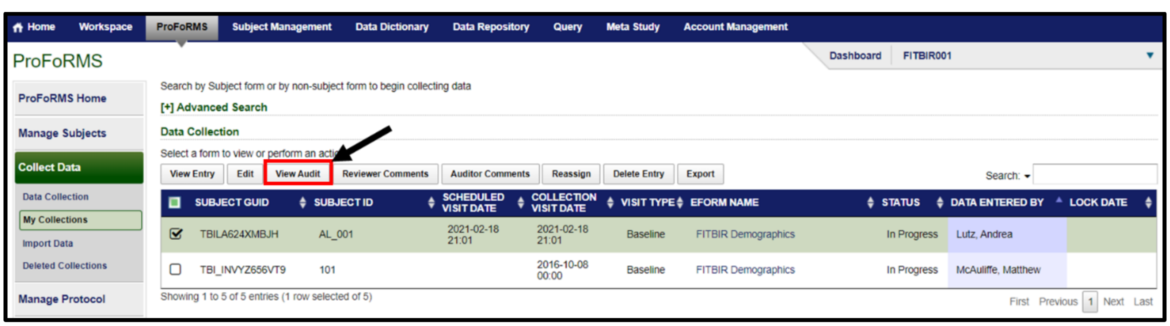
1. Perform steps 1-6 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in editing, then select **Edit**.
   a. **Note:** non-admin users are only able to edit forms with an **In Progress** or **Completed** status. If your form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

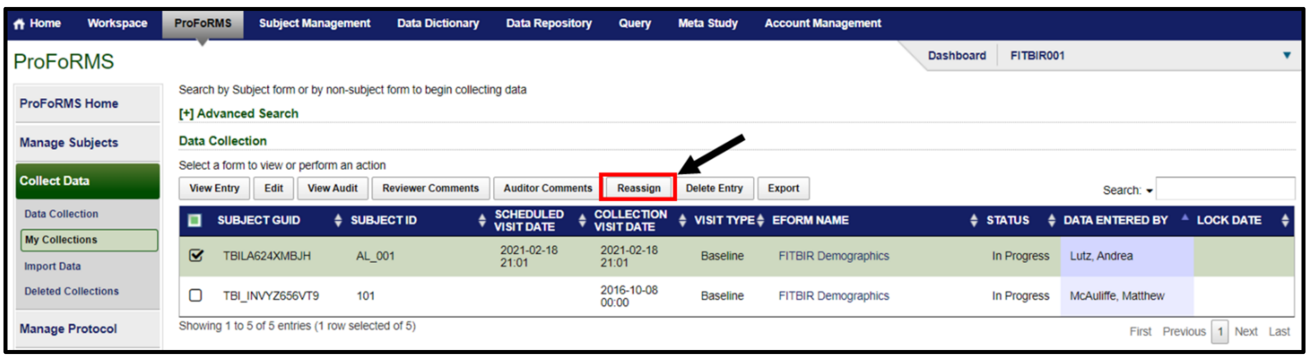
1. Perform steps 1-6 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in viewing, then select **View Audit.**
3. A new browser page will open with the **Data Collection Audit Log** details.



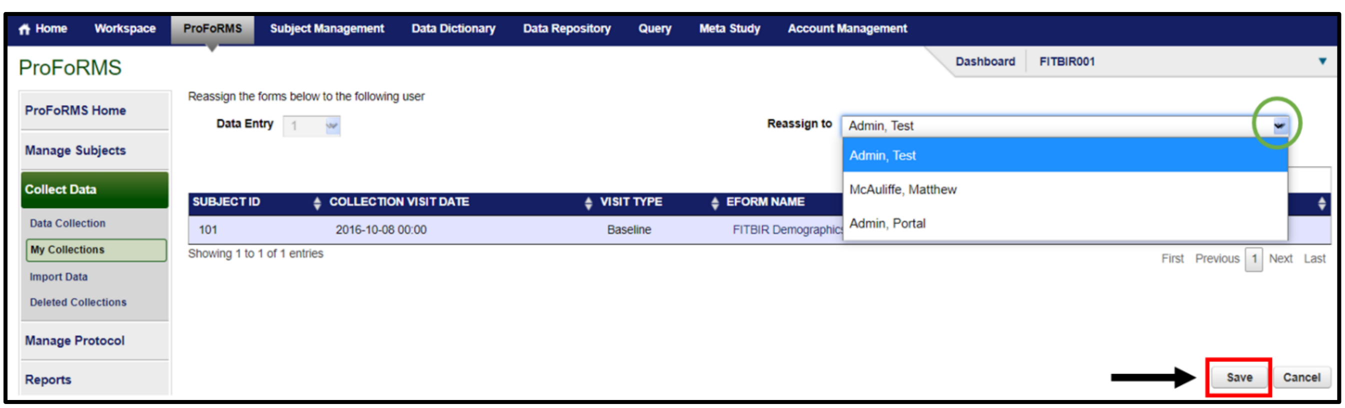
3.7.2.4 Reassign eForm

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***



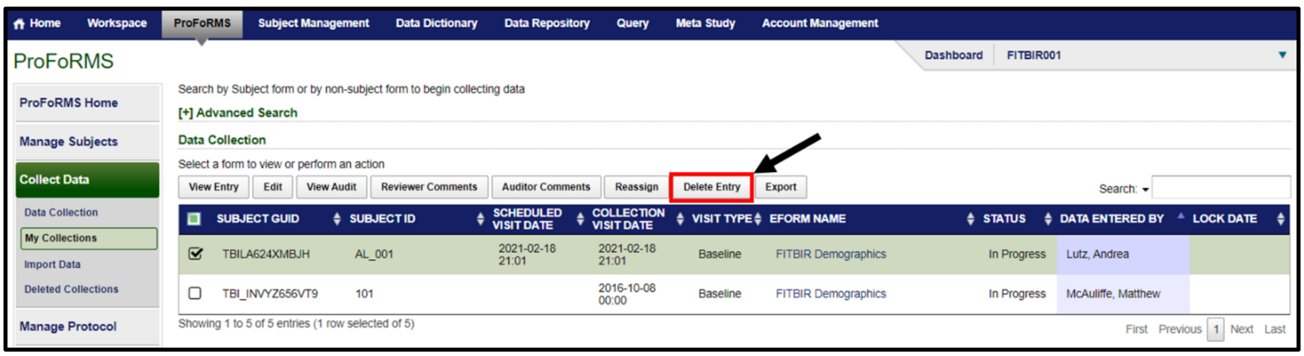
3. The **Reassign** data entry page appears.
4. Using the drop-down menu, select the desired user to reassign the eForm to, then select **Save**.
5. The **My Collections** page appears with the reassigned form update.



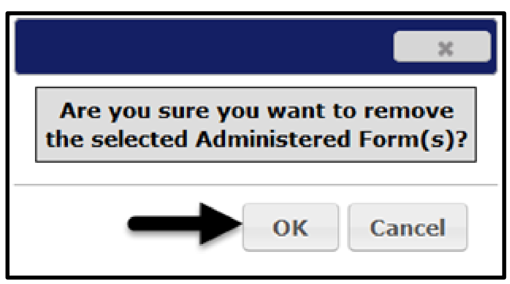
3.7.2.5 Delete Entry

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)?"

