

Subject – Status, Calendar, Visits and Other Events

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Subject – Status, Calendar, Visits and Other Events

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 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. The CRA Console also indicates which subjects need to review and accept a more recent version of the consent form.

CRA Console
 Protocol No.: 0C-19-1 Library: Oncology PI: Chang, Leslie Sponsor: Astex Pharmaceuticals, Inc.
 Protocol Target Accrual: 200 Accrual To Date: 0 Protocol Status: OPEN TO ACCRUAL IRB Expiration: 06/05/2020
 RC Total Accrual Goal (Upper): 10
 Short Title: This is a test study.

Accrued Subjects Table:

Status	Site	Research ID	Last Name	First Name	Sex	Age	Level	Status	Status Date	Ver	Last Visit	Last Visit Date	Select
	Keck Hospital of USC	1100480	TEST	TEST				CONSENTED	05/13/2020	1			

Switch Calendar Versions: 1 (12 JUL 2019) Replace Versions
 Select All | None Accrual
 Include PHI View PDF Save Preferences

Subject Console

This console allows you to view subject information within the context of a protocol. The console provides access to a subject’s demographic information, the protocols the subject is associated with, what consent forms the subject has signed, their eligibility status, etc.

Subject Console
 Protocol No.: 0C-19-1 Protocol Status: OPEN TO ACCRUAL Subject Status: CONSENTED
 Research ID: 1163480 Subject Name: TEST TEST Sequence No.:

Subject Demographics

Research ID: 1163480
 Last Name: TEST First Name: TEST Middle Name: Suffix: Last Date Known Alive: Birth Date: 11/11/1971
 Gender: F Ethnicity: Other
 Race: Other
 Subject Comments:

Additional Subject Identifiers

Identifier Type: Identifier: Identifier Owner: No information entered

Contact Information

Name: TEST TEST Primary: Address: 4650 SUNSET BLVD City: LOS ANGELES State: California ZIP: 90027 Country: Phone No.: (213)555-1212 Email Address:

Emergency Contacts

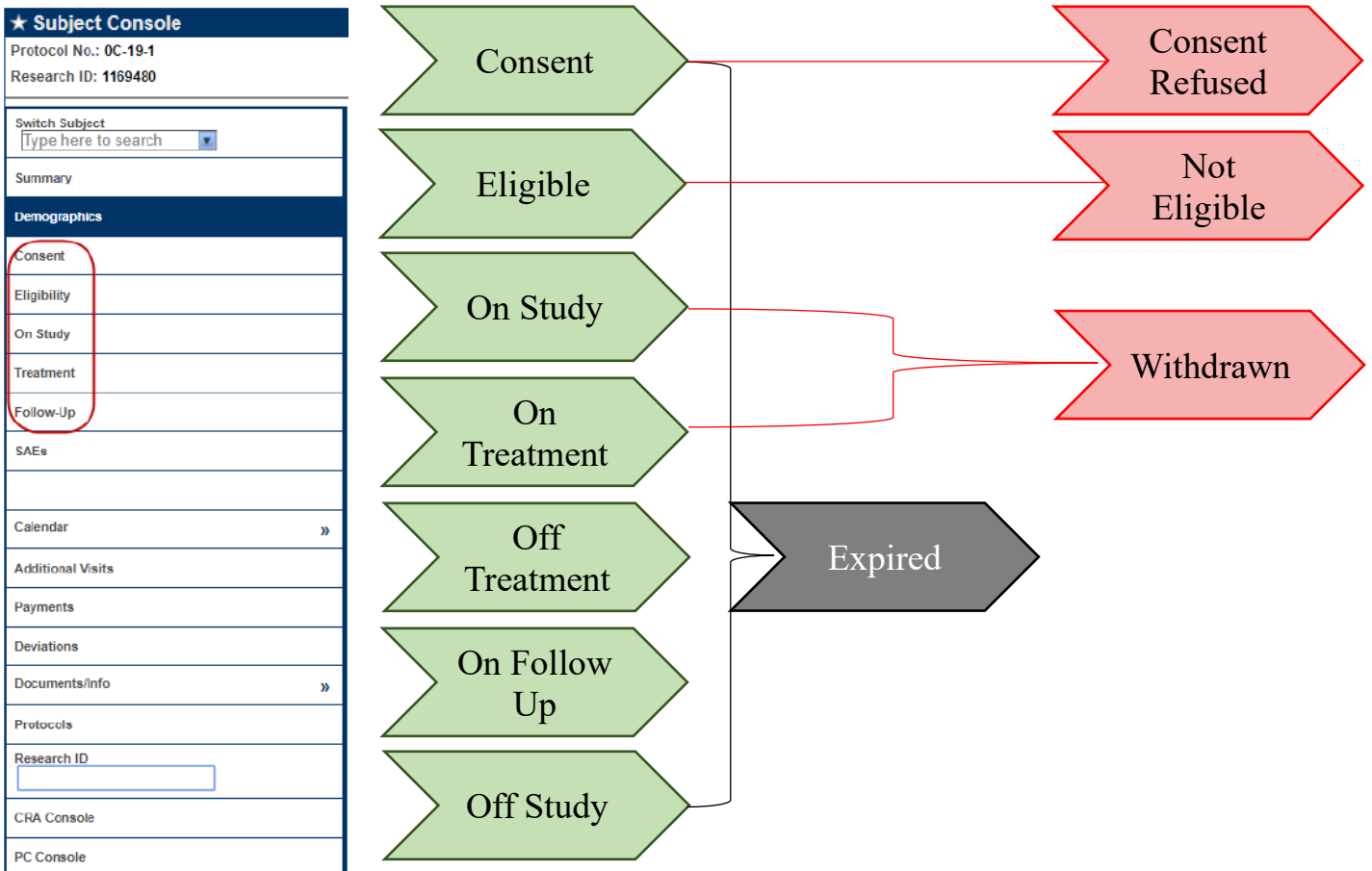
Name: Primary: Address: City: State: ZIP: Country: Country: Phone No.: Email Address: No information entered

