OCR801

OnCore Protocol Coordination

UF Office of Clinical Research

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OnCore Enterprise Research

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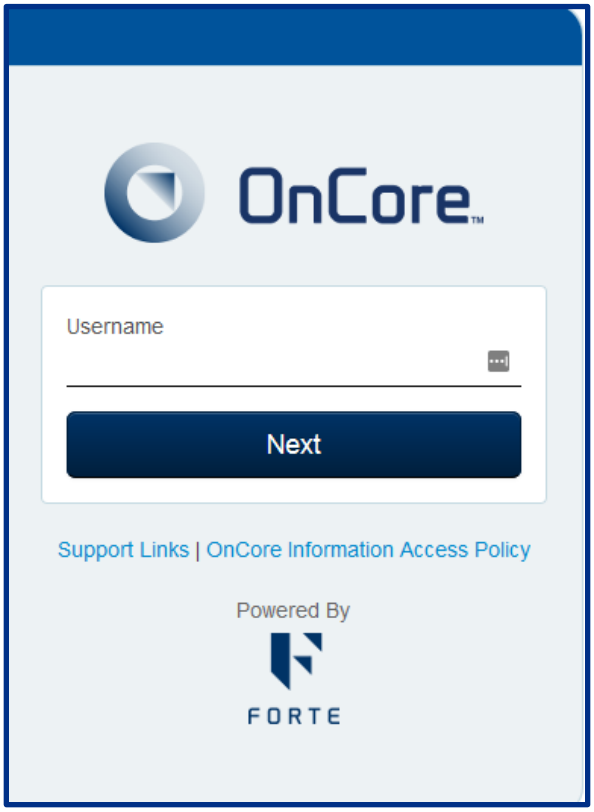
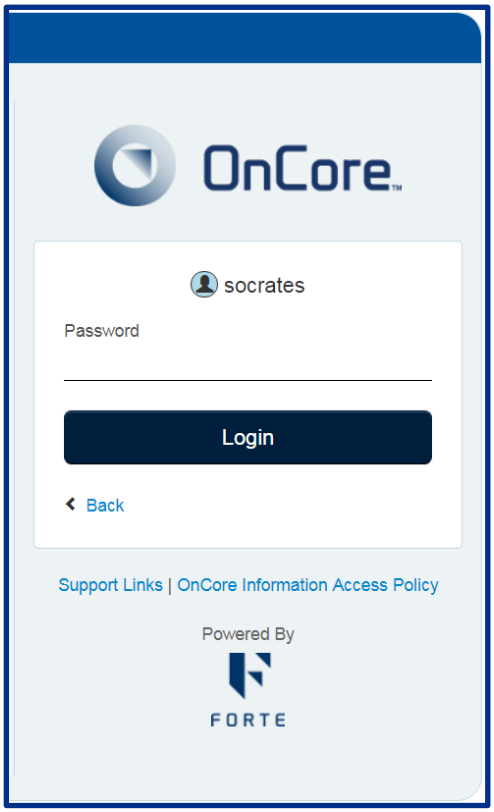
Login

1. Using the browser of your choice, navigate to https://oncore-training.ahc.ufl.edu.

First, the user enters their Gatorlink username.



Next, the user enters their Gatorlink password.



OnCore is accessed using your Gatorlink user ID and password. You can only change or administer your Gatorlink password using the myUFL website - https://my.ufl.edu.

2. The username is the name on your computer tower and the password will be provided.

Tips for Using OnCore Successfully

Disable pop-up blockers

OnCore uses many pop-up windows that allow you to make selections and enter data. You must set your browser to allow pop-ups in order to use OnCore.

1. Confirm that your browser is set to allow pop-ups:

- Chrome: Click  upper right > Settings > Advanced > Privacy > Content > Pop-ups
- Firefox: Click  upper right > Options > Content > Pop-ups
- IE: Click  upper right > Internet Options > Privacy > Pop-up Blocker
- Safari: Click 

upper left > Preferences > Security > Block pop-up windows

Avoid using the browser's back button

Use OnCore's buttons, tabs, and menus to navigate within the program; do not use the browser's navigation buttons. Using the browser toolbar to navigate might lead to unexpected results, such as unsaved data or webpage errors.

Use only one instance of OnCore at a time

Only one session (browser window or browser tab) of OnCore should be open at a time on a single system. Multiple sessions of OnCore could result in duplicate data and application misbehavior.

Supported browsers

Supported browsers are: Chrome, Firefox, Internet Explorer [8, 9, 10, 11], Safari.

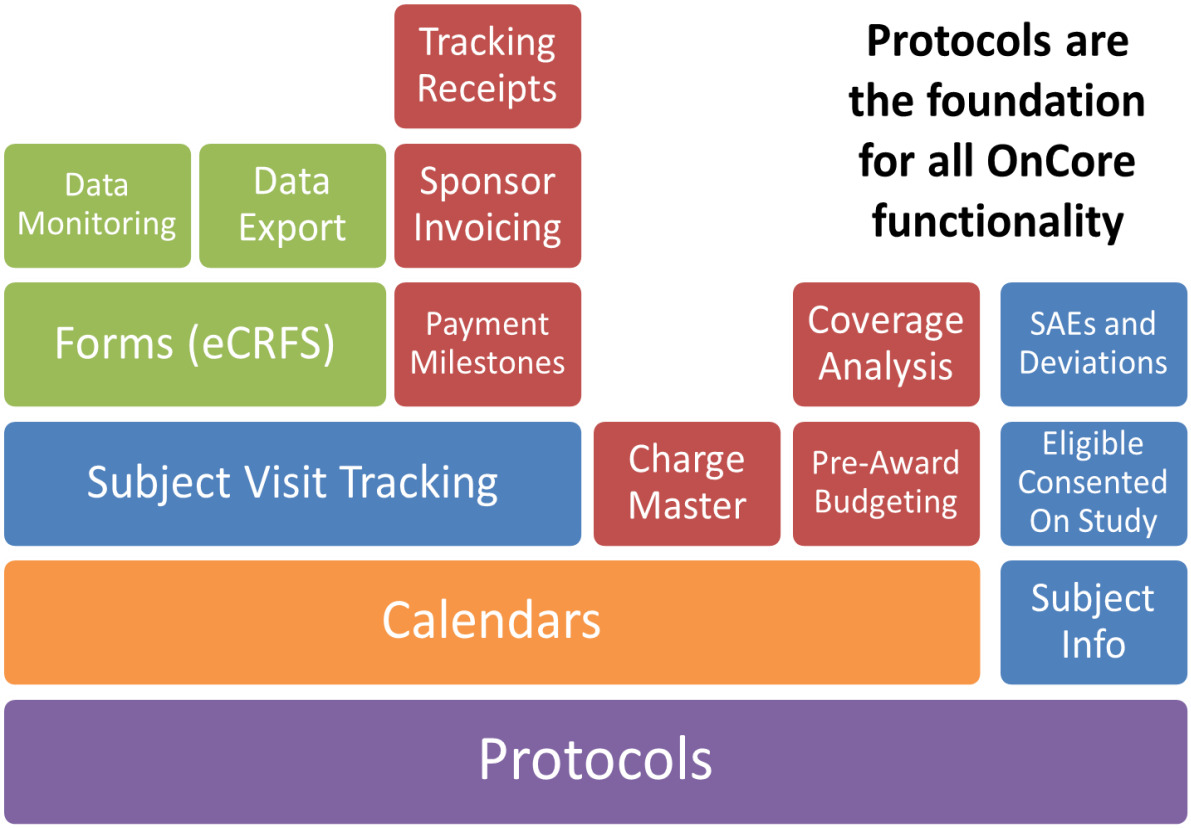
Minimum screen resolution

Minimum screen resolution is: 1024 x 768.

