OnCore Enterprise Research

Subject Administration – Full Study

Principal Investigator

Clinical Research Coordinator

August 2018
Table of Contents

What is the OnCore Enterprise Research System? .......................................................... 4
What is a Principal Investigator? ................................................................................. 6
What is a Clinical Research Coordinator? .................................................................. 8
Subject Administration – Full Study ......................................................................... 10
  Registering Subjects ............................................................................................... 12
  Register an Existing Patient .................................................................................. 12
  Create a New Patient .............................................................................................. 14
  Updating Subject Demographics ........................................................................... 15
Managing Subjects ..................................................................................................... 16
  Enter Subject Consent ........................................................................................... 16
  Determine a Subject’s Eligibility .......................................................................... 17
  Place a Subject On Study ....................................................................................... 18
  Add Subject Staff ................................................................................................... 20
  Place a Subject On Treatment ............................................................................... 21
  Enter Off Treatment, On Follow Up, and Off Study Statuses ................................ 22
  Create a Serious Adverse Event (SAE) ................................................................. 24
  Create a Follow-Up SAE ....................................................................................... 25
  Create a Subject Deviation ..................................................................................... 26
  Tracking Pre-Screenings ......................................................................................... 30
Create a Screening Record................................................................. 30
Add a Pre-Screening Subject to a Protocol.................................................. 31
Search the Pre-Screening Database .......................................................... 32
What is the OnCore Enterprise Research System?

OnCore stands for Online Collaborative Research Environment. It is a Clinical Trial Management System (CTMS) developed by Forte Research Systems that supports academic medical centers, cancer centers, and healthcare systems around the country. OnCore has been purchased by the University at Buffalo to support research activities and compliance, which will allow for enhanced trial management, robust reporting, enrollment tracking, and accurate clinical research billing.

Integration between OnCore and the Click portal will ensure that protocols submitted and reviewed by the IRB within Click are seamlessly transitioned to the OnCore system. The combined systems will manage the entire lifecycle of a research project, from protocol creation to project closeout.
What is a Principal Investigator?

The **Principal Investigator (PI)** is an Access Role in the OnCore Enterprise Research system. End users who are assigned this set of privileges are responsible and accountable for conducting the clinical trial or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

The Principal Investigator (PI) assumes full responsibility for the treatment and evaluation of human subjects, and for the integrity of the research data and results. The investigator is also responsible for entering the protocol into the Click portal, and ensuring that protocol was successfully transferred into the OnCore Enterprise Research system.

The PI is responsible for conducting clinical trials using **good clinical practice**:

- All trials are conducted ethically, as defined by the [Declaration of Helsinki](#)
- Benefits outweigh risks for each subject
- Rights, safety and well-being of subjects prevail over science
- All available non-clinical and clinical information on any investigational agent can support the trial as designed
- All trials are scientifically sound and clearly described
- All clinical trials have current Institutional Review Board (IRB) approval.
- Medical decisions and care are the responsibility of qualified health care professionals
- Everyone involved in the clinical trial is qualified by training, education, and experience
- Informed consent is given freely by every participant
- All study documentation is recorded, handled, and stored to allow accurate reporting, interpretation, and verification
- Confidentiality of subjects is respected and protected
- Investigational products maintain [good manufacturing practice](#) in storage, manufacturing, and handling
- Systems to ensure quality are implemented in all aspects of the trial
What is a Clinical Research Coordinator?

The **Clinical Research Coordinator (CRA)** is an Access Role in the OnCore Enterprise Research system. End users who are assigned this set of privileges typically handle most of the administrative responsibilities of a clinical trial. Their responsibilities may also include assisting in the preparation and submission of the study protocol, acting as a liaison to study sponsors and institutional officials, writing informed consent documentation, subject recruitment, patient care, adverse event reporting, preparing case report forms, and assisting with study close-out.