Update

Subject – Status, Calendar, Visits and Other Events

Subject Statuses

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. These statuses triggers visit segment in the subject calendar.



Subject – Status, Calendar, Visits and Other Events



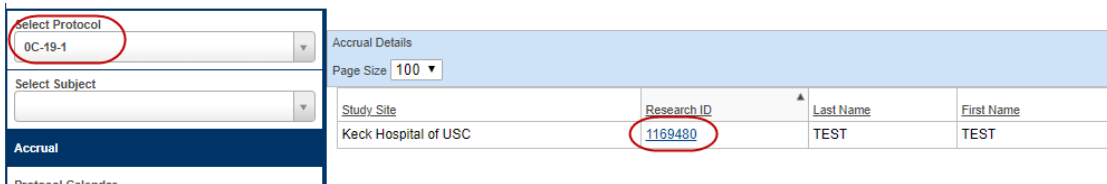
Subject understands and agrees to the details in the consent form.

Steps:

1. Navigate to Subjects-> CRA Console



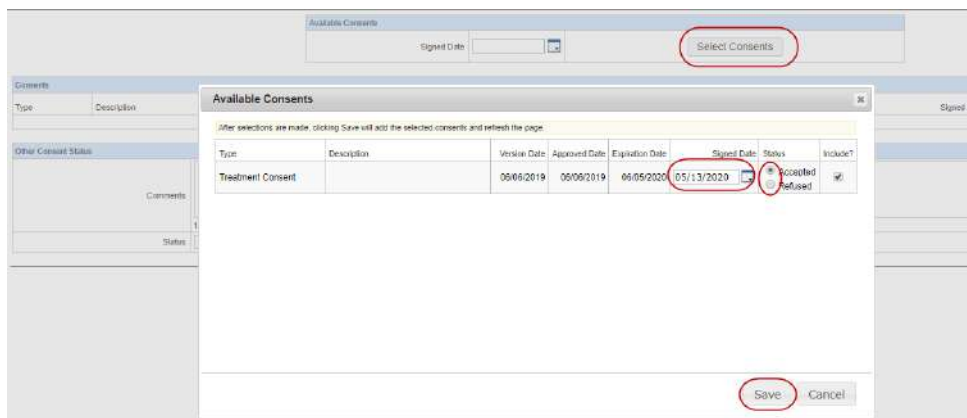
2. Select a Protocol
3. Click on the Research ID



4. Click Consent
5. Click Update



6. Click Select Consents
7. Enter Signed Date
8. Select Status
9. Click Save



Subject – Status, Calendar, Visits and Other Events

10. Click Close

Type	Description	Version Date	Approved Date	Expiration Date	Signed Date	Status	Delete?
Treatment Consent		09/06/2019	09/06/2019	06/05/2020	09/13/2020	Accepted	<input type="checkbox"/>

Coordinators are required to upload signed ICF and HIPAA forms for registered patients. Sponsor payments will not be processed if missing forms are not in OnCore. It is essential a timely upload of documents to avoid payments delay.

