OCR803

OnCore Subject Administration

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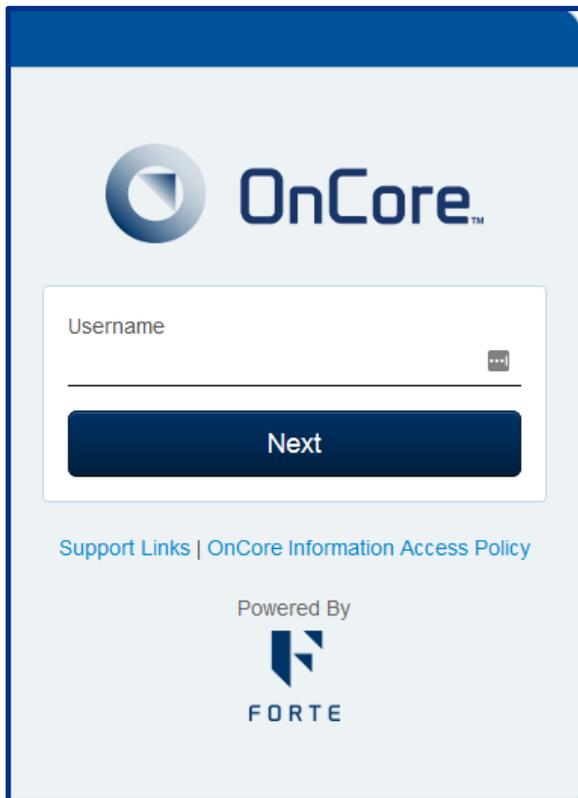
Next, the user enters their Gatorlink password.
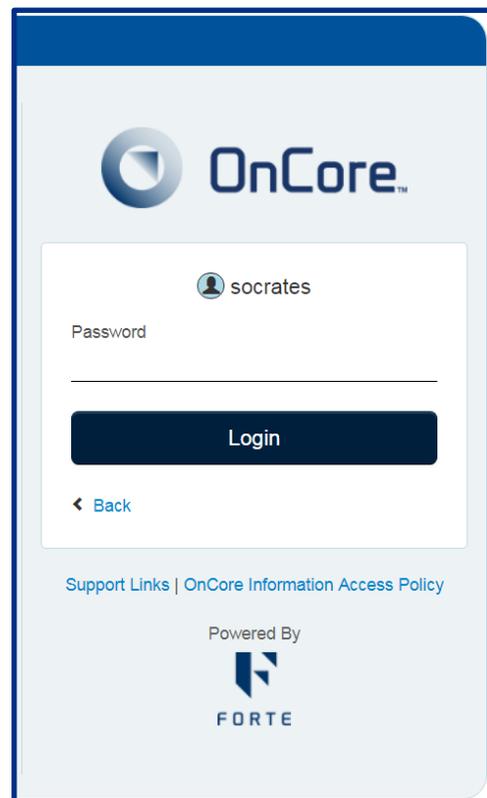
OnCore is accessed using your Gatorlink user ID and password. You can only change or administer your Gatorlink password using the myUFL website - https://my.ufl.edu.

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 Safari 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.

Subject Administration

The focus of this training section is **subjects**. In OnCore, a *subject* is a person who is participating in a protocol, who is considering participating, or who is being evaluated for their eligibility to participate. Each subject record in OnCore represents one patient (one person) who is registered to a protocol. A person might have several subject records in OnCore if they are participating in more than one study or if they register to a study multiple times.

Some information in OnCore is stored at the *patient* level; this information is the same throughout OnCore, no matter what protocol you are looking at. The patient information includes the MRN, demographics, address, emergency contact info, expiration date, and other optional identifiers such as the patient's driver's license number. If this information is updated anywhere in OnCore, it is reflected in all subject records for that patient.

Other information in OnCore is stored at the *subject* level; this information is specific to the person's enrollment on a particular study. The subject information includes the Sequence No., consent dates and versions, eligibility criteria, study site, treatment and follow-up start dates, and visit details. When this data is entered or updated in a subject record, it does <u>not</u> change any other subject records.

We will also cover some administrative tasks that a study coordinator might be expected to do, depending on their UF department-specific workflows. Examples:

- Review/QA the Protocol Calendar Prior to Enrolling First Subject
- Track Visits
- Document a Committee Review
- Open the Protocol to Accrual

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The Protocol Calendar

Quick calendar facts

- Calendars progress through three stages:

Specification

Think of this as a calendar-in-progress. Specifications define the schedule of visits, procedures, and forms in a protocol calendar.

Location: View and edit specifications in the **eCRFS/Calendars > Specifications** menu.

Protocol Calendar

The protocol calendar is the finalized schedule of visits, procedures, and forms that is used as a blueprint for the subject calendar.

Location: View only: PC Console or CRA Console. Edits must be made in the **specification**.

Subject Calendar

A personalized subject calendar is automatically generated based on the visit schedule defined in the protocol calendar. The subject calendar shows planned visit dates and occurred visit details.

Location: View and track visits in the **Subject Console**.

- UF OnCore calendars are either built by OCR or purchased from Forte
- A Protocol Calendar is built
    - BEFORE the budget parameters are entered
    - BEFORE the study is open to accrual
- When used with Financials, they are the basis of the OnCore billing grid

Protocol Calendar Specifications

Once the study calendar has been built, the UF OnCore Calendar Team (OnCore-Calendars@ahc.ufl.edu) will ask you to QA your calendar using the **OnCore Calendar QA Checklist** (see handout).

Note: In many UF departments, study coordinators may be asked to review the protocol study calendar prior to final release of the calendar. In other departments, the coordinators may not see the calendar until they are getting ready to enroll subjects.

A Walk Through the Calendar QA Checklist

- Review Treatment Arms – **Menu > Protocols >PC Console > Treatment**

- Segments – **Menu > eCRFs/Calendars > Specifications >Treatment Visits**

- Procedures – **Menu > eCRFs/Calendars > Specifications > Calendar**

- Footnotes – **Menu > eCRFs/Calendars > Specifications > Calendar**

- Visits – **Menu > eCRFs/Calendars > Specifications > Calendar**

Follow up questions? Contact OnCore-Calendars@ahc.ufl.edu.