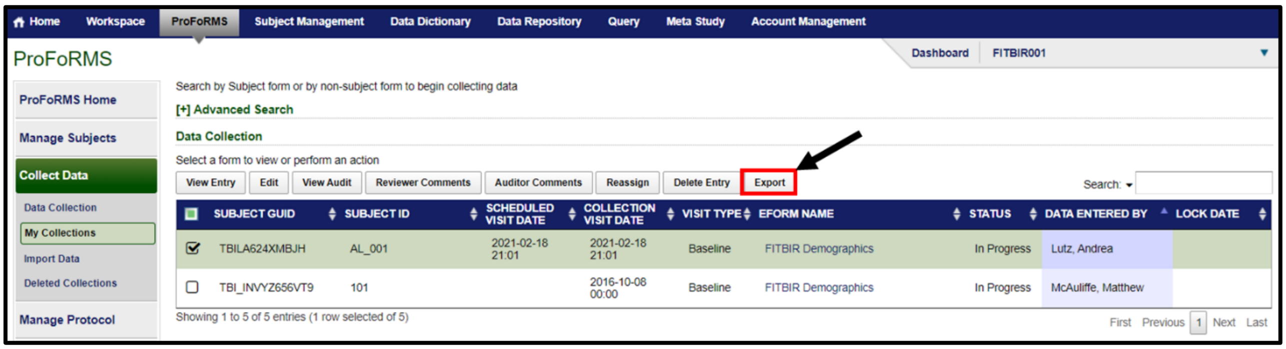


4. The **My Collections** page appears with the confirmation of the deleted eForm.

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.

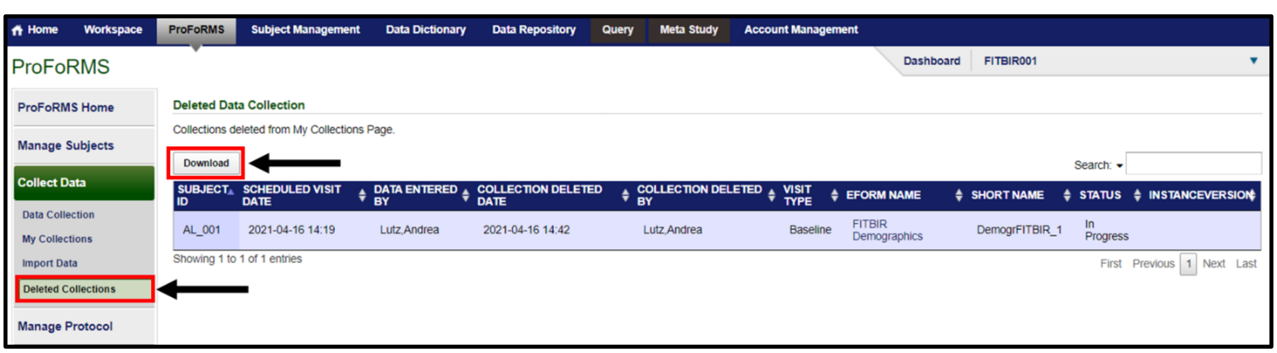


3.7.3 Deleted Collections

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

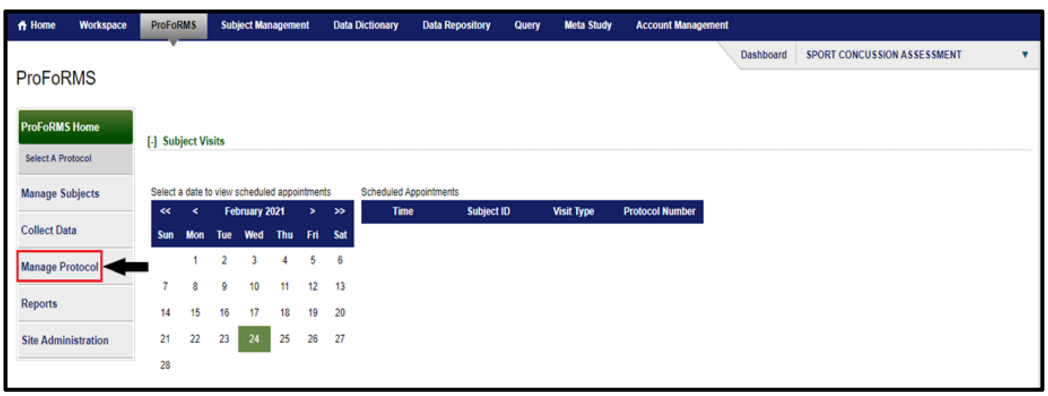
This feature is designed to help the researchers to add and edit study information, schedule create study visits, manage visit types individual subjects across multiple studies within the system, upload subject related document. The sub-sections available in the Manage Subjects menu are as follows:

