



ONCORE SUBJECT REGISTRATION AND REPORTING PROCESS
*Items marked with an * are required fields/steps*

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I. INTERVENTIONAL ENROLLMENTS: Pre-Screening and Subject Registration

The following steps should ideally be completed on the same day that informed consent was obtained. For studies involving bill review in Epic, the following steps notated via **bold text MUST** be completed BEFORE any study-related procedures are performed and no later than one business day following consent. For all other studies, subject reporting should occur on a monthly basis. Steps notated via an “*” are required for all subjects that sign consent. Please reference SOP ADM-004 for additional details.

STEP 1: Completing the OnCore Pre-Screening Record

Selected interventional studies through the CCPS DSG may not utilize the pre-screening console if it is determined to be not applicable by central UFHCC review. If not applicable, skip to step #2 to register subjects directly within the Subject CRA Console.

1. Under the Subjects tab choose Pre-Screening
2. Select the [New] button
3. Enter the required information
 - a. ***Management Group** > Choose from dropdown list.
The management group should be the group that is handling the screening/coordination efforts for the particular subject.
 - b. ***Contact Date** = Date subject initially approached about the study
 - c. Referral Channel (if none apply, select “Internal Referral or Consult”)
 - d. Referring Physician = Treating Physician
 - e. ***Subject Identifier** = UF Health medical record number (MRN)
 - i. Certain situations may allow for subjects who have a cancer diagnosis to be enrolled without a UF Health MRN. *Permission to create OnCore-only MRNs must be specifically requested from OCR before you will be able to complete this process.*
 - ii. If no UF Health MRN is found in the EMR and your protocol is configured to allow auto-generation of MRNs, you can auto-generate an OnCore-only MRN outside of the Pre-Screening console:
 1. In the ‘Find Subject’ block of Subject CRA Console (you may need to click “Register Subject” first on the left-hand side of screen), select the [Create New] option, and the ‘Subject Details’ block will populate;
 2. In the Subject Details block, select the blue arrow in the Study Site field and select “No UF Health MRN” from the drop down;
 3. In New Subject Details block, click the “Generate” button to auto-generate the Subject MRN.
 - f. *** Disease Site** for the Subject
 - i. For subjects with a diagnosed cancer: use Disease Site and choose the appropriate disease site from the dropdown list
 - ii. For subjects without a diagnosed cancer select: leave blank



NOTE: When reporting Race and Ethnicity, confirm the populated race/ethnicity options with the subject's self-reported data. Please use the UFHCC Research Subject Demographic Form to collect race and ethnicity data (Appendix A) and upload this form into OnCore after obtaining consent.

- g. ***Race**
*NOTE: Multiple Race entries are allowed; **reporting** "Subject refused" or "unknown" should only be used as a last resort.*
- h. ***Ethnicity**
*NOTE: Only one entry is allowed; **reporting** "Subject refused" or "unknown" should only be used as a last resort.*
- i. ***Subject Evaluated = 'Yes'**
- j. ***Evaluator** = Enter the name of the individual that screened the subject
- k. **Time Spent** = Enter the time spent evaluating this subject for study
- l. ***Protocol Number** = Enter the OnCore Protocol ID # (OCR Number)
- m. ***Subject Consented** = 'Yes' or 'No' as applicable.
 - i. 'Yes' -will populate the [Register Subject] button, please complete the rest of the form before selecting;
 - ii. 'No' – please provide a reason why the subject was not consented in the comments section after submitting the form.
- n. ***Subject Eligible** = 'Yes' or 'No' as applicable
 - i. **If 'No' a Reason Not Eligible MUST be provided.**
- o. ***Record Completed** = 'Yes' or 'No' as applicable
 - i. 'Yes' if all eligibility has been confirmed;
 - ii. 'No' if screening procedures are still in process. Once all eligibility has been met, revise this response to 'Yes'
- p. Select **'Submit'**
- q. Select **[Register Subject]** > This will re-direct you to the Subject CRA Console (Step #2 below)

STEP 2: Subject Registration in the OnCore Subject CRA Console

Manual creation of records in OnCore for subjects with a MRN is not allowed. If your subject cannot be found via MRN and/or last name, please contact the OnCore support team at: oncore-support@ahc.ufl.edu or 352-273-5924.