11. Click Documents/Info -> Attachments

12. Click Add

13. Select Document Type from the drop-down (HIPAA or Signed Treatment Consent or Signed Treatment Reconsent)

14. Click on File (select file to upload; ICF and HIPAA can either be a combined file or separate)

15. Enter Version Date

16. Click Add

17. Repeat 5-9 to upload additional file

Document Type	File Name / URL	Description	Version Date	Created Date	Created User	Edit	Delete?
HIPAA	HIPAA.PDF		05/13/2020	05/13/2020	CHUNGLES	<input type="checkbox"/>	<input type="checkbox"/>

Subject – Status, Calendar, Visits and Other Events



Subject has been evaluated and meets all criteria (Screening).

Steps:

1. Navigate to Subjects-> CRA Console



2. Select a Protocol
3. Click on the Research ID



4. Click Eligibility
5. Click Update



6. Select Eligibility Status from the drop-down
7. Enter Status Date
8. Click Submit
9. Click Close



Subject – Status, Calendar, Visits and Other Events

Not Eligible

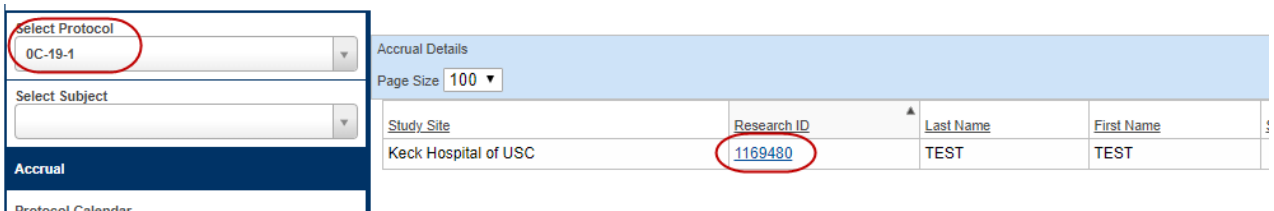
Subject has been evaluated and does not meet all criteria (Screening). However, some studies allow subject to re-screen after a screen failure. When ready to re-screen, register the patient using the same ResearchID but different Sequence No. Make sure to upload the new signed ICF and HIPAA to the corresponding record.

Steps:

1. Navigate to Subjects-> CRA Console



2. Select a Protocol
3. Click on the Research ID



4. Click Eligibility
5. Click Update



6. Select Eligibility Status from the drop-down
7. Enter Status Date
8. Click Submit
9. Click Close



Subject – Status, Calendar, Visits and Other Events



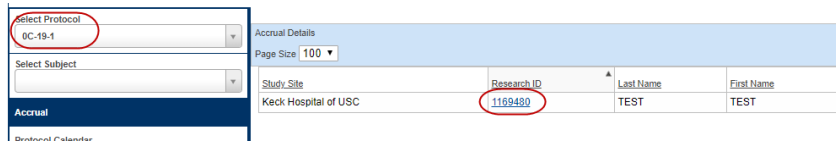
Subject has a recorded Consent and a status of Eligible.

Steps:

