Clinical Research Support Office ("CRSO")

Minimum Footprint - Subject Management
CTM-WI-2003 Work Instructions

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

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Important OnCore Terminology

**Subject:** A person who is participating on a protocol, who is considering participating, or who is being evaluated for their eligibility to participate. Each subject record represents a single patient who is registered to a protocol.

**Patient-Level Information:**
- MRN
- Demographics
- Address
- Emergency Contact Information
- Expiration Date
- Optional Identifiers (e.g. patient’s driver’s license number)

**Subject-Level Information:**
- Sequence Number (Study ID)
- Consent dates and versions
- Eligibility Criteria
- Study Site
- Treatment and Follow-Up start and end dates
- Visit Details

**Subject Console:** This console allows you to view subject information within the context of a protocol. The console provides access to a subject’s demographic information, the protocols the subject is associated with, what consent forms the subject has signed, their eligibility status, etc.

**CRA Console:** This console is designed to provide information about all subjects at a protocol level. When a protocol is selected in the CRA Console, it displays the subjects who have been accrued, which subject forms have been completed and are yet to be completed, a list of serious adverse events (SAEs), visits outside of tolerance, and other subject deviations in this protocol. The CRA Console also indicates which subjects need to review and accept a more recent version of the consent form. This is illustrated by a superscript RR next to the patient’s MRN, indicating that re-consent is required.

The following pages will go through the Subject Administration process:

CONSENTED > ELIGIBLE > ON STUDY > ON TREATMENT (ON ARM > OFF ARM) > OFF TREATMENT [DATE OF PROGRESSION (for Oncology Only)] > ON FOLLOW UP > OFF STUDY
Registering Subjects - Creating a New Subject in OnCore

1. **Create a new subject in OnCore**

   Navigate to: **MENU > SUBJECTS > CRA CONSOLE**

2. Once you are in the CRA Console, you will see the screen below. To locate the protocol you are looking for, start typing in the name of the protocol in the **Select Protocol** field. The protocol should become available for you to select. After you click on the appropriate protocol name, click on **Register Subject**.
3. The **Register Subject** page allows you to search for existing subjects in OnCore and UK’s HQPM, or you can add a new patient if necessary. Please note: you are still working within the context of a single protocol (selected in Step 2). A subject cannot be entered into OnCore without being associated to a protocol.

   **Always** start with the **Find Subject** field in the left-hand corner of the screen. This will allow you to search subject records that already exist within OnCore and allows you to search UK’s EMR. If you notice an error in the subject’s demographics, reference the UK IT demographics correction policy to correct it in the source system.

Select a **Study Site** from the drop-down menu. If the study site you are looking for is **NOT** there, please contact the CRSO, as the PC Console will need to be updated.

After selecting the appropriate **Study Site**, enter in subject information and then hit **Find**.
4. After clicking on **Find**, you will see the following screen below. You will need to find and click on the appropriate **Subject MRN** hyperlink (in blue). **Note:** you may get hundreds of patient names displayed at once.

5. Once you click on the **Subject MRN** you are looking for, the demographic information will be pulled and populated into the **Subject Details** fields on the right-hand side of the page. Click **Add** to register this specific subject to the protocol.
   a. **IMPORTANT NOTE:** Ethnicity and race will populate the first time a subject is searched for in OnCore. However, the Ethnicity and Race will not be updated if it changes within HQPM.

6. If the subject you are looking for is **NOT** found using the **Find Subject** contact CTMS support (**ctms.support@uky.edu**)

7. After clicking **Add**, OnCore will automatically redirect you to the **Subject Console** (you were previously working in the CRA Console). A gray message box will appear in the upper left-hand corner, stating that the **Subject was added to the protocol**. The Subject Console represents one subject, on one protocol. You may notice the subject name you selected and added in Step 5 is now in the header of the Subject Console and the demographic information is present down below; however, this subject does not yet have a status in OnCore.
Subject Statuses

1. Now that your subject has been registered to a specific protocol, you will need to document the subject’s status, starting with the Consent tab on the left-hand side of the screen. After clicking on Consent, you will see the screen below. (You may first need to select Update.)

