Clinical Research Support Office (“CRSO”)

Minimum Footprint - Protocol Entry
CTM-WI-2001 Work Instructions

Need Help?
Contact the CRSO at:
ctems.support@uky.edu

Contents
Introduction .................................................................................................................................................. 2
PC Console Entry ...................................................................................................................................... 2
Protocol Signoffs ....................................................................................................................................... 13
Summary Accrual ....................................................................................................................................... 13
Task Lists and Annotations ....................................................................................................................... 14
Introduction
The protocol shell for non-oncology protocols will be entered by the CRSO, excluding IRB review entry.
- All IRB reviews will be entered by the assigned regulatory staff or protocol manager.
- After the entry of the initial shell, any changes to applicable fields in the PC console should be made by the regulatory staff or protocol manager.

PC Console Entry
1. **Navigate to PC Console:** MENU > PROTOCOLS > PC CONSOLE
2. Now that you are in the PC Console, click on **NEW PROTOCOL** located in the lower left-hand corner of the screen.

3. Once the **NEW PROTOCOL** window opens, you will see the following screen. The fields outlined in black are **required**. The fields bordered in green are **optional**, and may not be applicable, depending on the study. Refer below the image for further clarification of each field.
REQUIRED Fields further defined (Entered by the CRSO):

**Protocol No.**
This is the unique identifier for a protocol. The protocol number displays in the Protocol Header and is used in most reports. It can also be used to search for a protocol in any of the Select Protocol “find-as-you-type” fields throughout OnCore.

**NCT Number**
NIH and ClinicalTrials.gov assign a unique identifier to each registered clinical trial. This number must be entered here. A hyperlink will then display. When clicked, the ClinicalTrials.gov website will open to the page for that protocol.

**Library**
The library associated with a protocol will affect what values are seen within the drop-down menus and annotations forms within OnCore. The library selection cannot be modified after the protocol is submitted in OnCore and a drop-down value has been submitted/saved.

**Department**
The department that is leading and financially responsible for the study.

**Organizational Unit (OU)**
The Organizational Unit is the highest level category used to group protocols and staff within OnCore. OUs are used to facilitate reporting by major groups.

**Title**
Full protocol title. The title entered here populates to other screens within OnCore and is displayed in many reports. The Title may be configured to display in the Study Information Portal (SIP).
Short Title
Abbreviated title (100 characters maximum). This may be configured to display on the SIP in place of the full Title. This title generally uses layman terms as it may be viewed by non-clinical individuals and potential patients.

Objectives
Identifies the purpose and end-point objectives of the protocol. For example, the primary objectives define the drug treatment used whereas secondary objectives identify the toxicity the subject experiences. When there is more than one phase, with primary and secondary objectives in each phase, use the objectives field to enter all of the phase and objective information. Objectives populate the SIP console and display on the public websites.

Phase
Indicates the study phase of the protocol. This will flow to the SIP and can be searched in OnCore.
For Oncology Phase definitions: National Cancer Institute
For Non-Oncology Phase Definitions: ClinicalTrials.gov

Scope
This indicates the scope of enrollment (Local or National.)

Age
This field defines the age group of subjects eligible for this protocol. The age group selected here populates the SIP Console and displays on the public website.

Investigator Initiated Protocol
Indicates whether or not the Principal Investigator initiated this protocol. This field is used for research center reporting.

Summary Accrual Only
This field defaults to a blank value which equates (functionally) to a ‘No’ value. This allows research personnel to enroll subjects using the Subject Console. Selecting “Yes” will allow research personnel to enter a summary (or tally) only accrual information through the PC Console. See instructions for Summary Accrual Entry.

Protocol Type
Indicates the type of protocol and is used for reporting purposes. Examples of protocol types include: Screening, Prevention, etc.

Protocol Target Accrual
The target accrual number entered will display in the top header of most screens within OnCore and populate in some reports. This number also triggers the system-generated Protocol Target Accrual Met notifications if the notification is activated. This is also an important field for Oncology trials regarding the Data Table 4 report for NCI.

RC Total Accrual Goal (Lower)
The minimum side of the range for the Research Center (RC) total accrual. Enter the minimum number of subjects to accrue for the research center running the protocol. Low Accrual Report utilizes this field and it is used in reporting. This information will also feed into the Insights dashboards. This is also an important field for Oncology trials regarding the Data Table 4 report for NCI.

RC Annual Accrual Goal
This is an estimated number of subjects that will enroll into the protocol for a single year. This is also an important field for Oncology trials regarding the Data Table 4 report for NCI.
Accrual Duration (Months) The Accrual Duration in months estimates the number of months the protocol will be accepting subjects to be enrolled. This field should include any affiliate institutions involved in enrollment. This is a required field for the use of Insights dashboards.

Primary Completion Date This is the protocol completion date used for CT.gov and CTRP reporting.

