



*The*  
**UNIVERSITY**  
*of* **VERMONT**



**OnCore**<sup>™</sup>

OnCore System Guideline  
Subject Management – Subject Console

Prepared for: OnCore Version 2023R3.4

Revision Number: 2

Revision Date: October 20, 2025

Overview .....	2
Subject Console Vertical Tabs.....	2
Demographics .....	2
Consent .....	2
Eligibility .....	2
On Study .....	2
Treatment .....	3
Subject Calendar .....	3
Additional (Unscheduled) Visits .....	4
Payments .....	5

## Overview

The Subject Console is focused on individual subjects, providing access to their demographic information, associated protocols, signed consents, and eligibility status. Users will also manage additional / unscheduled visits in the subject console.

## Subject Console Vertical Tabs

### Legacy Studies:

When enrolling patients, ensure they are moved all the way through to their current status to ensure there are no differences in Epic.

### Demographics

The subject information you see here is pulled over from Epic.

### Consent

This section contains the history of the subject's consent status, including re-consent's and age of majority consents.

### Legacy Studies:

- All consents entered in the Reviews tab will be available for selection; ensure you are adding all consents applicable to subjects for legacy studies.
- To filter the available consents, enter a signed date to remove consents that were not approved before the signed date.

### Eligibility

An eligibility status date must fall within the time the protocol is open to accrual and after the consent date.

**DO NOT USE:** Eligible(O) - this status is used in situations where the subject has been found ineligible, but the ineligibility has been overridden.

### On Study

Use this tab to track key details about the subject, like the On Study Date (date the subject was registered to the protocol). This is different for every organization, use what is best applicable for your department.

- Enter the sequence number
  - Tracks the order in which subjects are added to a protocol

## OnCore Guideline – Subject Console

- Manual entry or system generated – depends on how PC Console > Details > Management > Automated Sequence no. Settings are configured.
- Additional Protocol Subject Identifiers: 3 Options
  - Drug Kit ID
  - Randomization ID
  - Screening ID
- Staff can be added to the subject, not required but recommended for specific subject notifications such as re-consents or upcoming visit reminders.

## Treatment

This tab can trigger various events in the calendar when entering the On Treatment/On Arm/Off Arm dates.

- An On Treatment date can only be used once, while On Arm can be used multiple times.
- Keep in mind what is used in the calendar! If the calendar uses On Arm instead of On Treatment, and On Arm start date will not activate the correct section in the subject calendar.
- On Off Treatment date will need to be entered in the Treatment tab & the Follow Up tab.

## Subject Calendar

- Entering dates in the status tabs (Consent / Eligibility / On Study / Treatment / Follow Up) will activate the subject calendar visits associated with those start dates.
- Any visits entered outside of window will automatically be added as a deviation in OnCore.
- Subjects already registered to the protocol calendar, must be manually moved to the newest version of the calendar when it is released.

## Calendar Version(s)

When a new calendar version is created, subjects already enrolled to the study must be manually moved to the new version. This can be done two ways:

- **CRA Console** – grouped subject update
  - On the Accrual tab use the checkboxes under ‘Select’ to choose the subjects that need to be moved to the newest version of the calendar

## OnCore Guideline – Subject Console

- Switch the Calendar version to the newest version and select the ‘Replace Versions’.
- A notification will appear asking you to confirm the subjects you are moving to the new calendar version.
- **Subject Console** – individual subject update
  - Navigate to the Calendar tab of the subject you would like to move to the new calendar version.
  - In the bottom left corner, update the ‘Switch Version’ to the newest calendar version and select the ‘Replace Version’.
  - The header will update to “Current Subject Calendar – V#”

### Additional (Unscheduled) Visits

Additional and Unscheduled Visits can be prepped for you in the calendar build; however, you need to manually add these visits to the Subject Console.

- On the **Additional Visits** tab select the ‘New’ button and you are brought to the ‘Subject Visit Update’ page. Enter the visit details and click ‘Submit’.
- When adding an unscheduled visit, ensure you are adding comments/information for the visit and procedures added.
- Initial each comment to communicate with the rest of the team who has added this and why.
- Once you hit the submit button, a new ‘**Additional Procedures**’ button becomes available. Select this button to add the procedures that were completed at this visit.
- The calendar may have been set up to include an “Unscheduled Visit” procedure, which the coverage analyst/budgeting team ties the billing items to. The CA team will tie each of the expected procedures that occur at an unscheduled visit to the procedure, allowing for accurate billing.
  - If this procedure is not included, select all the procedures that were completed during this visit.

## OnCore Guideline – Subject Console

**Browse Results**

Charge Master | Protocol Procedures | Free-text Procedures

Protocol Calendar Procedures Filter:

Event Code	Additional Event ID	Event Description	Select?
		Adverse Events	<input type="checkbox"/>
		Blood Chemistries	<input type="checkbox"/>
		Drug Administration	<input type="checkbox"/>
		Imaging	<input type="checkbox"/>
		Physical Exam	<input type="checkbox"/>
		Pregnancy Test	<input type="checkbox"/>
		Unscheduled Visit	<input checked="" type="checkbox"/>

\* Items for protocol calendar specific additional procedures will be automatically added

Submit Clear Close

ADVARRA © 2022 Advarra, Inc.

- If a procedure is done on this visit that is not listed on the calendar, use the Additional Procedures button. Navigate to the charge master tab and search for the procedure from the list of items in the charge master. This process is similar to adding a calendar procedure; however, you cannot create a new option.

**Browse Results**

Charge Master | Protocol Procedures | Free-text Procedures

Charge Master Procedures/Labs

Event Description	Event Code	Additional Event ID	
			<a href="#">Add</a>

Search: [ ]

Event Description	Items	Event Code	Additional Event ID
00000 EXTRACT AND HOLD RESEARCH (CLIENT BILLING ONLY)		3000000068	3000000068
00000 RESEARCH OPTIMIZATION CHARGE		3100000014	3100000014
00008 NON RESEARCH SHIP/HANDL		3000000894	3000000894
00009 RESEARCH ONLY, PREP TIME PATHOLOGY		3000000971	3000000971
00009 RESEARCH TMA CONSTRUCTION		3000000972	3000000972

Displaying 50 out of 1532 results.

Submit Close

## Payments

Staff can track subject payments in OnCore using the Subject Console > Payment tab.

## OnCore Guideline – Subject Console

- In the Update mode, select the Add button to create subject payments.
- The installment type must be selected using the **magnifying glass** icon.

Subject Payment					Add
Installment Type	Inst. Date (MM/DD/YYYY)	Inst. Amount	Check No.	Comments	Delete?
<input type="text"/>	<input type="text"/> 	<input type="text"/>	<input type="text"/>	<input type="text"/>	<a href="#">Add</a> <a href="#">Cancel</a>

- This will open a pop-up allowing you to choose what type of payment this falls under. There are 4 options, that can be used multiple times.
  - Final Payment
  - Initial Payment
  - Travel Re-imbusement
  - Visit Stipend