Protocol Set-Up and Review

Protocols are the foundation of all OnCore functionality and features. Protocol information must be entered in OnCore before building calendars, creating a protocol budget, enrolling subjects, tracking subject visits, or invoicing sponsors.

The *PC Console* (Protocol Coordinator Console) is the central repository for protocol information. Protocol coordinators track protocol ID numbers, objectives, assigned staff, sponsors, participating institutions, regulatory information, investigational drug, and device information, and other details of each research study.



PC Console

At UF, OnCore protocols are created either by the UF Cancer Center (for cancer-relevant studies) or the Office of Clinical Research (OCR). OCR staff also ensure that ALL OnCore protocols include all UF “minimum footprint” fields using data submitted to OCR through the electronic HSR Intake Form.

Study team members with PC Console access will be asked to review and confirm the data entered. We will practice this process today.

Find an existing protocol

1. Navigate to **Menu - Protocols > PC Console**.

   Above the vertical tabs on the left is the **Select Protocol** field. You can find an existing study by searching for any of the following identifiers used at UF:

   - OnCore Protocol No.
   - IRB No.
   - Sponsor Protocol No. *See *Note below*
   - FDA IND No. *IND drug studies only*
   - FDA IDE No. *IDE device studies only*
   - ClinicalTrials.gov NCT No. *if applicable*
   - Study Nickname or acronym *See *Note below*

   ***Note:** Currently, there is not a designated field in OnCore for a study Nickname or acronym.*

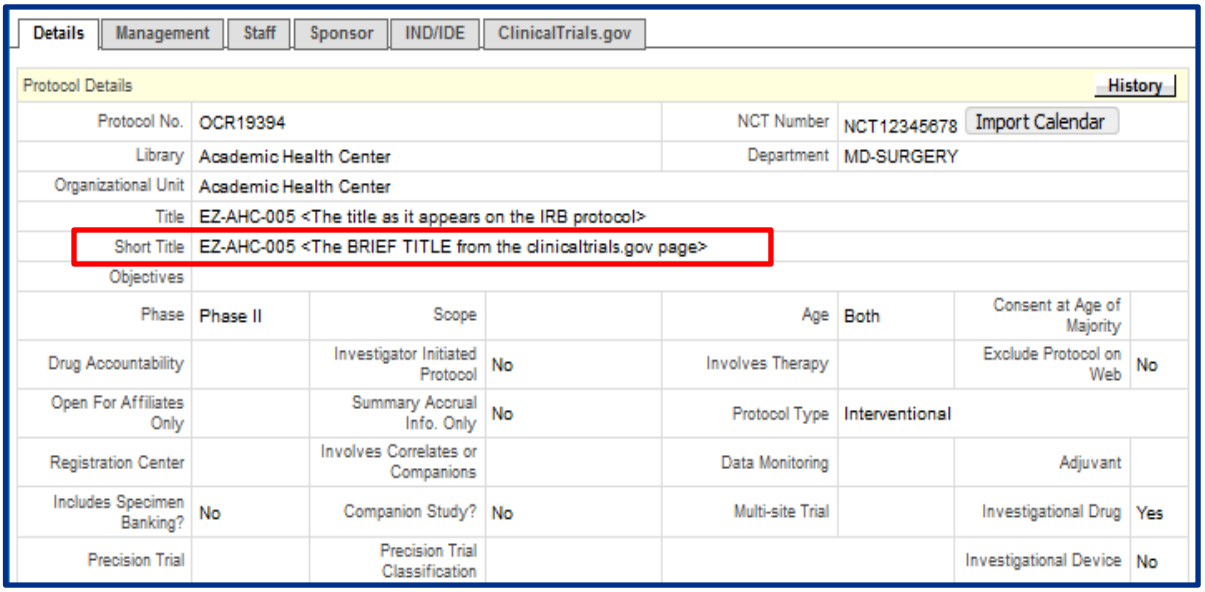
   *During set-up, OCR staff will add your study Nickname or acronym (if known) to the **Sponsor Protocol No**. field, which will enable you to use this as an additional searchable identifier.*

   *If your study does not include a Nickname or acronym, and you would like it added, please contact **OnCore-Support@ahc.ufl.edu.**.*

In class, we have set up the training studies to use **your training username** (the name on your training computer tower) in some of the training study identifier fields.

2. Find your training study by typing **your training username** into the **Select Protocol** field.

3. Verify that **your training username** appears in the **Short Title** field. *In production, this field will either be blank or have the BRIEF TITLE from ClinicalTrials.gov.*



Details | Management | Staff | Sponsor | IND/IDE | ClinicalTrials.gov

Protocol Details — History

Protocol No.	OCR19394			NCT Number	NCT12345678 Import Calendar		
Library	Academic Health Center			Department	MD-SURGERY		
Organizational Unit	Academic Health Center						
Title	EZ-AHC-005 <The title as it appears on the IRB protocol>						
Short Title	EZ-AHC-005 <The BRIEF TITLE from the clinicaltrials.gov page>						
Objectives							
Phase	Phase II	Scope		Age	Both	Consent at Age of Majority	
Drug Accountability		Investigator Initiated Protocol	No	Involves Therapy		Exclude Protocol on Web	No
Open For Affiliates Only		Summary Accrual Info. Only	No	Protocol Type	Interventional		
Registration Center		Involves Correlates or Companions		Data Monitoring		Adjuvant	
Includes Specimen Banking?	No	Companion Study?	No	Multi-site Trial		Investigational Drug	Yes
Precision Trial		Precision Trial Classification				Investigational Device	No

4. Confirm that all the **UF "minimum footprint"** data fields have been completed and are correct:

   1. **Protocol No.: OCRXXXXX** *auto-generated number*
   2. **NCT Number: NCTXXXXXXXX** *As available, when the study is in clinicaltrials.gov*
   3. **Library:** ***Oncology*** *for cancer studies and* ***Academic Health Center*** *for non-oncology studies. Library determines fields, drop-down lists, and signoffs available for the protocol. This field cannot be changed once the status of the protocol has changed from 'New'.*
   4. **Department:** *Principal Investigator's UF Department*
   5. **Organizational Unit:** ***Cancer Center*** *for cancer studies and* ***Academic Health Center*** *for non-oncology studies. Organizational Units are used to organize protocols into logical structural divisions, which is useful for reporting purposes and to restrict access to protocols.*

IMPORTANT!

