

# University of Florida – End User Subject Management Training

## IMPORTANT INFORMATION FOR SUBJECT MANAGEMENT:

1. Entry of visit information is expected to be documented in OnCore **within 10 business days** of the actual visit/procedure.
2. If you have any issues with Subject Management in the Production environment for OnCore, please contact: [OnCore-Support@ahc.ufl.edu](mailto:OnCore-Support@ahc.ufl.edu).
3. When checking in subject visits and adding Additional Procedures, if a procedure is not listed, please contact [OnCore-Calendars@ahc.ufl.edu](mailto:OnCore-Calendars@ahc.ufl.edu) to have it added.

## Training Steps:

### Opening your protocol

1. Log into OnCore using your credentials.
2. Navigate to the CRA Console. Click **Menu > Subjects > CRA Console**.
3. In the Select Protocol field enter your Protocol number.

**NOTE:** (The Protocol number will be given during training.)

### Registering (Adding) a subject to the protocol

1. Click **Register Subject**.
2. Enter the following information in the Find Subject section:
  - a. **Study Site:** UF Gainesville
  - b. **Patient MRN:** 123
3. Click **Find** or hit **Enter**.

4. OnCore will search the subject with the key string of 123 in the patient's MRN. Click on a **Subject's MRN**.
5. Click **Add**.

**NOTE:** If subject is not found during Find Subject workflow, please use the workflow below for Creating a new Subject.

### Creating a new subject on the protocol

On the Register Subject Page:

6. Click **Create New**.
7. Enter the Subject Details. (The fields that have an asterisk (\*) are required fields and must be filled in to continue.)
8. After all required fields are filled in, click **Add**.

### Updating Subject Statuses

1. Click the **Consent** tab and enter the following:
  - a. Enter Signed Date: **w-15**
  - b. Click **Select Consents** (Or hit Enter)
  - c. Click **Accepted** radio button for both consents
  - d. Click **Save**
2. Click the **Eligibility** tab and enter the following:
  - a. Enter Eligibility Status: **Eligible**
  - b. Enter **Version Date** of **w-20**
  - c. Enter your initials for **Verified By**
  - d. Status Date: **w-14**
  - e. Click **Submit**
3. Click the **On Study** tab and enter the following:
  - a. Enter On Study Date: **w-13**
  - b. Enter in a Sequence No. For training, enter **Your initials + 12345 (ABC12345)**
  - c. Select a Primary Diagnosis
  - d. Diagnosis Date: **w-30; Approximate**
  - e. Enter Subject Staff:
    - i. Role: Affiliate Coordinator
    - ii. Staff Name: Your name
    - iii. Click **Add**
  - f. Click **Submit** to save

4. Click the **Treatment** tab and enter the following:
  - a. Click **Add** (in the upper right corner)
  - b. Select an Arm: **Arm 1**
  - c. Enter On Arm date: **w-12**
  - d. Enter On Treatment date: **w-12**
  - e. Click **Save**

### Tracking subject visits

1. Navigate to **Subject Console > Calendar**.
2. Click the **Screening Visit**.
  - a. Change Visit Status to **Occurred**
  - b. Click **Submit and Close**
3. Click the **Baseline** visit.
  - a. Change Visit Status to **Occurred**
  - b. Click **Submit and Close**
4. Click the **Arm1: Treatment Visit – Week 1** visit.
  - a. Change Visit Status to **Occurred**
  - b. Mark the Lipid Profile as **Missed**
  - c. Add in the reason why along with your name or ID
  - d. Click **Submit and Close**

