

OnCore System Work Instruction Document

Subject Administration: For CTAs, Nurses, and Data Managers

Prepared For: Version 2020R2.1 OnCore

Revision Number: 8

Revision Date: September 1, 2020

The URL for OnCore is <https://oncore.ynhh.org>

For more information about OnCore please visit the website at <http://oncore.yale.edu>

OnCore Support oncore.support@yale.edu or 203.737.7039

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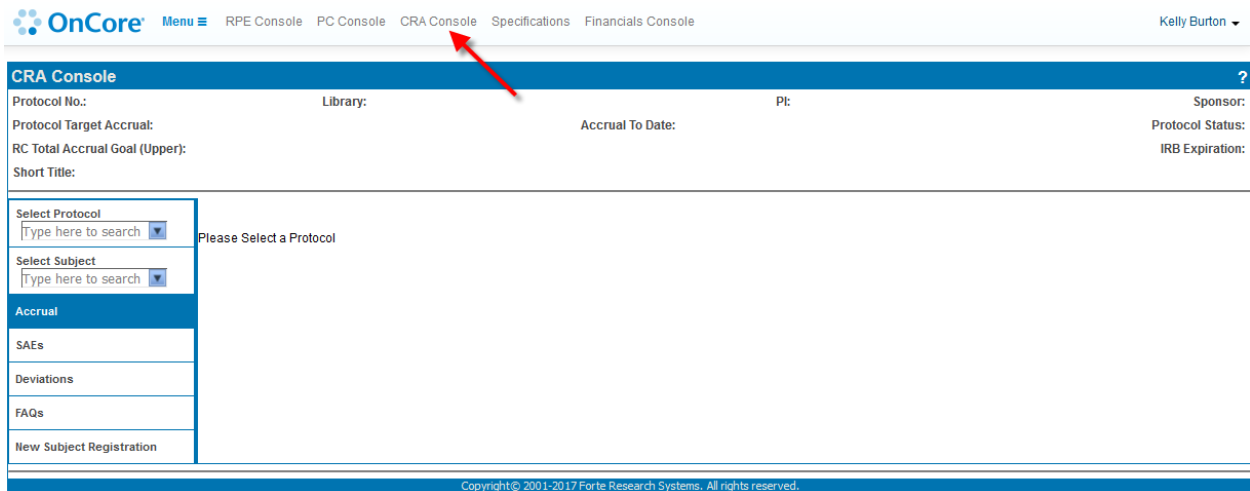
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Navigation Tip! Bookmark subjects by clicking the star in the upper left. This allows you to see them from your home screen as long as you have your preferences set up with subjects on the home page.

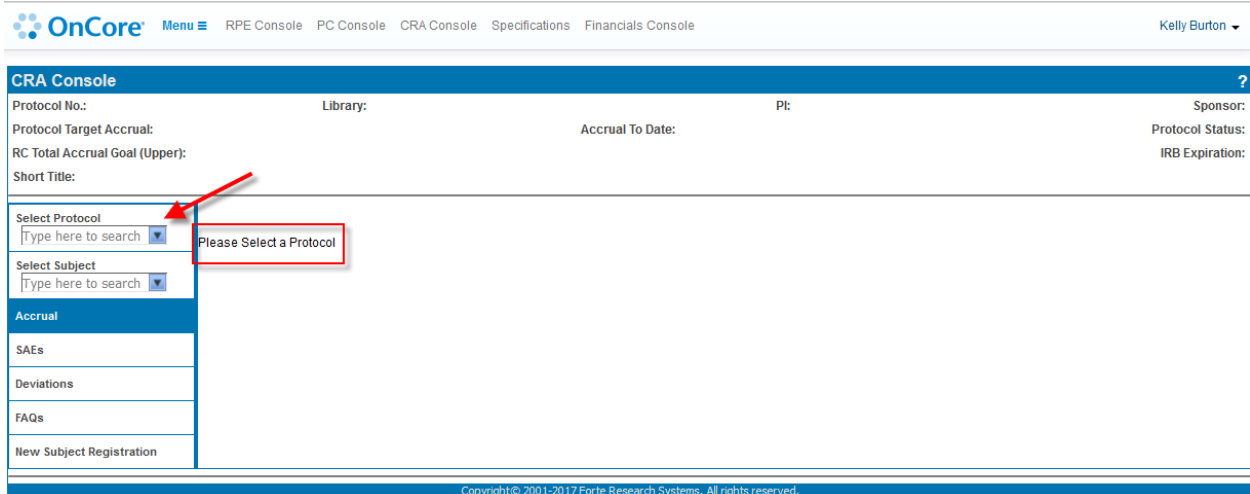
CRA Console

New Subject Registration

From the home page of OnCore select **CRA Console**. *Subjects must be associated with a protocol.*



1. **Select Protocol:** Begin typing the protocol number, the drop down will automatically filter. Select the correct protocol when it appears.



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- 2. Accrual Details:** Once you have selected a protocol this table should appear. If no subjects are enrolled it will say no records found.
- 3. New Subject Registration:** Click this vertical tab and a new screen will appear to enter the subject's information

None of the participating institutions for this protocol are currently OPEN TO ACCRUAL

If your protocol does not have appropriate approvals and signoffs you will get the above error message on the **New Subject** page. Contact oncore.support@yale.edu if this happens.