The Library and Organizational Unit ***MUST*** *align with each other:*

- *If Library =* ***Oncology****, Organizational Unit should be* ***Cancer Center***
- *If Library =* ***Academic Health Center****, Organizational Unit should be* ***Academic Health Center***

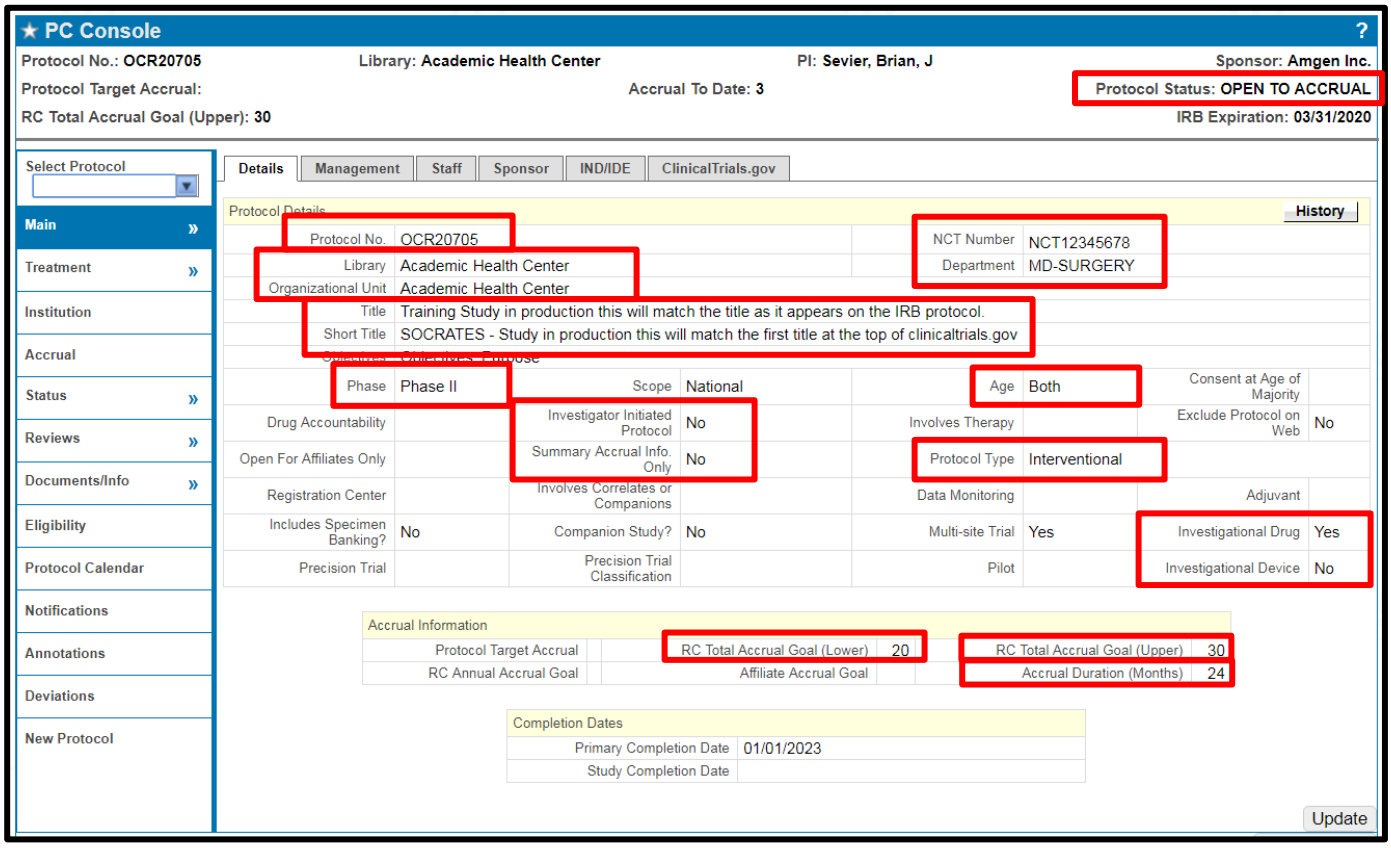
In production, if your study's Library does NOT align with the Organizational Unit, contact OnCore-Support@ahc.ufl.edu before proceeding!

6. **Title:** *The title as it appears on the IRB protocol*
7. **Short Title:** *As available, the BRIEF TITLE from clinicaltrials.gov entry. If the study is not in clinicaltrials.gov, you may see an abbreviated version of the protocol title that includes the phase, drug or treatment, and disease*
8. **Phase:** *As available/applicable from the protocol*
9. **Age: Adults / Children / Both** *The study population indicated in the protocol*
10. **Investigator Initiated Protocol: Yes / No**
11. **Summary Accrual Info. Only: Yes / No** *Yes = Observational studies with no clinical services, No = Interventional studies or observational with clinical services*
12. **Protocol Type: Interventional / Observational** *Interventional if ANY part of the study will be interventional. Oncology studies will list NCI protocol type.*
13. **Investigational Drug:** ***Yes*** *if an investigational drug is being used in the protocol. Otherwise,* ***No****.*
14. **Investigational Device:** ***Yes*** *if an investigational drug is being used in the protocol. Otherwise,* ***No****.*
15. **RC Total Accrual Goal (Lower):** *The TARGET number of participants to enroll* ***at UF***
16. **RC Total Accrual Goal (Upper):** *The MAXIMUM number of participants to enroll at UF, including screen failures*
17. **Accrual Duration (Months):** *The number of months this study will be open to accrual/actively recruiting* ***at UF***

Fields Missing or Incorrect?

In production, if you are missing any of these required fields,
or if any required field needs to be changed,
contact the OCR Intake team ***OCR-Intake@ahc.ufl.edu****.*

5. Your training study **Main** page should look similar to this:



6. Notice that for this training protocol the **Protocol Status** in the header may be either **NEW** or **OPEN TO ACCRUAL**. In production, your study could be in a different status depending on when you are looking at it in the process.

Note: We will discuss the meaning of the different statuses later.

IRB Number and Management Groups

*If not already in your protocol, navigate to **Protocols > PC Console > Main** and select your protocol number.*

1. Click on the **Management** horizontal tab.

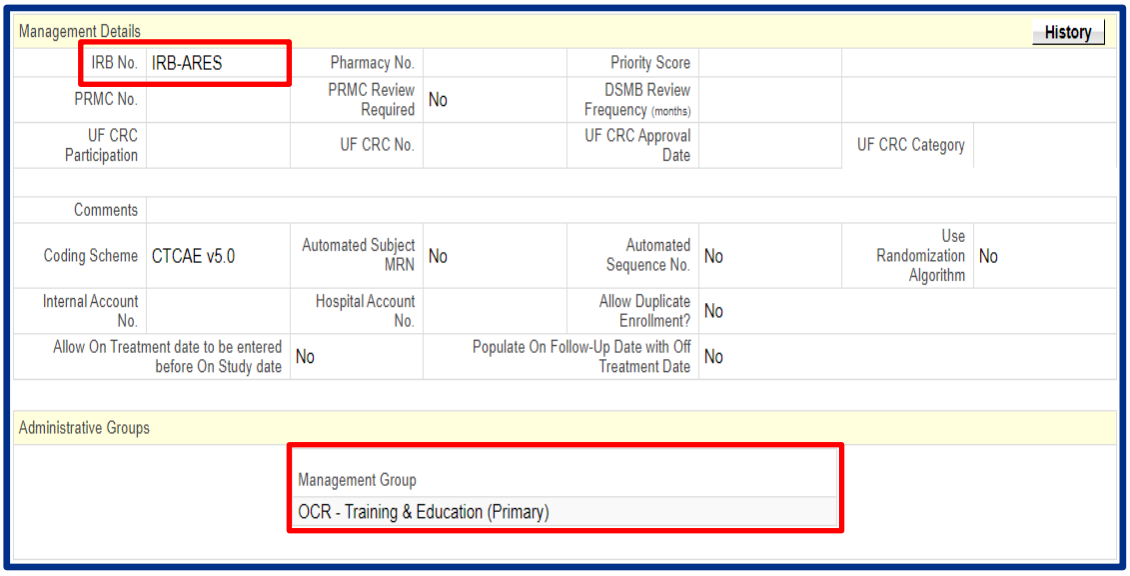
2. At top left, confirm that the **IRB No.** is **IRB**-<**Username**> where the username matches the name on your computer tower. In production, this field is typically entered by study staff and should reflect the study's IRB number as assigned by the IRB.