From the "Register Subject" screen upon completion of Step 1, or by navigating from Subject CRA Console [Menu → Subjects → CRA Console, find/confirm your study from the "Select Protocol" dropdown list, and click "Register Subject" on left side of screen]:

1. Under the "Find Subject" section, choose Study Site from the dropdown list
2. Search for UF Health subject by MRN and/or last name:



- a. Select the appropriate patient from the “Find Subject Results”; this will auto-populate the demographic data from the EMR.
 - i. If no UF Health MRN is found in the EMR and your protocol is configured to allow auto-generation of MRNs, you can auto-generate an OnCore-only MRN. *Permission to create OnCore-only MRNs must be specifically requested from OCR before you will be able to complete this process.*
 1. In the “Find Subject” block, click the [Create New] option, making available the “Subject Details” block;
 2. In the Subject Details block, select the blue arrow in the Study Site field and select “No UF Health MRN” from the drop down;
 3. In New Subject Details block, click the “Generate” button to auto-generate the Subject MRN.
- b. Confirm the populated race/ethnicity with the subject’s self-reported data.
NOTE: Please use the UFHCC Research Subject Demographic Form to collect race and ethnicity data (Appendix A).
*NOTE: Multiple race entries are allowed and only one ethnicity option is allowed; **reporting** “Subject refused” or “unknown” should only be used as a last resort.*
- c. Select the “Add” button to continue into the study-specific registration section.
- d. Review the Subject Demographics update that populates in the subject record.
 - i. Confirm: **Country** is added and accurate. (**Enter the country (or “United States”)**).
- e. Click ‘submit’ to save.

STEP 3: Additional Information

1. **Documents/Info:** (*required for all studies that have consent(s))
 - a. Upload a PDF of the signed consent form under the ‘Attachments’ tab
 - i. Select [Add]
 - ii. Document Type = Signed Informed Consent
 - iii. Version Date = Date of informed consent execution
 - iv. Attach PDF file of signed Informed Consent.
 File name should be: MRN_Study OCR#_Consent ID
 EXAMPLE: 0123456_OCR1234_ICF-A
 - v. Description = Initial ICF
 - vi. Select [Add]
 - b. Upload a PDF of the completed Research Subject Demographic Form (Appendix A) under the ‘Attachments’ tab
 - i. Description = Subject Demographic Form
 - ii. Select [Add]
 - c. Open files to confirm completeness of uploads

-
2. **Consent:** (*required for all studies that have consent(s))
 - a. In the Subject CRA Console, select the Consent tab
 - b. Select [Update] to add a signed consent form
 - c. In the Available Consents block, select the date the ICF was signed and then click [Select Consents]
 - d. Select the appropriate consent from the Available Consent pop up window
 - e. Check the 'Accepted' radio button, and then select [Save]

 3. **Eligibility:** (*leave blank until you know the subject's final eligibility status*)
 - a. Version Date = the version date of the protocol used to determine eligibility
 - b. Verified By = name of the Study Coordinator that confirmed the subject's eligibility
 - c. *Status Date = the date that the subject is deemed fully eligible or a screen failure
 - d. *Eligibility Status = Select the correct eligibility status (Eligible or Not Eligible) from the dropdown.
 - i. 'Eligible' indicates subject meets ALL inclusion criteria, and no exclusion criteria
 - ii. 'Not Eligible' - **if Not Eligible is chosen, a 'Reason Not Eligible' MUST be selected from the corresponding dropdown.**
 - iii. 'Eligible (O)' should only be used in the rare circumstances that a waiver of eligibility is granted on a study for which waivers are permitted per UFHCC SOP SM-010: *Study Subject Review and Verification Processes*.
 - e. Select [Submit]

 4. **On Study:** (*REQUIRED at time of consent, even if the subject does not go on study*)***Make sure the patient is closed out of EPIC***
 - a. Sequence number (*required if subject goes on study);
Can be entered later, once the subject has been formally registered/randomized or is otherwise considered 'On Study' per protocol (please *see subject status definitions below*) AND/OR automatically assigned by OnCore.
 - b. On Study Date = The date the subject is registered/randomized for studies that have a formal process or the date that Eligibility is confirmed for studies that do not have a formal registration/randomization process. (*Required if subject goes on study; please see subject status definitions below.)
Can be entered later once registration/randomization/eligibility is confirmed.
 - c. ***Disease site** > select from dropdown;
 - i. If subject does not have a cancer diagnosis (i.e. is a healthy volunteer or control subject) select: C999 – Healthy Volunteer**.
 - d. Histology > select from dropdown.
 - i. If the exact histology is not listed in the drop down, select "View All" from the top of the list, to search the full list for the desired histology. If the histology is not listed in the full list, confirm histology with treating investigator;