- 4. Study Site:** Begin typing the study site name, the drop down will automatically filter. Select the correct site when it appears

Find Fields Table

Enter any portion or combination of the fields in this table AND select a **Study Site** to find a patient already in the system. **Use this before trying to enter a new subject.**

- 5. Subject MRN:** Enter the subject's EPIC record number.
- 6. Last Name:** Enter the subject's last name.
- 7. Birth Date:** Enter the subject's date of birth.
- 8. Find:** Click this button once you have entered the subject information. A **Subject Find Results** table will appear where you can search for your subject in the system. If your subject is present click the **Subject MRN** hyperlink and the subject information will automatically populate in the New Subject Details Table.

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If your subject has a valid Epic MRN use the **New Subject Details** table. If you do not have a valid Epic MR# for a subject please contact oncore.support@yale.edu

9. **Subject MRN:** Enter the subject's medical record number.
10. **Last Name:** Enter the subject's last name.
11. **First Name:** Enter the subject's first name.
12. **Middle Name:** Enter the subject's middle name as applicable.
13. **Suffix:** Enter the suffix to the subject's name (e.g. 'Jr') as applicable
14. **Birth Date:** Enter the subject's date of birth.
15. **Approx:** Check this box to record that **Birth Date** is an approximate date.
16. **Not available:** Check this box to record that **Birth Date** is not available.
17. **Gender:** Enter the gender of the subject.
18. **Ethnicity:** Enter the subject's ethnicity.
19. **Expired Date:** Enter the date the subject expired as applicable.
20. **Approx:** Check this box to record that **Expired Date** is an approximate date.
21. **Last Date Known Alive:** Enter the date the subject was last known to be alive.
22. **Race:** Check all of the applicable boxes for the subject's race. If 2 or more races are chosen in Epic only one race will populate across the interface. OnCore does allow "check all that apply", additional detail can still be captured
23. **Add:** Click this button once all subject information has been entered correctly. You will be taken to the subject console **Demographics** tab.

Subject Console

Demographics

Any information that you entered in the **New Subject Details** table will automatically populate in this table. This information is shared among protocols.

★ Subject Console ?																																																																																																																																																																																																					
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1. **Subject Comments:** Enter text about the subject. **If your subject is on multiple studies these comments will be available for study staff on different protocols.**

Additional Subject Identifiers

Additional Subject Identifiers			
Identifier Type 2	Identifier 3	Identifier Owner 4	5
<input type="text"/>	<input type="text"/>	<input type="text"/>	Add Cancel
No information entered			

2. **Identifier Type:** From the drop down select a subject identifier that is not an Epic MRN or Social Security number.
3. **Identifier:** Enter the data for this Subject Identifier type.
4. **Identifier Owner:** Enter text when a generic Identifier Type is selected.
5. **Add:** Click this hyperlink to add more than one additional subject identifier.

Effective immediately, all Non-US citizens and Yale (University) employees need to be identified as such, to ensure that taxes are reported properly on all trials that use ePayments.

- To meet tax reporting requirements, a bi-annual report of all study subject ePayments (including Yale employees) will be sent out to Yale Shared Services (YSS) - Accounts Payable & Vendor Compliance.
- Non-US citizens and other individuals without a valid US address will be issued gift cards from the departments instead of the reloadable ePayment cards.
- Permanent residents Green Card holders, are treated like US citizens from a tax point of view

For Identifier (box 3) please use:

- YE for Yale Employee
- NUSC for Non-US citizen

Additional Subject Identifiers
Identifier Type
<input type="text"/>
Clinical trial pre-authorization not required
Clinical trial pre-authorization obtained
Enrollment
Non-US citizen
Pre-Screening
Screening
St. Francis MRN
Yale Employee
Yale Legacy MRN

Contact Information

You must validate subject’s address and phone number for all studies using ePayment

Contact Information					
6	Street Address	123 Main Street			
7	Address Line 2				
8	City	New Haven	9	State	Connecticut x v
			10	ZIP	06519
11	County	Type here to search v	12	Country	Select a Country v
13	Phone No.	203-555-1234	14	Alternate Phone No.	203-222-1234
15	Email			16	<input type="checkbox"/> Primary Patient Contact?

6. **Street Address:** Enter the subject's street address.
7. **Address Line2:** Enter additional subject street address data as applicable (apt # etc).
8. **City:** Enter the subject's address city.
9. **State:** From the drop down select the subject's address state abbreviation.
10. **ZIP:** Enter the subject's address postal code.
11. **County:** Enter the subject's county of residence.
12. **Country:** Enter the subject's country of residence.
13. **Phone No.:** Enter the subject's main contact number.
14. **Alternate Phone No.:** Enter the subject's secondary contact number.
15. **Email:** Enter the subject's email address.
16. **Primary Patient Contact?:** Check this box to confirm this information should be used as the subject's primary contact.