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

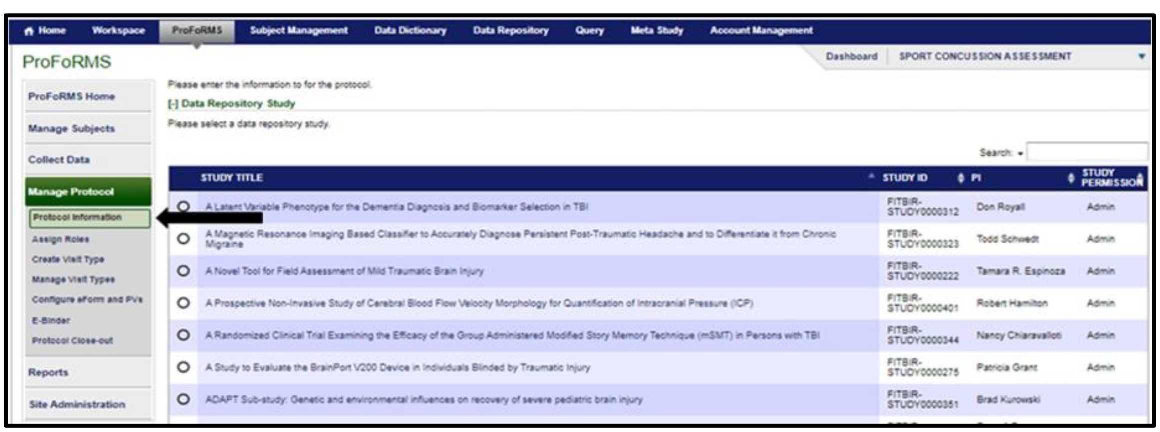
3.8.1 Viewing Protocol Information

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

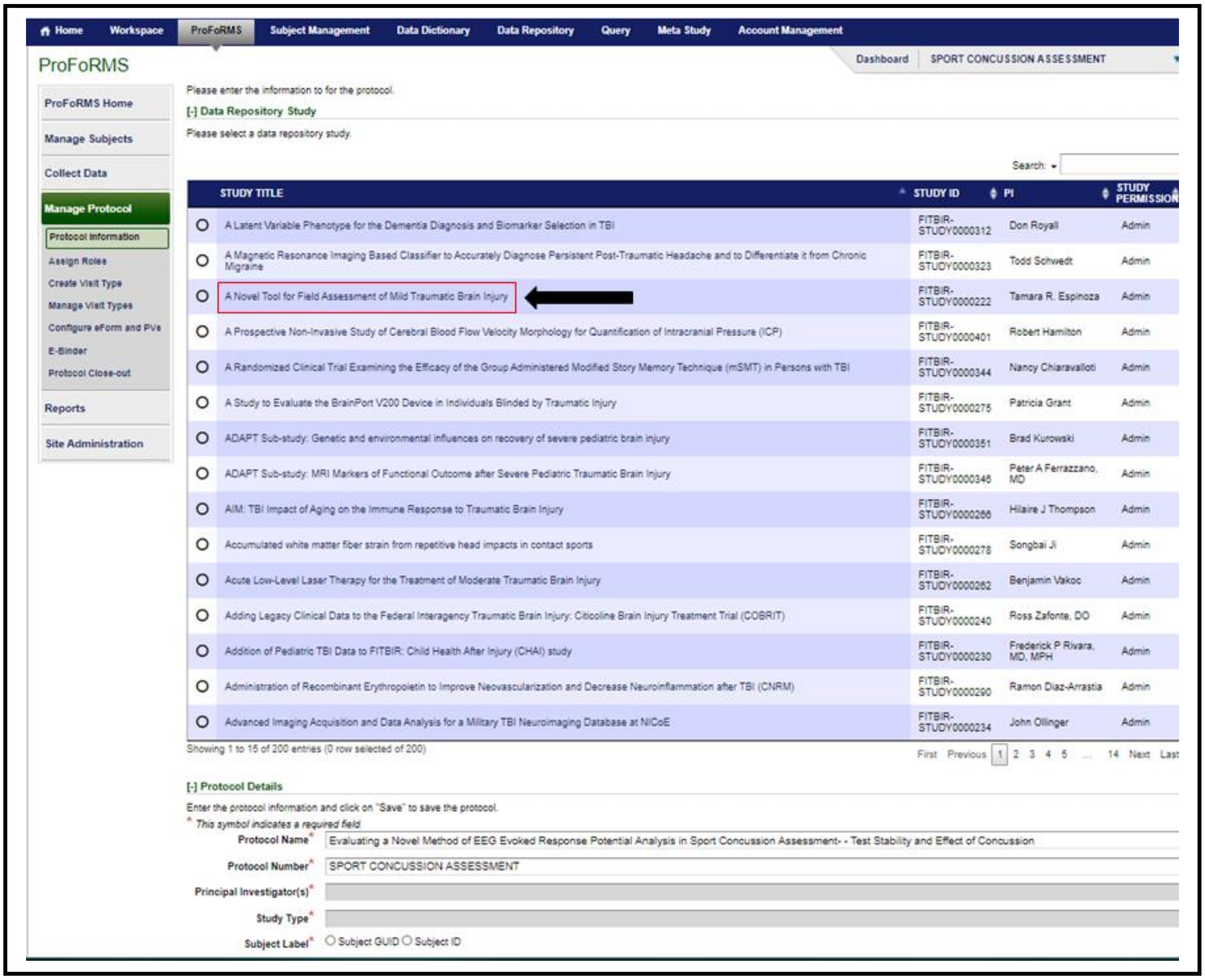
1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar.



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



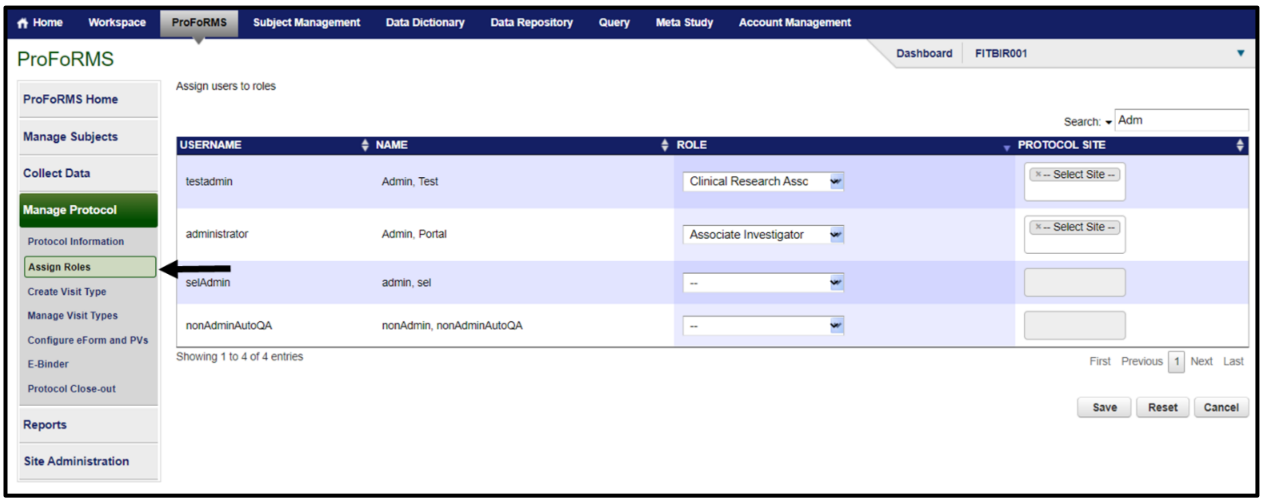
5. Click on the **Study Title** to open the Protocol.



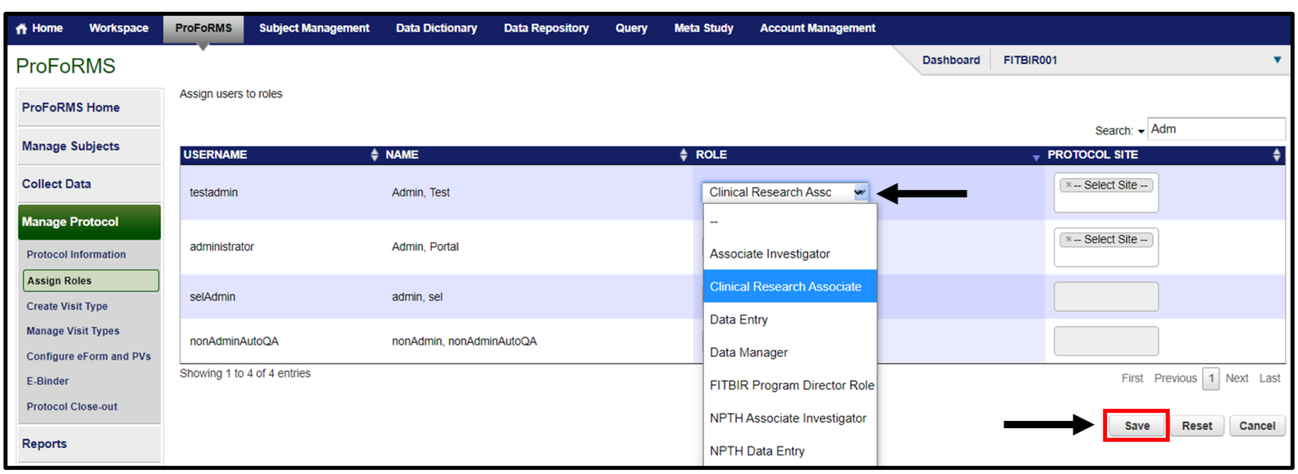
3.8.2 Assign Roles

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.