The CRA is responsible for conducting clinical trials using good clinical practice under the auspices of the Principal Investigator (PI):

- All trials are conducted ethically, as defined by the [Declaration of Helsinki](#)
- Benefits outweigh risks for each subject
- Rights, safety and well-being of subjects prevail over science
- All available non-clinical and clinical information on any investigational agent can support the trial as designed
- All trials are scientifically sound and clearly described
- All clinical trials have current Institutional Review Board (IRB) approval.
- Medical decisions and care are the responsibility of qualified health care professionals
- Everyone involved in the clinical trial is qualified by training, education, and experience
- Informed consent is given freely by every participant
- All study documentation is recorded, handled, and stored to allow accurate reporting, interpretation, and verification
- Confidentiality of subjects is respected and protected
- Investigational products maintain [good manufacturing practice](#) in storage, manufacturing, and handling
- Systems to ensure quality are implemented in all aspects of the trial
Subject Administration – Full Study

The focus of this training section is on subjects. In OnCore, a Subject is a person who is participating in a protocol, who is considering participating, or who is being evaluated for their eligibility to participate. Each subject record in OnCore represents one patient (one person) who is registered to a protocol. A person might have several subject records in OnCore if they are participating on more than one study or if they register to a study multiple times.

Levels of Information

Some information in OnCore is stored at the patient level; this information is the same throughout OnCore, no matter what protocol you are looking at. The patient information includes the Medical Record Number (MRN), demographics, address, emergency contact info, expiration date, and other optional identifiers such as the patient’s driver’s license number. If this information is updated anywhere in OnCore, it is reflected in all Subject records for that patient.

Other information in OnCore is stored at the subject level; this information is specific to the person’s enrollment on a particular study. The subject information includes the Sequence Number, consent dates and versions, eligibility criteria, study site, treatment and follow-up start dates, and visit details. When this data is entered or updated in a subject record, it does not change any other subject records.

Relevant Consoles

There are two consoles used in Subject Administration:

- **Subject Console**: This console allows you to view subject information within the context of a protocol. The console provides access to an individual 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 subject information at a protocol level. When a protocol is selected in the CRA Console, it displays all of 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.

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 links to the corresponding subject in the Subject Console. Conversely, the Subject Console has a vertical tab to transfer to the CRA Console.

As you manage subjects, you will move between these consoles. This section of the manual covers the basic tasks when dealing with a subject: registering the subject, logging consent information, and placing the subject on study. An important part of this discussion will be centered on entering data, especially key dates.
Registering Subjects

The first task is to create a new subject. Subjects must be associated with a protocol.

Register an Existing Patient

1. Navigate to Menu > Subjects > CRA Console.

2. Enter a search term in the Select Protocol field to locate and open the desired protocol.

3. Click the Register Subject tab.

   The Register Subject page allows you to search for existing subjects or add a new patient. Note that you are still working within the context of your protocol; a subject cannot be entered into OnCore without a protocol association.

4. Choose a Study Site from the drop-down menu. This field indicates the location where the subject is enrolled or where they are seen most by the study staff. This will show up on some reports and may be useful for your reference.
5. When entering a new subject, first check to see whether they have already been entered into OnCore, in order to avoid duplicate subject entries. In the Find Subject section on the left, enter the subject’s last name in the Last Name field and click the Find button.

**NOTE:** The Subject Find Results table shows subject records that already exist in OnCore. These subjects are already associated with another protocol. If you want to know if they are currently active in another study, contact CTMS@buffalo.edu.

6. The Subject Find Results table shows all subjects matching the search criteria. The Subject MRN, or OnCore Subject ID, displays as a link.

7. Click the OnCore Subject ID to populate the fields in the New Subject Details screen with the selected subject’s data.

8. Click the Add button to add the subject to the protocol.
Create a New Patient

If the patient does not yet exist in OnCore, you must create a new patient record. The new patient will be enrolled on a protocol and a subject record will be generated.

1. On the Register Subject page, click Clear All.

2. Choose a Study Site from the drop-down menu. If the patient will be seen at multiple sites, pick the one that the patient will be seen at most of the time.

3. Click the Generate button to create an OnCore Subject ID for the patient. This is a unique ID number that is only used to identify a subject within OnCore across all protocols. This is not the subject number designated by the sponsor, which will be documented on the “On Study” tab in the Subject Console.

4. Enter demographic information for the patient in the required fields, and in any additional fields that are appropriate.

5. Click the Add button to add the subject to the protocol.
The Subject Console page will open on the Demographics tab. The Subject Demographic information you entered will appear on the page.