3. **Management Groups** are used for access and to indicate who is managing the study. Users with Management Group permissions can view all protocols within their management group even if they are not listed on the protocol staff list. Not all users have management group permissions.

   Management Groups may not always correspond to the Principal Investigator's department.

4. Confirm your training protocol has the following Management Groups entered:

   - **OCR – Training & Education**, which should be marked as **Primary**



In production, confirm that the Management Groups are entered for your study and that a Primary management group has been indicated with a **Y.**

Confirm additional required Management Groups, if necessary:

- **Investigational Drug Pharmacy –** required if study involves drugs dispensed by UF Health Investigational Drug Service (IDS).
- **CTSI Biorepository –** required if study involves any study UF CTSI Biorepository services.
- **Research Billing Office –** required if study involves any UF Health patient-based billable services (e.g. Epic charges).

In Production, if any of the management groups are missing, email OCR-Intake@ahc.ufl.edu and ask OCR staff to correct.

Study Staff

UF study teams **MUST** keep OnCore study staff data current. This is even more important for OnCore studies that are also in Epic; some of the OnCore staff records are sent to the study's Epic Research Administration record.

Study team members with either the PC or CRA role are allowed to update protocol staff records. UF Management groups need to determine who will be responsible for keeping the records up to date.

There are several ways to assign and inactivate protocol staff members.

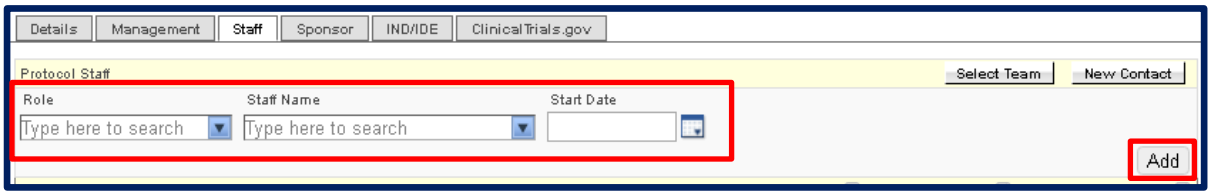
Assign Staff to a protocol individually

If not already in your protocol, navigate to Menu > Protocols > PC Console > Main and select your protocol number.

1. Click on the **Staff** horizontal tab. *Click **[Update]** if needed.*

2. At the top section, add a staff member to this protocol by entering the following:

   - **Role**: Other Staff
   - **Staff Name**: *<pick anyone in the drop-down list that has the last name of "**Rules**">*
   - **Start Date:** y-1



3. Click **Add**.

Missing Staff Names?

*In production, if you are trying to add a staff member and their name does not appear in the Staff Name drop-down menu, please complete an "**Add New Staff**" request via the OnCore Support webpage http://clinicalresearch.ctsi.ufl.edu/oncore/support/add-new-staff.*

Assign additional Staff to a protocol by selecting team members from another study

If staff members often work together on protocols, you can save time when assigning staff by copying staff assignments from another study.

If not already in your protocol, navigate to Protocols > PC Console > Main > Staff, select your protocol number and click [Update].

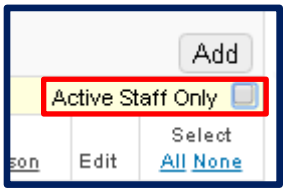
1. Click **Select Team** (upper right hand side of page).
2. Type **EZ-AHC-005** into the protocol search box in the middle of the screen and then click **Show Team**.
3. Click on the **Select** check boxes next to two or three staff members currently assigned to **EZ-AHC-005.**
4. Click **Submit** to save the Staff details.

Add Staff Start Dates

While not required, it is a good idea to add **Start** and **Stop Dates** for staff members. Using these dates can help filter out "Inactive Staff" in reports and displays, while maintaining historical information on which staff members have worked on the study.

If not already in your protocol, navigate to Protocols > PC Console > Main > Staff, select your protocol number and click [Update].

1. Display **Start** and **Stop Dates** by ensuring that the **Active Staff Only** check box is off.



2. For any staff member missing a **Start Date**, click on the tiny **Edit** hyperlink next to that staff member's name.

3. For this training protocol, add a **Start Date** of **y-1** to the pop-up for all displayed roles.

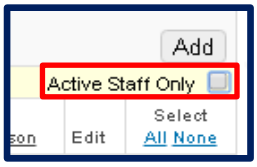
4. Click the **Submit** button on the pop-up.

5. Repeat for the other Staff members missing a start date (as needed).

Add Staff Stop Dates

If not already in your protocol, navigate to Protocols > PC Console > Main > Staff, select your protocol number and click [Update].

1. Display **Start** and **Stop Dates** by ensuring that the **Active Staff Only** check box is off.



2. Select any one of the Staff members and click on the tiny **Edit** hyperlink next to that Staff member's name.

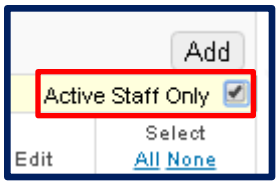
3. Add a **Stop Date** of **y-1** and a reason of **Retired** to the pop-up for all displayed roles.

4. Note: Do NOT click the **Delete** button to inactivate someone from a study; if you do, you will lose their history. The **Delete** button should only be used when you have entered a staff record by accident.

5. Click the **Submit** button on the pop-up.

6. Notice that this person's dates now show up in **red.**

7. Now click on the **Active Staff Only** button.



8. The inactive staff member will no longer display on your staff table.

Add/inactivate a staff member from multiple studies at once

Staff Turn Over?

If you have staff member who needs to added or inactivated from a large number of OnCore studies, please contact the OnCore Support team via OnCore-Support@ahc.ufl.edu.

Confirm that all UF-required roles are assigned

If not already in your protocol, navigate to Protocols > PC Console > Main > Staff, select your protocol number and click [Update].

1. Sort the staff table by clicking on the **Role** column header.

2. Confirm that there is **at least one active person** assigned to the following **UF-REQUIRED** roles. Note: A staff member can have more than one role.

   - **Authorized Prescriber –** Only required for studies that involve investigational drugs dispensed by the UF Health Investigational Drug Services (IDS).
   - **Billing Coordinator** - pays patient care costs invoices.
   - ***Epic Charge Reviewer** - *Only required for studies that are/will be in Epic.
   - **Financial Coordinator** - negotiates the budget, and/or performs coverage analysis on the billing grid, and/or is responsible for invoicing sponsor.
   - **IRB Coordinator** - responsible for IRB submissions and consents
   - **Primary Study Coordinator**
   - **Principal Investigator**
   - **Study Site Contact** – Only required for studies that will be published on the public UF website using data from OnCore (e.g. Study Connect).