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Identify Segments

The calendar is composed of visits and events. To understand how these were set up in a calendar, the first step is to understand calendar **segments**.

Segments are "chunks" of time that have a **Start Date** based on a subject milestone date. Visits are scheduled within segments. There are two types of segments – treatment segments and follow-up segments. Each segment must have a trigger or milestone date that indicates the beginning of the segment.

Segments are collections of visits that are triggered or activated at the same time. For example, a subject's treatment visits might be triggered by the subject status changing to *On Study* or *On Treatment*, at which point the treatment-related visits can be checked in. If the subject does not yet have a status of On Follow Up, then their follow-up visits are *not* activated and cannot yet be checked in.

A calendar segment **Start Date** trigger can be one of the following:

- Consent Signed
- On Study
- On Arm
- On Treatment
- Off Treatment
- Off Arm
- Off Study
- On Follow Up
- End Of Previous (simply allows one segment to follow another segment)
- Date of Progression (only available for oncology protocols)

> ***Note: The following pages 11-17 are supplemental to the "Walk" with the OnCore Calendar Team.***
>
> ***Please turn to page 18.***

View study segments

1. Navigate to **Menu > eCRFs/Calendars > Specifications.**

2. If you are not still in your protocol, type **your username** in the **Select Protocol** field *<where your training study is the name on your computer tower>.*

3. Click on the **Treatment Visits** vertical tab.

4. You will see a summary of the sample training study calendar that outlines **Segments** and **Start Date** triggers.

Treatment									
Seg No.	Name	Start Date		Unit	No. of Repetition	Visit(s)	Duration	Exclude Weekend	Arms
10	Baseline	Consent Signed		Day		1	1		
20	On Treatment	On Treatment		Day	6		28		ArmA, ArmB
30	Maintenance	End Of Previous		Day	3		15		ArmA
40	Off Treatment	Off Treatment		Week		1:2	2		

Follow-Up										
Seg No.	Name	Start Date	Unit	Visit(s)	Duration	Duration Begin	Duration End	Interval	Starting Number	Arms
50	In-clinic Follow-Up	On Follow Up	Month			6	24	6		
60	Annual Follow Up	On Follow Up	Year	3:6	6					

5. In the sample study, we have six segments:

    *   **Baseline** - triggered by the date the subject signs consent
    *   **On Treatment** - triggered by the status date entered for **On Treatment**
    *   **Maintenance** - triggered by the end of the **On Treatment** segment
    *   **Off Treatment** - triggered by the status date entered for **Off Treatment**
    *   **In-clinic Follow-up** - triggered by the status date entered for **On Follow Up**
    *   **Annual Follow-up** - triggered by the status date entered for **On Follow Up**

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6. Look at your study calendar handout and verify that you see the segments on your handout:

treatment segments====>	Baseline	On Treatment Arm A, Arm B		Maintenance Arm A Only	Off Treatment		In-Clinic Follow Up	Annual Follow Up
	Within 14 days of signing consent	6 cycles x 28 days All visits +/- 1 day		3 cycles x 14 days immediately after treatment	2 weeks following disease progression		6M after all goal then every 6M for 2 years	(by phone) Y3, Y4, Y5, Y6
	Screening	Day 1	Day 15		W1 DX Prog.	W2 DX Prog.		
Adverse Events	X	X					X	X
Physical Exam	X					X	
Blood Chemistries: Amylase, LDH, Sodium, Uric Acid		2X	2X	2X	2X		2X	
Lipid Panel: Cholesterol, HDL, LDL, Triglycerides		X	X	X	X		X	
Treatment Administration		X						
Imaging (MRI)			X					
Tumor Biopsy			X					
Survival Status	X							X

View the Protocol Calendar

Now we will look at the final manifestation of the calendar specifications; a viewable calendar with all the detail we are used to seeing in a Table of Events or Billing Grid. We are going to check the sample training study protocol calendar against the sample Table of Events handout.

1. Navigate to **Menu > eCRFs/Calendars > Specifications**

2. If you are not still in your protocol, type **your username** in the **Select Protocol** field. *<where your training study is the name on your computer tower>.*

3. Click on the **Calendar** vertical tab.

Study Specification

Protocol No.: OCR17638   Library: Academic Health Center   Title: TRAIN01 - Study in production this will match the first title at the top of clinicaltrials.gov   Version: 1   Specification Status: New

Arm All

Protocol Calendar   Show Items   Hide Items   Charge Master Version:2 (01/01/1991)   Preview Calendar

Treatment

Procedure (Toggle Full Screen)	Forms	ArmA : Drug + Stabilizing agent																	ArmB : Drug					
		Baseline 1@1Days	On Treatment 6 Cycles @28Days												Maintenance 3 Cycles @15Days			Off Treatment 1.2@2Weeks		Baseline 1@1Days	On Treatment 6 Cycles @28Days				
		Screening	C1D1	C1D15	C2D1	C2D15	C3D1	C3D15	C4D1	C4D15	C5D1	C5D15	C6D1	C6D15	C7D1	C8D1	C9D1	W1	W2	Screening	C1D1	C1D15	C2D1	C2D15	C3D
Informed Consent		S																			S					
Adverse Events		S	S		S		S		S		S		S							S	S		S		S
Physical Exam		S																S		S					
Blood Chemistries Amylase; LDH ; Sodium; Uric Acid			2S	2S	2S	2S	2S	2S	2S	2S	2S	2S	2S	2S	2S	2S	2S	2S			2S	2S	2S	2S	2S
Lipid Profile (Lipid Panel)			S	S	S	S	S	S	S	S	S	S	S	S							S	S	S	S	S
Study Drug administration			S		S		S		S		S		S								S		S		S
MRI				S		S		S		S		S		S								S		S	
Tumor biopsy A				S		S		S		S		S		S								S		S	
Survival Status		S																		S					
Phlebotomy / Blood collection																									

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Review calendar procedures

1. Look at your Table of Events handout and verify that all of the events are listed:

   - Informed Consent <Note: These were not on the original Table of Events but the calendar builders added to calendar for participant initiation>.
   - Adverse Events
   - Physical Exam
   - Blood Chemistries
   - Lipid Panel
   - Study Drug Administration
   - MRI
   - Tumor Biopsy
   - Survival Status
   - Phlebotomy <Note: These were not on the original Table of Events but the calendar builders knew this needed to be added to calendar for possible billable draws>.