Emergency Contacts (Multiple emergency contacts may be created)

Emergency Contacts					
17	Name	Sally Test	18	Use Contact Address	
	Street Address	123 Main Street 19			
	Address Line 2	20			
21	City	New Haven	22	State	Connecticut x v
			23	ZIP	06519
24	County	v	25	Country	Select a Country v
26	Phone No.	203-555-1234	27	Alternate Phone No.	203-444-1234
28	Email				
29	Relationship	Wife v	30	<input type="checkbox"/> Primary Contact?	
			31	Clear Add	
			32	Submit Clear Close	

17. **Name:** Name of the emergency contact.
18. **Use Contact Address:** Click this button if the emergency contact has the same address as the subject and the fields will automatically populate.
19. **Street Address:** Enter the emergency contact's street address.
20. **Address Line2:** Enter additional emergency contact street address data as applicable (apt # etc).
21. **City:** Enter the emergency contact's address city.
22. **State:** From the drop down select the emergency contact's address state abbreviation.
23. **ZIP:** Enter the emergency contact's address postal code.
24. **County:** Enter the emergency contact's county of residence.
25. **Country:** Enter the emergency contact's country of residence.
26. **Phone No.:** Enter the emergency contact's main contact number.

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27. **Alternate Phone No.:** Enter the emergency contact's secondary contact number.
28. **Email:** Enter the emergency contact's email address.
29. **Relationship:** From the drop down select the relationship the emergency contact has with the subject.
30. **Primary Contact:** Check this box if the emergency contact is the subject's primary contact.
31. **Add:** Click this button to add more than one emergency contact for the subject.
32. **Submit:** Click this once all subject demographic data has been entered.

Consent Tab

Select the vertical **Consent** tab. Then click the **Update** button on the right-hand side. Enter the consent signed date then click on the **Select Consents** button.

Available Consents

Signed Date

Select Consents

Available Consents ✕

After selections are made, clicking Save will add the selected consents and refresh the page.

Type 1	Description	Version Date 3	Approved Date 4	Expiration Date 5	Signed Date 2	Status 6	Include? 6
3 <input type="checkbox"/> Compound Authorization and/or Informed Consent	Main CAF YCC v4.0_2016.08.17 WIRB Approved 2016.09.13	08/17/2016	09/13/2016	04/05/2017	04/01/2017	<input checked="" type="radio"/> Accepted <input type="radio"/> Refused	<input checked="" type="checkbox"/>
Consent Short Form	Croatian Short Form v1.0 dated 17-May-2016	05/17/2016	05/20/2016		<input type="text"/>	<input type="radio"/> Accepted <input type="radio"/> Refused	<input type="checkbox"/>

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Save

Cancel

1. **Consent Type:** From the drop down select the consent form type signed by the subject.
2. **Signed Date:** Enter the date the subject signed the consent form. Edit signed date if necessary.
3. **Version Date:** If there are multiple versions of the consent form, the + box will display the subject's consent form.
4. **Approved Date:** This will automatically populate with the date that the review with the consent type was approved.
5. **Expiration Date:** This will automatically populate with the date that the review with the consent type expires.
6. **Status:** Accepted or Refused – must select one and then will default to the Include button.
7. **Save or Cancel**

Consent Forms

Once you click **save** the information will be populated into a Consent Forms table. This table also has the two areas detailed below:

8. **Description:** The free-text description for the consent type entry in the review. This field can be used to differentiate consents of the same consent type.
9. **Delete:** Check this box and click submit to delete consent forms from the subject.

Other Consent Status

Information in this area affects the subject status.

10. **Comments:** Enter any comments about the other consent status. If there are subparts to the consent you must clearly state to which parts the patient consented and which parts they refused.
11. **Status:** From the drop down select the consent status.
12. **Status Date:** Enter the date the subject changed to this status.
13. **Submit:** Click this button once all consent data has been entered.

Eligibility

Subject Eligibility Update

1. **Version Date:** Enter the version date of the eligibility form used or the version date of the protocol from which the criteria was taken.
2. **Verified By:** Enter the first and last name of the qualified staff member who verified the eligibility details.
3. **Status Date:** Enter the date the eligibility details were verified. This is the subject's eligibility date.
4. **Eligibility Status:** From the drop down select the eligibility status of the subject.

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- a. Eligibility (O): Eligibility override (subject does meet part of the criteria but permission has been given to override)
5. **Comments:** Enter any comments about the eligibility of the subject
6. **Reason Withdrawn:** When applicable from the drop down select a reason from the list if the subject is withdrawn.
7. **Reason Not Eligible:** If **Eligibility Status** is “Not Eligible” this functionality will become available. From the drop down select the appropriate details.
8. **Submit:** Click this button once all eligibility data has been entered.

On Study

Subject On Study Update

Switch Subject [Type here to search]	Subject On Study Update			
	3 Sequence No.	XY-123	4 On Study Date (MM/DD/YYYY)	05/11/2017
	5 Disease Site	Kidney	Ready for Registration	<input type="checkbox"/>
	6 Histology	Renal Cell Carcinoma		
	7 Diagnosis Date			
	8 Disease Unit	Cancer Prevention and Control	9 ZIP at Registration	
	10 Study Site	Yale University	11 Transferred Date (MM/DD/YYYY)	
	12 Comments			
	Additional Protocol Subject Identifiers			
	Identifier Type 13	Identifier 14	15	Add Cancel
	No information entered			
	Subject Staff See All			
Role 16	Staff Name 17	Start Date 18	30 Team	
<input type="text"/>	<input type="text"/>	<input type="text"/>	19 Add	
Role	Last Name	First Name	Middle Initial	
Clinical Research Coordinator	Burton	Kelly	R	
Home Organization				
Yale Center for Clinical Investigation				
Insurance				
No information entered				
Select				
Submit Clear Close				