*If any of the required roles is missing, pick anyone in the drop-down list with the last name of "**Rules**" and assign the missing role to them.*

OCR Staff Assignments

*In production, you will see several assigned Roles that start with "**OCR**".*
These are OCR staff members who have been assigned to this protocol by the OCR office.
DO NOT EDIT OR DELETE THE OCR ROLES.

Sponsors

Multiple sponsors can be assigned to a protocol, but only one can be the **Principal Sponsor.** All sponsors can be invoiced for procedures or visits during this protocol.

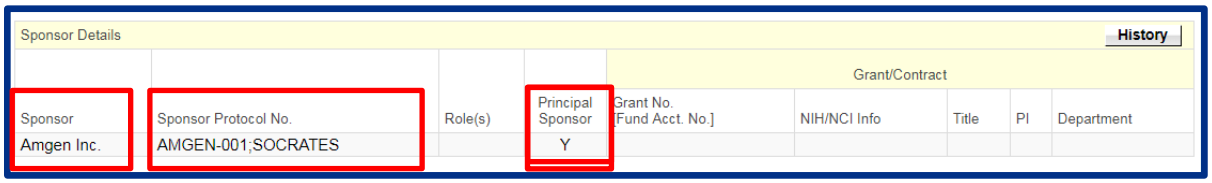
The **Principal Sponsor** appears in the header of the PC Console, Financials Console, and other OnCore tools.

If not already in your protocol, navigate to Menu > Protocols > PC Console > Main and select your protocol number.

1. Click on the **Sponsor** horizontal tab.

2. Confirm that your training protocol has a

    - **Sponsor** of **Amgen, Inc.**
    - **Sponsor Protocol No.** of **Amgen-001** plus a Nickname that matches **your training username**
    - **Principal Sponsor** indicator checked



Adding Sponsors in Production

In production, contact OnCore-Support@ahc.ufl.edu to add or correct Sponsor information, including the addition of your UF study Nickname.

Optional: Investigational Drugs and/or Devices

If not already in your protocol, navigate to Menu > Protocols > PC Console > Main and select your protocol number.

1. Click on the **IND/IDE** horizontal tab.

2. This screen has pulled through **Investigational Drug** = **Yes** and the **Investigational Device** = **No** from the **Details** tab for this study.

3. Confirm the IND training data for the following data fields:

    - **ID:** 40897
    - **Holder Type**: Industry
    - **Holder Name:** Amgen Inc.

In Production, this data is optional and can be updated by the study team.

Treatment Details

This section tracks the protocol's steps, treatment arms, treatment levels, drugs, devices, and modalities. OCR staff enter this information based on the information provided in the Study Registration and Initiation Packet.

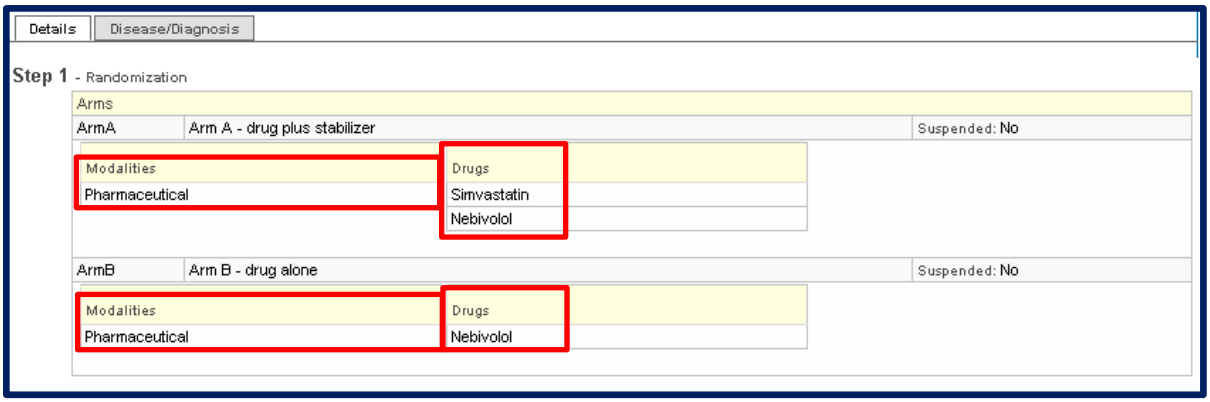
In the training protocol, subjects will be randomized to two arms (A and B).

- Subjects on **ArmA** of this study will receive the active ingredient (**Nebivolol)** plus a stabilizing agent (**Simvastatin**), which is thought to help increase absorption of the drug.
- Subjects on **ArmB** will only receive the **Nebivolol.**

If not already in your protocol record, navigate to Menu > Protocols > PC Console and select your protocol number.

1. Click on the **Treatment** vertical tab.

2. Verify that your screen looks like this:



Disease and Diagnosis

Disease/Diagnosis – This data does not drive functionality – It is used in the Study Information Portal that exports information about the study to a webpage that lists research studies at UF. **Currently this is not being used by AHC studies.**

Participating Institutions and Study Sites

In order to register subjects to a protocol, you must have at least one active study site at UF (or another participating institution).

Institutions are recorded on the **Menu > PC Console > Institutions** tab.

Adding Institutions

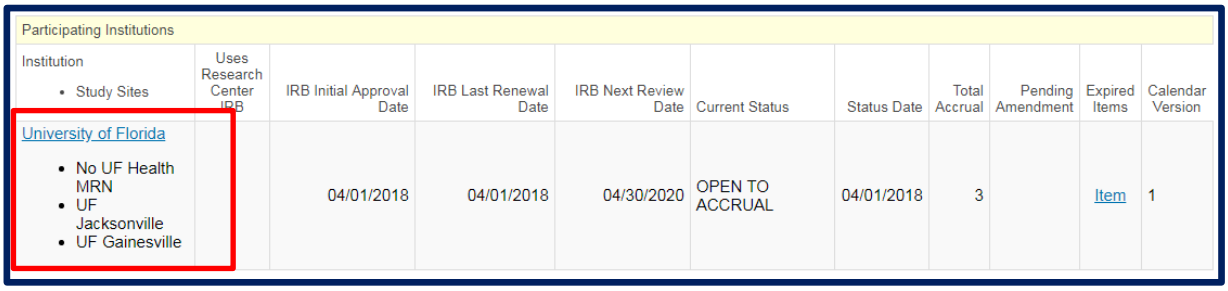
In production, contact OnCore-Support@ahc.ufl.edu to add or correct Institutions, including any other participating affiliates or consortium members

NOTE: We will not cover affiliate institution processes and procedures today. For studies where this applies, we will have specific affiliate institution end user training.

If not already in your protocol record, navigate to Menu > Protocols > PC Console and select your protocol number.

1. Click on the **Institution** vertical tab.

2. Verify that your screen looks like this:



Participating Institutions

Institution • Study Sites	Uses Research Center IRB	IRB Initial Approval Date	IRB Last Renewal Date	IRB Next Review Date	Current Status	Status Date	Total Accrual	Pending Amendment	Expired Items	Calendar Version
University of Florida • No UF Health MRN • UF Jacksonville • UF Gainesville		04/01/2018	04/01/2018	04/30/2020	OPEN TO ACCRUAL	04/01/2018	3		Item	1

Note: There are five “Study Sites” associated to the UF Institution: No UF Health MRN, Gainesville, Jacksonville, Villages, and Leesburg. Study Site distinctions are made based on several factors:

- Clinical location within UF Health (e.g. UF JAX and/or UF Gainesville).
- Location of home department of PI or study staff who are managing the enrollees (UF JAX or UF Gainesville).
- Registering participants who have not been seen within the UF Health system and have no UF Health MRN.