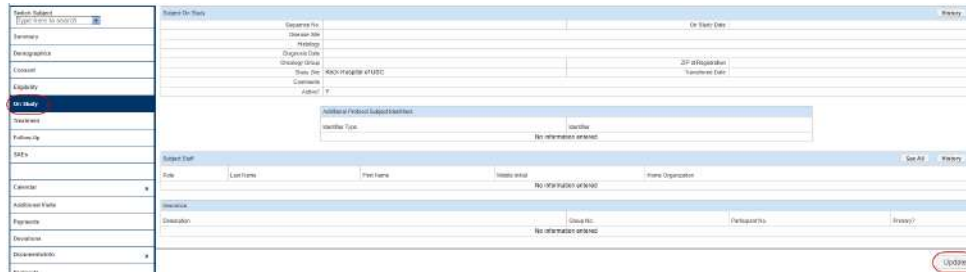
1. Navigate to Subjects-> CRA Console



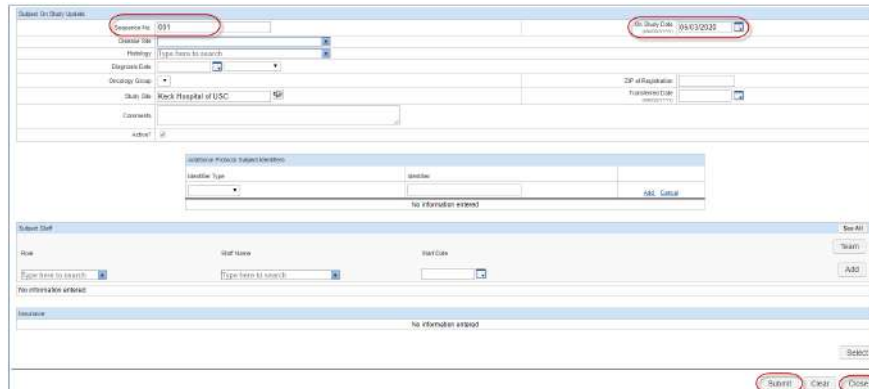
2. Select a Protocol
3. Click on the Research ID



4. Click On Study
5. Click Update



6. Enter Sequence No (Subject protocol no from sponsor or IVRS)
7. Enter On Study Date
8. Click Submit
9. Click Close



Subject – Status, Calendar, Visits and Other Events



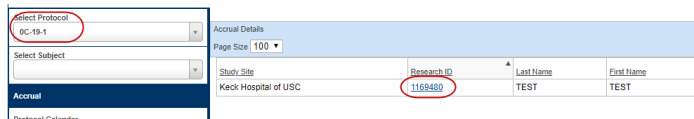
Subject has been enrolled on an Arm and will begin Treatment.

Steps:

1. Navigate to Subjects-> CRA Console



2. Select a Protocol
3. Click on the Research ID



4. Click Treatment
5. Click Add

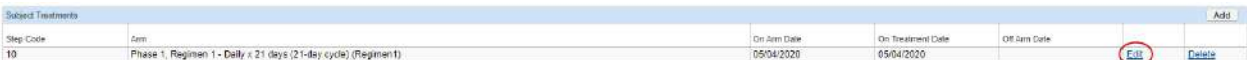


6. Select Arm from the drop-down
7. Enter On Arm Date
8. Enter On Treatment Date
9. Click Save

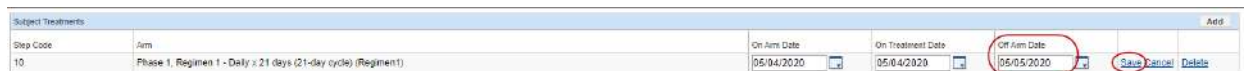


When a patient is assigned to a specific Arm and switches to another Arm at a later point.

10. Click Edit



11. Enter Off Arm Date
12. Click Save



13. Click Add
14. Select Arm from the drop-down
15. Enter On Arm Date
16. Enter On Treatment Date
17. Click Save



Subject – Status, Calendar, Visits and Other Events



Subject will receive no additional Arm Treatment.

Steps:

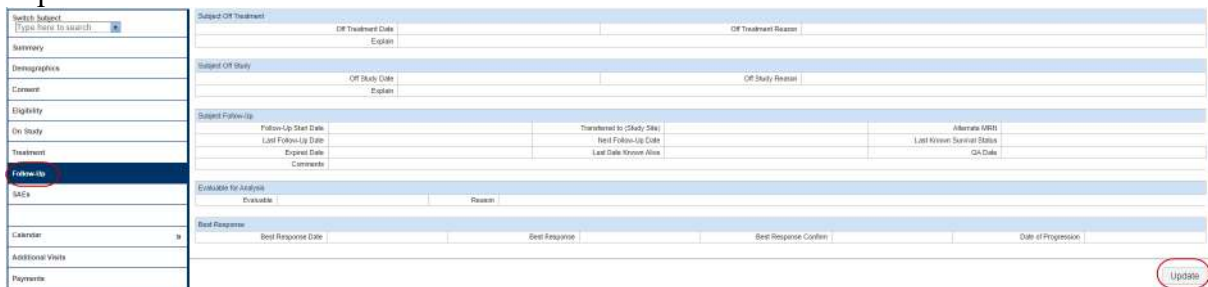
1. Navigate to Subjects-> CRA Console



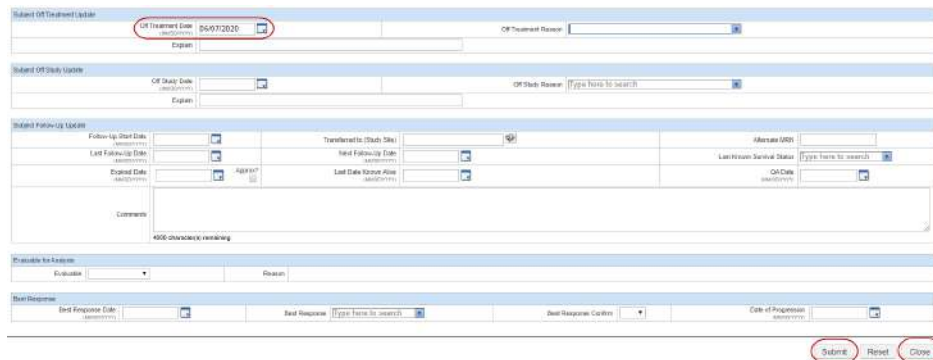
2. Select a Protocol
3. Click on the Research ID