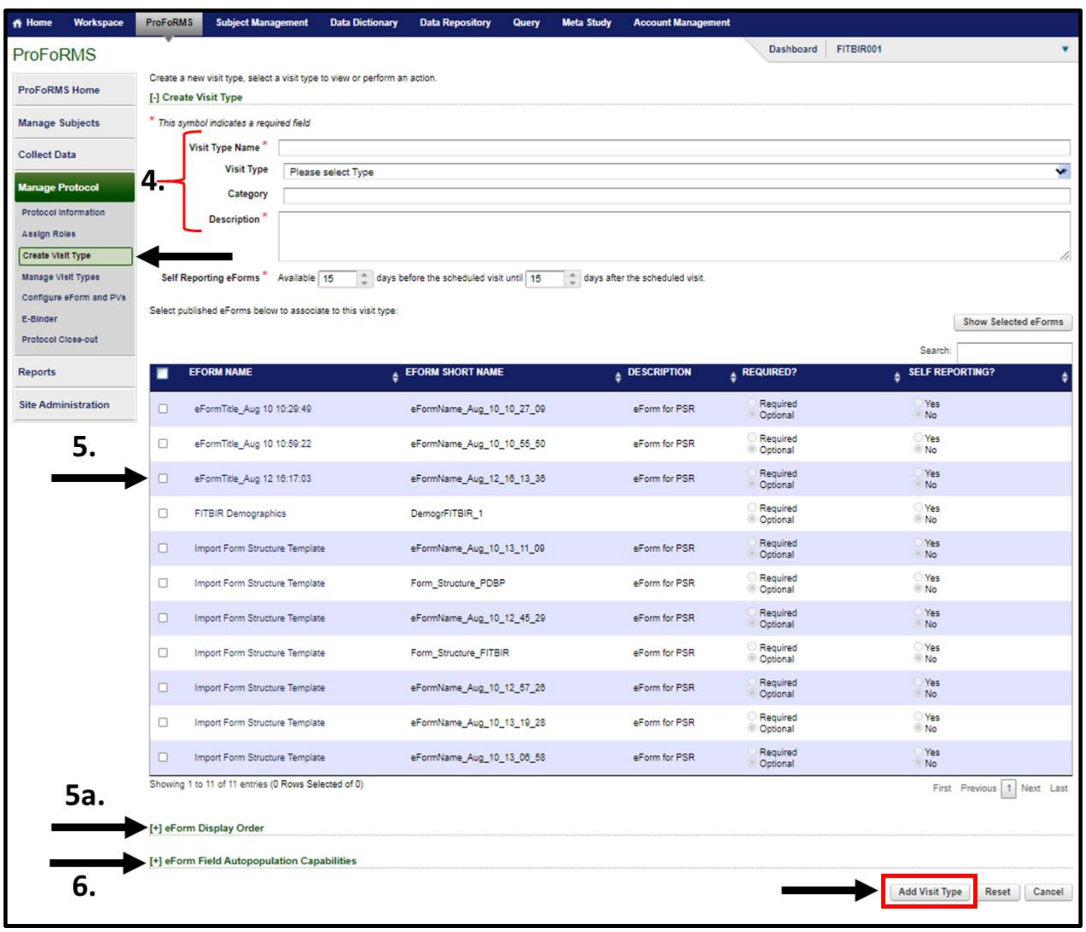


5. Click the **Save** button. The new user role(s) appear in the protocol setup.

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 autopouplated 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.

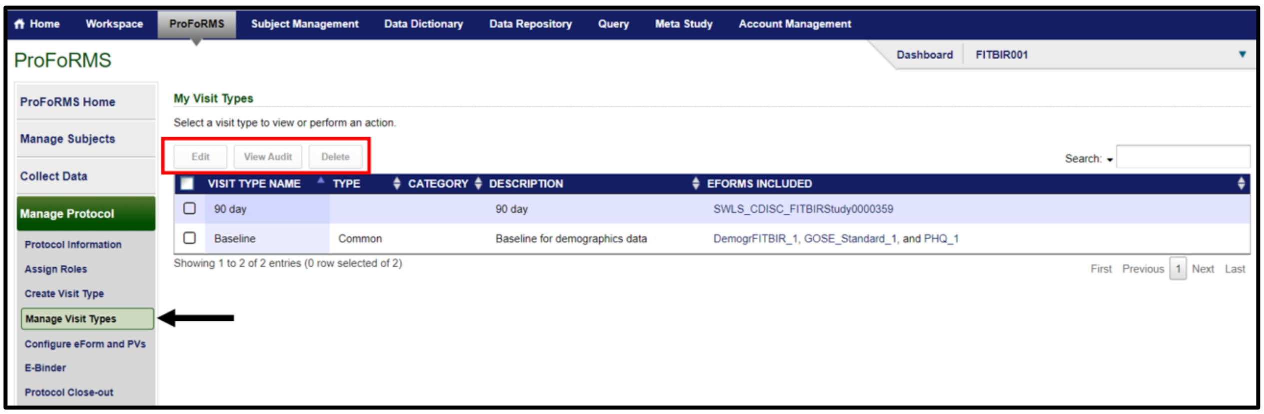


	EFORM NAME	EFORM SHORT NAME	DESCRIPTION	REQUIRED?	SELF REPORTING?
☐	eFormTitle_Aug 10 10:29:49	eFormName_Aug_10_10_27_09	eForm for PSR	Required / Optional	Yes / No
☐	eFormTitle_Aug 10 10:59:22	eFormName_Aug_10_10_55_50	eForm for PSR	Required / Optional	Yes / No
☐	eFormTitle_Aug 12 16:17:03	eFormName_Aug_12_16_13_36	eForm for PSR	Required / Optional	Yes / No
☐	FITBIR Demographics	DemogrFITBIR_1		Required / Optional	Yes / No
☐	Import Form Structure Template	eFormName_Aug_10_13_11_09	eForm for PSR	Required / Optional	Yes / No
☐	Import Form Structure Template	Form_Structure_PDBP	eForm for PSR	Required / Optional	Yes / No
☐	Import Form Structure Template	eFormName_Aug_10_12_45_29	eForm for PSR	Required / Optional	Yes / No
☐	Import Form Structure Template	Form_Structure_FITBIR	eForm for PSR	Required / Optional	Yes / No
☐	Import Form Structure Template	eFormName_Aug_10_12_57_26	eForm for PSR	Required / Optional	Yes / No
☐	Import Form Structure Template	eFormName_Aug_10_13_19_28	eForm for PSR	Required / Optional	Yes / No
☐	Import Form Structure Template	eFormName_Aug_10_13_06_58	eForm for PSR	Required / Optional	Yes / No

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.