**NOTE:** If there is a duplicate subject created or you need to have a subject record deleted, please contact CTMS@buffalo.edu.

**Updating Subject Demographics**

Subject demographic information is updated on the Demographics tab of the Subject Console. Clicking Update allows you to make changes to a subject’s demographic and contact information.

- **Contact Information** - Contact information, such as address, phone number, and e-mail address, and the subject’s emergency contacts.

![Contact Information](image1)

- **Additional Subject Identifiers** - Identifiers for the subject other than the OnCore System ID. Information in the Identifier Type field is selected from a pre-defined list; free text can be entered in both the Identifier and Identifier Owner fields. An example of an additional Subject Identifier is a Hospital ID from another system.

![Additional Subject Identifiers](image2)

**NOTE:** Do not enter the patient’s Social Security Number into OnCore.
Managing Subjects

Subjects in OnCore can progress through several statuses during the course of the protocol. The vertical tabs in the Subject Console - Consent, Eligibility, On Study, Treatment, and Follow-Up - allow you to record this status information. These statuses may also trigger calendar dates within the subject’s protocol calendar.

Enter Subject Consent

When you select a subject, the Subject Console header displays the Protocol, Protocol Status, the OnCore Subject ID, and Subject Name. Note that the subject does not yet have a Subject Status. In the next procedure, you will set the subject’s status as having consented to the protocol.

1. Navigate to Menu > Subject Console > Consent.

The Consents section will list signed consent forms for this subject. If the subject is a new registration, the message ‘No Subject Consent Found’ will appear in the Consents section because no consent forms have yet been signed.

2. Enter the date that the subject signed a consent in the Signed Date field and then click Select Consents. A subject needs to have a documented date before you can put the patient “On Study” or check them into study visits within the protocol calendar.

3. A list of available Consents opens, showing consent forms for the subject that have been approved by the IRB at the subject’s Study Site. There may be multiple consent versions which will be indicated by a + to the left of the consent. A list of other versions will appear and you can enter additional signed dates here.
4. Enter the **Signed Date** (if not already populated), select **Accepted** for the appropriate **Consent (s)**, and then click **Save**.

5. The **Consent** form information appears along with the **Subject's Signed Date**, and the **Subject Status** field at the top of the page will be updated to **CONSENTED**.

   - **NOTE**: If a subject was consented on an older version of the **Consent form**, an **RR superscript ("RR")** will appear next to the patient’s **OnCore Subject ID** in the **CRA Console**, to indicate that the subject needs to reconsent on the newer version.

   - The **Other Consent Status** table records comments related to consent information, consents being refused, waived, or withdrawn.

   - The **Age Reconsent Details** table records re-consents when a minor subject has reached the legal age, and will only appear once the age of consent has been reached by the **Subject**.

6. Click the **Close** button.

---

**Determine a Subject’s Eligibility**

Confirming a subject’s eligibility is **not** required by **OnCore** prior to placing that subject **On Study**, but it is helpful in recording screen failures and triggering invoices if applicable. To confirm a subject’s eligibility, use the following procedure:

1. Navigate to **Menu > Subject Console > Eligibility**.
The **Eligibility** tab is used to record the subject’s eligibility status and the date of that status.

2. To record the subject’s eligibility, click the **Update** button (if necessary).

3. Complete the form as directed, entering information into the fields:
   - Indicate an **Eligibility Status** by selecting from the drop-down menu
   - Enter your initials in the **Verified By** field
   - Select a date in the **Status Date** field. This is the date patient was confirmed eligible or not eligible.
   - Click the **Submit** button

4. Note that the **Subject Status** has been changed to match your selection.

5. Click **Close**.

**Place a Subject On Study**

Once a subject has been deemed eligible for the study, they need to be **placed On Study**.

1. Navigate to **Menu > Subjects > Subject Console > On Study** and click **Update**.

2. Enter the **Sequence Number**. This is the patient’s ID number related to the study. It is a number assigned by the sponsor or study team.
3. Select the **On Study Date**. This is usually the date that the patient is randomized in the study to receive treatment, a device, or other therapy, signifying that the patient has successfully enrolled in the study.