4. Click Follow-Up
5. Click Update



6. Enter Off Treatment Date
7. Click Submit
8. Click Close



Subject – Status, Calendar, Visits and Other Events



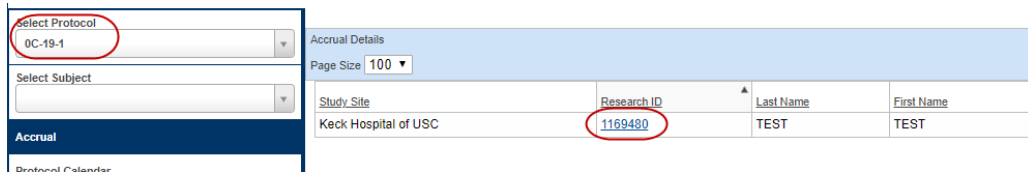
Subject will receive Follow-Up and all Arm Treatment complete.

Steps:

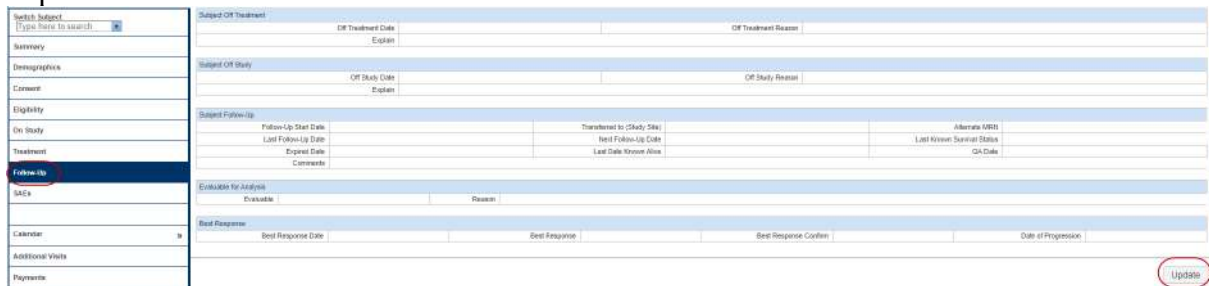
1. Navigate to Subjects-> CRA Console



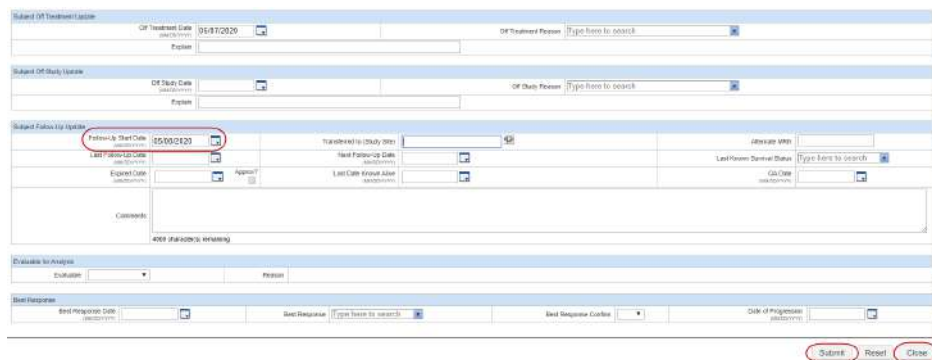
2. Select a Protocol
3. Click on the Research ID



4. Click Follow-Up
5. Click Update



6. Enter Follow-up Start Date
7. Click Submit
8. Click Close



Subject – Status, Calendar, Visits and Other Events



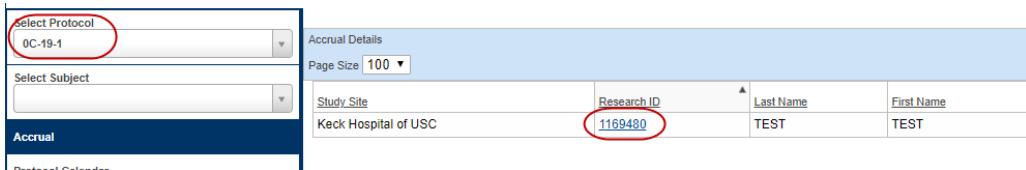
Subject completed all visits and no longer in the study.