- ii. If subject does not have a cancer diagnosis (i.e. is a healthy volunteer or control subject or has a non-malignant diagnosis) – leave Histology blank.
- e. Diagnosis Date > select “not available” if not known; otherwise, enter the actual or approximate date.
- f. ***Disease Site Group** > the group selected should reflect the subject’s disease site. This field will default to the primary DSG that was designated when the protocol was initially entered into the system, HOWEVER, some protocols serve more than one DSG and it is important to credit the correct DSG with the enrollment as this information feeds into the Cancer Center’s DSG Progress Reports (refer to ADM-005 on how to select the correct DSG).
 - i. All subjects under the age of 18 must be assigned to the Pediatric DSG.***
- g. ***Study Site** > Enter the site where the subject will be seen/treated if not already defaulted to the correct site.
- h. *** Zip at Registration (Full 9-digit zip code)**
(NOTE: this is the zip code field that is pulled for data reporting.)
 - i. Full 9-digit zip codes can be found through the USPS website:
9-digit Zip Code Lookup: <https://tools.usps.com/zip-code-lookup.htm?byaddress>)
 - ii. If the subject is not from the United States and no zip code is available, please leave blank and enter the Country of Residence into the subject’s Demographic page.
- i.
- j. Under the Subject Staff block, assign an individual to the following required roles (select [Add] after assigning an individual to each role):
 - i. ***Consenting individual** = Person who co-signed the ICF
 - ii. ***Enrolling Faculty** = MUST be listed for every subject consented to an interventional protocol.
Enrolling Faculty may be the same as the consenting individual
 - iii. ***Primary Study Coordinator** = primary study coordinator for this subject.
If multiple coordinators work on the same study, assign the coordinator who will be primarily responsible for this subject. Only one primary coordinator should be assigned per subject.
- k. ***Insurance** >Select the accurate subject medical insurance option(s).
 - i. If multiple options are selected, a “primary” insurance type must be selected.
 - ii. This information can be verified within EPIC.
 - iii. Only the type of insurance is needed. No additional information is required.
- l. Select [Submit].

II. NON-INTERVENTIONAL ENROLLMENTS: Subject Registration

Enrollments to non-interventional studies may be logged into OnCore using the interventional steps outlined above or via the summary accrual steps described below. **Summary accrual for each study should be updated on a monthly basis at a minimum. Data entry will be confirmed each quarter** (e.g. 1/1-3/31, 4/1-6/30, 7/1-9/30, and 10/1-12/31).

Enter the subject into the OnCore Accrual Record (Study status must be “Open to Accrual” to allow subject accrual entry).

1. Under the Protocols -> PC Console tab, enter the select Protocol and then choose Accrual on the left-hand side
2. Select the [Update] button (right-hand side)

NOTE: If the study is not approved for summary accrual reporting, this [Update] button will not appear. If you think that you should have the option to report accruals via summary mechanism but no [Update] button appears, please contact Ashley Anderson at adanderson@ufl.edu.)

3. Enter the required information

- a. ***From Date** = 1st of the month
- b. ***Thru Date** = End of the month
- c. ***Accrual**= Enter number of patient(s) enrolled during the month*

NOTE: a, b, and c can either be individual subject/date entry or can be a cumulative range if the demographic information is the same. These dates should reference when the subject(s) formally enrolled in the study (i.e. signed consent or offered a waiver of documentation of consent/registered with study/randomized)

Example: If 5 subjects were enrolled over a one-month period and their demographic information was similar, then all 5 accruals could be entered at the same time. Any enrollments added using a cumulative range must be entered within the same calendar year (i.e. enrollments must be broken down by year).

- d. Select Institution from the drop down
- e. ***Internal Accrual Reporting Group** (this should populate automatically; if not, and you are unsure what to choose, please contact Ashley Anderson at adanderson@ufl.edu)
- f. ***Gender**
 - i. **Select biological sex (sex assigned at birth)**
 1. **Male**
 2. **Female**
 - ii. **If unknown, select “Unknown”**
- g. ***Age Group** (Age ranges in OnCore are presented in 10-year increments)
- h. ***Ethnicity**
Please confirm the race/ethnicity with the subject’s self-reported data (Appendix A can be used to collect this data).