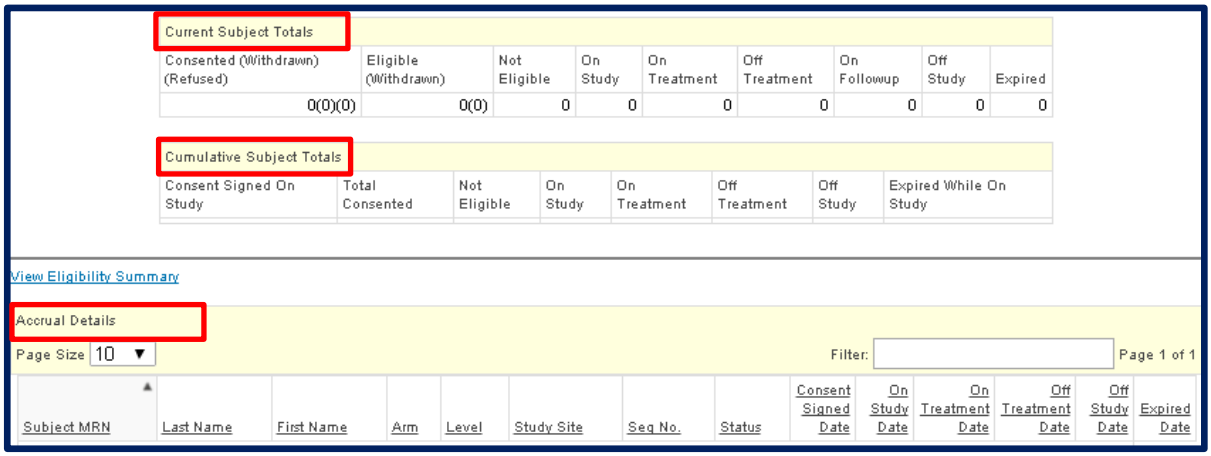
Accrual Summary

If not already in your protocol record, navigate to Menu > Protocols > PC Console and select your protocol number.

1. Click on the **Accrual** vertical tab.

2. This page displays summary subject accrual data for the protocol including:

   - Current Subject Totals
   - Cumulative Subject Totals
   - Subject-specific Accrual Details



Protocol Status History

OnCore protocols have a status of **NEW** until the first required committee review is documented for the study (see committee section below).

If not already in your protocol record, navigate to Menu > Protocols > PC Console and select your protocol number.

1. Click on the **Status** vertical tab.

2. Notice that the training protocol's **OPEN TO ACCRUAL** status is displayed in the header – upper right.

This page displays the history of changes to this protocol's status. OnCore protocol statuses are assigned (and unassigned) in a predetermined order. Users with the appropriate privileges will see buttons that can be used to assign the next status, undo the current status, or update the order of the protocol's approval statuses.

Sequence of statuses for a protocol

- **New:** Protocol has been created in PC Console Submission Console
- **Protocol Review and Monitoring Committee (PRMC) Approval:** Protocol has been reviewed and/or approved by the UF Cancer Center Scientific Review and Monitoring Committee. At UF, all "cancer relevant" studies must be reviewed by the PRMC/SRMC.
- **IRB Initial Approval:** Protocol has an approved IRB initial review. Note: If applicable, the system allows this approval to occur prior to the cancer study PRMC Initial Approval.
- **Sign-offs:** Depending on configuration settings, dates must be entered for a series of sign-offs.
- **Open to Accrual:** Protocol has an *Open to Accrual* date entered and subjects can be placed *On Study* on or after that date.

- **Closed to Accrual:** Protocol has a *Closed to Accrual* date entered. Subjects may be active in treatment or follow-up, however no additional subjects may be placed *On Study*.

- **IRB Study Closure:** Protocol has gone through its entire life cycle, no more subjects are in treatment or on follow-up and the IRB considers the study as completed.

Other statuses

- **Abandoned:** Protocols that are ended prior to ever being *Open to Accrual*.

- **Suspended:** Protocols that had been *Open to Accrual* but currently should not accrue any more subjects until issues are resolved. Protocols often re-open after suspended.

- **Terminated:** Protocols that have a shorter than expected life cycle due to SAEs, low accrual, etc. (Some centers do mark IRB Study Closure protocols as *Terminated* as well to get a complete count of all non-active or non-pending protocols.)

Groupings of statuses

- **Pending**: Any status prior to *Open to Accrual* (excluding Abandoned)

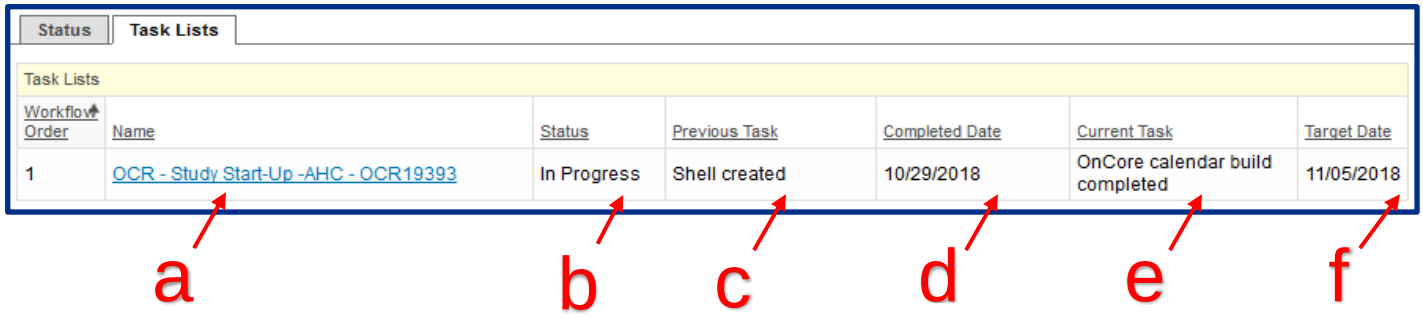
- **Active:** *Open*, *Suspended* or *Closed* protocols

- **Complete:** IRB Study Closure, Abandoned or Terminated protocols

Task lists

Notice that this page includes a **Task Lists** horizontal tab. Task Lists are used to direct and track the Office of Clinical Research internal team workflows. This functionality allows for transparency with study teams.