Steps:

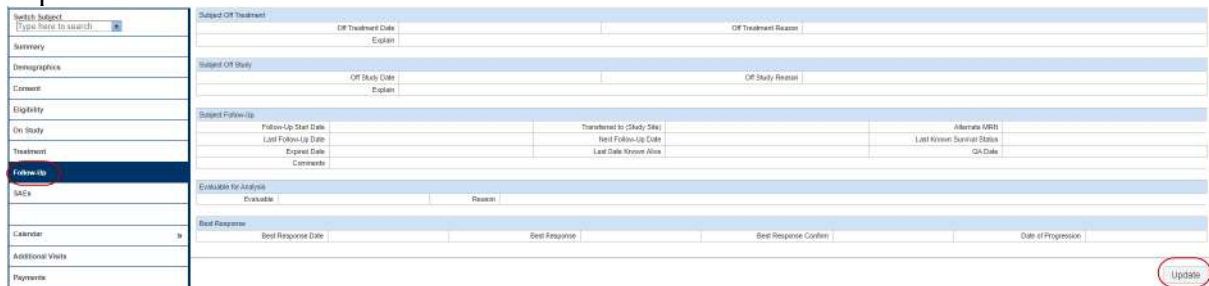
1. Navigate to Subjects-> CRA Console



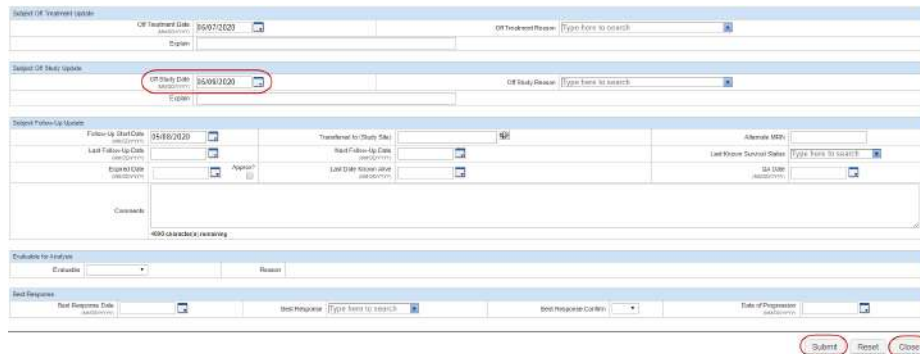
2. Select a Protocol
3. Click on the Research ID



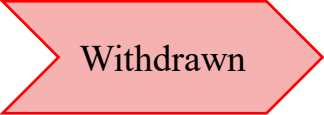
4. Click Follow-Up
5. Click Update



6. Enter Off Study Date
7. Click Submit
8. Click Close



Subject – Status, Calendar, Visits and Other Events



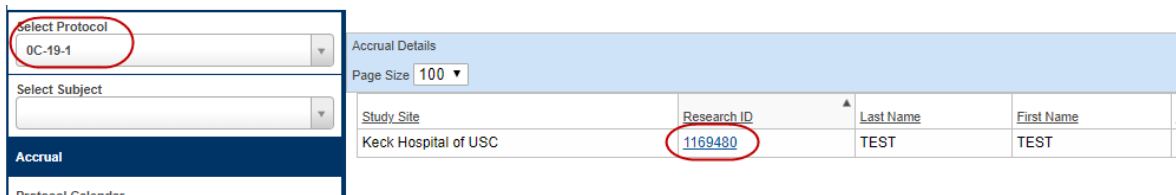
At some point after being presented with a consent form, the subject changes his/her mind and no longer consents to treatment and withdraws from the study.