**OPTIONAL Fields further defined (Entered by CRSO):**

Consent at Age of Majority By choosing this option, OnCore will flag subjects at the age of majority for reconsent. This field is only active when the Age selected has Children or Both chosen.

Exclude Protocol on Web Optional, and depends on the study. Checking this box will stop the protocol from flowing to the SIP. Note: This box should be checked for non-oncology studies until SIP is set up for the Enterprise.

Open for Affiliates Only Optional, and may not apply. Enter “Yes” when the protocol is open to subjects at Affiliates only (not at the Research Center). Protocol Search provides searching by Open by Affiliates Only.

Involves Correlates or Companions Optional, and may not apply. This field is used to indicate whether the protocol involves correlative or companion protocols. This will cause a new tab to become available in PC Console called Correlates & Companions. OnCore will alert research personnel in Subject Console if a correlate or companion study has been associated with the protocol they are enrolling in to.

Includes Specimen Banking Optional, and may not apply. Indicates whether the protocol is a specimen banking protocol. Checking this box causes the Specimen Collection Configuration tab to display.

Companion Study Optional, and may not apply. Indicates that the protocol is a companion to another study. This must be checked to be able to search for it through the Correlates & Companion tab in PC Console.

Multi-Site Trial This is an optional field that is information-only for non-Oncology trials. This field indicates the trial as being multi-site or not for the NCI Data Table 4 report. When left blank, the Institution tab within PC Console will determine whether it is multi-site or not.

Investigational Drug Options are Yes, No, or N/A. This field sets the value of the Investigational Drug field on the Main > IND/IDE tab, and vice versa.

Investigational Device Options are Yes, No, or N/A. This field sets the value of the Investigational Device field on the Main > IND/IDE tab, and vice versa.

RC Total Accrual Goal (Upper) The maximum side of the range for the Research Center (RC) total accrual. Enter the maximum number of subjects to accrue for the research center running the protocol. Currently, this does not populate in other fields.
4. Enter the appropriate fields and click **Submit**.
   a. Once all the fields have been entered appropriately and submitted, you will see the screen below. You have just entered all the information under the **Details** page.

5. The next step is to navigate to the **Management** Tab.

**REQUIRED Fields further defined (Entered by the CRSO):**

**IRB No.**
Used to hold a protocol number assigned by the IRB, if applicable. This number can be used to find a protocol in any of OnCore’s Select Protocol find-as-you-type fields. **This field should be entered by the department or CRSO regulatory team, once obtained.**

**CCTS Participation**  *(Required when applicable)*
This field is used to indicate whether CCTS services have been requested for the protocol.

**CCTS No.**  *(Required when applicable)*
This field should be populated with the REDCap Coding Scheme
Determines the option list used in Adverse Event (AE) and Serious Adverse Event (SAE) reporting.

**Hospital Account No.**
The plan code will be entered here.

**Management Group**
Management groups are used for reporting and permissions.

**OPTIONAL Fields further defined if needed for the protocol (Entered by the CRSO):**

**Automated Subject MRN**
A value of “Yes” causes subject medical record numbers to be automatically populated for enrolled subjects.
6. Next, navigate to the **Treatment tab** and fill in the applicable protocol arms. The step code and selection of registration or randomization will be entered depending on the protocol. To enter the arms, click the Arms hyperlink and enter the code and description, sample below:

![Protocol Arms Example](image)

7. Click the **Disease/Diagnosis tab** and click **select**. The list of codes populate from the ICD10 coding scheme for non-oncology. Entry of the appropriate diagnoses will allow the coordinators to enter the diagnosis specific information during the subject milestone entry.
8. Next, navigate to the **Staff Tab** and fill in the required fields (indicated by black outline). You may notice that your name has already been added as protocol creator. The CRSO will enter a **Principal Investigator** and any other research staff as defined during the protocol in-take process. Any alterations to the staff list will need to be managed by the protocol research staff. This is a permission driven component within OnCore. If you do not have the ability to add staff to the staff tab, for help contact the CRSO (ctms.support@uky.edu).

This tab will be important to maintain throughout the life of the protocol and should be updated with every key personnel change with the IRB. This will allow staff to have access to the protocol and will allow protocol-level notifications to be sent to the active staff.

9. Next, navigate to the **Sponsor Tab** and select “Add Sponsor.” You can start to type your sponsor’s name. If the sponsor’s name is NOT in the drop-down list, contact the CRSO. The CRSO will enter the initial sponsor information. If there are multiple sponsors, all sponsors will be entered as applicable.
10. Enter the SAP account number in the Grant No [Fund Acct. No] field. After the sponsor is entered, click **update**. Click **grant/contract** hyperlink.