2. You will need to enter in a Consent Signed Date and then click on Select Consents.

3. After putting in a Signed Date and clicking on Select Consents, a window will pop up (see below) and you will see a list of available consents that have been approved at the subject’s study site. (Note: if you do not have a list of consents, please contact the CRSO, as the PC Console will need to be updated).

Select the appropriate consent for the subject and indicate whether if they Accepted or Refused the consent. Then click Save.

4. After clicking Save, you will be redirected to the Subject Console, and the header for your subject will be updated. The Subject Status should now say CONSENTED. Note: The subject calendar is now available if the consent date was a segment trigger.
5. Next, navigate to the **Eligibility** tab on the left-hand side of the screen. Enter in the **Eligibility Status** of the subject, **Verified By** (who deemed the subject eligible) and the **Status Date**. After all the information is entered, click **Submit**. Your subject status should now be updated to say **ELIGIBLE** or **NOT ELIGIBLE**. The Eligible(O) should not be used.

   **Note:** Eligibility Status is not a mandatory field functionally for OnCore; however, it is required by the CRSO.

   a. An **Eligibility Questionnaire** can also be built in the PC Console to help study staff determine eligibility. This is optional. The CRSO will discuss with you if an eligibility checklist should be built in.

   b. If your protocol has an **Eligibility Questionnaire** built into the PC Console, when you click on the **Eligibility** tab, you will see the following screen with inclusion and exclusion criteria questions (eligibility questionnaire). The questions are followed by **Yes** and **No** radio buttons labeled in **red** or **green**. A **red** answer indicates ineligibility. After selecting the appropriate responses, click **Submit**. Your subject status should now be updated to **ELIGIBLE** or **NOT ELIGIBLE**.

6. After Consent and Eligibility are determined, the next step is to place the subject **On Study**. Click on the **On Study** Tab and click **Update**. You will see the screen below. At the top left of the page is the **Sequence No.**, a number that is unique to each subject within the protocol (i.e. subject ID).

   a. The **Sequence Number** may be the sponsor identified number, a manually entered number, or generated automatically by OnCore. During the intake meeting this will be reviewed to make sure the protocol is set up correctly so this field can accommodate the appropriate scenario (automatic or manual).
7. Next, enter in the **On Study Date** for the subject. **This is one of the most important fields in OnCore.** The On Study Date is what OnCore uses to determine subject accrual to the protocol.

8. Enter the subject’s primary diagnosis, and secondary if applicable, along with the diagnosis date. The drop-down list made available for this section will depend on the Disease/Diagnosis tab within PC Console. For healthy participants, this field may be left blank. Click **Submit**.

9. **The departments should enter subject level staff.** Entering staff on a subject level allows them to benefit from additional use of **My Console.**

10. **IMPORTANT:** The **Transferred Date** field indicates that a subject was first enrolled to the protocol at another institution and was then **transferred** to the current study site. The Transferred Date field will prevent the subject from counting as an accrual for the current study site, giving the original institution credit for accruing the individual.

    **Note:** Now that the subject has been placed On Study, more of the subject calendar may become available.

11. After a subject is placed **On Study**, the next step is to put the subject **On Treatment**. The **Treatment** tab allows you to select the protocol arm assigned to the subject. Click on the Treatment tab and then click **Add**.

12. You will see the screen below. You will need to select an **Arm** for the subject and then enter in an **On Arm Date**.

13. Next, enter in an **On Treatment Date**. **Note:** The On Treatment Date can be the same date as the On Arm Date **OR** it can be a different date, depending on how the protocol and sequence of events (protocol calendar) is outlined. Click **Save** to capture all your changes. The **Subject Status** in the top right-hand corner of the screen should now read: **ON TREATMENT**.

    a. **NOTE:** Subjects can be placed on more than one arm at a time. Please refer to the Calendar Build Notes supplied by the CRSO regarding the arms of treatment and whether a subject may be placed on more than one arm at a time.
14. Now that the subject has been placed **On Treatment**, more of the subject’s calendar has become actionable. Click on the **Calendar** tab. All the visits with a blue hyperlink can now be checked-in or worked on by study staff.
   a. In the PC Console documents and info tab, the calendar build notes include the specific trigger dates for the calendar if needed for reference.