**NOTE:** The **On Study** status is tied to the subject’s calendar and is **specific to each study**. The definition for this date will be communicated to you by the CTMS team once the calendar has been built.

4. Enter a **Primary Diagnosis**, and a **Secondary Diagnosis** as appropriate. This is for reporting purposes. If there is not an applicable diagnosis listed in the drop down list, please contact the CTMS team.

5. Enter a **Diagnosis Date**, and indicate the status from the drop-down menu. This is not required and is for your reference.

6. Enter a **Zip at Registration**. This is **mandatory**, and is needed to generate accurate reports from the system.

7. The **Study Site** will pre-populate. You can edit the information here by clicking on the search icon (🔍).

8. If applicable, select a **Transferred Date**; this field indicates the date that a subject who was enrolled on the protocol at another institution was transferred to the study site.

9. Enter **Comments**, if necessary.

10. Click **Submit**. The **Subject Status** in the header will change to **ON STUDY** and a **Sequence Number** will appear.

11. **Additional Protocol Subject Identifiers**, such as the **Subject Screening ID #**, can be added if useful to your team. Select from the **Identifier Type** drop-down menu.

12. Enter the number in the **Identifier** field, and click the **Add** link.
Add Subject Staff

The Subject Staff section on the Subject Console > On Study page holds information about the treatment staff assigned to the subject. Assigning staff to a subject is very helpful and will allow the staff to quickly access the subject and their visit dates.

1. Select a Role from the drop-down menu.

2. Begin typing a name in the Staff Name field to search for and select a staff member. This staff member will be able to view this subject in My Console and in the Subjects widget on the home screen.

3. Select a Start Date; the date the staff member will begin working with the subject.

4. Click the Add button.

When staff members have been added to the subject record, their first and last names appear as links in the Subject Staff section. In view-only mode, selecting the name link displays a staff member’s contact information. In update mode, selecting the name link opens a window where additional staff information can be added, or where the staff member can be deleted.

Click See All to display additional subject staff fields.

5. Click Team to create subject staff from the already-defined Study Team list (the list of all study team members assigned to the protocol).
6. To add study team member(s), simply place checkmarks in the Select column. Then click the Submit and Close buttons. To add all members at once, choose Select All and then submit.

**Place a Subject On Treatment**

In the Subject Console, the Treatment tab allows you to select the protocol arm assigned to the subject. You can also enter additional dates used in subject visit scheduling. This date may trigger dates in the subject protocol calendar, and will be specified in the Calendar Notes located in the footnotes section of the Subject Calendar.

1. Navigate to Menu > Subject Console > Treatment, and then click Add.
2. Select an Arm from the drop-down menu.
3. Select the On Arm Date. This is the date the subject was randomized or assigned to a specific arm of a study. For example, this could be the date the patient goes on the “Randomized” arm or the “Open-Label” arm of a study.
4. Select the On Treatment Date; this date activates the Treatment section of the Subject Calendar. As you’ve been doing these steps, visits have been populating on the subject’s calendar (if a calendar has been created for the protocol). The planned dates for the visits in the calendar are relative to the dates entered for each individual subject.
5. Click Save. The Subject Status in the upper right of the page will change to ON TREATMENT.

**Note:** When the subject is off of the study Arm, you can edit this page to include the Off Arm Date.
Enter Off Treatment, On Follow Up, and Off Study Statuses

Additional subject statuses are available after On Treatment, including Off Treatment, On Follow Up, and Off Study. These statuses can also be triggers for visits in the Subject Calendar. If the protocol doesn't have a follow up portion, the On Follow Up status isn't required.

Off Treatment

1. Navigate to Menu > Subject Console > Follow-Up, and then click Update.

2. Select an Off Treatment Date. This is typically the last date the patient is receiving study treatment, and can be specific to each protocol.

3. Select an Off Treatment Reason.

4. Add comments to the Explain field, if necessary.

5. Click the Submit button. The Subject Status will change to OFF TREATMENT.

On Follow Up

1. Select a Follow-Up Start Date. This is the date the patient has completed study treatment visits or the last day of treatment, and is now being followed up per protocol.

