Subject Administration

The primary focus of this section of training is on **Subjects**. In OnCore, a **Subject** is a person who is participating in a Protocol or may participate in a Protocol.

Consoles

There are two Consoles used in Subject management - the **CRA Console** and the **Subject Console**.

The Subject Console is designed with a Subject focus. The console provides access to a subject's demographic information, the Protocols the subject is associated with, what consents the subject has signed, what is their eligibility status, etc.

The CRA Console is designed to provide Subject information at a Protocol level. When a protocol is selected in the CRA Console it displays the subjects that have been accrued, which subject forms have been completed and are yet to be completed, a list of SAEs (Serious Adverse Events), visits outside of tolerance and protocol deviations in this protocol.

It is quite easy to move from one Console to the other. The CRA Console lists the subjects associated with the current protocol, and each subject has a link to display the subject in the Subject Console. Conversely, the Subject Console has a vertical tab to transfer to the CRA Console.

We will move between these Consoles as we discuss Subject Management. We will discuss the basic tasks when dealing with a Subject - registering the subject, logging consent information, placing them on study. One important part of this discussion will be entering data, especially key dates.

Creating a New Subject

Our first task will be to create a new Subject. Subjects must be associated with a Protocol.

1. Select the Subjects → CRA Console menu link.

2. Use the **Select Protocol** Find-As-You-Type field to locate the protocol that we will use in training.

   The CRA Console finds the protocol and displays the Accrual information (note the highlighted vertical tab).

3. Click the **New Subject Registration** vertical tab.

   You are presented with a screen to enter the Subject's information. Note that you are working in the context of your Protocol - you cannot enter a Subject into OnCore without a Protocol association!

   The first entry field is Study Site. Here you enter the Institution where the Subject will accrue. This is a find-as-you-type field, and allows you to choose from the Study Sites that are participating in this protocol.

4. In the Study Site field, choose the **Yale University**.

THIS SECTION WILL NOT WORK IN THE TRAINING ENVIRONMNENT BUT IS REQUIRED WHEN ENTERING NEW SUBJECTS IN PRODUCTION

When entering a new Subject, it is a requirement to see if they have already been entered into the OnCore system. OnCore in the live environment has an interface with Epic so we will need to search for the subject every time to see if they are already in the system.

On the left side of the page you may enter a Subject's MRN, last name, and birth date, then use the Find button to see if they are already in the system.

5. **Enter the MRN 123 and click the Find button.**

   A window of results appears. If any Subject matches are found, they display with hyperlinked Subject MRN values. Selecting the hyperlink will populate the fields in the New Subject screen. We will not select from this list – we will enter a brand new subject.

6. **Click the Close button in the result window.**

7. Enter the following into the **New Subject Details** table (asterisks next to the screen prompts indicate required fields):

   - **Subject MRN**: *Your Initials*123 (e.g. JFK123)
   - **Last Name**: *Your choice*
   - **Birth Date**: *Your choice*
   - **First Name**: *Your choice*
   - **Gender**: *Your choice*
   - **Ethnicity**: *Your choice*
   - **Race**: *Your choice*

8. Click the **Add** button to register the new subject to the Protocol.

   When you add the Subject, you are taken to the **Subject Console.**

Now that you are in the Subject Console, note the header area. It displays the Protocol, Protocol Status, the Subject's MRN and Subject Name. Note that the Subject has yet to be assigned a Subject Status.

The Subject Console is displayed with the **Demographics** tab active and the screen in Update mode. Here is where you can add additional Subject information - SSN, Contact Info, etc. This information is for the Subject, separate from the Protocol that the Subject is registered to.

Subject demographics information is at the top of the page. One field in particular, **Expired Date**, may drive some functionality. With the system configured to do so, entering an Expired Date can cause that date to cascade down to the **Off Treatment Date** and **Off Study Date** fields. It will also do the same for other protocols the subject is on at the time.

Additional Subject Identifiers Table

The **Additional Subject Identifiers** table holds identifiers for the subject that are in addition to the MRN. The Identifier Type is selected from a pre-defined list (a Domain), and free text can then be entered for the Identifier and Identifier Owner. An example of this is a hospital ID from another system.