2. Notice that the **Blood Chemistries** lab has been broken down into separate billable items – you can click on the **Hide Items** or **Show Items** to expand or contract this detail.

Use two tools to help review calendar time points

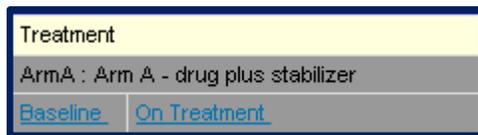There are two tools that can help you view a calendar timeline:

1. Click **Freeze Panes** – This freezes the **Procedure column** so that when you use the scroll bar at the bottom of the calendar, you can still see the procedure label.

2. Click the tiny **Toggle Full Screen** link (right under the **Procedure column header**) – This allows you to use your full screen to see the timeline more clearly.

Review the timeline and segments

1. Notice that the **calendar** is divided at top by sections:

    - Treatment

    - Follow Up

    Treatment

Treatment
ArmA : Arm A - drug plus stabilizer
Baseline	On Treatment

    Follow Up

Follow Up
In-clinic Follow-Up

2. The **Treatment** section is divided by Arms:

    - ArmA

    - ArmB

3. The **Arms** are divided by segments:

    - Baseline

    - Treatment

    - Maintenance (only for ArmA)

    - Off Treatment

4. The **Follow-Up** section is divided into the Follow-Up segments:

    - In-clinic Follow-Up

    - Annual Follow-Up

Review the visit schedule and visit tolerances

1. Confirm that **Baseline** segment matches your paper **Table of Events** handout.

- Notice that the segment has only one visit: **Screening**.
- Click on the **Baseline** link and confirm the **Visit Tolerances**: **-0/+14.**

2. Confirm that the **Treatment** segment matches.

- This segment should have twelve visits in six cycles of 28 days labeled:
  - **C1D1** (cycle 1 day 1)
  - **C1D15** (cycle 1 day 15)
  - **C2D1** (cycle 2 day 1)
  - Etc. . . .
- Click on the **Treatment** link and confirm the **Visit Tolerances**: **-1/+1.**

3. Confirm that the **Maintenance** segment matches,

- Notice that this segment is only applicable to **Arm A.**
- This segment should have **three visits** in three cycles of 15 days.
- Click on the **Maintenance** link and confirm the **Visit Tolerances**: <n/a>

4. Confirm that the **Off Treatment** segment matches.

- This segment should have two visits in two weeks.
- Click on the **Maintenance** link and confirm the **Visit Tolerances**: <n/a>

5. Confirm that the **In-clinic Follow-Up** segment matches.

- This segment should have **four visits** every six months thru M 24.
- Click on the **In-clinic Follow-Up** ink and confirm the **Visit Tolerances**: <n/a>

6. Confirm that the **Annual Follow-Up** segment matches.

- This segment should have **four visits** every year from Y3 to Y6.
- Click on the **Annual Follow-Up** ink and confirm the **Visit Tolerances**: <n/a>

7. Click on the **Toggle Full Screen** link to return to the normal screen view of the calendar.

Preview the calendar's auto-generated dates

OnCore's calendar preview feature allows you to double-check the visit structure using test subject milestone dates.

1. Click the **Preview Calendar** button in the upper right corner of the **Calendar** tab.

2. Select **ArmA**.

3. Enter the following testing milestone dates:
   - **Consent Signed Date**: 1/1/17
   - **On Treatment Date**: 2/1/17
   - **Off Treatment Date**: 9/1/17
   - **On Follow Up Date**: 10/1/17

4. Click **Preview**.

   Planned Dates are generated for each of the Arm A visits. In production, the coordinator should check the generated dates to make sure they make sense.

5. Click the **Preview Calendar** button again.

6. Change to **ArmB** and click **Preview** again to check ArmB generated dates.

7. Click **Close.**

8. Click the **red X** towards upper left to remove the test dates.

Subject Management

Pre-Screening

UF study teams/management groups can opt to use OnCore's **Pre-Screening** functionality, which allows study teams to track information and time spent pre-screening participants. The information collected includes subject referral data, subject characteristic data, and protocol evaluation specifics. By collecting this information, study teams are able to gauge the effectiveness of various referral channels as well as track pre-screening failures in more detail.

1. Navigate to **Menu > Subjects > Pre-Screening.**

2. Select the **New** button.

> **Important!** *Search for your subject (by name and/or MRN) before making a new entry to avoid duplicate records*

3. Enter the following information:

   - **Management Group**: <Pick one>

   - **Contact Date**: y-1

   - **Subject Identifier**: *<your initials>*-PreScreening-10

   - **Subject Evaluated**: Yes

   - **Evaluator**: Florida

   - **Protocol No**.: *<In production, if you know your protocol number at the time of pre-screening, it will populate a **Register Subject** button if you mark **Subject Consented** as "Yes". You should go back and update the protocol number if you want to be able to link the screening record.>*

   - **Subject Consented**: Yes

   - **Subject Eligible**: Yes

   - **Subject on Study**: Yes

   - **Record Completed**: Yes

Note: If your group opts to use this console, be aware that the only field **required** by the system is the **Contact Date**. Enter additional data fields as directed by your group supervisor.

4. Click the **Submit** button.

The Subject and CRA Consoles

There are two consoles used in subject management:
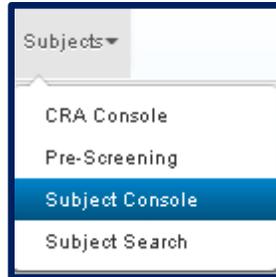
Menu > Subjects > Subject Console: This console allows you to view **one subject's** information. The console provides access to a subject's demographic information, the protocols the subject is associated with, what consent forms the subject has signed, their eligibility status, etc.
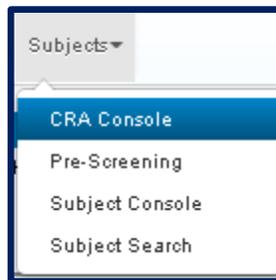
Menu > Subjects > CRA Console: This console is designed to provide **multiple subjects** information at a **protocol level**. When a protocol is selected in the CRA Console, it displays the subjects who have been accrued, a list of Serious Adverse Events (SAEs), and a list of subject deviations (including visits outside tolerance) for this protocol.