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1. **On Study:** Click this vertical tab to enroll the subject on the study
2. **Update:** Click this button on the lower right (*not shown in the screen shot above*)
3. **Sequence No.:** Enter a unique number that can be used for subject identification purposes on the protocol.
 - This is typically called the subject study number at Yale.
 - The Sequence Number is populated in one of two ways:
 - 1) Manually entering the sequence number that was provided by the sponsor or the cooperative group.
 - 2) Allowing Oncore to automatically generate the sequence number for investigator initiated studies. (PC Console > Management Tab)
4. **On Study Date:** Enter the registration date to get the accrual number to increase for the protocol. **If your subject is Not Eligible they will not have an On Study date.**
 - Cooperative group trials: Registration date is when you call and get a treatment assignment
 - Industry trials: Registration date is when you call and get a treatment assignment
 - Investigator-initiated randomized trials: Registration date is when you get a treatment assignment
 - Investigator-initiated, not randomized trials: Registration date is the date the consent form is signed

5. **Disease Site:** Begin typing the disease site, the drop down will automatically filter. Select the correct disease site when it appears. The disease site drop down will be pre-filtered based on what you indicated in the protocol console for that study. To see more disease sites click the **view all** hyperlink.
6. **Histology:** Begin typing the histology, the drop down will automatically filter. Select the correct histology when it appears.
7. **Diagnosis Date:** Enter the date of diagnosis for this subject on this protocol. This is the date pathology confirmed the diagnosis.
 - If you only know the month and year, enter the first of the month and the year: e.g. 01/10/2010
 - If you only know the year, enter the first of the year e.g. 01/01/2010.
8. **Disease Unit:** From the drop down select the disease unit.
9. **Zip at Registration:** Enter the zip code of the subject at registration.
10. **Study Site:** The Study Site will populate with the study site selected during the new subject registration entry.
11. **Transferred Date:** If the subject originally accrued to another center but then transferred to your center, enter the date the subject started on study at your site. Subject will not be counted as an accrual.
12. **Comments:** Enter any comments about the subject specifically related to this study. This will only be visible to staff for this study.

Additional Protocol Subject Identifiers

13. **Identifier Type:** Enter an identifier for the subject that applies to [this protocol](#).
14. **Identifier:** Enter the data for this Identifier Type.
15. **Add:** Click this button to add more than one additional subject identifier.

Subject Staff

- Research Nurse should enter him/herself
 - CTA should enter her/himself and the treating physician
16. **Role:** Begin typing the role of the staff person with the subject, the drop down will automatically filter. Select the correct role when it appears.
 - Principal Investigator should not be entered in this screen. If the PI is also the treating physician, enter their role as Treating Physician
 - If your home screen is set-up with the subject widget adding yourself as subject staff will make the subject appear on your home screen.
 17. **Staff Name:** Begin typing the first or last name of the staff member, the drop down will automatically filter. Select the correct staff member when his/her name appears.
 18. **Start Date:** Enter the date this staff member is assigned to the subject.
 19. **Add:** Click this button to add more than one treating staff member.
 20. **Team:** For your convenience click this button and a pop up screen will appear from which you can select staff members from the already defined **Protocol Staff List**.

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Subject Staff See All

Role Staff Name Start Date 30 Team

Type here to search

Study Team (Protocol 1607018104)					
Name	Role	Phone No	Email Address	Start Date 21	Select 22
Murphy, Juliann	Budget			<input type="text"/>	<input type="checkbox"/>
Burton, Kelly	Clinical Research Coordinator			<input type="text"/>	<input type="checkbox"/>
Palm, Noah Wolcott	Principal Investigator			<input type="text"/>	<input type="checkbox"/>
Costa, Constance	Protocol Creator			<input type="text"/>	<input type="checkbox"/>
Gray, Jennifer	Research Nurse			<input type="text"/>	<input type="checkbox"/>
Tyc, Kristine	YCCI Contact for Subject Management Maintenance			<input type="text"/>	<input type="checkbox"/>
Burton, Kelly	YCCI Contact for Subject Management Maintenance			<input type="text"/>	<input type="checkbox"/>

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23

21. **Start Date:** Enter the date this staff member is assigned to the subject.
22. **Select:** Check the boxes for the applicable staff members treating the subject.
23. **Select all:** Click this button if you would like to have all staff from the protocol listed as treating staff for the subject (don't forget to enter **Start Date** for each one if you do this).
24. **Submit:** Click this once you have selected all applicable staff members and entered the start dates.
25. **Staff Name Hyperlink:** Click on the name of the staff member to edit information, a pop up window will appear.

Burton, Kelly

Phone Email

1607018104 Add

Role	Start Date	Stop Date 26	Stop Reason 27	Delete? 28
Clinical Research Coordinator	04/01/2015	05/11/2017	left department	<input type="checkbox"/>

26. **Stop Date:** Enter the date this staff member becomes unassigned to the subject.
27. **Stop Reason:** Enter the reason this staff member became unassigned to the subject.
28. **Delete?:** Check this box and click submit to remove the staff entry.
29. **See All/See Active:** The See All button will display all staff ever assigned to a subject. The See Active option will only display the current active staff members.
30. **Team:** The Team button allows Subject Staff to be created from the already– defined Protocol Staff list.