Subject Contact and Emergency Contact Information

The final tables on the **Demographics** tab hold subject **Contact Information**, such as address, phone number, and e-mail address, and the **Subject's Emergency Contacts**. This information may be kept in OnCore or it may be kept in another electronic registration system.

Entering Subject Consent

1. Select the **Consent** vertical tab.

   At the top is a list of signed Consent forms - as this is a new registration, no Consent Forms have yet been signed.

2. Click the **Add** button at the upper right to display the Add Consent add block.

   The add block presents a dropdown list of Consent Forms that have been approved at the Subject's Study Site for this Protocol.

3. Use the dropdown list to select the **Compound Authorization and/or Informed Consent**.

4. Enter a **Signed Date** of 01/10/2011.

5. Click the >> button.

   Clicking the >> button is required. It causes OnCore to display the Version Date and Description for all Consents that match the chosen Consent Type that were approved by the Signed Date. If multiple Consents match the criteria, they are displayed as a selectable list. If only one Consent matches, it is selected by default.

   If more than one Consent displays, choose the latest one.

6. Select **Accepted** from the **Consent Status** dropdown.

7. Check the **Verified** checkbox (confirming your selections) and clicking the **Add** button.

   The Consent Form information is displayed along with the Subject's Signed Date. Note that the Subject Status has been changed to **CONSENTED**.

The "Other Consent Status" table is used to record comments related to consent information, record consents being refused or waived or withdrawn. If the study enrolls minors, an additional section called

“Age Reconsent Details” would display here to record when a minor subject has been reconsented when they reach the legal age limit.

8. Click the **Close** button.

Reconsents

When a newer consent is available for a Subject to sign (a new Consent was approved with a “Reconsent Required” indication), an **RR** superscript will appear next to the Consent Form type (e.g. **Compound Authorization and/or Informed Consent^{RR}**). This superscript will also appear next to the Subject MRN on the CRA Console → Accrual list. In a reconsent situation, OnCore does not restrict the Subject from receiving Treatment.

To deal with a reconsent situation, follow the procedure described above and add the newer version of the consent for the Subject.

If the newer version of the consent is not applicable to this Subject's situation, you can go to the Subject Console → Consent tab and select the consent hyperlink that includes the RR superscript. A box will appear allowing you to specify that reconsenting is not applicable. If you make this choice, the superscript will changed to “N/A” (e.g. **Compound Authorization and/or Informed Consent^{NA}**).

Subject Eligibility

Confirming Subject Eligibility is <u>not required</u> by OnCore before a Subject goes On Study, but it is usually done.

1. Select the **Eligibility** vertical tab.

   The Eligibility tab is used in one of two ways:

   - If the Protocol has defined an Eligibility questionnaire to assist in determining Eligibility status, the tab provides a way to supply answers to eligibility questions.
   - **If there is no Eligibility questionnaire, the tab can be used to directly enter the Eligibility Status.**

   Our Protocol does not have a questionnaire, and this is reported by the tab.

2. Click the **Update** button.

   The New Subject Eligibility table is displayed.

3. Enter the following:

   - **Version Date**: 04/05/2009
   - **Eligibility Status:** Eligible
   - **Verified By**: enter your initials
   - **Status Date**: 01/15/2011

   The Version Date refers to the Eligibility questionnaire. The Status Date is the date the eligibility CRF is completed and the subject is deemed officially eligible.

4. Click the **Submit** button.

   Note that the Subject's Status has been changed to **ELIGIBLE**.

5. Click the **Close** button.

Subject On Study

Our subject has Consented, and is deemed Eligible. Now let's place our subject On Study.

1. Select the **On Study** vertical tab.

2. Click the **Update** button.

Subject On Study Update Table

In the top table, the first field is **Sequence No**. This is a unique number identifying a particular Subject accrued to a Protocol. It may be manually entered, or OnCore can automatically generate it. Manual entry is generally used for co-op or industry sponsored studies (in which you receive a sequence number from the co-op group or sponsor). Automatic sequence numbering will occur if the Protocol has been set up that way. (This is the case for our training Protocol, and the reason that no entry field is provided.) Automated Sequence Numbers start with the value 1 by default, but the numbering scheme can be designated in the protocol.

One of the most important fields is **On Study Date**. When this is filled in and the data is submitted, this subject is considered **Accrued** to the study.