View your study in CRA console

1. Navigate to **Menu > Subjects > CRA Console.**

2. If you are not still in your protocol, type *your username* in the **Select Protocol** field. *<where your training study is the name on your computer tower>.*

3. CRA console defaults to the **Accrual** screen, which shows patients that have been enrolled into the study so far. *In the training protocol, there may already be some enrollment recorded.*

4. Click on the display filter arrow at the top right of your screen and make sure that the filter is set to "**All**". This will show all subjects who have been associated with this study.

Note: Once participants are enrolled you can set the default display by choosing the preferred view and then clicking the **Save Preferences** link at the bottom of the page.

Find your patient's MRN and demographic data

1. Click the **Register Subject** (bottom vertical tab).

2. In the **Study Site** field, choose **UF Gainesville**.

   When enrolling a new subject, first check to see whether they already have a Medical Record Number (MRN) in OnCore. In production, this data is pulled from the UF Health Epic EMR system.

3. In the **Find Subject** section on the left, enter "**Zed**" in the **Last Name** field and click **Find**. You will see a list like the following:

Subject MRN	Addl Subj IDs	Last Name	First Name	Middle Name	Suffix	Gender	Birth Date
E4416829	E4416829 , 14132757 , 14132757	ATTEST	TESTONE			F	09/19/1977
E4416830	E4416830 , 14132765 , 14132765	ATTEST	NOBDP			F	09/19/1977
E4416838	E4416838 , 2306826 , 02306826	FEVERTEST	ONETWO			M	02/02/1942
E4415935	E4415935 , 2306489 , 14127955 , 02306489 , 14127955	JNSONIFITEST	LMMADT			M	12/31/1984
E2966972	E2966972 , 2618643 , 02618643	NOTESTEIN	KAYLA			F	09/08/1998
E3077343	E3077343 , 254873 , 00254873	NOTESTEIN	JAMES	EDISON		M	10/28/1943

Subject Find Results — Count: 84

4. In production, you would look for your patient either by using the MRN they provide to you or by searching by last name and birthdate.

> **Important!**
> *In production, if you cannot find your patient using the provided MRN, or Last Name and Birth Date, contact the Oncore Support Team via*
>
> *OnCore-Support@ahc.ufl.edu.*
>
> *The OCR staff will work to obtain the patient's Epic MRN.*

IN TRAINING, select any one of **"Zed"** patients by clicking on the Subject MRN blue hyperlink to populate the **Subject Details** from the patient's records.

5. Click the tiny **Add** button on the right.

6. The **Subject Console** page opens on the **Demographics** vertical tab.

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Update subject demographics

OnCore allows you to make changes to a subject's demographic and contact information such as:

- **Additional Subject Identifiers**

  This section lists identifiers for the subject other than the MRN. An example of an additional subject identifier is a Hospital ID from another system.

- **Contact Information**

  This section is where you can add contact information, such as address, phone number, and e-mail address.

- **Emergency Contacts**

  This section is where you record the subject's emergency contacts. You can record more than one emergency contact by using the **Add** button.

1. Add an additional contact to the **Emergency Contacts** section:

   - **Name**: <your choice>
   - **Street Address**: 12345 Serenity Lane
   - **City**: Gainesville
   - **County**: Alachua
   - **State**: Florida
   - **Country**: USA

2. Click **Add**.

3. Click **Submit** and **Close**.

> *In production, add other data fields as instructed by your department.*

Subject statuses

Subjects in OnCore can progress through several statuses during the course of the protocol.

The vertical tabs in the Subject Console (Consent, Eligibility, On Study, Treatment, Follow-Up) allow you to record this status information.

The Subject Console **header** also displays the subject's status. The "normal" sequence of statuses for a subject:

Start-up

- **Consented**: Subject has at least one consent signed date entered and linked to a consent as added in the PC Console to the subject's study site.

Eligibility

- **Eligible**: Eligible status has been entered with associated verified date.
- **Ineligible**: Ineligible status has been entered with associated verified date.
- **Eligible(O):** Patient was ineligible but PI approved an eligibility override and Eligible(O) status has been entered with associated verified date.

Enrolled

- **On Study:** Subject is considered accrued when the **On Study Date** is entered in OnCore.
- **On Treatment**: Subject is considered **On Treatment** when associated with a Treatment Arm and an On Treatment date is entered.
- **Off Treatment**: An **Off Treatment Date** is entered for the subject
- **On Follow-up:** A **Follow-up Start Date** is entered for the subject
- **Off Study:** An **Off Study Date** is entered for the subject

Other statuses

- **Expired**: An **Expired Date** is entered for the subject
- **Consent Refused:** Subject is never considered consented, therefore, the subject either remains at New status or if allowed to proceed, skips over the Consented status.
- **Consent Waived**: The protocol meets federal regulations such that consenting is waived. Subjects will be considered "consented" when this status is used.
- **Consent Withdrawn**: The subject initially consented, but withdrew consent. Depending on procedures, often subject is taken Off Study.

OnCore-Epic Interface for Subject Registration/Statuses

One of the OnCore-Epic interfaces that has been implemented at UF is the **Subject Registration** interface. This interface associates OnCore subjects to the corresponding research study in Epic and automatically updates Epic subject statuses throughout the subject lifecycle.

For studies that are in both OnCore and Epic, subject registration and status updates should **only be made in OnCore.**

The only exception is for the newer Epic-only **Pre-Consent status** and **Long Term Follow Up status** - See http://ctsi-clinicalresearch-intranet.sites.medinfo.ufl.edu/oncore-user-guides/oncore-epic-interfaces/rpe/ for more information.

Important!

When registering a subject or updating a subject status in OnCore, make sure that you do <u>NOT</u> have the corresponding study or patient record open in Epic.

If the Epic record is open, the subject status will <u>NOT</u> update from OnCore.