Warning: Disease site or Histology does not match Protocol site

When you finish entering data and click submit you may get this warning message at the top of the screen. The information has still been saved in the subject console just check to make sure you have entered the information correctly. If you have, you can disregard this message.

★ Subject Console ?		
Protocol No.: 2000020035	Protocol Status: OPEN TO ACCRUAL	31 Subject Status: ON STUDY
MRN: MR123654	Subject Name: John Test	Sequence No.:

31. **Subject Status:** Note that the subject status has now changed to **On Study**

Treatment Tab

★ Subject Console ?		
Protocol No.: 2000020154	Protocol Status: OPEN TO ACCRUAL	Subject Status: ON TREATMENT
MRN: MR9006853	Subject Name: JASMINE ZZZTEST	Sequence No.: zzz123

Switch Subject [Type here to search]	Subject Treatments			5	6	7	2	Add
	3	4					8	
	Step Code	Arm	On Arm Date	On Treatment Date	Off Arm Date			
	1	Treatment group without PK study (ArmB)						Save Cancel
Demographics	1	Treatment group with PK study (ArmA)	04/10/2017	04/10/2017			Edit Delete	
							9 10	

1. Within the **Subject Console** select the **Treatment** vertical tab.
2. **Add:** Click this button to add treatment details
3. **Step Code:** Automatically populates and represents what step of treatment the subject is on.
4. **Arm:** From the drop down select the description of the treatment for the arm.
5. **On Arm Date:** Enter the date the subject went on the arm (this can be a future date)
6. **On Treatment Date:** Enter the date the subject went on treatment (this can be a future date).
7. **Off Arm Date:** Enter the date the subject went off the arm (only if the protocol calls for switching arms, otherwise this field will not be used).
8. **Save:** Click this when you have all relevant data entered for that arm.
9. **Edit** Click this hyperlink to edit the arm entry for a subject.
10. **Delete:** Click this hyperlink to remove the treatment arm from the subject if entered in error.

Subject Calendars

OnCore Calendars and Calendar Activation

The protocol has a calendar that defines a schedule of **visits** (when a subject is to be seen) and what treatment will be done during each visit.

Because subjects accrue to the protocol at different times, the protocol schedule cannot contain “hard” dates like “March 15”. Instead, schedules are based upon subject **status dates** like the subject’s Consent Signed date and On Study date. Offsets from these dates (e.g. “the tenth day after the subject goes On Study”) are used to determine the “hard” date of a subject’s visit.

When you enter a number of subject milestone dates, you **activated** their calendar. OnCore has now generated a personalized treatment schedule for the subject.

Viewing the Subject Calendar

To see the subject’s calendar, you need to go to the **Calendar** tab of the **Subject Console**.

OnCore Work Instructions Document – Subject Administration

1. If you are not on the Subject Console, navigate there via the **Subjects → CRA Console** or **Subjects → Subject Console** menu link. Once you are viewing your subject in the Subject Console, select the **Calendar** tab.

You should see something similar to this:

Calendar		Orphaned Visits								
Freeze Panes		Summary		Manage Optional Segments						
Current Subject Calendar Version - V1										
Procedure Toggle Full Screen	Forms	Treatment								
		Screening 1@45Days	Treatment Period- Part 1 & Part 2 1:2,8,15,29,43,57,84@84Days							
		1	2	3	4	5	6	7	8	9
		Day -45 to -3⁹	Day 1	Day 2¹¹	Day 8	Day 15	Day 29	Day 43¹¹	Day 57	Day 84
Planned Date		04/01/2017	04/11/2017	04/12/2017	04/18/2017	04/25/2017	05/09/2017	05/23/2017	06/06/2017	07/03/2017
Visit Status										
Visit Date										
Informed Consent/Assent		X	X							
Demographics		X								
Inclusion / exclusion criteria		X	X ¹²							
Medical history ¹⁰		X	X							
Brief Physical Examination		X					X		X	X
Vital Signs ¹³		X					X		X	X
Height & Weight		X								
Beaker Labs HCG, Urine		X	X				X		X	X
Assessment ¹		X								
Central lab chemistry		X					X		X	X

In the **first column**, each row following “Visit Date” displays the name of a Lab, Panel, or Procedure.

The **second column** displays the names of the eCRFs (Forms) that will be used to capture data from the corresponding Lab, Panel, or Procedure.

The **Planned Date row** displays the subject’s scheduled visit dates. Hovering the mouse cursor over the date in the Planned Date row will show which day of the week it is (and the visit tolerances if they were entered).

Below each **visit date**, an **X** indicates which Labs, Panels, and Procedures are scheduled for that date. If the procedure is supposed to happen multiple times on a visit, there may be a number in front of the indicator to show how many times it should happen, like **2X**. To view Research and Standard of Care designation see the protocol calendar on the PC console or CRA Console.

Below the calendar are **Footnotes** if added to a specific procedure or procedure visit.

The **Calendar** tab has two horizontal tabs: **Calendar** and **Orphaned Visits**. The **Calendar** horizontal tab is the default and is where the screenshot comes from. The **Orphaned Visits** horizontal tab shows visits that were on one version of the subject’s calendar, but aren’t showing anymore for some reason, perhaps because the schedule changed and they were removed from the newer calendar version.