2. Edit the Transferred To (Study Site) by clicking on the search icon to locate the site where the subject will be seen for follow-up visits, if different from current location.
3. Enter information in the additional fields, as necessary:

   - **Alternate MRN** – The MRN for the subject at the follow-up site when the follow-up will be performed at another study site, if applicable.

   - **Last Follow-Up Date** - The last date verified from the Follow-Up section of the subject calendar can be entered here when the patient completes the study.

   - **Next Follow-Up Date** - Date of the next follow-up visit can be entered here.

   - **Last Known Survival Status** – The patient’s survival status.

   - **Expired Date** - The date of death reported to institution personnel. The Approx? checkbox can be used if the reported date is not exact.

   - **Last Known Date Alive** - This is the last date that institution personnel knew the subject was alive.

   - **QA Date** - The date the subject’s record was reviewed for accurate and complete data.

   - **Comments** - A free-text entry field for comments related to the subject follow-up.

4. Click the **Submit** button. The **Subject Status** will change to **ON FOLLOW UP**.

**Off Study**

1. Select an **Off Study Date**. This is the very last visit date for the patient.

2. Select an **Off Study Reason** and add comments to the **Explain** field, if necessary.

3. Click the **Submit** button. The **Subject Status** will change to **OFF STUDY**.
Create a Serious Adverse Event (SAE)

The SAEs tab in the Subject Console records any serious adverse events associated with a subject. SAEs must be entered at the subject level; however, SAEs can be viewed across all subjects at the protocol level in the CRA Console. Documenting SAEs are useful for safety monitoring as well as triggering invoices.

1. Navigate to Menu > Subjects > Subject Console > SAEs tab and click New.

2. Enter the required information for this Serious Adverse Event (SAE), as well as any other appropriate details:
   - Event Date – Enter the date the SAE occurred (required)
   - Reported Date – Enter the date that the SAE was reported (required)
   - Reported By – Enter your name/initials
   - Outcome - Select from the dropdown menu (required)
   - Event Narrative – Enter a brief description of the adverse event
   - Protocol Attribution – Select from the drop-down menu

   **NOTE**: The Event Date must be on or after the subject’s Consent Date.

3. The following optional sections of an SAE allow you to track additional details, if desired:
   - SAE Classification - Allows you to select one or multiple SAE classifications from a drop-down list.
• **Adverse Event Details** - This section is optional, but if information is entered in this section, all required fields must be filled before clicking Add.

• **Tracking Details** - Records the dissemination of information regarding the SAE.

• **Additional SAE Identifiers** - Records other identifiers for the SAE, such as a number assigned by the IRB. An Identifier Type can be selected from the drop-down list and free text can be entered into the Identifier and Identifier Owner fields.

• **Supporting Documents** - Allows you to upload files relevant to the SAE

4. Click **Submit**. Upon submission, an **Event Number** will be assigned to the SAE. This unique number appears at the top of the page.

5. SAEs can be locked when you are finished to prevent edits to all but the **Tracking Details** section. Click **Complete and Lock**.

**NOTE:** Even though the SAE has been locked, you have the ability to update the **Tracking Details** section of the SAE and to create a follow-up SAE.

**Create a Follow-Up SAE**

**OnCore** allows you to create a follow-up to an existing SAE. The follow-up SAE copies most of the parent record’s information; you can then make modifications as needed (most commonly this involves changes to the **Outcome** field).

1. Select the **SAEs** tab and click on the SAE’s **Event No.** link.

2. Click **Create Follow-Up**.

   A follow-up SAE is created and a new **Event No.** is assigned to this SAE. The **Event No.** of the parent SAE appears next to it in parentheses. The **Follow-Up Number** appears on the right side of the header band.
3. Enter the required information for this follow-up SAE, as well as any other appropriate details.

4. Click Submit to save your entries, and then click the SAEs vertical tab.

You can see that the Event No. of the SAE shows its relationship to the parent.

**Note:** The follow-up SAE has a Delete link in the Delete column but its parent SAE does not. When SAEs are deleted, they must be deleted in reverse order of creation (the child SAE must be deleted before the parent SAE).

**Create a Subject Deviation**

A deviation is a variance from the approved protocol procedures. Deviations specific to an individual subject are entered via the Subject Console > Deviations tab.