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Record the subject's consent

*If you are not already in your subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink **MRN** of your subject (make sure the "Accrued" drop-down is set to "All").*

1. Click on the **Consent** vertical tab. *Click Update if needed.*

2. In the **Available Consents** section at the top, click **Select Consents.**

3. A list opens, showing available consent forms that have been approved and added at the protocol level via PC Console > Reviews > IRB record.
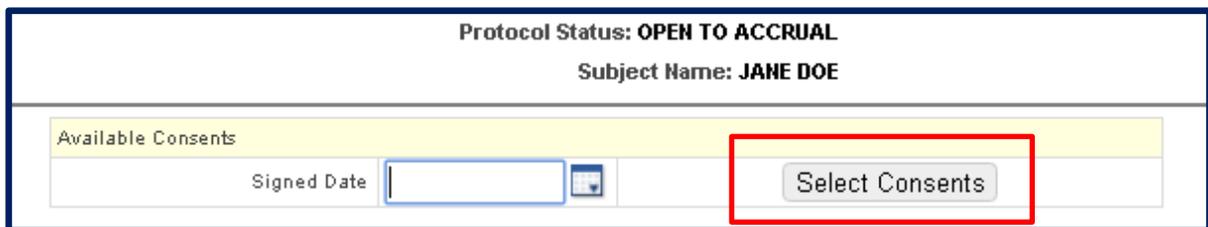
Protocol Status: **OPEN TO ACCRUAL**

Subject Name: **JANE DOE**

Available Consents

Signed Date [   ] [▦]   [Select Consents]

4. If there are multiple versions of the consent, you will see a tiny **"+"** sign in the **Type** column. **Click it!**

5. On the most recent version, enter **y-1** in the **Signed Date** field and select **Accepted.**

6. Click **Save**.

Now the consent form information appears along with the subject's signed date in the **Existing Consents** section.

Note that the **Subject Status** field at the right top of the page has been updated to CONSENTED.

7. Click **Close**.

If this study is in both OnCore and Epic, and as long as you do not have the Epic record open for this patient, the ***Epic*** research enrollment status for this patient will now automatically be updated to "**Active-Consented**".

Subject Console screenshot showing:

★ Subject Console

Protocol No.: OCR17117
Subject MRN: E4418096
Protocol Status: OPEN TO ACCRUAL
Subject Name: RASPBERRY ONCORE
Subject Status: CONSENTED
Sequence No.:

Subject Registration Notice

Switch Subject — Type here to search
Summary
Demographics
Consent
Eligibility

Consents

Type	Description	Version Date	Approved Date	Expiration Date	Signed Date	Status
Informed Consent		01/01/2018	01/01/2018	12/31/2018	01/01/2018	Accepted

Other Consent Status — No Information Entered

Update

Raspberry Oncore was consented in OnCore. OnCore sent an interface message to Epic and Epic filed that status. The subject now has an 'Active – Consented' enrollment status in Epic.

Research Studies

Add a new study to list — Add

Show: ☑Inactive ☑Pre-consent ☑Deleted

Active - On Study
Charge master
Study Code: OCR17117
Principal Investigator: Nelson, David R, MD
NCT #: 12345678
Start Date: 01/01/2018
IRB #: IRB201800001
Study Type: Interventional

Additional Info Past Updates

Study Description — Charge Master

Patient Timeline and Associated Encounters

Display Options: By Patient Timeline / ⊙ By Encounter Date
No encounters have been associated with the study.

Add to Timeline

Past Updates

Updated	Status	Branch	Coordinators	Start Date	End Date	Modifying User	Source
07/09/2018 10:14 AM	Active - On Study			01/01/2018		Interface, Clinical Trials And Research Study	Interface
07/09/2018 10:14 AM	Active - Eligible			01/01/2018		Interface, Clinical Trials And Research Study	Interface
07/09/2018 10:11 AM	Active - Consented			01/01/2018		Interface, Clinical Trials And Research Study	Interface

REMINDER!

When recording a subject's consent in OnCore, make sure that you do NOT have the corresponding study or patient record open in Epic.

If the Epic record is open, the subject status of "Consented" will NOT update from OnCore.

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The Subject Calendar

Earlier, we viewed the generic protocol calendar for this study. Now let's explore how this calendar morphs into a subject-specific calendar as we start entering subject-specific milestone dates and checking in visits.

View the subject calendar

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

2. The Subject Console opens on the Calendar tab:

Procedure Toggle Full Screen	Forms	Treatment			Follow Up							
		Baseline 1@1Days	Off Treatment 1:2@2Weeks		In-clinic Follow-Up				Annual Follow Up			
		1	2	3	1	2	3	4	5	6	7	8
		Screening	W1	W2	M6	M12	M18	M24	Y3	Y4	Y5	Y6
Planned Date		10/01/2016										
Visit Status												
Visit Date												
Adverse Events		X			X	X	X	X	X	X	X	X
Physical Exam		X		X								
Blood Chemistries Amylase; LDH ; Sodium; Uric Acid			2X		2X	2X	2X	2X				
Lipid Profile (Lipid Panel)			X		X	X	X	X				
Study Drug administration												
MRI												
Tumor biopsy												
Survival Status		X							X	X	X	X
Phlebotomy / Blood collection												

Procedure column - In the first column, each row following **Visit Date** displays the name of a lab, panel, or procedure.

Planned Date row -This row displays the subject's scheduled visit dates. Hovering your cursor over the end of any date in this row reveals the day of the week (and any visit tolerances).

Visit Dates - Listed below each visit date are the labs, panels, and procedures scheduled for that date, indicated by an **X**. If the procedure is supposed to take place multiple times on a visit, there is a number inserted before the **X**, indicating the number of times the procedure will take place (such as **2X**).

3. Notice that only **Baseline/Screening** segment of the calendar has a projected date populated. This calendar segment is triggered by the "**Consent Signed**" milestone date, which we have just entered for our subject.

Track Visits

Typically, subject visits and milestones can be invoiced to the sponsor as soon as they are checked in (marked as **Occurred**) by the study team. Study team members use the CRA Console and Subject Console to document subject information and track subject visits.

Invoiceable items and visit variations can be generated when:

- Subject visits are checked in as **Occurred**
- Subject visits are marked as **Missed**
- Additional procedures are performed during a subject visit
- Additional (unscheduled) subject visits occur
- Pass-thru procedures are performed during a subject visit
- Subject events are recorded (e.g. OSRs, SAEs, or screen failures)
- Subject statuses are achieved (e.g. a subject reaches a status of **On Study**)

<div>

Remember!