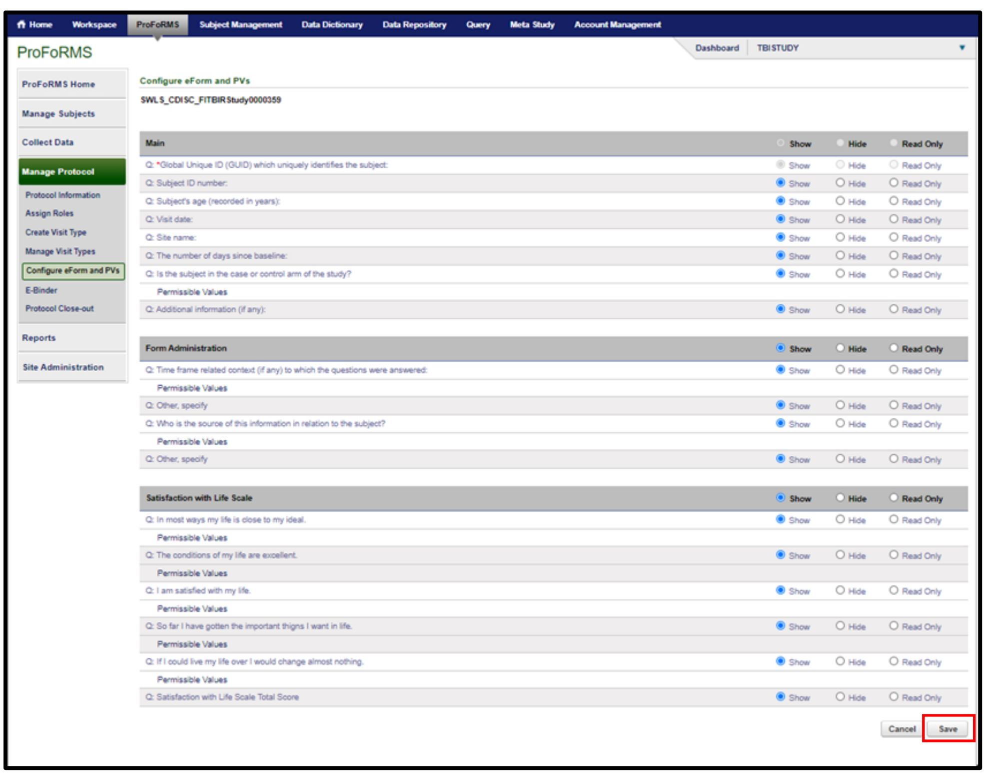
3.8.5 Configure eForm and PVs

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.**

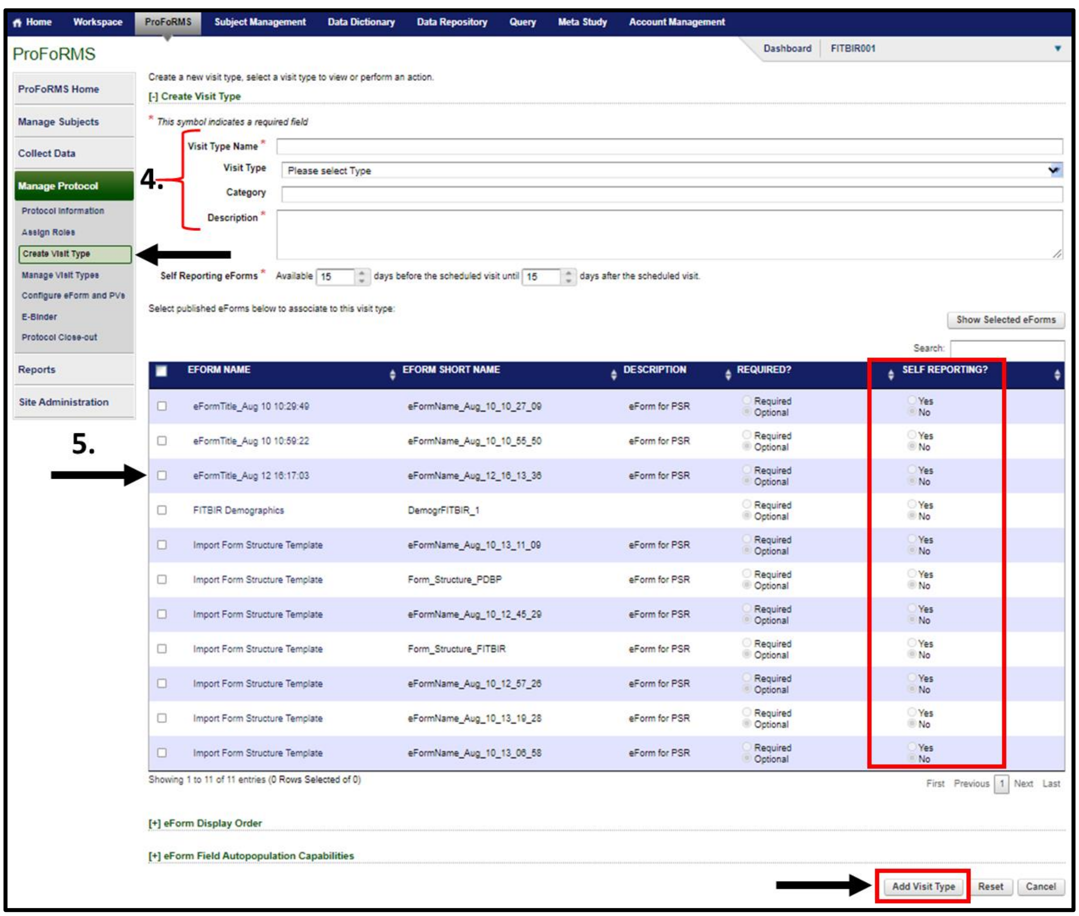


3.8.6 Patient Self-Reporting

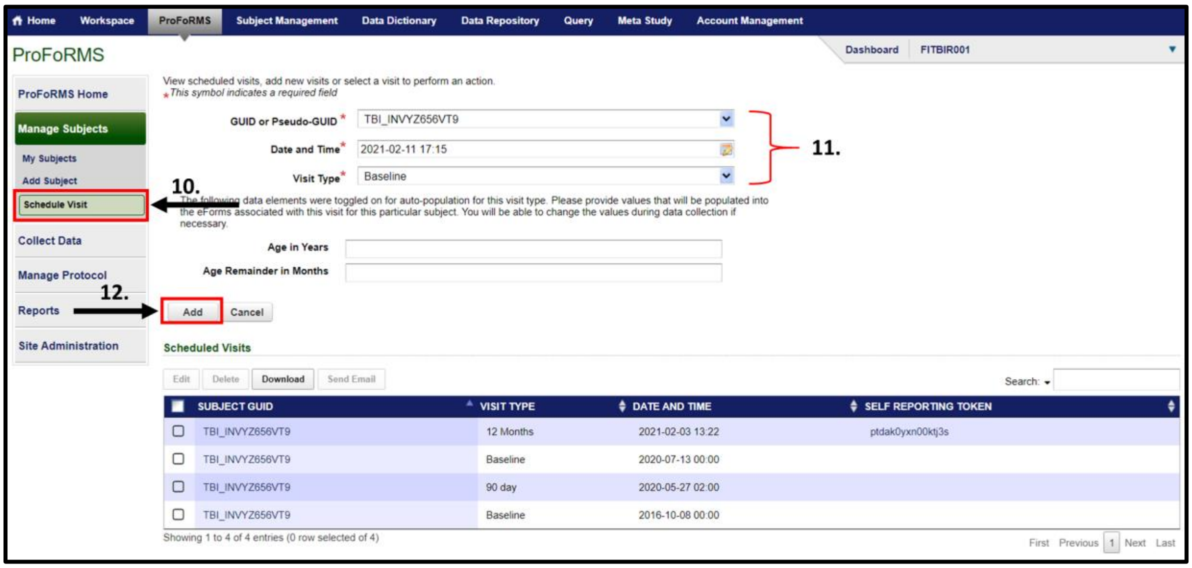
Patient Self-Reporting is an Admin-enabled function. You must have an administrative privilege in order to use this feature. Ensure you have Administrative privileges enabled before attempting to set up patient self-reporting in ProFoRMS.

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

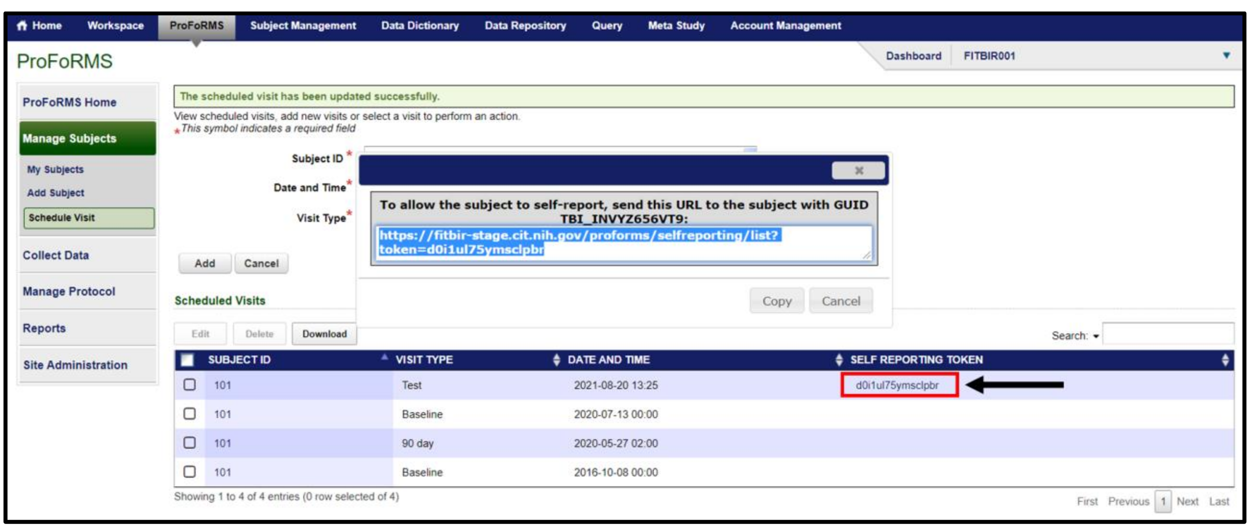
1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar then select **Create Visit Type**.
4. Create a new Visit Type by entering the **Visit Type Name, Visit Type,** and a **Short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



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.



