



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



**OnCore**™

OnCore System Guideline

PC Console Review

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## Overview

Protocols serve as the basis for all the functionalities and features in OnCore. Protocols are required to be built in OnCore before other activities can occur, such as building calendars, budgeting, subject enrollment, visit tracking, and invoicing. The PC Console acts as the main repository for this information, enabling protocol coordinators to manage details such as protocol ID numbers, objectives, staff assignments, sponsors, participating institutions, regulatory information and investigational drug and device details for each research study.

## Searching for your protocol:

There are two ways to find your protocol.

- Using the Favorites Bar or the Menu drop down navigate to Protocols > PC Console. Use the ‘Select Protocol’ field, to search for an existing protocol by using one of the following identifiers:
  - Protocol ID
  - IRB No.
  - Pharmacy No.
  - Sponsor No.
  - NCT ID
  - Short Title

The screenshot shows the 'PC Console' interface. At the top, there is a dark blue header with the text 'PC Console' and a question mark icon. Below the header, there are several search and filter fields: 'Protocol No.:', 'Library:', 'PI:', 'Sponsor:', 'Protocol Target Accrual:', 'Accrual To Date:', 'Protocol Status:', and 'RC Total Accrual Goal (Upper):' with 'IRB Expiration:' below it. A 'Select Protocol' dropdown menu is visible on the left. Below these fields, there is a row of navigation tabs: 'Details', 'Management', 'Staff', 'Sponsor', 'IND/IDE', and 'ClinicalTrials.gov'. The 'Management' tab is currently selected. At the bottom of the interface, there is a message that says 'Please Select a Protocol'.

- Use your widgets for easy navigation to your protocol! Customize the protocols widget for easy access to your protocol.
  - Select the gear icon to edit the widget to display your Favorited (bookmarked) protocols
  - Or select the roles you are assigned to on protocols to view the protocols you are assigned.

## Protocol Builds

### Manual Builds (studies in UVM Click BEFORE September 25, 2024)

#### New Protocol Tab

Select the **'New Protocol'** tab, the last tab listed on the vertical tabs.

When creating a new protocol, please refer to the **UVM Minimum Footprint** tip sheet. OnCore has **14** system required fields when creating a new protocol. You can complete the required fields and come back later to complete the UVM Minimum footprint.

Field	Definition / Functionality
Protocol Number	Protocol OR IRB Study Number.
Library	Medicine OR Oncology.
Department	Institutional funding for study.
Organizational Unit	Medical OR Cancer Center.
Title	Enter full name of protocol.
Age	Age of subject participants. Children or Both will activate Consent at Age of Majority question.
Investigator Initiated Protocol	Determines if the PI at the Research Center (RC) initiated the protocol.
Protocol Type	Type of protocol / Used for reporting.
Investigational Drug	Is this protocol studying an investigation drug?
Investigational Device	Is this protocol studying an investigation device?
Protocol Target Accrual	Number of subjects to accrue for this protocol.
RC Total Accrual Goal (Upper)	Maximum side of the range for the research center to accrue.
Accrual Duration (Months)	The estimated number of months the protocol is accepting patients to enroll.
Primary Completion Date	The date the final subject was examined/received intervention. Estimate, this can be changed later.

1. On the **'New Protocol'** landing page, enter the required fields noted above OR all required information noted on the [UVM Minimum Footprint Tipsheet.pdf](#) tip sheet.
  - When entering information like the protocol short title, or objectives, you can copy and paste the information from the protocol PDF to avoid discrepancies.
  - Be aware of special characters, as most are not recognized in OnCore.
2. Click **Submit**.
  - Confirm that the protocol number now appears in the header of the PC Console, and that the study now has a status of New.
3. Link to UVMClick IRB.

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- Now that your protocol has been created in OnCore, you will need to link the protocol with the protocol in UVMClick. Use the [Linking CLICK study to OnCore Tip Sheet.pdf](#) for guidance on linking protocols.

## Integration Builds (studies submitted to UVMClick IRB AFTER September 25th, 2024)

### PC Console

All new studies submitted to UVM Click IRB after September 25<sup>th</sup>, 2024 are considered integration builds. To view your protocol, use the ‘Select Protocol’ field to search for the IRB #, protocol #, or any one of the other identifiers listed above. After locating your protocol, you will need to complete the UVM Minimum Footprint, get that work validated, and then begin working on your calendar.

### PC Console Vertical Tabs

#### Main Tab

- Details:
  - Ensure you are entering the NCT number, this can be found at [clinicaltrials.gov](https://clinicaltrials.gov)
- Management
  - IRB No. is found in Click and should match the UVM No.
  - Ensure to select the Primary Management Group.
- Staff
  - Complete this tab to mirror the Delegation of Authority log
  - Each staff role provides unique functionality and enables role-specific notifications & task list assignments. One staff member can have multiple staff roles on a protocol (stacked roles)

**NOTE:** Contacts can be added to the system without needing to be a user.

Activating the user will require training. Please use the Access Request Form found at:

[OnCore: Request Access | OnCore Clinical Trials Management System \(CTMS\) | The University of Vermont](#)

- Sponsor
  - Ensure to select the primary sponsor to enable functionality with PeopleSoft
  - If a sponsor is not currently in OnCore, please contact System Admin

#### Treatment Tab

Main	»
Treatment	»
Institution	
Accrual	
Status	»
Reviews	»
Documents/Info	»
Eligibility	
Notifications	
Deviations	
New Protocol	

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- Details
  - Step Code – 0 should only be used for pre-registration
  - Arms – click to add/edit treatment arms within the step

**NOTE:** It is best practice to create multiple arms for different treatment paths.

### Institution Tab

- A list of prepopulated institutions is live in OnCore
- Please contact System Admin ([OnCoreSupport@med.uvm.edu](mailto:OnCoreSupport@med.uvm.edu)) if an institution is not listed
- Affiliate Institutions will need their own IRB reviews and approvals entered prior to accruing subjects. Click the name of the Affiliate Institution & enter the Review/Approval on the “Protocol Institution: INSTITUTION NAME > IRB Reviews” tab.

### Accrual Tab

- This tab displays detailed subject accrual data for the protocol selected.
- View current vs. Cumulative subject totals
- These display subject totals across multiple subject statuses and how many subjects are on each status.

### Status Tab

- The status tab displays the protocol's status history and where you will move the protocol through the statuses (New, Activation/Regulatory Signoff, Open to Accrual, etc.).
- This is the first checkpoint when entering a protocol, ensure the protocol validation has been completed prior to the “Activation/Regulatory Signoff”.
- **LEGACY STUDIES:**
  - When entering the dates for Activation/Regulatory Signoff and Open to Accrual make sure you are entering dates that are BEFORE the first patient was consented. You will not be able to enter valid consent dates for patients if these dates are after subject consents.

**NOTE:** Task lists can also be activated here – refer to the task list guidance document for more information. [Task List Tip Sheet.pdf](#)

### Reviews Tab

- Summary displays the history of each tab within the Reviews section, in read-only mode.

**NOTE:** PRMC is for Oncology use only.

### IRB TAB

- Required dates:
  - Submit date – date the review was submitted to the IRB.



## Notifications Tab

Staff can configure notifications to send emails that are triggered by various actions in OnCore. Notifications can be triggered by protocol status, signoffs, subject status, etc.