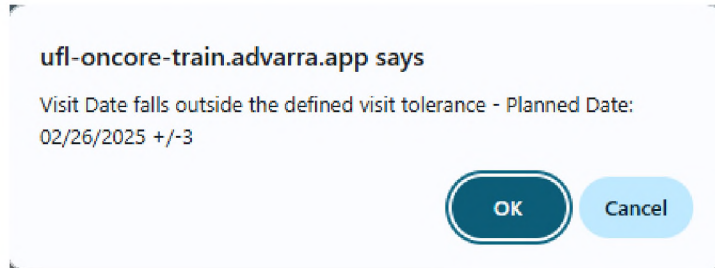
Procedure	Procedure Date	SOC	SOC Modifier	Missed	Missed Count	N/A	Location
Epic Timeline Management		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Physical Exam		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Weight		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Blood Chemistries #05,NA? [Amylase; LDH ; Sodium; Uric Acid]		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Hematology INV		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
PTT, PT/INR		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Lipid Profile (Lipid Panel) [Cholesterol ; HDL; LDL; Triglycerides]		<input type="checkbox"/>		<input checked="" type="checkbox"/>		<input type="checkbox"/>	
Study Drug administration		<input type="checkbox"/>					
Echocardiogram		<input type="checkbox"/>					
6MWT		<input type="checkbox"/>					
MRI		<input type="checkbox"/>					
Adverse Events		<input type="checkbox"/>					
Concomitant Medications		<input type="checkbox"/>					
Patient Diary		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
PK Substudy (optional) #02,NA?		<input type="checkbox"/>		<input type="checkbox"/>		of 5	<input type="checkbox"/>
Subject Stipend BUD		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	

Lipid Profile (Lipid Panel) Reason for Change

Missed Subject was lightheaded - Name/ID

67 character(s) remaining

5. Click the **Arm1: Treatment Visit – Week 2** visit.
  - a. Change Visit Status to **Occurred**.
  - b. Change the Visit Date to four (4) days after the planned visit date.
  - c. Click **Submit and Close** .



**NOTE:** OnCore will have a dropdown that tells you that the visit is outside of tolerance.

6. Click **OK**.

**NOTE:** These visits will be automatically logged in the Visit Variations tab in the Subject Console.

### Unscheduled Visits

**IMPORTANT:** Unscheduled Visits will be built out using Optional Segments. When all Optional Segments have been used, please create Additional Visits when needed. (Both workflows are listed below.)

1. Click **Manage Optional Segments**.

Calendar		Orphaned Visits		
Freeze Panes		Summary		Manage Optional Segments
<b>Current Subject Calendar Version - V1</b>				
Procedure <a href="#">Toggle Full Screen</a>	Forms	Treatment		
		Screening Visit 1@14Days 1	Baseline 1@1Days 2	Treatment Visits - ARM1 1,8,15,22,29,36,43,50,57,64,71,78
		<a href="#">Screening_Visit</a>	<a href="#">Baseline#03</a>	<a href="#">ARM1: Treatment Visit - Week 1</a>
Planned Date		01/29/2025	02/12/2025	02/19/2025
Visit Status		Occurred	Occurred	Occurred
Visit Date		01/29/2025	02/12/2025	02/19/2025

2. In the modal window, select **Unscheduled Visit #1**.

### Manage Optional Segments

Select the optional segments to include in the subject's calendar.

**Consent Signed**

Segment Name	Select?
Rescreening Visit	<input type="checkbox"/>

**On Study**

Segment Name	Select?
Unscheduled Visit #1	<input checked="" type="checkbox"/>
Unscheduled Visit #2	<input type="checkbox"/>
Unscheduled Visit #3	<input type="checkbox"/>

3. The **Unscheduled Visit** will appear on the subject calendar to be checked in.

Calendar
Orphaned Visits

Freeze Panes
Summary
Manage Optional Segments

**Current Subject Calendar Version - V1**

	Forms	Treatment			
		Screening Visit 1@14Days	Baseline 1@1Days	Unscheduled Visit #1 (Opt) 1@1Days	Treatment Visits - ARM1 1,8,15,22,29,36,43,50,57,64,71,7
		1	2	3	4
		<a href="#">Screening Visit</a>	<a href="#">Baseline#03</a>	<a href="#">Unscheduled Visit</a>	<a href="#">ARM1: Treatment Visit - Week 1</a>
Planned Date		01/29/2025	02/12/2025	02/12/2025	02/19/2025
Visit Status		Occurred	Occurred		Occurred
Visit Date		01/29/2025	02/12/2025		02/19/2025
Epic Timeline Management		X	X	X	X
Informed Consent		X			
Physical Exam		X	X	X	X
Height		X			
Weight		X	X	X	X

4. Please check in the visit as appropriate using the same workflow as above.

**IMPORTANT:** If additional procedures must be added please follow the steps from the next section.

### Adding Additional Procedures to a Visit

**IMPORTANT:** Add Protocol Procedures only. If what you need is not there, please contact [OnCore-Calendars@ahc.ufl.edu](mailto:OnCore-Calendars@ahc.ufl.edu).