Steps:

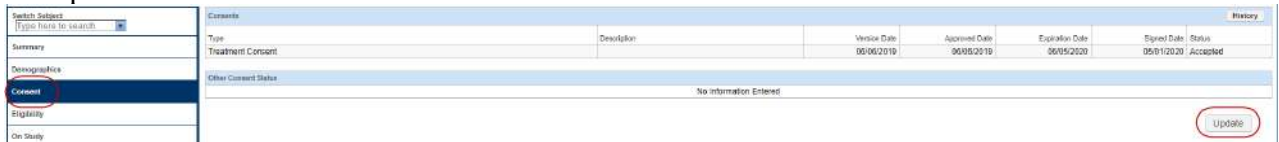
1. Navigate to Subjects-> CRA Console



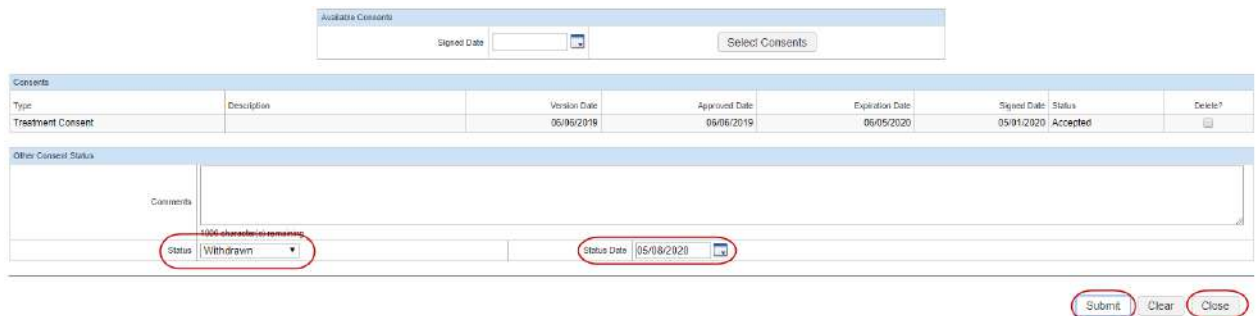
2. Select a Protocol
3. Click on the Research ID



4. Click Consent
5. Click Update



6. Select Status from the drop-down
7. Enter Status Date
8. Click Submit
9. Click Close



Subject – Status, Calendar, Visits and Other Events



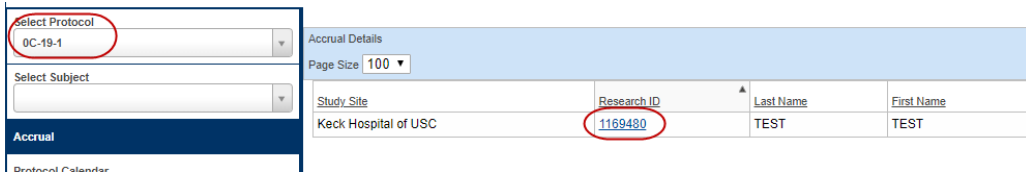
Subject is no longer alive (may or may not be related to treatment or procedures received during the study).

Steps:

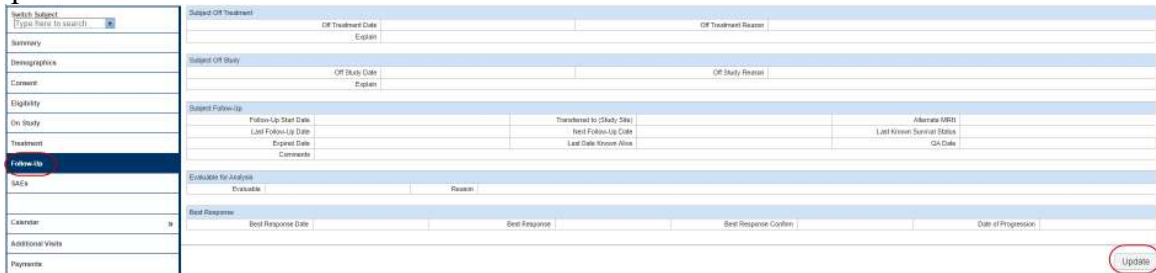
1. Navigate to Subjects-> CRA Console



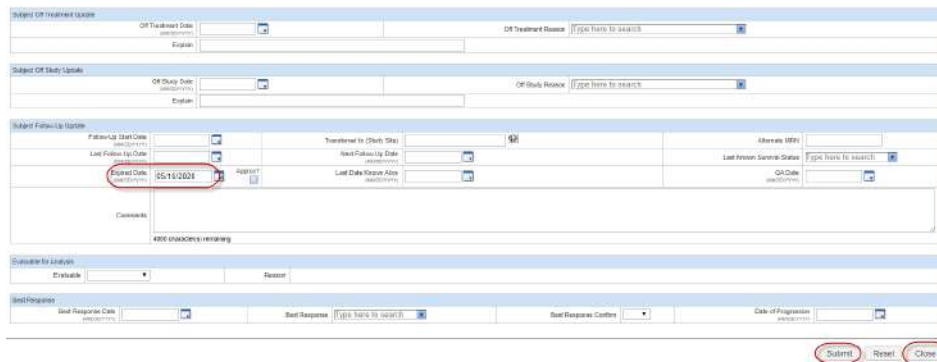
2. Select a Protocol
3. Click on the Research ID