*NOTE: Only one entry is allowed; **reporting** "Subject refused" or "unknown" should only be used as a last resort.*

i. ***Race**

Please confirm the race/ethnicity with the subject's self-reported data.

*NOTE: Multiple Race entries are allowed; **reporting** "Subject refused" or "unknown" should only be used as a last resort.*

j. ***Disease Site** for the Subject

i. For subjects with a diagnosed cancer, use Disease Site and choose from dropdown list

ii. For subjects without a diagnosed cancer, leave this blank.

k. **Recruited by** either the investigator or treating physician (if they are the same; if the name on the signed consent form is not a physician or faculty member, enter the investigator name]. If not known, leave blank.

l. Zip at Registration (**Full 9-digit zip code**) = subject's zip at registration.
(Full 9-digit zip code is preferred if available but not required.)

m. Select [Add] > this will update the below listing of accruals and update the Accrual table.

n. Select [Close]

III. UNDERSTANDING SUBJECT STATUS FOR INDIVIDUALLY REGISTERED SUBJECTS

The Cancer Center requires that all subject status updates for interventional enrollments be made within **one business day** of adjustment. The primary study coordinator is responsible for ensuring OnCore accurately reflects the current status of all subjects. The most common sequence of statuses for a subject is as follows:

1. **Consented:** Subject has at least one consent signed date entered and linked to a consent as added in the PC Console to the subject's study site. This is the initial status for all subjects who consent to a study.
2. **Eligibility:**
 - (1) **Eligible:** Subject met all eligibility criteria and will be moved to On Study;
 - (2) **Ineligible:** Subject failed one or more eligibility criteria, withdrew consent prior to registration/randomization, or will otherwise not be moved to On Study;
 - (3) **Eligible(O):** Eligible with override;
Eligible (O) should only be used in the rare circumstances that a waiver of eligibility is granted on a study for which waivers are allowed per UFHCC SOP *SM-010: Study Subject Review and Verification Processes*.
3. **On Study:** Subjects may be moved to the On Study status once they have been formally registered/randomized or are otherwise considered eligible per the protocol. This step typically occurs following verification of eligibility. Subject is considered *accrued* when On Study date is entered in OnCore.
4. **On Treatment:** Subject is considered On Treatment when associated with a Treatment Arm and an On Treatment date is entered within the Subject CRA Console.

NOTE: For studies that do not include a "treatment", subjects will not be moved to the On or Off Treatment statuses. Instead, those subjects will remain On Study during the study participation/intervention period and then will move to an On Follow-up or Off Study status as appropriate.

5. **Off Treatment:** This date should reflect either the day after the last dose of therapy for subjects that complete treatment per protocol or the day that the decision is made to discontinue therapy otherwise. An Off Treatment Date must eventually be entered for any subject that has an On Treatment date. All subjects should be immediately moved into follow-up status or off study depending on the study.



6. **On Follow-up:** Typically, the On Follow-up date is the day after the subject's Off Treatment date. All subjects in long term follow-up should be in this status.

7. **Off Study:** This status is used when it is determined that no further interaction with the subject is required. You should confirm how long each subject is to be followed per protocol and their consent. If they are followed indefinitely, this date is only entered upon death (will populate automatically if you enter an expiration date), the subject withdraws from further follow-up, or the study is closed at the IRB (you will have to manually enter this date for all subjects).

IV. SERIOUS ADVERSE EVENT REPORTING

The Cancer Center requires that all SAEs occurring in subjects enrolled on UF Interventional IITs be logged into OnCore.