1. Click on the **Arm1: Treatment Visit – Week 3** visit.
2. Mark the visit as **Occurred**.
3. Click **Submit** at the bottom of the page. Clicking Submit (and not Submit and Close) will save the information on the page while keeping you on the page.
4. New buttons will appear:
  - a. Additional Procedures
  - b. Billing Slip
  - c. Delete
5. Click **Additional Procedures**. This will open a pop-up window with procedures to be added.

6. Select the event(s) that need to be added and click **Submit**.
7. Add the reason(s) for adding the additional procedure with your name/ID.

## Adding an Additional Visit and Additional Procedures

This option should only be used when the Optional Segments (Unscheduled Visits) are all used up.

1. Click the **Additional Visits** tab in the Subject Console.
2. Click **New**.
3. Enter in the **Date** and the **Visit Description**.
4. Click **Submit**.

**Subject Visit Update** User: Erick Sperloen

Protocol No.: OCR47320      Protocol Status: OPEN TO ACCRUAL      Subject Status: ON TREATMENT  
Subject MRN: 11231      Subject Name: Cardinal Oak      Sequence No.: EWS98765

**Visit Details**

Visit Date: 02/21/2025

Visit Description: "Reason for adding visit here"

Data Collection Completed Date:      Monitored Date:      Submitted Date:      Locked Date:      Collection Location:      Collection Time (minutes):

Clinical Comments:   
1000 character(s) remaining

Data Comments:   
1000 character(s) remaining

**Procedures**

Procedure	Procedure Date	SOC	SOC Modifier	Missed	Missed Count	N/A	Location
No Procedures Found							

Clear    **Submit**    Close  
Submit And Close

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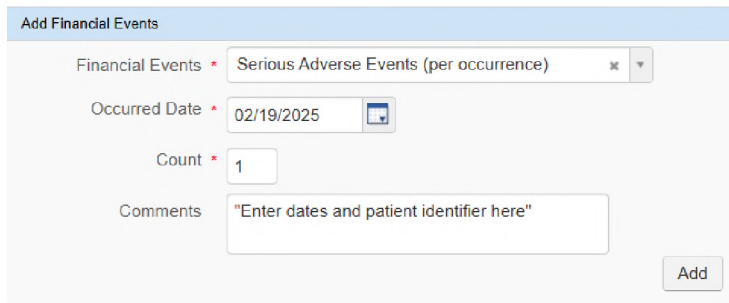
5. Click **Additional Procedures**.
6. Select the Protocol Procedures that need to be added.
7. Click **Submit**.
8. Click **Submit and Close**.

**NOTE:** Adding Additional Procedures is the same workflow when adding either to a scheduled visit or an Additional (Unscheduled) Visit.

## Adding an SAE (Serious Adverse Event) and other Financial Events

The example below only shows SAEs, however other Financial Events will need to be manually triggered in the CRA Console such as (but not limited to): Monitor Visits, Safety Reports, Auditing, After-hours Support, PI Training, etc. All of the steps remain the same after you choose one of the options.

1. When you are in the CRA Console, click **Financial Events**.
2. Click **Update**.
3. Choose **Serious Adverse Events (per occurrence)**.



**Add Financial Events**

Financial Events \* Serious Adverse Events (per occurrence) x v

Occurred Date \* 02/19/2025

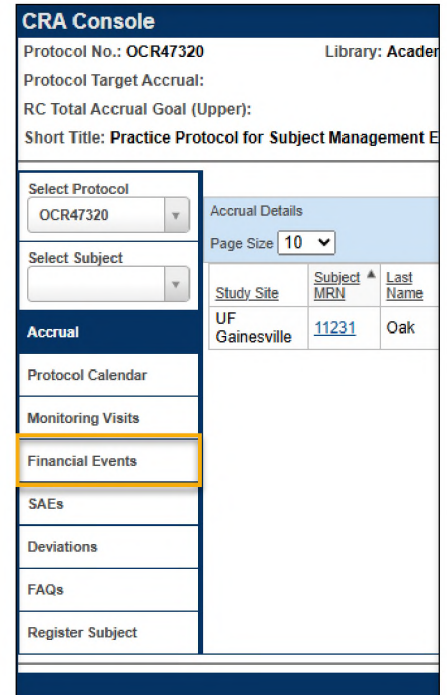
Count \* 1

Comments "Enter dates and patient identifier here"