3. Enter an On Study Date of **02/01/2011**.

   The Primary Diagnosis and Secondary Diagnosis fields are dropdown selections based upon the protocol definition (values entered in the PC Console →Treatment → Disease tab).

4. Select the Diagnosis being studied on this protocol **(_______________________________)**.

The Study Site field will populate with the Study Site selected during the New Subject Registration entry. The study site browse will display all the study sites participating in the study.

The Transferred Date can be used to indicate the date that a Subject, who was enrolled on the protocol at another Institution, was transferred to the Study Site.

5. Click the **Submit** button.

   Note that the Subject's Status has been changed to **ON STUDY**.

Additional Protocol Subject Identifiers Table

The Additional Protocol Subject Identifiers table holds identifiers for the subject that apply to this protocol. The Identifier Type is selected from a pre-defined list, and free text can then be entered for the Identifier.

Subject Staff Table

The Subject Staff table holds information about the treatment staff assigned to the subject.

6. Select the following:

   - **Role**: Treating Physician
   - **Staff Name**: Your Choice

   Click the **Add** button.

   When a staff member has been added as subject staff, their name displays as two hyperlinks. In view only mode, selecting the hyperlink displays the staff members contact information (phone number and address). In update mode, selecting the hyperlink displays a screen where the staff member may be deleted or additional staff data (Stop Date, Stop Reason) may be entered.

   Clicking the **See All** button will display additional table fields (including a Stop Date and Stop Reason), as well as show staff with a past Stop Date.

   The **Team** button allows Subject Staff to be created from the already-defined Protocol Staff list.

7. Add yourself as a subject staff with the **Clinical Research Associate** role.

Subject On Treatment

In the Subject Console, the Treatment tab is where you select the **Arm** of the protocol that the Subject is assigned. You may also enter additional dates that are used in subject visit scheduling.

1. Select the **Treatment** vertical tab.

2. Click the **Add** button at the upper right.

   A table displays where you can choose the **Arm** from a dropdown list. Additional fields are provided that may be necessary for subject visit scheduling: **On Arm Date**, **On Treatment Date**, and **Off Arm Date**.

3. Select/enter the following:

   - **Arm:** Arm A
   - **On Arm Date**: 02/20/2011
   - **On Treatment Date:** 02/20/2011

   Click the Save hyperlink.

   Note that the Subject's Status has been changed to **ON TREATMENT**.

As you've been doing these steps, the visits have been populating on the subject's calendar if one has been created for the protocol. The calendar visits will be relative to the dates entered for each individual subject.

Off Treatment, On Followup, and Off Study

Additional subject statuses are available after **On Treatment**. They are: **Off Treatment**, **On Follow Up**, and **Off Study**. These can also be triggers for visit sections in the subject calendar. If the protocol doesn't have a follow up portion, the On Follow Up status isn't required.

We will see how to enter these statuses as an exercise, but will remove them afterwards so there won't be problems with the subject calendar.

1. Click the **Follow-Up** vertical tab.

   Four tables display. The first three store information relevant to the statuses.

2. Click the **Update** button (if necessary).

3. Enter an **Off Treatment Date** of **05/01/2011** and click the **Submit** button.

   Note the change in Subject status – they are now **OFF TREATMENT**. This table also holds a field for the **Off Treatment Reason** and a field for a free-text note.

4. Enter a **Follow-Up Start Date** of **05/15/2011** and click the **Submit** button.

   Note the change in Subject status – they are now **ON FOLLOW UP**.

   If you are using a protocol calendar, treatment visits with **Planned Dates** after the **Follow-Up Start Date** will no longer be available.

   There are many fields in the Subject Follow-up Update table. A few are related to tracking follow-up when there isn't a calendar and others are related to the last known status of the subject. The **Expired Date** field is also here in addition to being on the **Demographics** tab. It may be entered in either place.

5. Enter an **Off Study Date** of **06/01/2011** and click the **Submit** button.

   Note the change in Subject status – they are now **OFF STUDY**. This field should be filled in for subjects when they go off study or when they expire. The table contains two fields similar to the **Off Treatment** table: **Off Study Reason** and a free-text note field.

   You do not want your subject to be Off Study at this point, however.

6. Remove the **Off Treatment Date**, **Off Study Date**, and **Follow-Up Start Date** and click the **Submit** button.