Regulatory Work Practice

OnCore – Updating the PC Console

Purpose: OnCore is a Clinical Trial Management System (CTMS) from Advarra and gives research teams a single, comprehensive system for managing a trial throughout its life cycle. The University of Arizona Health Sciences (UAHS) uses OnCore for a variety of purposes, including managing all clinical trials conducted within UAHS, housing current and approved study documents, housing study calendars and documenting when patient visits have occurred, housing electronic case report forms (eCRF's) for investigator initiated trials (IIT's), creating and running reports, reporting data directly to the National Cancer Institute (NCI), and tracking staff effort on trials.

The PC Console in OnCore has the vital information related to regulatory. Reports and websites are linked to many fields on the PC Console and thus are important that the fields be updated.

Scope: This applies to regulatory staff.

Tools

- Learning Portal: https://oncore-docs.advarra.com/index.php
  In addition, you can log into OnCore and from your profile drop down, select Help → Learning Portal

Process / Steps:

1. For General Medicine studies, once a protocol has been entered into OnCore, the Primary IRB Coordinator (PIRBC) will be notified by email and to go in and update and enter information.
2. Log into OnCore: https://login.advarracloud.com/
3. Go to "Protocols" → "PC Console," and search for the appropriate protocol.
4. UAHS Research Administration (UAHS RA) will have created the basic shell for the protocol based on the information in the Research Administration Portal (RAP) New Study submission. The PIRBC will need to confirm the information entered. If incorrect, the PIRBC should modify it unless it is noted below that the field should not be changed. If the PIRBC feels that a field marked "do not change" is incorrect, please reach out to regulatory@arizona.edu and OnCoreSupport@arizona.edu for assistance. The fields that UAHS RA will enter initial data for are:
   a. Main-Details Tab

i. Protocol No – this will be the local UA IRB number; if this has changed since RAP submission (i.e. due to moving to a new eIRB submission), this should be updated to the current UA IRB number
ii. NCT Number, if provided in RAP submission
iii. Library – do not change
iv. Department – do not change
v. Organizational Unit – do not change
vi. Title
vii. Short Title
viii. Investigator Initiated Protocol
ix. Open for Affiliates Only – do not change
x. Summary Accrual Info Only – do not change
xi. Protocol Type

b. Main-Management Tab
   i. IRB No
   ii. SRC No, if applicable
   iii. Primary Management Group

c. Main-Staff Tab
   i. Principal Investigator
   ii. Primary IRB Coordinator
   iii. Primary CRC if known

d. Main-Sponsor Tab
   i. Sponsor
   ii. Sponsor Protocol No, if known/applicable
   iii. Principal Sponsor check box

e. Institution
   i. Add institution but not study sites

5. The following fields need to be entered by the PIRBC:
   a. Main-Details Tab-Protocol Details
      i. Phase
      ii. Scope – Local (state of Arizona) or National
      iii. Age
      iv. Consent at Age of Majority - if this is set to Yes, the coordinator will receive an alert that the participant needs to be consented once they reach the age of majority (this will usually be age 18)

v. Drug Accountability
vi. Involves Therapy
vii. Exclude Protocol On Web – check to prevent study from being posted to publicly available UAHS Clinical Studies website
viii. Protocol Type – confirm and update if necessary
ix. Registration Center – should always be UAHS
x. Involves Correlates or Companions – Leave blank – Contact OnCoreSupport@arizona.edu if yes
xi. Data Monitoring
xii. Adjuvant
xiii. Includes Specimen Banking
xiv. Companion Study -- Leave blank – Contact OnCoreSupport@arizona.edu if yes
xv. Multi-Site Trial – select yes if multi-institutional
xvi. Investigational Drug
xvii. Precision Trial
xviii. Precision Trial Classification – available only if Precision Trial = Yes
xix. Pilot
xx. Investigational Device
xxi. Rare Disease
xxii. Certificate(s) of Confidentiality
xxiii. Pragmatic Trial
xxiv. Exclude Protocol From Analytics

b. Main-Details Tab-Accrual Information
i. Do not check Not Applicable unless the study ONLY involves record review
ii. Protocol Target Accrual – overall enrollment goal for the study as a whole. For large multi-site trials, this number includes accrual for all participating sites.
iii. RC (Research Center) Total Accrual Goal (Lower) – can be the same as RC Total Accrual Goal (Upper)
iv. RC Total Accrual Goal (Upper)
v. RC Annual Accrual Goal – this should be calculated by dividing the RC Total Accrual Goal (Upper) by the total anticipated accrual duration in

years. For example, if the goal is 15 accruals over 3 years, divide 15 by 3 for an annual accrual goal of 5 subjects per year.

vi. Affiliate Accrual Goal – Leave blank

vii. Accrual Duration (Months)

c. Main-Details Tab-Completion Dates

i. Primary Completion Date – the date the study is anticipated to close to accrual. Update from Anticipated to Actual when the true date is known.

ii. Study Completion Date – date it is anticipated that data collection and follow-up will be complete, and the study is ready to close with the IRB. Update from Anticipated to Actual when the true date is known.

d. Main-Management Tab-Management Details

i. IRB No – enter all associated IRB numbers, separated by a comma

ii. Internal Account No – KFS number

iii. Generate Subject MRN – only use if not all patients are Banner patients; select Optional

iv. Automated Sequence No – allows assignment of study numbers via OnCore. This is an optional feature that should only be used if study numbers are not already being assigned by other means. Please select yes and not the other options unless you have had separate training on the randomization/stratification blocks.
If this is set to Yes, click Submit and you will be able to Edit the prefix and starting number. It is recommended to start with 100 or higher.

v. All other fields are not required

e. Main-Management Tab- Administrative Groups

i. Confirm primary Management Group – this should always be the PI's department

ii. Add any additional management group as appropriate – add departments that any study coordinators are associated with, if different than the PI's department

f. Main-Staff Tab

i. Refer to the Updating Study Staff List guidance for information on updating this section

g. Main-Sponsor Tab

i. Confirm or add Sponsor

1. If Sponsor name does not appear in the header information, be sure to check the Principal Sponsor box.
2. If the sponsor that you want to add is not available to select, submit a ticket to TicketCat to request that it be added

h. Main-IND/IDE Tab
    i. This is optional. Enter at own discretion.
i. Main-ClinicalTrials.gov Tab
    i. This is optional. Enter at own discretion.
j. Treatment-Disease/Diagnosis Tab
    i. Select the appropriate parent disease/diagnosis category/ies. You will not be able to add a specific code, just the range of codes that includes the diagnosis of interest.
    ii. Genetic information – optional. If you wish to include this, request the addition of the biomarker and alteration via TicketCat.
k. Institution Tab
    i. Confirm Institution (should be UAHS).
    ii. Add any study sites as appropriate: Click the hyperlink for UAHS. In the console that opens, click on Study Sites and select the appropriate study sites where consenting is being done for this project. Do not use the option for UAHS; instead select the specific location where the study activities are being done. If you do not see the specific location in this list, submit a ticket to TicketCat to have additional study site(s) added.
l. Status Tab
    i. Refer to the document Updating Study Status (https://research.uahs.arizona.edu/oncore/resources)
m. Reviews Tab - Refer to the Updating IRB Reviews guidance for information on updating this section