Add

4. Click **Add**.

**IMPORTANT:** SAEs will only be billed when they are closed/done and they have been fully adjudicated.



**CRA Console**

Protocol No.: OCR47320 Library: Acader

Protocol Target Accrual:

RC Total Accrual Goal (Upper):

Short Title: Practice Protocol for Subject Management E

Select Protocol: OCR47320

Select Subject:

Accrual Details

Page Size: 10

Study Site	Subject MRN	Last Name
UF Gainesville	11231	Oak

Accrual

Protocol Calendar

Monitoring Visits

Financial Events

SAEs

Deviations

FAQs

Register Subject

WHAT IF SCENARIO: What if all the procedures are not completed on the visit date

**IMPORTANT:** If there is a visit that does not have all of the procedures completed on the Visit Date, document the procedures that were completed with the correct date, and mark the Visit Status as **Planned**. When the rest of the procedures have been completed, mark the Visit Status as **Occurred**.

1. Mark the Visit Status as **Planned**.

Phase: Treatment Visit: ARM1: Treatment Visit - Week 4 History

Visit Date: 03/12/2025

Visit Status:  Planned  Occurred  Missed  N/A

Visit Tolerance: +/-3

2. Enter the Procedure Dates for all completed procedures. (See image below.)

Procedure	Procedure Date
Physical Exam	03/12/2025
Weight	03/12/2025
Urine pregnancy Test #01,NA?	03/12/2025
Blood Chemistries #05,NA? [Amylase; LDH ; Sodium; Uric Acid]	03/12/2025
Hematology INV	03/12/2025
PTT, PT/INR	
Lipid Profile (Lipid Panel) [Cholesterol ; HDL; LDL; Triglycerides]	

3. In the Clinical Comments add a note that this visit must still be completed.

Phase: Treatment Visit: ARM1: Treatment Visit - Week 4 History

Visit Date: 03/12/2025

Visit Status:  Planned  Occurred  Missed  N/A

Visit Tolerance: +/-3

Reset Calendar?: No

Data Collection Completed Date: Monitored Date: Submitted Date: Locked Date:

Collection Location: Collection Time:

Clinical Comments: "This visit has not been completed. PTT and Lipid Profile need to be completed."

920 character(s) remaining

4. Click **Submit and Close**.

**NOTE:** On the Subject Calendar the visit will be blue, and there will be a (C) next to the number of the visit. You can hover over the (C) to read any clinical comments.

7 (C)	8	9
ARM1	Clinical Comments: "This visit has not been completed. PTT and Lipid Profile need to be completed."	
03/12/2025	03/19/2025	03/26/2025
Planned		
03/12/2025		

## My Console

My Console is a tool built specifically for study staff to easily track, check in, and enter subject information all in one spot. My Console allows study staff to see all of the subjects that they are assigned to across all protocols, bypassing having to load each protocol and navigate to the Subject Console through the CRA Console.

1. Navigate to **Menu > My Console**.
2. Click on the **Subjects** tab. Here you can click on the **subject's MRN** to be taken to the Subject Console > Demographics tab.

My Console													
Protocols	Subjects <span>Show Active Protocols Only <input checked="" type="checkbox"/></span> <span>Subject Status: <b>Active</b></span>												
Subjects	Protocol No.	Subject MRN	Last Name	First Name	Seq. No.	Arm	Level	Study Site	Consent Signed Date	On Study Date	Off Treatment Date	Off Study Date	Expired Date
Subject Visits	OCR19660	<a href="#">10016</a>	Upas	Sparrow	97321	Control1		UF Gainesville	07/22/2021	07/22/2021			
My Calendar	OCR47281	<a href="#">117125</a>	Walnut	Owl	1235556	Arm A		UF Gainesville	12/05/2024	12/19/2024			
	OCR47320	<a href="#">11231</a>	Oak	Cardinal	EWS98765	Arm 1		UF Gainesville	01/29/2025	02/12/2025			

3. Click on the **Subject Visits** tab.
4. Click on the **Pending Visits (Horizontal)** tab.

**NOTE:** Here you can filter the subjects you are assigned to based on Protocol, Subject Name, or even based on visit dates. These subjects are linked to you when you add yourself as a staff member on the On Study tab in the Subject Console.