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

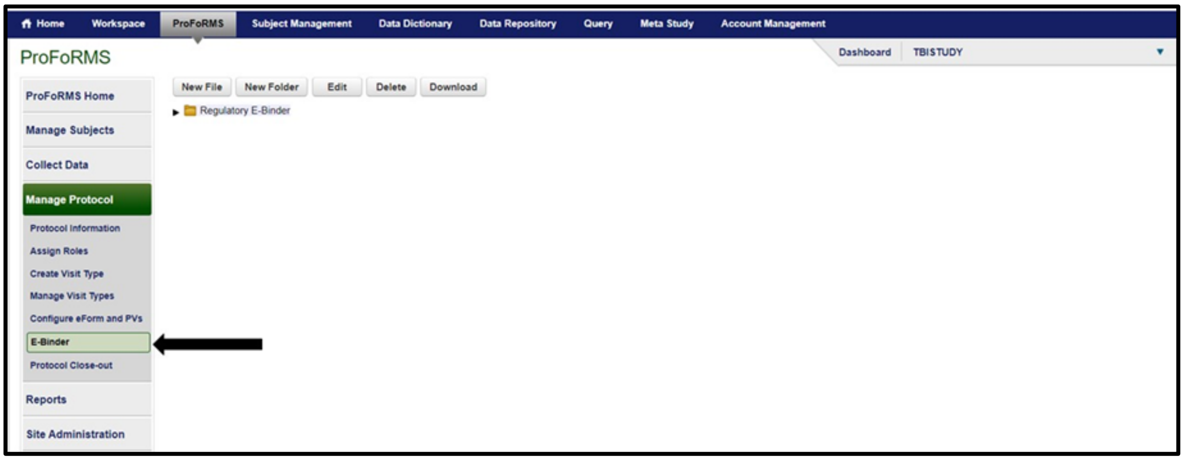


3.8.7 E-Binder

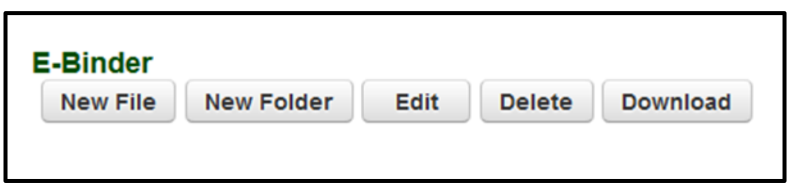
The E-Binder is used to Add/Edit documents or view existing documents.

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



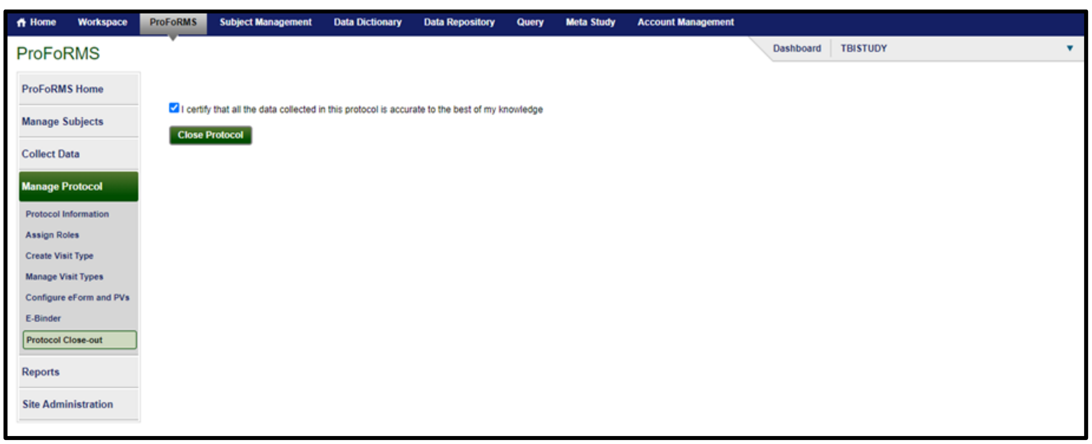
3.8.8 Protocol Closeout

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.

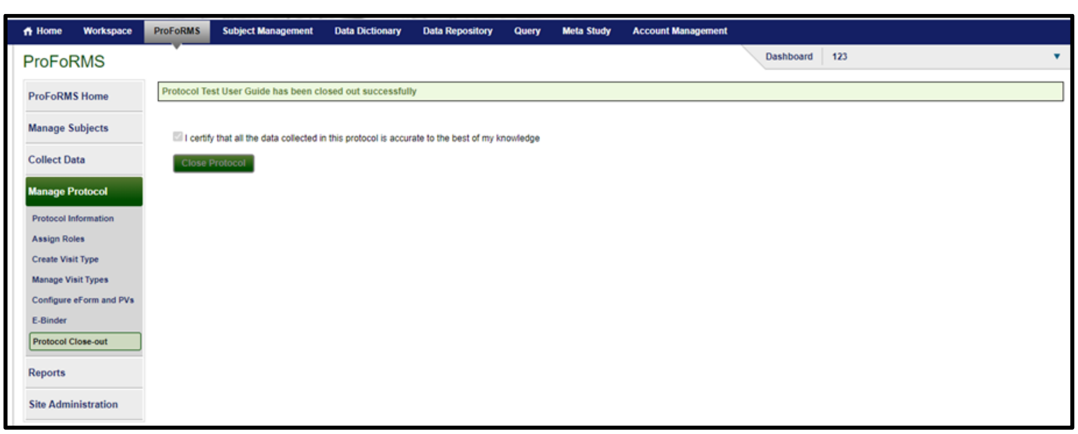
- ❖ The e-form will state that the PI acknowledges that the data collected is accurate to the best of their knowledge
- ❖ The e-form will capture the signature of the PI
- ❖ The e-form will capture the full legal name of the PI
- ❖ The e-form will capture the date and time that the form was signed
-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

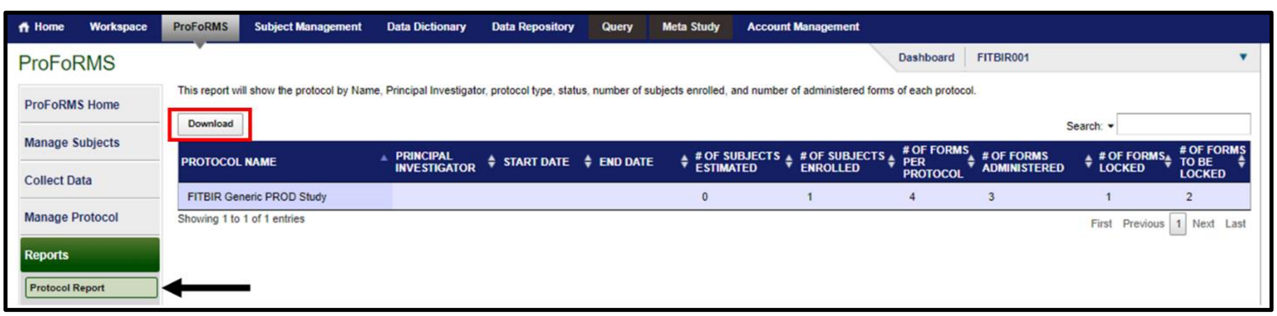
- Protocol Reports
- Detailed Protocol Report
- Without Collections
- Forms Requiring Completion & Lock
- Locked Forms
- Submission Summary
- Form Status
- View Auditor Comments
- View Reviewer Comments

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.