When registering a subject or updating a subject status in OnCore, make sure that you do <u>NOT</u> have the corresponding study or patient record open in Epic.

If the Epic record is open, the subject status will <u>NOT</u> update from OnCore.

</div>

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Subject milestone dates

How does a **Milestone Date** get entered in order to trigger a calendar segment? Once you register a subject to the study, there will be OnCore pages that have fields for you to enter these dates as each subject reaches those milestones.

For our sample study, the **Milestone Start Dates** we will need are:

- **Consent Signed Date** - Entered on **Menu > Subject Console > Consent** page

- **On Treatment Date** - Entered on **Menu > Subject Console > On Treatment** page

- **Off Treatment Date** - Entered on **Menu > Subject Console > Follow Up** page

- **Follow-Up Start Date** - Entered on **Menu > Subject Console > Follow Up** page

Now let's practice checking in visits and entering a subject's milestone dates.

Check in the screening visit

*If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console**, select your protocol and then the blue hyperlink __MRN__ of your subject.*

1. If needed, click the **Calendar** vertical tab.

2. Click the **Screening** visit link.

The **Subject Visit Update** page opens. The first field on this page is the **Visit Date**. The date in this field defaults to the **Planned Date** shown on the calendar. You can change this date as necessary. Note: If there are Tolerances set for this visit and your new date falls out of the Tolerance you will get a warning message.

Next to the Visit Date is the **Visit Status** box. By default, **Planned** is selected.

3. Click **Occurred** to verify the visit.

4. Click **Submit And Close** to return to the Subject Calendar.

On the Subject Calendar, the Screening Visit Status is **Occurred** and the Visit Date field has been entered.

		Treatment
Procedure Toggle Full Screen	Forms	Baseline 1@1 Days
		1
		Screening
Planned Date		10/01/2016
Visit Status		Occurred
Visit Date		10/01/2016
Adverse Events		X

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Record the subject's eligibility

The next thing that would happen to our sample subject is that we would use the screening visit data to determine if he is eligible for our study. Once we have confirmed that he is, we will record the **eligibility milestone date** in OnCore and place him on the study.

*If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink **MRN** of your subject.*

1. Click on the **Eligibility** vertical tab. *Click Update if needed.*

2. Enter the following:

    - **Version Date**: The date of the document used to verify eligibility (ex. IRB Approved ICF)
    - **Eligibility Status:** Eligible
    - **Verified By**: *your initials*
    - **Status Date**: **t-300**

3. Click **Submit**.

    Note that the **Subject Status** field at the right top of the page has been changed to ELIGIBLE.

    Any sponsor invoicing that has been set up to use "Eligible" as a milestone will be triggered.

4. Click **Close**.

If this study is in both OnCore and Epic, and as long as you do not have the Epic record open for this patient, the ___Epic___ research enrollment status for this patient will now automatically be updated to "**Active-Eligible**".

Raspberry OnCore was then marked Eligible in OnCore. OnCore sent an interface message to Epic and Epic filed that status. The subject now has an 'Active – Eligible' enrollment status in Epic.

Remember!

When registering a subject or updating a subject status in OnCore, make sure that you do <u>NOT</u> have the corresponding study or patient record open in Epic.

If the Epic record is open, the subject status will <u>NOT</u> update from OnCore.

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Place the subject on the study

*If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink [MRN](#) of your subject.*

The only required field on the **On Study** form is the **On Study Date**, however the **Sequence No.** is strongly recommended.

1. Click on the **On Study** vertical tab. *Click Update if needed.*

2. Enter the following data fields in the top Subject On Study Update table:

- **Sequence No.:** *<your initials>*-Subject-10 *<In production, the Sequence No: is the typically the subject's "alias" or study-specific identifier provided either by the study sponsor or by your UF study management team.>*

- **On Study Date: t-300**

- **ZIP at Registration [REQUIRED]: 32606**

3. Click **Submit.**

4. In the **Subject Staff** table at the bottom, enter the following:

- **Role:** Primary Study Coordinator
- **Staff Name:** *Add your **training name** (look at the top right of the console)*
- **Start Date: t-300**

OCR recommends that **Enrolling Faculty** and/or **Consenting Individual** if they are different be included as well.

5. Click **Add**.

6. Click **Team** to see a pop-up list of all staff assigned to this protocol. In training, select a couple of the staff with the last name of "Rules".

Note: In PRODUCTION, you should ensure that you add anyone to the subject staff who is working with this subject in OnCore. They will then be able to see this subject on their Home Page Subjects widget and on **My Console**.

7. Click **Submit.**

If this study is in both OnCore and Epic, and as long as you do not have the Epic record open for this patient, the ***Epic*** research enrollment status for this patient will now automatically be updated to "**Active-On Study**".

Remember!

When registering a subject or updating a subject status in OnCore, make sure that you do <u>NOT</u> have the corresponding study or patient record open in Epic.

If the Epic record is open, the subject status will <u>NOT</u> update from OnCore.

Place a subject on treatment

If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** *select your protocol and then the blue hyperlink MRN of your subject.*

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

2. Click **Add**.

3. Enter the following information:

- **Arm:** Arm A or Arm B
- **On Arm Date**: **t-300**
- **On Treatment Date**: **t-300**

4. Click the teeny tiny **Save** button. Notice that the Subject Status in the upper right of the page changed to **ON TREATMENT**.

If this study is in both OnCore and Epic, the Epic research enrollment status for this patient will now automatically be updated to "**Active-On Treatment**".

Remember!

*When registering a subject or updating a subject status in OnCore, make sure that you do **NOT** have the corresponding study or patient record open in Epic.*

*If the Epic record is open, the subject status will **NOT** update from OnCore.*

---

5. Click on the **Calendar** vertical tab.

Notice that the treatment segment of this subject's calendar now has date populated. These dates were triggered by the "**On Treatment**" milestone date you entered.