Verifying Subject Visits – Visit Dates

The hyperlinks above each visit date ([Screening](#), [Pre-Procedure](#), etc.) are links to pages where you enter visit information. This is called **verifying** the visit.

1. Select the first visit hyperlink.

Subject Visit Update User: Kelly Burton

Protocol No.: 2000020154 Protocol Status: OPEN TO ACCRUAL Subject Status: ON TREATMENT
MRN: MR9006853 Subject Name: JASMINE ZZZTEST Sequence No.: zzz123

Visit Details Phase: Treatment Visit: Day -45 to -3

Visit Date ⁹ Visit Status
 Planned Occurred Missed N/A Visit Tolerance -3

Visit Description

Data Collection Completed Date Monitored Date Reset Calendar?

Collection Location Collection Time (hhmm) Submitted Date Locked Date

Clinical Comments
1000 character(s) remaining

Data Comments
1000 character(s) remaining

The **Subject Visit Update** page is displayed. The first field on the page is the **Visit Date**, and the data in this field defaults to the planned date shown on the calendar. You may change this date as necessary.

The box next to the Visit Date shows the **Visit Status**. By default, the status is **Planned**, but not yet **Occurred**.

2. Verify the visit by selecting the **Occurred** radio button. Verify all procedures occurred as planned then click the **Submit and Close** button to return to the Subject Calendar.

On the Subject Calendar the **Visit Status** shows **Occurred** and the **Visit Date** displays.

That was the simplest of Visit verifications. As you saw on the Subject Visits Update page, there are a number of data entry fields to deal with Subject Visits.

3. Select the next visit hyperlink.
4. The Subject missed the entire visit. Verify the visit by selecting the **Missed** radio button. Click the **Submit and Close** button to return to the Subject Calendar.

For missed visits, the Subject Calendar displays the Visit Status and Visit Date in red.

Take note of the visit dates for the missed visit and a few subsequent visits.

5. Select the missed visit hyperlink again.
6. Mark the visit as **Occurred** (which resets the date to the default).
7. Edit the Visit Date, changing it to **two days later** (2/22/2011).
8. In the **Reset Calendar?** field, select **All Visits**.

9. Click the **Submit and Close** button to return to the Subject Calendar.

The Subject Calendar shows the Visit Status as **Occurred** and displays the Visit Date you supplied. Note that all subsequent dates have been reset to two days after their previous values.

Verifying Subject Visits – Visit Details

10. Select the last visit hyperlink again.

Most fields in the top half of the display collect details about the visit, and are self-explanatory. The **Submitted Date** is the date the data has been submitted to the Sponsor. Entering a **Locked Date** means no more changes should be performed on the data (this is not enforced – you can change data on this page later). **Collection Location** is the location of correlative specimen collection for this visit.

The **Procedures** table lists the Labs, Panels, and Procedures that have been scheduled for the Visit. Each procedure has a set of data entry fields:

- **Procedure Date** - Enter a date only if it is different than the Visit Date above.
- **SOC** - If the procedure is standard-of-care (as defined in the Financials portion of OnCore), this will be pre-checked. Changing the state of this checkbox has Financial implications. There is a security privilege that controls access to this checkbox.
- **SOC Modifier** - Indicates whether the SOC procedure is Q1, Q0, or Unknown.
- **Missed** - Check if procedure was missed during the visit.
- **Missed Count** - You can have the calendar schedule a procedure to happen multiple times during a visit. If some of those procedures were missed, indicate how many.
- **N/A** - Check if procedure was not applicable for this visit.
- **Location** – If the procedure can be performed at different locations, this indicates which location was used. This field is only available when the Cost Center configuration is enabled.

OnCore Work Instructions Document – Subject Administration

The screenshot displays the 'Subject Visit Update' interface. At the top, it shows the protocol number (2000020154), protocol status (OPEN TO ACCRUAL), subject name (JASMINE ZZZTEST), and subject status (ON TREATMENT). The visit details section includes fields for Visit Date (04/01/2017), Visit Status (Planned, Occurred, Missed, N/A), Visit Tolerance (-3), and various dates for completion, monitoring, and submission. A popup window is open over the 'Brief Physical Examination' section, with a red circle highlighting the 'Reason for Change' field. Below the popup, a table lists procedures with columns for Procedure, Procedure Date, SOC, SOC Modifier, Missed, Missed Count, and N/A.

Procedure	Procedure Date	SOC	SOC Modifier	Missed	Missed Count	N/A
Informed Consent/Assent		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
Demographics		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
Inclusion / exclusion criteria		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
Medical history ¹⁰		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
Brief Physical Examination		<input checked="" type="checkbox"/>	<input type="radio"/> Q0 <input checked="" type="radio"/> Q1 <input type="radio"/> U	<input type="checkbox"/>		<input type="checkbox"/>

Unless they are marked as **Missed** or **N/A**, it is assumed that if the visit has occurred, the procedures have been performed.

ePayment – if an ePayment does not apply for the subject at the visit check in, mark as **N/A** or the subject will receive payment.

Verifying Subject Visits – Additional Procedures

If a procedure is done during the visit that is not part of the calendar, the **Additional Procedures** button can be used to record it. This button is available after the visit is marked as occurred. When the button is clicked, a popup window displays with multiple horizontal tabs.