My Console													
Protocols	Occurred Visits <span>Pending Visits</span>												
Subjects	Protocol Filter	Subject Filter	From Date: 12/28/2024	Thru Date: 05/22/2025	Refresh								
Subject Visits	Protocol No.	Subject MRN	Last Name	First Name	Seq. No.	Ethnic	Serment	Visit	Planned Visit Date	Tsk	Clinical Comments		
My Calendar	OCR47281	117125	Walnut	Owl	1235556	Treatment	Treatment	D8	01/16/2025				
	OCR47281	117125	Walnut	Owl	1235556	Treatment	Treatment	D15	01/23/2025				
	OCR47281	112341	Elm	Duck	1234567	Treatment	Treatment	D22	01/30/2025				
	OCR47281	117125	Walnut	Owl	1235556	Treatment	Treatment	D22	01/30/2025				
	OCR47281	112341	Elm	Duck	1234567	Treatment	Treatment	D29	02/06/2025				
	OCR47281	117125	Walnut	Owl	1235556	Treatment	Treatment	D29	02/06/2025				
	OCR47320	11231	Oak	Cardinal	EWS98765	Treatment	Unscheduled Visit #1	Unscheduled Visit	02/12/2025				
	OCR47281	117125	Walnut	Owl	1235556	Treatment	Treatment	D38	02/13/2025				
	OCR47320	11231	Oak	Cardinal	EWS98765	Treatment	Treatment Visits - ARM1	ARM1: Treatment Visit - Week 4	03/12/2025	+/-3	*This visit has not been completed. PTT and Lipid Profile need to be completed.*		
	OCR47320	11231	Oak	Cardinal	EWS98765	Treatment	Treatment Visits - ARM1	ARM1: Treatment Visit - Week 5	03/19/2025	+/-3			
	OCR47320	11231	Oak	Cardinal	EWS98765	Treatment	Treatment Visits - ARM1	ARM1: Treatment Visit - Week 6	03/26/2025	+/-3			
	OCR47320	11231	Oak	Cardinal	EWS98765	Treatment	Treatment Visits - ARM1	ARM1: Treatment Visit - Week 7	04/02/2025	+/-3			
	OCR47320	11231	Oak	Cardinal	EWS98765	Treatment	Treatment Visits - ARM1	ARM1: Treatment Visit - Week 8	04/09/2025	+/-3			
	OCR47320	11231	Oak	Cardinal	EWS98765	Treatment	Treatment Visits - ARM1	ARM1: Treatment Visit - Week 9	04/16/2025	+/-3			
	OCR47320	11231	Oak	Cardinal	EWS98765	Treatment	Treatment Visits - ARM1	ARM1: Treatment Visit - Week 10	04/23/2025	+/-3			
	OCR47281	112341	Elm	Duck	1234567	Follow Up	In Clinic Follow Up	M1	04/26/2025				
	OCR47320	11231	Oak	Cardinal	EWS98765	Treatment	Treatment Visits - ARM1	ARM1: Treatment Visit - Week 11	04/30/2025	+/-3			
	OCR47320	11231	Oak	Cardinal	EWS98765	Treatment	Treatment Visits - ARM1	ARM1: Treatment Visit - Week 12	05/07/2025	+/-3			

5. Click on the **Visit** link to be taken directly to that subject visit to be completed or reviewed.

**NOTE:** If you use My Console to check in visits make sure that once in a subject visit to click submit to save the information entered for the visit, and then click the **Back to: MyConsole > Subject Visits > Pending** link.

Back to: [MyConsole > Subject Visits > Pending](#)
View PDF
Delete
Clear
Submit
Close

Submit And Close