15. If a subject is on a Utility Arm for scans on a different schedule than treatment, the coordinator will need to toggle between the two calendars and mark visits as occurred on both as appropriate for their subject. However, **only scan visits should be checked in on the scan calendar**. Other visits (like Screening or End of Treatment) that may be seen on the Scan calendar should not be marked occurred here and should only be marked occurred on the treatment calendar.
Managing Subject Visits

The subject visit check-in practices should be in accordance with the Subject Visit and Procedure Tracking policy.

1. Clicking on one of the blue hyperlink visits (e.g. D1) will bring you to screen below, where you can enter in the specific subject visit details. You can mark whether the visit is Planned (i.e. scheduled, but has not happened yet), if the visit has Occurred, if the visit was Missed, or if the visit is N/A (not applicable).

By marking the visit as Occurred, you are indicating that the visit happened as scheduled. You can manually change the Visit Date on the left-hand side of the screen if it varies from what was pre-populated.

If everything happened as planned, and all the procedures were performed, click Occurred and then Submit and Close at the bottom of the screen.

If everything did not happen as planned (e.g. a procedure was Missed, Not Applicable, or Additional Procedures needed to be added to the visit), you will need to indicate this in the Procedures section.

The following scenarios outline how to handle if a visit does not occur as planned:
Important Note: Any pop-up comments will be reviewed by the financial team. Please include details as to why it was missed or N/A, any applicable dates or information that the finance team may need for billing purposes, screen shot below:

- Mark the visit as missed once the window is over.
  - Depending on the scenario of the missed visit, if it makes sense to mark the visit as occurred and choose the “Reset Calendar”: YES to update the rest of the visits in the calendar, this is also an option. This may be used when treatment and cycles are held (and not skipped). This will be protocol dependent.

- If one procedure in the visit was missed, mark the visit as occurred and then mark that procedure as missed.
  - If marking a procedure as missed, enter in the comment why it was missed and if there are plans to make up the procedure.

- If the procedure was N/A at that visit, use the N/A checkbox and enter the comment about why it was not needed.

- Add an additional visit with the applicable additional procedures if there was a visit that happened outside of the protocol window or if there was an extra visit that occurred.

- If an extra procedure was performed at an already built in visit, use the additional procedures button to add a procedure to an existing visit on the calendar. The additional procedures button will appear after a visit is marked as occurred (and submitted).

- Enter any date of a procedure that occurred on a different date than the visit. OnCore assumes the same date as the visit if nothing is entered.
These dates can be entered even if the visit has not fully occurred yet. For example, if a lab happens the day before the visit, the date of the lab can be entered and then the full visit marked as occurred the next day.

- If a procedure was performed that is different than set forth in the protocol or than the original billing designation, enter the comment in Clinical Comments describing the procedure and scenario (circled in red).
  - The clinical comments will be available on the billing slip for the financial staff working on charge segregation.

- To review the billing grid with the designations, click the calendar in the PC Console to see the billing grid. In each calendar visit, there is also the ability to see the SOC check box next to each procedure indicating this procedure was marked as Bill to patient/insurance.
Additional Subject Statuses

After a subject has completed the study treatment, his or her status needs to be updated. Additional subject statuses include: **Off Treatment**, **On Follow Up**, and **Off Study**. These statuses act as triggers for visits in the subject calendar. For example, changing a subject’s status to **On Follow Up** will likely allow the Follow Up visits in the subject calendar to become actionable and after a **On Follow Up** date is entered the treatment visits are no longer available to be marked as occurred.

**Note:** there is an important distinction between **Off Treatment** and **Off Study**. **Off Treatment** means that the subject is no longer receiving the study treatment/intervention, but he or she may still be followed. **Off Study** means that the subject has completed the protocol and that no more study visits, follow up procedures, etc., will occur.