1. In the **Subject Console > SAEs** tab, click **New**.
2. Enter the following information in the Subject SAE Update section (at the top):
 - **Event Date:** enter the start date of the event
 - **Event End Date:** enter the end date of the event
 - **Reported Date:** enter the date you initially reported the event (to sponsor, IRB, DISC, etc.)
 - **Reported By:** enter your name
 - **Event Narrative:** enter the symptoms/diagnosis, relevant testing, required interventions, etc. as applicable
 - **Protocol Attribution:** select attribution from the drop-down list
 - **Outcome:** select outcome from the drop-down list
 - **Consent Form Change Required:** yes/no
 - **SAE Classification:** select from list
3. In the Adverse Event Details section in the middle of the page, enter the following information:
 - **Category:** *select the appropriate CTCAE category from list*
 - **AE Detail:** *select the appropriate CTCAE term from list*
 - **Grade/Severity:** *select grade from drop down list*
 - **Unexpected:** *yes/no*
 - **DLT:** *yes/no*
 - **Action:** *select action from drop down list*
 - **Attribution:** *select the attribution for each component of the trial from the drop-down lists*
4. Click **Add** (in the middle of the page). The details you enter appear in the table.
5. In the Adverse Events Details section in the middle of the page, document a second category using the **Select Detail** link if necessary.
6. Click **Submit** to save the basic SAE information.

V. DEVIATION REPORTING

The Cancer Center requires that, **all** deviations/violations related to subjects enrolled on UF interventional IITs and CRO managed trials be logged into OnCore. A deviation/violation is a variance from the approved protocol procedures. Deviations specific to an individual subject are entered via the Subject Console > Deviations tab. Additional information regarding deviation reporting can be found in SOP: Reg-005.

1. Navigate to the **Subject Console > Deviations** tab.

The table at the top of the page shows the subject's deviations. The bottom table shows any visits with a visit date outside of the planned date's tolerance. This table is for informational purposes, and you can use it as a guide for entering deviations if needed.

2. Click **New** to create a deviation.

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

Enter the following:

- **Date Discovered:** *enter the date of discovery*
- **Reported By:** *enter your name*
- **Information Source:** *enter the root cause of the deviation*
- **Deviation Date:** *enter the date the deviation occurred*
- **Category:** *select category from drop down list*
- **Description of Deviation:** *describe the deviation including whether or not the deviation occurred to prevent an immediate risk to the subject*
- **Effect on Patient Safety:** *please describe whether or not the event affected the safety or clinical care of the subject*
- **Action Taken:** *please describe any corrective and preventative actions taken*
- **Did the deviation put the participant or others at increased risk and/or negatively affect the primary study aims:** *select yes/no from the drop-down list; if yes, an explanation must be entered in the text box that will populate*
- **Report to IRB?** *select from drop down list*

3. Click **Submit** to create the deviation.

4. PI or Sub-I review and oversight will be documented via signed deviation log, email, or other approved methods.

Other information can be entered to record when it should be reported to the IRB, the date it was reported, and the date it was reported to the sponsor.



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Click the **Deviations** vertical tab to see the updated page.

The **Delete** link allows you to delete a deviation record entered in error.

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Approved By:

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VI. Appendix A: Research Subject Demographic Form

Research Subject Information Sheet

The following demographic information is required by one or more research studies for which you have given consent to participate. This information may be reported to the study sponsor(s) for statistics on the demographics of research subjects. Study sponsors can be an industry sponsor, academic institution, national health organization or other type of cancer group. This information may also be used for internal quality improvement activities within the University of Florida Health Cancer Center. Unless otherwise specified in your research study's informed consent, your name will not be reported to the study sponsor(s).

Subject's Name: _____

Date of Birth: _____

Primary Race: *Select all that apply*

American Indian or Alaska Native
 Asian
 Black or African American
 Native Hawaiian or Other Pacific Islander
 White
 Decline to report

Biological Sex (sex assigned at birth): *Choose One*

Male
 Female
 Decline to report

Ethnicity: *Choose One*

Hispanic or Latino
 Not Hispanic or Latino
 Decline to report

Gender: *Choose One*

Male
 Female
 Other (Please Specify) _____

The information below is optional and will only be used by University of Florida Health Cancer Center staff in order to perform follow up activities or to schedule/re-schedule appointments.

Home Address: _____

Phone # (if applicable): _____

If you do not have a phone, please provide a caregiver's phone number: _____

Spouse or Caregiver's Name: _____

Local address (if applicable): _____

Email Address (only if you prefer to be contacted by email*): _____

If email contact is preferred, please make sure that the patient completes the UF Health Consent to Communicate via Electronic Means Consent.

Type of Insurance (circle all that apply):

Private Insurance

Medicare

Medicaid

Military or Veterans Sponsored NOS

Military Sponsored (Including CHAMPUS or TRICARE)

Veterans Sponsored

Self-pay (No Insurance)

No Means of Payment (No insurance)

Other

Unknown

Managed Care

Name of Person Completing Form: _____