11. Click **select/edit**. Add the applicable account number in the **Grant No.** field and click **add**.

12. Next, navigate to the **Institution** tab on the left-hand of the screen. Once you click on **Institution** click the **Update** button in the bottom right-hand corner. If you do not see the update button, please contact the CRSO, as your permissions will need to be updated in OnCore.
Once you click on **Update**, you will see the screen below. The required fields are outlined in black.

**Click ADD > Choose your INSTITUTION > Indicate whether it will use the RESEARCH CENTER IRB > SAVE.**

13. The assigned regulatory staff will enter the IRB review information. Next, navigate to the **Reviews** tab on the left-hand side of the screen. Click on the **IRB** tab across the top. Once you click on **Add**, you will see the screen below (number 14.)
14. After clicking Add, you will see the screen below. The required fields are outlined in black. **An Initial IRB Review must be entered into OnCore** to be able to Open to Accrual. Any subsequent Continuing Review (CR) and amendment should also be added as they occur. Modification Requests are optional and at the discretion of the department.

15. Any documents reviewed at the time of the IRB review should be added to the **Details** tab.
   a. The list of staff as approved by the IRB should be uploaded in addition to IRB approved documents with the document type Key Personnel.

16. Note: for **Continuing Reviews, Amendments/Modifications**, etc. you will follow the same steps above (numbers 13 & 14) to complete additional review information.

17. Upload any additional documents to the **Documents/Info tab**.
   a. IRB approved documents
   b. CRSO Calendar Build notes
   c. Any documents that individuals could reference either centrally in the department, or outside of the department (i.e., CRSO)
Protocol Signoffs

Protocol Signoffs are required as part of the process to open a study to accrual. Please refer to the OnCore Signoffs Visio for the full description and order of signoffs.

Summary Accrual

For protocols where only summary accrual is required, follow the steps below.

1. Navigate to the Accrual tab on the left-hand side of the screen. Once you click on Accrual, you will see the screen below. The required fields are outlined in black. If Gender, Age Group, Ethnicity, Race, and/or Disease Site are unknown for a subject, those fields can be left blank.

Enter each subject, one at a time, to represent a single accrual. For further clarification, see below the figure.

From Date: You can use a subject's “On Study” date, date of Randomization or Registration, or date of Consent to fill out this field.
Thru Date: Enter the same date as the From Date. This will enable you to capture a single subject's date of accrual.

Accrual: Always enter ‘1’ into the accrual field. This will represent a single subject's accrual.

Institution: Institution where subject was registered. All protocols (Oncology and Non-Oncology) must choose “University of Kentucky”.

Internal Accrual Reporting Group: Institution where subject was registered. All protocols (Oncology and Non-Oncology) must choose “Research Center.”

Gender: If known, enter the subject’s gender.

Age Group: If known, choose the most applicable age group for the subject, at the time of his or her enrollment.

Ethnicity: If known, choose the most applicable ethnicity of the subject.

Race: If known, choose the most applicable race of the subject.

Disease Site: If known, enter the most applicable disease site for the subject.

Zip Code: If known, enter the subject’s residential zip code at the time of registration/enrollment.

2. Repeat step number 1 as many times as necessary to capture your accrual information. **NOTE:** there are other ways to enter accrual; however, this will enable the most data to be captured and reported on later.

**Task Lists and Annotations**

There are specific task lists and annotations that should be added to each protocol at the time of protocol creation.

1. Navigate to the **Status** tab on the left-hand side of the screen and click the >> on the right side of the tab which will bring you to the Task Lists screen.
2. Click **Copy Template** to add the applicable task lists, and click **Save**.
3. The following task lists should be added to the initial protocol shell to help track study activation work:
   - CRSO Calendar Build
   - Budgets
   - Coverage Analysis
   - Study Start Up
4. Click the **Annotations** tab.
5. Click the **Create Annotations Form** hyperlink.

6. The available annotations for Non-Oncology additional tracking will become available. These should be filled out to assist with institutional reporting.
Department Details

1. Date form is completed: *

2. Please select your department (select more than one, if applicable)

3. Please select the college in which your department is located (select more than one, if applicable)
   - College of Agriculture
   - College of Arts and Sciences
   - College of Dentistry
   - College of Education
   - College of Engineering
   - College of Health Science
   - College of Medicine
   - College of Nursing
   - College of Pharmacy
   - College of Public Health
   - College of Social Work

Protocol Population Details (Note: these questions can be found on the CCTS Service Request Form)

4. Does your protocol involve any of the following health disparity topics? (Please select all that apply)
   - Cancer
   - Cardiovascular Disease/Stroke
   - Diabetes/Obesity
   - Neurological Disorders
   - Other
   - Substance Use Disorder

5. Does your protocol involve any of the following special populations? (Please select all that apply)
   - Aging/Elderly
   - Individuals with Disadvantageous Backgrounds
   - LGBTQIA
   - No Special Population
   - Other
   - Pediatric
   - Rural/Appalachian
   - Under-represented Racial & Ethnic Groups