1. To change the subject status to **Off Treatment**, **On Follow Up** or **Off Study**, navigate to the **Follow Up** tab and click **Update**. You will see the screen below. You can enter the Off Treatment, On Follow Up or Off Study date information, with reasons, as appropriate.
Financial Events

Your financial team will let you know if you need to enter any financial events. These are protocol level events that are tied to the budget and can be invoiced for. As an example, any time you use dry ice, a financial event can be entered to trigger invoicing.

1. Go to Financial Events in the CRA Console
2. Click update
3. From the drop down, select the appropriate event (i.e., dry ice).
4. Enter the date of the event.
5. Add a description of the event including any subject or visit specific details.
6. Click submit.
Subject Reports

- The Subject Visit Detail report allows the user to search for subject visits on a particular protocol by their status.
  - For example, to see all the upcoming visits for the next month, select the date range and choose the status “Planned.” This will show all visits that are listed as planned for the coming month on that particular protocol.

![Subject Visit Details](image)

- The Subject Search allows the user to search for subjects by certain parameters across the protocols they have access to. Navigate to Subject > Subject Search. You can also save your searches if it is something you will perform regularly.
Amendments: Reconsent and Calendar Versions

If a reconsent is required as part of a protocol amendment, the regulatory review will mark “Reconsent” as required in the PC Console. This will add an “RR” superscript next to any subject’s name who needs to reconsent. To remove the RR, enter the new consent version via the instructions provided above.

<table>
<thead>
<tr>
<th>Study Site</th>
<th>Subject MRN</th>
<th>Last Name</th>
<th>First Name</th>
<th>Seq No</th>
<th>Arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Kentucky</td>
<td>001003096RR</td>
<td>Andrews</td>
<td>Abigail</td>
<td>aa123</td>
<td>Arm2, SingleArm</td>
</tr>
<tr>
<td>University of Kentucky</td>
<td>002004006RR</td>
<td>Norton</td>
<td>Nathan</td>
<td>nn123</td>
<td>SingleArm</td>
</tr>
<tr>
<td>University of Kentucky</td>
<td>08051982</td>
<td>Odinson</td>
<td>Thorr</td>
<td>333</td>
<td>SingleArm</td>
</tr>
<tr>
<td>University of Kentucky</td>
<td>111111111RR</td>
<td>Ducky</td>
<td>Daffy</td>
<td>013</td>
<td>SingleArm</td>
</tr>
<tr>
<td>University of Kentucky</td>
<td>12345678RR</td>
<td>Vader</td>
<td>Darth</td>
<td></td>
<td>SingleArm</td>
</tr>
<tr>
<td>University of Kentucky</td>
<td>12345678RR</td>
<td>America</td>
<td>Captain</td>
<td>bl-001</td>
<td>SingleArm</td>
</tr>
<tr>
<td>CCTS - Inpatient Unit</td>
<td>234392575224RR</td>
<td>Widow</td>
<td>Black</td>
<td></td>
<td>SingleArm</td>
</tr>
<tr>
<td>University of Kentucky</td>
<td>50546564</td>
<td>Odinson</td>
<td>Lokke</td>
<td></td>
<td>SingleArm</td>
</tr>
<tr>
<td>CCTS - Inpatient Unit</td>
<td>645645645RR</td>
<td>smith</td>
<td>John</td>
<td></td>
<td>SingleArm</td>
</tr>
</tbody>
</table>

If there is a new calendar as part of the amendment, the Coordinator will move the subject to the new calendar version once the subject has signed the new consent.

1. Select the subject using the checkbox under Select
2. Pick the applicable calendar version from the drop down
3. Click “Replace version”

NOTE: This CANNOT be undone once complete. Contact CRSO support if there is a problem with the calendar version.
Appendix: Adding Demographic Information

For protocols where there will not be medical record numbers used, you will have to manually enter all the subject’s details on the right-hand side of the page. Required fields are denoted with an asterisk (*). Once you have entered in all of the subject’s information, click **Add** to register them to the protocol.