1. Navigate to Menu > PC Console > Status > Task Lists.
2. Find your study using the Select Protocol search field.
3. The Task Lists tab will display a list of all task lists associated to this study.
4. For each task list, you will see a summary which includes the following for each task list:



a. **Name –** Name of the task list *Note: All OCR task list names begin with **"OCR"***

b. **Status -** New, In Progress, or Complete

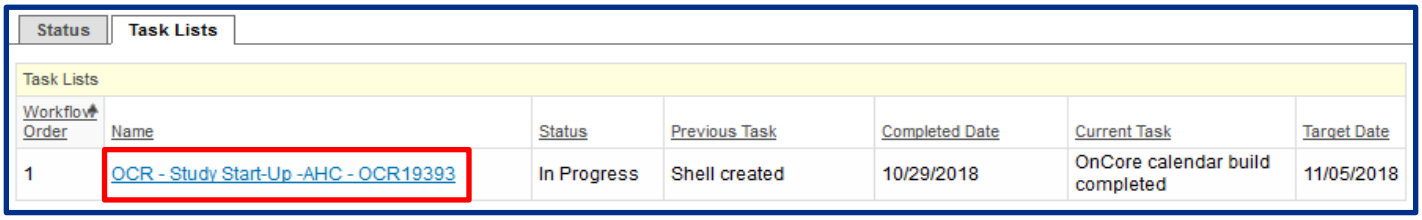
c. **Previous Task -** Most recently completed task within the Task List

d. **Completed Date -** Date that the Previous Task was completed

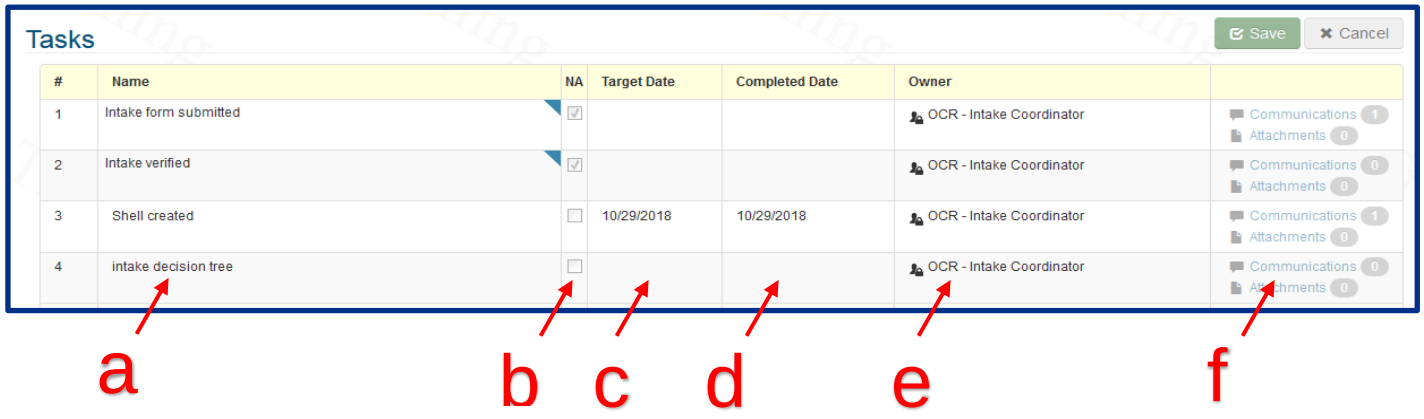
e. **Current Task -** The task that OCR is currently working on

f. **Target Date -** The date that OCR expects to complete the Current Task.

5. To see all tasks within a particular Task List, click on the blue Task List hyperlink in the Name column.



6. You will see a list off all possible OCR tasks associated with this task list.



7. For each task, you will see the following:

   a. **Name** – Task name

   b. **NA** – If OCR determined that this task is not applicable to your study, the NA box will be checked

   c. **Target Date** – The date that OCR expects or expected to complete that task

   d. **Completed Date** – Date the task was completed

   e. **Owner** – The OCR staff role assigned to this task. To determine the specific OCR staff member who was assigned, you will need to look at the study's Staff tab and see who in OCR was assigned to this role.

   f. Each task also has a place to view **Communications** and **Attachments** that pertain to that task.

8. Click on the blue Communications link to open a pop-up window where you can view any communication notes that have been added by OCR staff.

9. Click on the blue Attachments link to open a pop-up window where you can view any attachments that have been added by OCR staff.

Committee Reviews

Various research committee reviews can be tracked in OnCore.

If not already in your protocol record, navigate to Menu > Protocols > PC Console and select your protocol number.

1. Click on the **Reviews** vertical tab. You will see the following horizontal tabs:

   - **Summary** - Summarizes committee review information
   - **PRMC** - Protocol Review and Monitoring Committee
   - **DSMB** – Data Safety Management Board
   - **IRB** – Institutional Review Board
   - **LTFU Transfer** – Long Term Follow Up Transfer
   - **Other External Committee Actions**

All protocols in OnCore must have an **IRB review** documented before opening to accrual.

All other committee reviews can be tracked in OnCore but they are not required by the application. Institutions can require additional review. For example, most UF oncology studies must also be approved by the UF Cancer Center's PRMC.

Once a required review is entered into OnCore, the system can send notifications to appropriate staff members whenever the review is about to expire.

Confirm the study status

The current protocol status appears in the PC Console header. You can also see the history of the protocol's status changes and reviews in the PC console.

1. Navigate to **Menu > PC Console > Status**. This screen page displays the date of each change in the protocol's status.

   OnCore protocols have a status of **NEW** until the first required committee review is documented for the study (either an IRB review for AHC studies or PRMC review for oncology studies).

   Note: Your training study has already had several IRB reviews, so it is no longer **NEW**; it should have a status of **OPEN TO ACCRUAL**.

Document an IRB review

If not already in your protocol record, navigate to Menu > Protocols > PC Console and select your protocol number.

1. Click on the **Reviews** vertical tab. *Click **[Update]** if needed.*

3. Click the **IRB** horizontal tab.

4. Click teeny tiny **Add**.

5. Type in the **Review Date** for this protocol using the date exactly **one year ago** but in the following format: **MM/DD/YYYY**

> *The **Review Date** field is unique in that it does not have "date widget" functionality. You must type dates using MM/DD/YYYY format. In production, when you start typing in this field, you will start to see a list of Review Dates already entered for other protocols. If a **Review Date** is not already available in the list, you can add a date as long as you use the **MM/DD/YYYY** format.*

6. Enter the following information:

   Submit Date: y-1

   Committee: WIRB

   Review Reason: **Revision**

   Review Type: Full

   Action: Approved

   Action Date: y-1

   Expiration Date: y+2

7. Click **Submit.**

> *Notice that in the **IRB Expiration Date** in the header was not updated.*
>
> *The **IRB Expiration Date** only updates in the case of a **Continuing Review.***
>
> *Note: This date will be shown in red if the study is past the IRB Expiration date.*

Add a revised IRB-approved consent form

Approved informed consents should be uploaded into OnCore and attached to the applicable record of the IRB review at which they were approved.

NOTE: Approved consent forms added here will also appear in the Subject Console when registering new patients.

1. With the applicable IRB review open, in the **Details** section at the bottom, click the teeny tiny **Add** button.

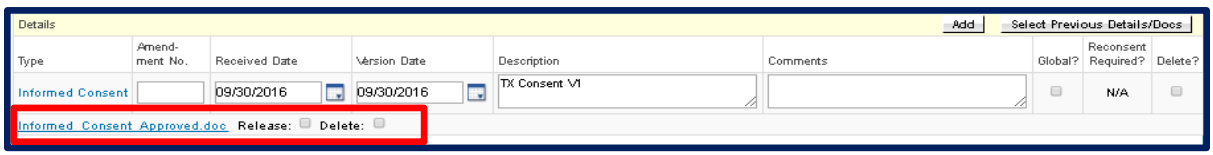
2. Enter the following:
   - **Type:** Informed Consent
   - **Received Date**: y-1
   - **Version Date**: y-1
   - **Description:** TX Consent V# *where "#" is the next version number for this consent*

3. Click teeny tiny **Save**.

8. Attach the actual approved consent:
   - Click **File**
   - Click **Browse**
   - Find and select the **Informed_Consent_Approved** file on your computer
   - Click **Open**

9. Click **Submit.**

10. **VERY IMPORTANT!** Select the **Release** checkbox. – This allows you to see the consent in document search.