Browse Results

Charge Master
Protocol Procedures
Free-text Procedures

Protocol Calendar Procedures/Labs Filter:

Event Code	Additional Event ID	Event Description	Forms	Select?
		Adverse Events		<input type="checkbox"/>
		Assessment		<input type="checkbox"/>
		Assessment of Signs and Symptoms		<input type="checkbox"/>
BKR LRR		Beaker Labs HCG, Urine		<input type="checkbox"/>
		Brief Physical Examination		<input type="checkbox"/>
		Central lab chemistry		<input type="checkbox"/>
		Central Lab Haematology		<input type="checkbox"/>
		Central lab urinalysis		<input type="checkbox"/>
		Compliance Assessment		<input type="checkbox"/>

* Items and forms for protocol calendar specific additional procedures will be automatically added

Submit Clear Close

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The **Protocol Procedures** tab lists the Labs, Panels, and Procedures that have been assigned to the protocol, along with any associated forms. Use the checkboxes and the **Submit** button to add these events and forms to the visit record.

The **Charge Master** tab lists all events in your protocol’s library by description or CPT code. Use the checkboxes and the **Submit** button to add one of these events to the visit record. No form will be associated with these events.

The Search tab provides ways to search for and select events from your protocol’s library. Use checkboxes and the **Submit** button to add one of these events to the visit record. No form will be associated with these events. The **Free-text Procedures** is not being used at Yale.

1. Click the **Additional Procedures** button.
2. Select the checkbox for a procedure on that visit, and click the **Submit** button.
3. In the popup box, enter a **Reason for adding**. Click the **OK** button to return to the Subject Visit Update page.

The new procedure is listed in the bottom table. The **Procedure** hyperlink will display the reason for adding.

If data has been recorded in a visit in error, the Delete button on the Subject Visit Update page can be used to delete the visit. Visits with activated electronic case report forms (eCRFs) cannot be deleted until the forms have been deleted.

4. Click the **Submit and Close** button to return to the Subject Calendar.

When you need to add an Additional ePayment to a scheduled visit or unscheduled visit

OnCore Work Instructions Document – Subject Administration

Procedures

[Expand All](#) [Collapse All](#)

Procedure	Procedure Date	SOC	SOC Modifier	Missed	Missed Count	N/A
Informed Consent	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>
Inclusion/Exclusion Criteria	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>
<input type="checkbox"/> Central Lab	<input type="text"/>					
Charge Master Events						
36415- ROUTINE VENIPUNCTURE OR FINGER/HEEL/EAR STICK FOR COLLECTION OF SPECIMEN(S)		<input type="checkbox"/>		<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>
Tech- ROUTINE VENIPUNCTURE OR FINGER/HEEL/EAR STICK FOR COLLECTION OF SPECIMEN(S)						
ECG	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>
93005- ELECTROCARDIOGRAM, ROUTINE ECG W/AT LEAST 12 LEADS;TRACING ONLY,W/O INTRP AND R						
<input type="checkbox"/> HRU Research Charges	<input type="text"/>					
Charge Master Events						
HRU RN		<input type="checkbox"/>		<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>
<input type="checkbox"/> ePayment \$100	<input type="text"/>					
Charge Master Events						
ePAYMENT \$100		<input type="checkbox"/>		<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>

If a subject visit is marked as Occured, you will see the **Additional Procedures** button on the bottom of the page.

Additional Procedures

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Browse Results

Protocol Calendar Procedures/Labs Filter:

Event Code	Additional Event ID	Event Description	Forms	Select?
		Central Lab		<input type="checkbox"/>
		ECG		<input type="checkbox"/>
		ePayment \$100		<input type="checkbox"/>
		ePayment \$30		<input type="checkbox"/>
		ePayment \$50		<input type="checkbox"/>
		HRU Research Charges		<input type="checkbox"/>
		Inclusion/Exclusion Criteria		<input type="checkbox"/>
		Informed Consent		<input type="checkbox"/>

* Items and forms for protocol calendar specific additional procedures will be automatically added

Browse Results

Protocol Calendar Procedures/Labs Filter:

Select an event from the Protocol Procedures Tab

Event Code	Additional Event ID	Event Description	Forms	Select?
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OnCore Work Instructions Document – Subject Administration

The calendar has a **Summary** button at the top. It is a way to shorten the number of visits showing. This may be useful when there are a lot of visits and you would have to scroll to the right to see the first unverified visits. When clicked, it will show the most recently verified visit and a number of unverified visits. Your view will be narrowed to show only the most relevant visits. The total number of visits shown is a configuration setting. In summary mode, there is a **Full Calendar** button that will return you to the full calendar view.

Additional Visits

At times, subjects will be seen for visits that are not on the standard schedule. These visits can be recorded via the Additional Visits tab. Clicking the [New] button on the Additional Visits tab displays a Subject Visit Update page where visit details can be entered.

