OnCore System Work Instruction Document

Subject Management: Tip Sheet

Prepared For: OnCore Version 15+
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The URL for OnCore is https://OnCore.ynhh.org
For more information about OnCore please visit the project website at http://OnCore.yale.edu
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Subject Administration

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 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.

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 MRN, demographics, address, emergency contact info, expiration date. 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 No., 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.

To insure proper billing compliance:

- Subjects must be Consented in OnCore on the day of signing consent, close of business day.
- Subsequent visits must be occurred in OnCore within 24 hours after visit completion.
Getting started in the CRA Console

The CRA Console provides a summary of subject information, including each subject’s study site, sequence number, treatment arm, and current status.

Use the CRA Console to find a subject record, then click the Patient MRN to open that subject’s record.

Registering Subjects

First, choose a Study Site

Then, use the Find Fields to search for an existing patient record...

...or enter New Subject Details to create a new patient record...
Subject sequence numbers

Subject sequence numbers (Patient ID number from sponsor) needs to be populated in the “on study” tab in OnCore to reconcile invoices.

Subject Status

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, Follow-Up) allow you to record this status information.

Always update subject status to reflect the subjects’ proper status. Once subjects go off study be sure to populate the off-study date. Calendars are set up in segments linked to a subject’s status. If you need assistance knowing which status will populate a segment you can contact OnCore Support to assist you.

If you see something like this on your calendar:

<table>
<thead>
<tr>
<th></th>
<th>Follow Up</th>
<th>Off Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>ET Visit</td>
<td>Follow-Up</td>
<td>End of Study</td>
</tr>
<tr>
<td>28@28 Days</td>
<td>1@1 Days</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>1</td>
<td>19</td>
</tr>
</tbody>
</table>

It means that you have skipped a status and need to correct it or you will never be able to occur the ET Visit.
Visit Check-in

Be sure to mark all visits as Occurred, Missed or NA

When occurring a visit be sure that all information is correct.

1. If a procedure in the procedures list was done on a different date than the visit date, fill in the date for that individual procedure.
2. If a procedure in the procedures list was missed and not completed, check the missed box.
3. If a procedure in the procedures list does not apply for this subject for this visit, check the N/A box.
4. When you have a procedure alternative for YCCI Research Charges or a Choose ePayment Amount, you must choose an option from the dropdown or mark as N/A if it does not apply.

If your subject gets off schedule, you can reset the subjects calendar.

After you occur the visit select the “Reset Calendar” dropdown and select “All Visits”
Updating the version of a calendar

If a new version of your calendar is released and you need to update the subjects to the new version.

1. Select subjects that need to be updated.
2. Switch Calendar Versions dropdown to version you want to update to.
3. Click Replace Versions