Procedure Toggle Full Screen	Forms	Baseline 1@1Days	On Treatment 6 Cycles @28Days										
		1	2	3	4	5	6	7	8	9	10	11	12	13
		Screening	C1D1	C1D15	C2D1	C2D15	C3D1	C3D15	C4D1	C4D15	C5D1	C5D15	C6D1	C6D15
Planned Date		10/01/2016	10/01/2016	10/15/2016	10/29/2016	11/12/2016	11/26/2016	12/10/2016	12/24/2016	01/07/2017	01/21/2017	02/04/2017	02/18/2017	03/04/2017
Visit Status		Occurred												
Visit Date		10/01/2016												

Enter a missed visit

*If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink MRN of your subject and click the **Calendar** vertical tab.*

1. Click the **C1D1** visit link.

2. Verify the visit by clicking the **Missed** button in the **Visit Status** box, and then click **Submit And Close**.

   The Subject Calendar opens, displaying the Visit Status and Visit Date in red.

Procedure Toggle Full Screen	Forms	Treatment		
		Baseline 1@1Days	On Treatment 6 Cycles @28Days	
		1	2	3
		Screening	C1D1	C1D15
Planned Date		10/01/2016	10/01/2016	10/15/2016
Visit Status		Occurred	Missed	
Visit Date		10/01/2016	10/01/2016	
Adverse Events		X	X	

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Enter a rescheduled visit

*If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink [MRN](#) of your subject and click the **Calendar** vertical tab.*

1. Click the missed visit link **[C1D1](#)**.

2. Click **Delete,** and then click **OK**.

   Note that this has undone (or removed) the visit information, allowing you to go back and mark the visit as Occurred.

3. Click the **[C1D1](#)** link again, and then click **Occurred** in the Visit Status box (which resets the date to the default).

4. In the **Visit Date** field, change the date to **one day later**.

5. In the **Reset Calendar?** field, select **All Visits**.

6. Click **Submit And Close**.

   The Subject Calendar opens, showing the Visit Status as **Occurred** and displaying the Visit Date that you entered.

   Note that all subsequent planned dates have been adjusted to one day after their previous values.

Enter a N/A visit

*If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink **MRN** of your subject and click the **Calendar** vertical tab.*

1. Click the **C1D15** link and then click **N/A** in the **Visit Status** box.

   N/A indicates that this visit does not apply to this subject. Marking a visit N/A will create a visit variation in the Financials Console.

2. Click **Submit And Close**.

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Enter visit procedure variations

1. Click the **C2D1** visit link (remember this date!).

The **Procedures** table at the bottom of the screen lists the labs, panels, and procedures that have been scheduled within the visit. Unless they are marked as Missed or N/A, it is assumed that if the visit has occurred and that the procedures have been performed on that Visit Date, unless otherwise indicated by editing the Procedure Date.

Procedure	Procedure Date	SOC	SOC Modifier	Missed	Missed Count	N/A	Location
Adverse Events		☐		☐		☐	
Blood Chemistries [Amylase; LDH ; Sodium; Uric Acid]		☐		☐	of 2	☐	
Lipid Profile (Lipid Panel) [Cholesterol ; HDL; LDL; Triglycerides]		☐		☐		☐	
Study Drug administration		☐		☐		☐	

- **Procedure Date -** Enter a date only if it is different than the Visit Date.

- **SOC –** This box is selected if the procedure is a Routine Cost billable to the patient/Insurance, as carefully determined by the Coverage Analysis performed earlier. **Warning! Do not change the state of this checkbox!**

- **SOC Modifier –** Shows applicable Q1, Q0, modifier or Unknown.

- **Missed -** Select this checkbox if the procedure was missed during the visit.

- **Missed Count -** You can have the calendar schedule a procedure to happen multiple times during a visit. If some of those procedures were missed, indicate how many in the Missed Count field.

- **N/A -** Select this checkbox if the procedure was not applicable for this visit.

- **Location -** This field is only available when the Cost Center configuration is enabled.

2. Click the **Missed** checkbox for the **Lipid Profile.**

3. Enter the reason for the variation in the pop-up box.

4. Click **Occurred** to verify the visit.

5. Click **Submit And Close** to return to the Subject Calendar.

Enter additional procedures to a visit

*If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink MRN of your subject and click the **Calendar** vertical tab.*

1. Click the **C2D1** visit link again.

2. Click **Additional Procedures** at the bottom of the screen.

    A pop-up window opens with multiple horizontal tabs:

    *   **Charge Master –** Used exclusively by the Office of Clinical Research.

    *   **Protocol Procedures -** This tab lists the labs, panels, and procedures that have been assigned to the protocol, along with their associated forms.

    *   **Free-text Procedures –** If the unexpected procedure is not already in the protocol list, you can add by typing the new procedure in the box.

3. In the Protocol Procedures tab, select the checkbox for the **Phlebotomy** procedure, and click **Submit**.

4. In the pop-up box, enter a reason for adding the procedure. Click **OK**.

    You will return to the Subject Visit Update page. Note that the new procedure is listed in the lower table. If necessary, you can click Delete to delete the visit if visit data has been recorded in error.

5. Click **Submit And Close** to return to the Subject Calendar.

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Enter additional and/or unexpected subject visits

At times, subjects will be seen for visits that are not on the schedule. These visits can be recorded on the Additional Visits vertical tab.

*If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console**, select your protocol and then the blue hyperlink **MRN** of your subject.*

1. Click the **Additional Visits** vertical tab.

2. Click **New**.

3. Enter the following data:

- **Visit Date**: **m-9**

- **Visit Description**: Possible Adverse Event.

- Click **Submit,** the **Additional Procedures** button will appear.

- Click **Additional Procedures** at the bottom of the screen.

- Select the checkbox for the **Physical Exam, Phlebotomy,** and **Blood Chemistries**, and click **Submit**.

- Enter "Possible Adverse Event" in all three of the **Reason for adding** pop-up window fields and hit **OK**.

- Click **Submit And Close**.

NOTE: Additional visits do not appear on the subject calendar.

Check in more subjects visits

*If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console**, select your protocol and then the blue hyperlink **MRN** of your subject and click the **Calendar** vertical tab.*

1. Check these visits in as "Occurred", **make one of these visits fall outside the visit Tolerance -/+1**:

   - **C2D15, C3D1,** and **C3D15**.

Good to Know!

The *Summary* button at the top of the page allows you to limit the number of visits that appear. This option is useful when several visits appear on the page, requiring you to scroll to the right to view the first unverified visits.