1. Navigate to Menu > Subjects > CRA Console.
2. Enter a search term in the Select Protocol field to locate and open the desired protocol.
3. Locate the desired Subject from the list on the right, and click the OnCore Subject ID.
4. The Subject Console will open; click on the Deviations vertical tab.

There are two tables on the Deviations tab:

- **Subject Deviation Details** - Shows the subject’s deviations
- **Visits Outside Tolerance** – This will automatically show any visits that have been checked in with a visit date outside of the planned date’s tolerance
5. Click the New button.

**NOTE:** The Date Discovered and Reported By fields default to the current date and user, but they can be changed. When entering Deviation data, the required fields are marked with an asterisk (*).

6. Enter the required information for this Subject Deviation and complete additional fields as appropriate.

These can be:

- Date Discovered - Enter the date that the deviation was detected
- Deviation Date - Enter the date that the deviation occurred
- Category – Select the type of deviation
- Description of Deviation - Enter a brief description of what occurred
- Action Taken – Enter a description of the action taken by the research team

7. Click Submit to create the deviation.

8. You can also print out or save a PDF of the deviation that can be used for your records or to send to the PI or sponsor.
9. Click the **Deviations** vertical tab to see the updated page.

The **Delete** link allows you to delete a deviation record entered in error.
Tracking Pre-Screenings

OnCore supplies a way to track pre-screening efforts for potential subjects and the time spent pre-screening these candidates. This feature is available to your site but it is optional. The information captured includes subject referral data, subject characteristic data, and protocol evaluation specifics.

Create a Screening Record

1. Navigate to Menu > Subjects > Pre-Screening.

   The initial page is a search tool. See the Search the Pre-Screening Database section for instructions on how to use this tool.

2. Click New to create a new pre-screening record.

   The Referral Information table is where you can record referral and contact information.

3. Choose a Management Group from the drop-down menu.

4. Select a Contact Date; the date the subject was contacted. This is a required field.
5. Select a **Referral Channel**, and if referred by a physician, select a **Referring Physician**.

6. The next section records **Subject Characteristics**. All data-entry fields are optional. Enter a **Subject Identifier**.

7. Select a **Disease Site** from the drop-down menu if the study is an oncology study.

8. Select a **Diagnosis Group**, if applicable.

9. Select one or more **Race** checkboxes, and select an **Ethnicity**.

### Add a Pre-Screening Subject to a Protocol

After the potential subject has been evaluated, you can enter evaluation data in the bottom portion of the screen.

1. Select your protocol number in the **Protocol No.** field.

2. Select **Yes** for **Subject Consented?**, and then click elsewhere in the screen.
When a Protocol No. is entered and the patient is listed as having consented, the Add Subject to Protocol button appears.

3. Click Add Subject to Protocol.

You are transferred to the Register Subject screen. On this page you can add a new subject to the protocol; the patient’s demographic information will carry over.

Search the Pre-Screening Database

In the Pre-Screening Database Search window, you can enter or select data in the various fields to narrow your search.

1. Navigate to Subjects > Pre-Screening.

2. Enter a date range for your search, using the Entered Date From and Entered Date Thru fields.

3. Use the additional fields to narrow your search:
   
   o Entered By – The name of the person who entered the original pre-screening record.

   o Management Group – The Management Group identified with the original pre-screening entry.
- **Evaluated By** – The name of the person listed in the ‘Evaluator’ field in the pre-screening record.

- **Subject Identifier** – Initials or other identifier of the person captured with the original pre-screening entry.

- **Protocol No.** – Any protocol currently entered into OnCore.

4. Click Submit.

5. The **Search Results** screen displays the search criteria in the header and the found records in a table below. The column headers in the table are links; click the links to sort the records in that column.

6. Click the **Pre-Screening ID** link to display the **Pre-Screening Record**. Click Update.

   Additional fields allow you to indicate who did the evaluation and the time it took, if the patient is eligible. After the patient goes On Study, the **Patient On Study** and **Record Completed** fields can be set to Yes. You can enter additional information in the **Subject Notes** section that appears at the bottom of the page.

7. Click **Submit** to save the information, and then click **Close**.