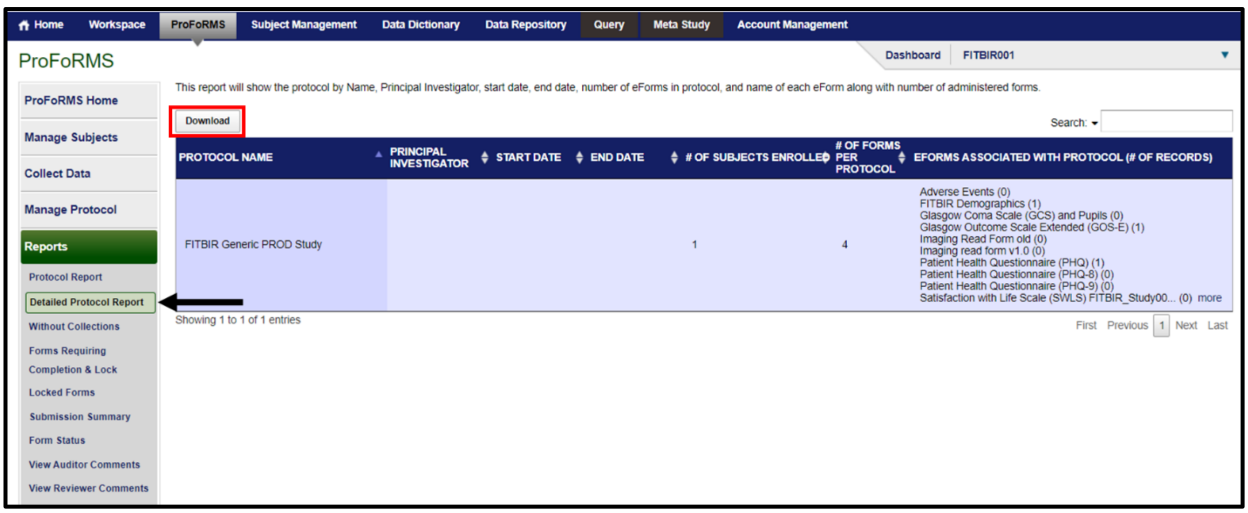


3.9.2 Detailed Protocol Report

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.

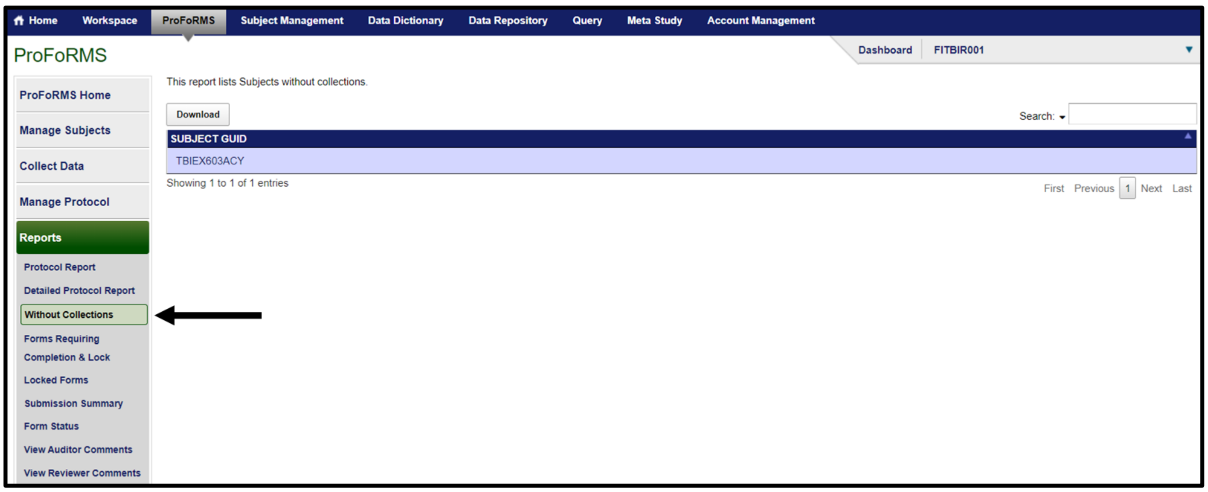


3.9.3 Without Collections

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.

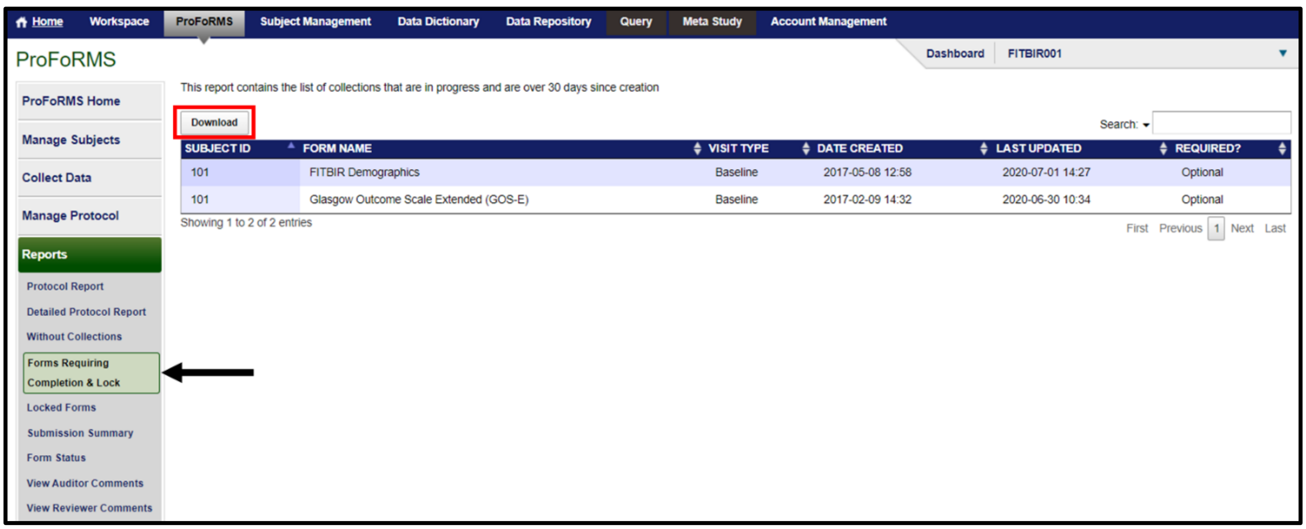


3.9.4 Forms Requiring Completion & Lock

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.

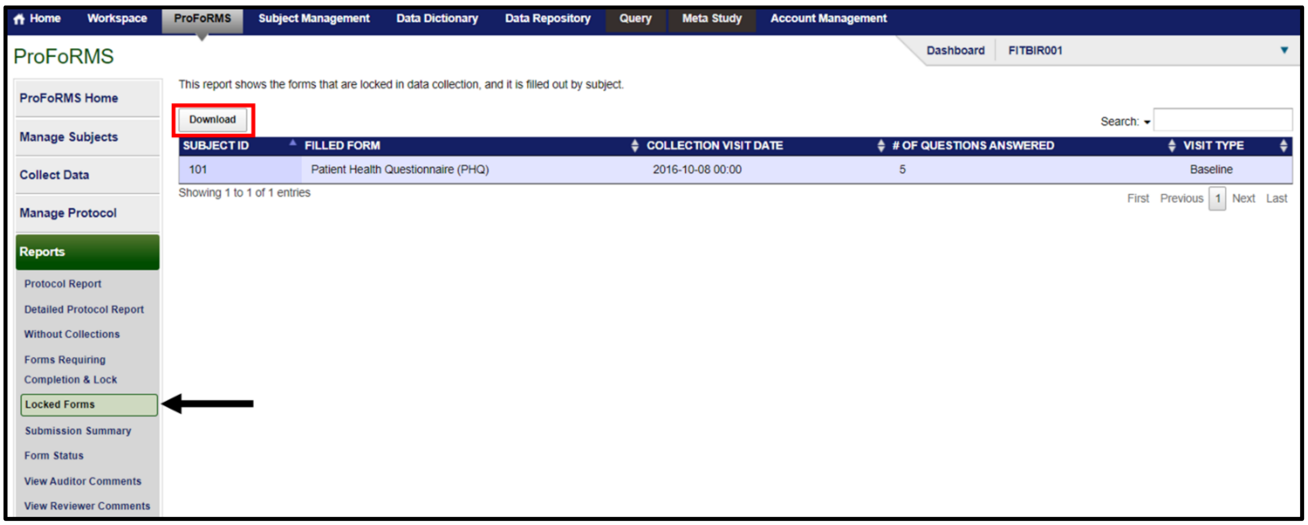


3.9.5 Locked Forms

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.