Clicking **Summar**y allows only the most recently verified visit and a number of unverified visits to appear.

Clicking **Full Calendar** returns you to the full calendar view.

View orphaned visits

The Calendar tab contains two horizontal tabs: Calendar and **Orphaned Visits**. Clicking the Orphaned Visits tab displays any visits that were checked in on an older version of the subject's calendar, but aren't on the subjects current calendar version (likely due to a schedule change in the most recent version).

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Record a subject deviation

*If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink **MRN** of your subject.*

1. Click the **Deviations** vertical tab.

The table at the top of the page shows the subject's deviations. The bottom table shows any visits with a visit date outside of the planned date's tolerance. This table is for informational purposes and you can use it as a guide for entering deviations if needed.

2. Click **New** to create a deviation.

The Date Discovered and Reported By fields default to the current date and user, but they can be changed. When entering Deviation data, the required fields are marked with an asterisk.

3. Enter the following:

1. **Date Discovered**: m-8
2. *Reported By*: *keep the default (your user name)*
3. **Deviation Date:** m-9
4. **Category:** Treatment
5. **Description of Deviation:** Missed lipid panel on the visit

4. Click **Submit** to create the deviation.

Other information can be entered to record when it should be reported to IRB, the date it was reported, and the date it was reported to the sponsor.

5. Click the **Deviations** vertical tab to see the updated page.

The Delete link allows you to delete a deviation record entered in error.

Record a Serious Adverse Event (SAE)

The SAEs tab in the Subject Console records any serious adverse events associated with a subject. SAEs must be entered at the subject level; however, SAEs can be viewed across all subjects at the protocol level in the CRA Console.

*If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink [MRN](#) of your subject.*

1. Click the **SAEs** vertical tab.

2. Click **New**.

3. In the **Subject SAE Update** section, type the following information in the required fields listed below:

   - Event Date: **m-9**
   - Reported Date: **m-8**
   - Protocol Attribution: Possible
   - Outcome: Recovering/Resolving

4. The following optional sections of an SAE allow you to track additional details, if desired:

   - **SAE Classification -** Allows you to select one or multiple SAE classifications from a drop-down list.

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- **Adverse Event Details -** This section is optional, but if information is entered in this section, all required fields must be filled before clicking Add.
- **Tracking Details -** Records the dissemination of information regarding the SAE.
- **Additional SAE Identifiers -** Records other identifiers for the SAE, such as a number assigned by the IRB. An Identifier Type can be selected from the drop-down list and free text can be entered into the Identifier and Identifier Owner fields.
- **Supporting Documents -** Allows you to upload files relevant to the SAE.

5. Click **Submit**.

Upon submission, an Event Number will be assigned to the SAE. This unique number appears at the top of the page.

6. SAEs can be locked when you are finished to prevent edits to all but the Tracking Details section. Click **Complete and Lock** at the bottom of the screen.

NOTE: Even though the SAE has been locked, you have the ability to update the Tracking Details section of the SAE and to create a follow-up SAE.

Record a follow-up SAE

OnCore allows you to create a follow-up to an existing SAE. The follow-up SAE copies most of the parent record's information; you can then make modifications as needed (most commonly this involves changes to the Outcome field).

*If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink MRN of your subject.*

1. Select the **SAEs** vertical tab and click on the SAE's **Event No.** link.

2. Click **Create Follow-Up** at bottom of the screen.

A follow-up SAE is created and a new Event No. is assigned to this SAE. The Event No. of the *parent* SAE appears next to it in parentheses. The Follow-Up Number appears on the right side of the header band.

3. Enter the following:

6. **Reported Date**: m-8
7. **Outcome**: Intervention for AE Continues

4. Click **Submit** to save your entries, and then click the **SAEs** vertical tab.

You can see that the Event No. of the SAE shows its relationship to the parent.

Place a subject on off-treatment, off study, or follow-up

*If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink MRN of your subject.*

1. Click on the **Follow-Up** vertical tab. *Click Update if needed.*

2. Enter a date in the relevant **Off Treatment, Off Study, or Follow-Up** date fields. Once the date has been entered that segment of the calendar will populate with planned visit dates.

3. Click **Submit.**

If this study is in both OnCore and Epic, the Epic research enrollment status for this patient will now automatically be updated to either "**Active – Off Treatment**", "**Active - On Follow-up**" or "**Inactive – Off Study**", as applicable.

> **Remember!**
>
> ***When registering a subject or updating a subject status in OnCore, make sure that you do NOT have the corresponding study or patient record open in Epic.***
>
> ***If the Epic record is open, the subject status will NOT update from OnCore.***

Document monitor visits

Subject staff can now alert financial staff when monitor events have taken place and are ready for inclusion on an invoice to the sponsor by documenting a financial event in the CRA Console.

1. To add a financial event, navigate to the **CRA Console > Financial Events** tab and click **Update**.

2. Select the event from the drop-down list for the Financial Event field. The events that appear in the drop-down list are configured by the pre-award coordinator in the Financials Console.

3. Add any comments. Comments entered here are visible for the financial team in the Financials Console.

4. Click **Add** to submit the event.

After an event is submitted, it appears on the Financials Console > Invoiceable Items tab in the Protocol Items section. A **?** icon appears in the Triggering Event column for events with comments, and the financial team can hover over the icon to view the comments.

My Console

Designed specifically to assist subject staff in managing subject visits across all of the staff's protocols. It provides a means to view and verify visits without having to access each subject individually from the CRA Console and Subject Console. Capabilities include:

- View all protocols to which you are currently assigned as Protocol Staff. In order for a protocol to be listed in My Console, you must be listed as a current Protocol Staff

- View all subjects to which you are currently assigned as Subject Staff

- View a list of occurred and pending visits for Subjects assigned to you

- Check-in non-verified visits currently assigned to you
- Mark occurred visits currently assigned to you as completed, submitted, and/or monitored.

My Calendar vertical tab displays a monthly, weekly or daily calendar with the visits of your currently assigned subjects and/or all subjects in your currently assigned protocols.

NOTE: Only subjects where you assigned as a current Subject Staff will appear in My Console. Staff assignments are done in the Subject Console under the On Study tab.

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.