Subject Visit Update User: Kelly Burton

Protocol No.: 0801003413 Protocol Status: OPEN TO ACCRUAL Subject Status: ON TREATMENT
MRN: MR5764597 Subject Name: AMEILA TESTZZZ Sequence No.:

Visit Details

Visit Date:

Visit Description:

Data Collection Completed Date: Monitored Date: Submitted Date: Locked Date:

Clinical Comments:
1000 character(s) remaining

Data Comments:
1000 character(s) remaining

Procedures

Procedure	Procedure Date	SOC	SOC Modifier	Missed	Missed Count	N/A	
No Procedures Found							

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Once a Visit Date is entered and the [Submit] button clicked, an [Additional Procedures] button displays at the bottom of the page. Only procedures selected from the Protocol Procedures tab have the ability to have Forms associated with them. When the forms are displayed on the Forms by Status > To Do Forms tab, the visit will be named 'Additional'. Additional visits do not appear on the subject calendar. Additional visits cannot be deleted once placed on an invoice, even if that invoice has been voided.

Follow-up Tab

Subject Off Treatment Update

1. **Follow-up:** While in the subject console select this vertical tab to open a table on which you can enter follow-up information about the subject.
2. **Update:** Click this button on the lower right to add long term follow-up information (*not shown on the screen shot above*).
3. **Off Treatment Date:** Enter the date the subject went off treatment*.
4. **Off Treatment Reason:** From the drop down select the reason the subject went off treatment.
5. **Explain:** Add any extra details about the off treatment reason.

Subject Off Study Update

6. **Off Study Date:** Enter the date the subject went off study†.
7. **Off Study Reason:** Enter the reason the subject went off study.
8. **Explain:** Add any extra details about the off study reason.

Subject Follow Up Update

9. **Follow-up Start Date:** Enter the date the follow up cycles begin‡.
10. **Transferred to (Study Site):** Click the browse button to select a study site if the subject is transferring sites for follow up treatment.
11. **Alternate MRN:** Enter the MRN for the subject at the follow up site when the follow up will be performed at another study site.
12. **Last Follow-up Date:** Enter the last date of follow up treatment.
13. **Next Follow-up Date:** Enter the next date scheduled for follow-up with the subject.
14. **Last Known Survival Status:** From the drop down select the last known survival status.

* Entering the Off Treatment Date will activate the End of Treatment portion of the subject’s calendar.

† Entering the Off Study Date will activate the Off Study portion of the subject’s calendar.

‡ Entering the Follow Up Start Date will activate the Follow Up portion of the subject’s calendar and will disable any remaining treatment visit hyperlinks after this date.

OnCore Work Instructions Document – Subject Administration

15. **Expired Date:** Enter the date the subject expired.
 16. **Approx?:** Check this box if the date the subject expired is approximate. Please note approximate dates should be entered as the first of the month if the month and year are known and first of the year if only the year is known.
 17. **Last Date Known Alive:** Enter the last date the subject was known to be alive. Only use this field if the subject was lost to follow-up.
 18. **QA Date:** Enter the last date of quality assurance.
 19. **Comments:** Enter any comments related to the follow-up status for the patient. The rest of your study team will be able to see these comments about the patient.
- Evaluable for Analysis
20. **Valuable:** From the dropdown select yes, no, not assessed.
 21. **Reason:** Add reason
 22. **Submit:** Once all data has been entered correctly click this button.

Documents/Info:

While in the subject console follow this guidance to upload a subject specific document such as signed consent or dose randomization notice.

The screenshot shows the OnCore Subject Administration interface. On the left is a vertical navigation menu with tabs for Summary, Demographics, Consent, Eligibility, On Study, Treatment, Follow-Up, SAEs, Calendar, Additional Visits, Payments, Deviations, Documents/Info (highlighted with a red '1'), and Protocols. The main content area has two horizontal tabs: 'Archive/Notes' and 'Attachments' (highlighted with a red '2'). Below the 'Attachments' tab is a table titled 'Subject Attachments' with a red '4' and an 'Add' button. The table has columns for Document Type, File Name / URL, Description, Version Date, Created Date, Created User, Edit, and Delete?. The table is currently empty, displaying 'No Records Found.' At the bottom right of the main content area are 'Submit' and 'Clear' buttons.

1. **Documents/Info:** Select this vertical tab from the left hand side of the screen
2. **Attachments:** Select this horizontal tab
3. Current documents will display
4. **Add:** Click this button to open the attachment details table

OnCore Work Instructions Document – Subject Administration

Archive/Notes
Attachments

Add Attachment

Document Type **5**

Attach a [File](#) or [URL](#) **6**

Description **8**

Version Date **7**

9

Subject Attachments **11**

Document Type	File Name / URL	Description	Version Date	Created Date	Created User	Edit	Delete?
Patient Questionnaire	test.docx	Smoking Questionnaire	01/15/2016	06/15/2017	krb39	Edit	<input type="checkbox"/>
Signed Consent Form	Re HIC# 1506016041.msg		01/15/2017	06/15/2017	krb39	Edit	<input type="checkbox"/>

5. **Document Type:** Select the document type from the drop down menu.
6. **File Name:** Click the **Browse** button and a pop up window will appear. Search the folders on your computer for the document you would like to upload select it and then click **open**.
 - a. Please note:
 - i. Documents should be uploaded as a PDF so that they cannot be altered.
7. **Version Date:** Enter the date on which the document was created or last modified, in general this will be the version date on the protocol and consent form documents.
8. **Description:** Enter additional document details.
9. **Add:** Once you have entered the information click this button.
10. **Created Date:** The date the document was attached to the protocol it is automatically populated.
11. **Created User:** Provides the name of the user who attached the document to the protocol in Oncore.