11. Click **Submit and Close**.

Open the Protocol to Accrual

While a protocol approved by an IRB can technically be opened to accrual in OnCore, other intermediate steps will be required.

Complete signoffs required by the UF

After all required signoffs are completed, an **Open** button appears on the PC Console > Status screen. This means the study is ready to be opened for accrual.

Confirm protocol accrual status

1. In the **Menu > PC Console > Status** tab, click **Open**.

2. If your training study is not already **OPEN TO ACCRUAL**, enter a **Status Date** of **m-11** and then click **Submit**.

   Note: In production, you would enter the actual date you were ready to open this study for accrual.

Documents

OCR Approved documents (e.g. FLAs, Drug Tables, etc) as well as calendar build notes will be uploaded by our office.

If not already in your protocol record, navigate to Menu > Protocols > PC Console and select your protocol number.

1. Click on the **Documents/Info** vertical tab.

2. Click the **File Name / URL** hyperlink to view an example of build notes.

Optional: Creating FAQs

The FAQs (frequently asked questions) section of this page can be used by study teams as a reference to assist staff. Common questions and answers regarding the protocol, subject eligibility, subject treatment, and so on can be entered here.

If not already in your protocol record, navigate to Menu > Protocols > PC Console and select your protocol number.

1. Click on the **Documents/Info** vertical tab.
2. Click on the **FAQs** horizontal tab.
3. Click **New**.
4. Enter a Question, Answer, and Keywords. For example:
   - **Question**: Will subjects be reimbursed for mileage?
   - **Answer**: Subjects whose home address is more than 15 miles from their registration site will be reimbursed $0.42/mile for each study visit.
   - **Keywords**: Reimbursement, mileage
5. Click **Submit**.

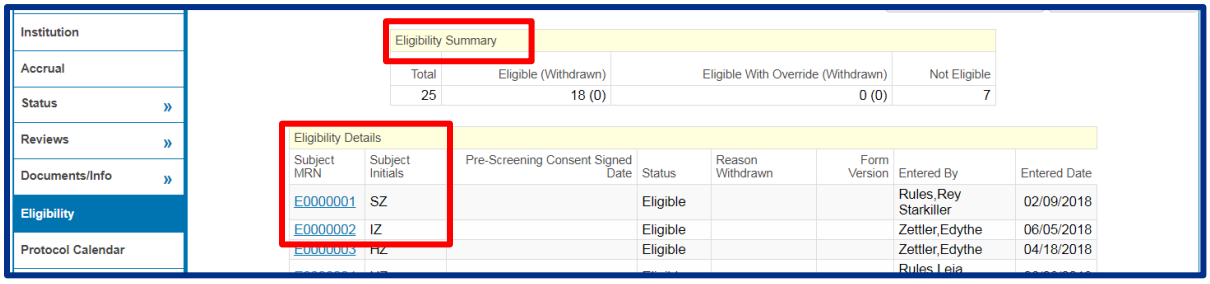
Eligibility Summary

The PC Console > Eligibility page is used to create and manage the protocol's eligibility questionnaires, and to provide a summary of subject eligibility records.

If not already in your protocol record, navigate to Menu > Protocols > PC Console and select your protocol number.

1. Click on the **Eligibility** vertical tab.

2. The bottom of the screen shows an eligibility summary and eligibility details about all subjects for whom the research staff has recorded eligibility statuses:



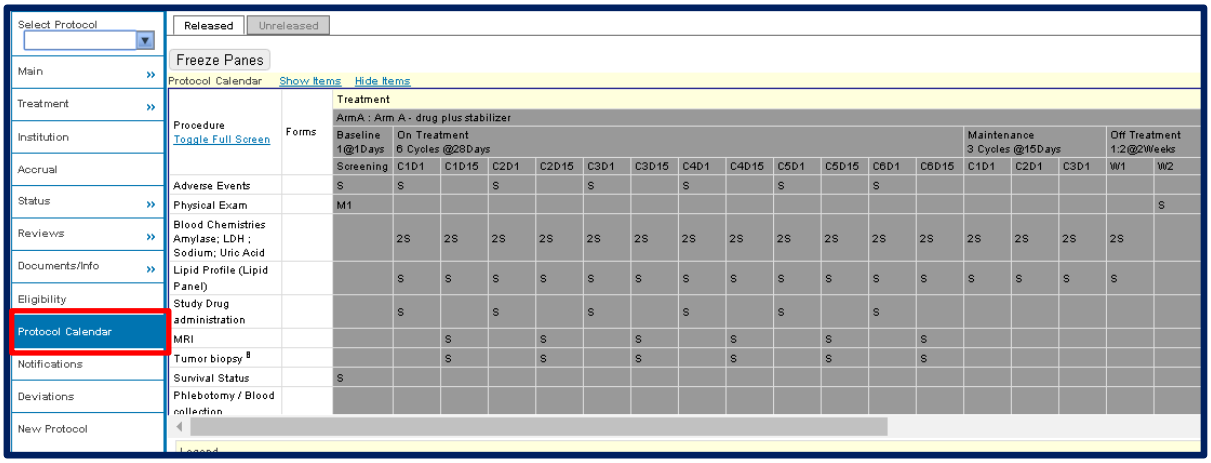
Protocol Calendar

The **Menu > PC Console > Protocol Calendar** page displays the details of the Protocol Calendar once it has been set up for this study. It shows scheduled visits and procedures to be performed during each visit.

If not already in your protocol record, navigate to Menu > Protocols > PC Console and select your protocol number.

1. Click on the **Protocol Calendar** vertical tab.

2. Verify that you can see the training study calendar:



Note: If you plan on taking **OCR 803 OnCore Subject Administration** class, you will be exploring this calendar in more detail.

Notifications

The PC Console > Notifications page is used to view and manage a protocol's notifications. (Notification management is done per library, but this page allows the library's settings to be overridden at the protocol level.)

Deviations

The PC Console > Deviations > Protocol Deviations page is used to view protocol and subject deviation records.

How to Get Help

OnCore Intranet Website

- https://ctsi-clinicalresearch-intranet.sites.medinfo.ufl.edu/
- Includes web-based user guides, tip sheets, videos, OnCore Dictionary, and Support Desk Information.
- For computers not on the UF Health Science Center network, VPN access is required.

OnCore User Guides

- UF OnCore User Guides
- For computers not on the UF Health Science Center network, VPN access is required.

OnCore Support Desk

- Phone: (352) 273-5924
- Email: OnCore-Support@ahc.ufl.edu

OnCore Online Help Desk Ticket System

The UF OnCore support webpages provide a way for UF OnCore users to easily create trackable help desk tickets for:

- Adding or Updating Staff Contacts in OnCore
- Requesting an OnCore User Account
- Other Support Requests (technical support, report requests, etc.)

OnCore Support Consults

The UF OnCore support staff love to work “face-to-face” with new UF OnCore users, especially when they need help with their first “real study”. Our most popular consults involve showing new users how to:

- Review the protocol calendar and budget
- Enter an IRB review
- Upload approved study consents
- Open the study to accrual
- Register new subjects
- Check-in visits
- Enter visit variations and deviations

To schedule a consult, please complete the Request an OnCore Consult form.