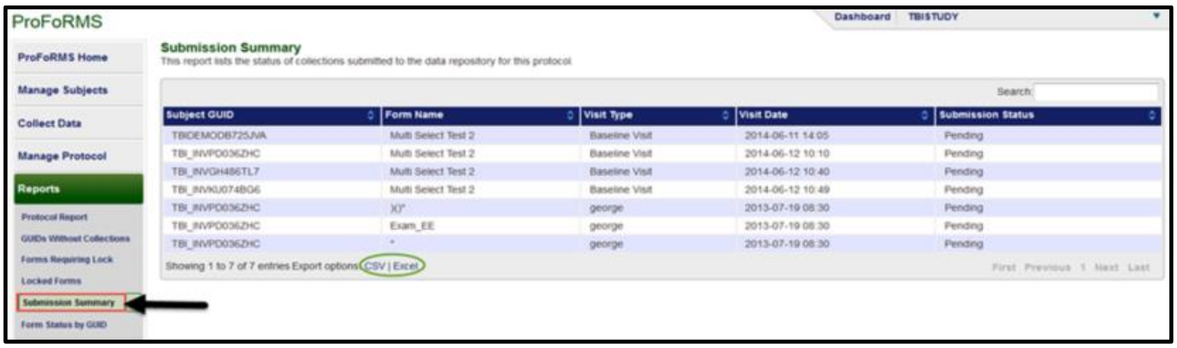


3.9.6 Submission Summary

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.

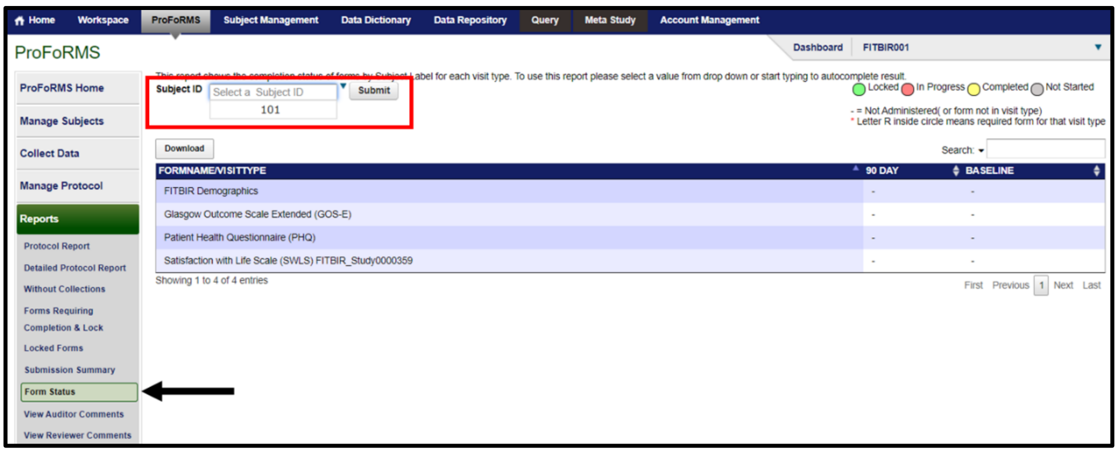


3.9.7 Form Status

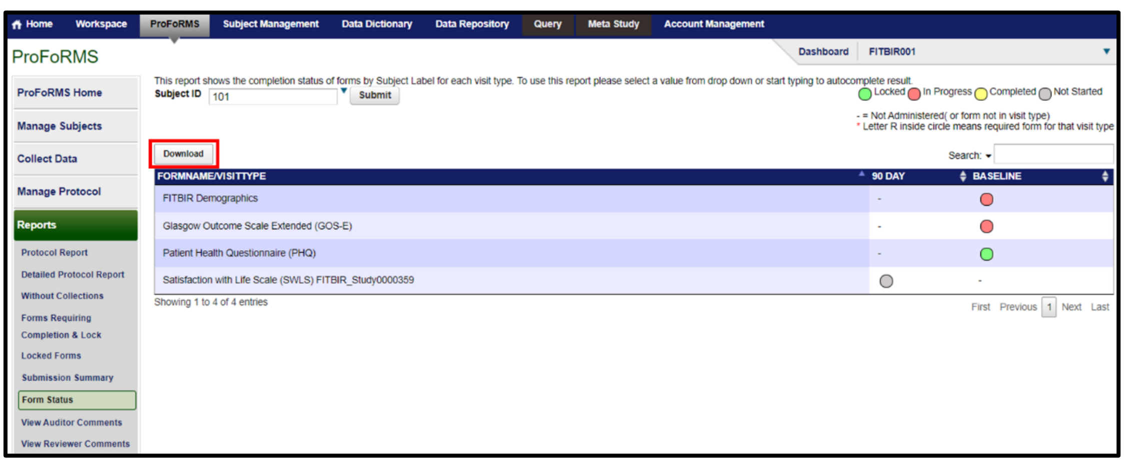
This report shows the completion status of forms by Subject Label for each visit type.

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.

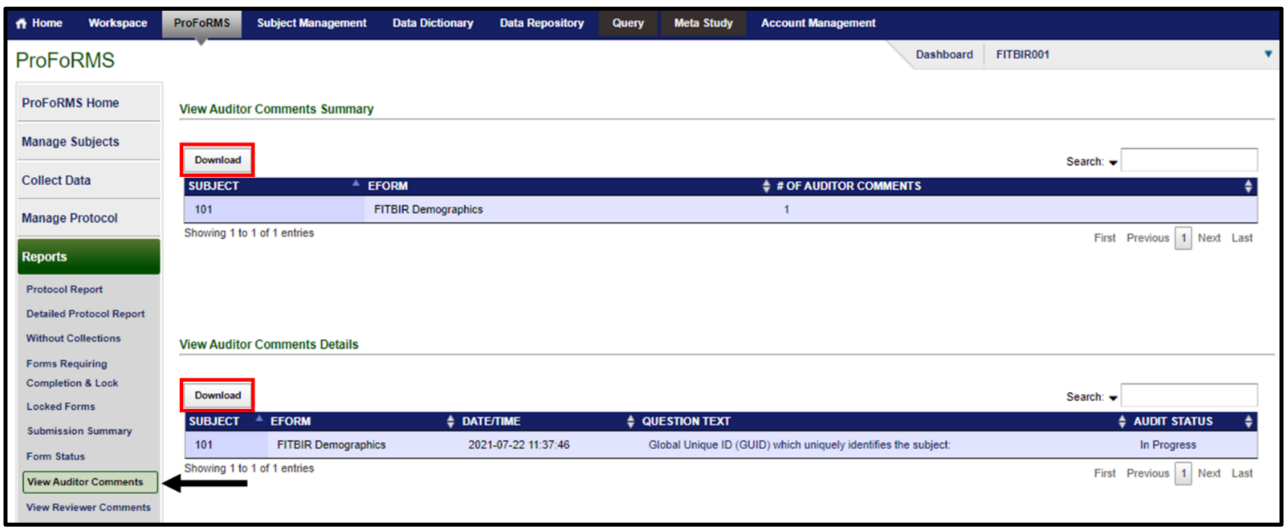


3.9.8 View Auditor Comments

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.



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.