4. Click Follow-Up
5. Click Update



6. Enter Expired Date
7. Click Submit
8. Click Close



Subject – Status, Calendar, Visits and Other Events

Viewing Protocol Calendar

A protocol calendar will display ALL visit schedule, expected procedures as well as the billing designations. It is typically built in segments triggered by date entered in the Subject Console.

- Screening/Pre-Treatment – consent signed date
- Treatment – treatment arm, on/off arm date, on/off treatment date
- Off Study – off treatment date, off study date
- Follow-up – follow-up start date

Steps:

1. Navigate to Subjects-> CRA Console



2. Select a Protocol
3. Click Protocol Calendar

The image shows the 'Protocol Calendar' interface. On the left, there are dropdown menus for 'Select Protocol' (OC-19-1) and 'Select Subject'. Below these are several tabs: 'Actual', 'Protocol Calendar', 'Monitoring Visits', 'Financial Events', 'SAEs', 'Deviations', 'IRBE', and 'Register Subject'. The 'Protocol Calendar' tab is active, showing a grid of visits and events. The grid is organized into columns for different treatment regimens and visits. The rows represent various events such as 'Screening', 'Treatment', 'CRF', 'Safety', and 'Follow-up'. The grid is divided into sections for 'Regimen 1' and 'Regimen 2', each with its own set of visit columns.

Subject – Status, Calendar, Visits and Other Events

Viewing Subject Calendar

Subject calendar defines a schedule of visits and what procedures will be performed based on the Treatment Arm the subject is assigned.

Steps:

1. Navigate to Subjects-> CRA Console



2. Select a Protocol
3. Click on the Research ID



4. Click Calendar -> Calendar

Planned Date row displays the subject's schedule visit dates.

Procedure column displays the name of lab, panel or procedure

Visits that have been activated based on the status date appear as links

X indicates labs, panels or procedures supposed to take place

Screening	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Screening	C1D1*	C1D2*	C1D3*	C1D4*	C2D1*	C2D2*	C2D3*	C2D4*	C3D1*	C3D2*	C3D3*	C3D4*	C4D1*	C4D2*
Planned Date	05/01/2020	05/04/2020	05/05/2020	05/11/2020	05/18/2020	05/25/2020	05/29/2020	06/01/2020	06/06/2020	06/13/2020	07/03/2020	07/27/2020	08/17/2020	
Visit Status	Occured													
ASTX029 PO		X	X	X	X		X	X	X	X	X	X	X	
ASTX029 PO Dispensation		X	X	X	X		X	X	X	X	X	X	X	
Dosing Compliance Information			X	X	X				X	X	X	X	X	X
Informed Consent	X													

Subjects transferred from one Treatment Arm to another Treatment Arm will have multiple calendar treatment. To view calendar based on the treatment arm.

5. From the subject calendar, scroll down and select the treatment arm calendar to view

u. Beginning 3 months after the 30-day Safety Follow-up visit, subjects will be contacted by teleph...

AN. As Needed

Regimen1
Regimen2
Arm Regimen1

Subject – Status, Calendar, Visits and Other Events

Entering Subject Visits

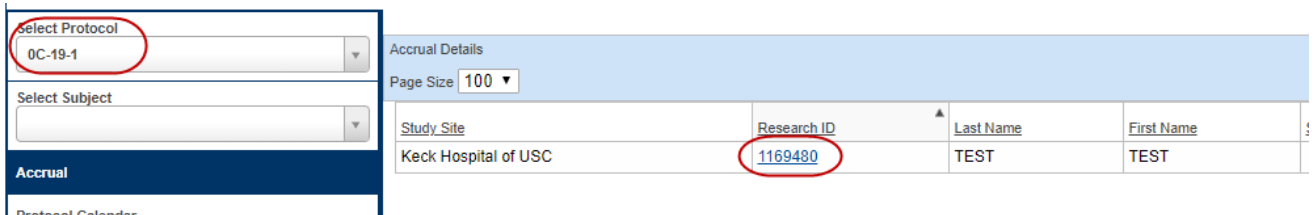
Verifying a visit involves submitting visit information, which consequently updates the status of the visit.

Steps:

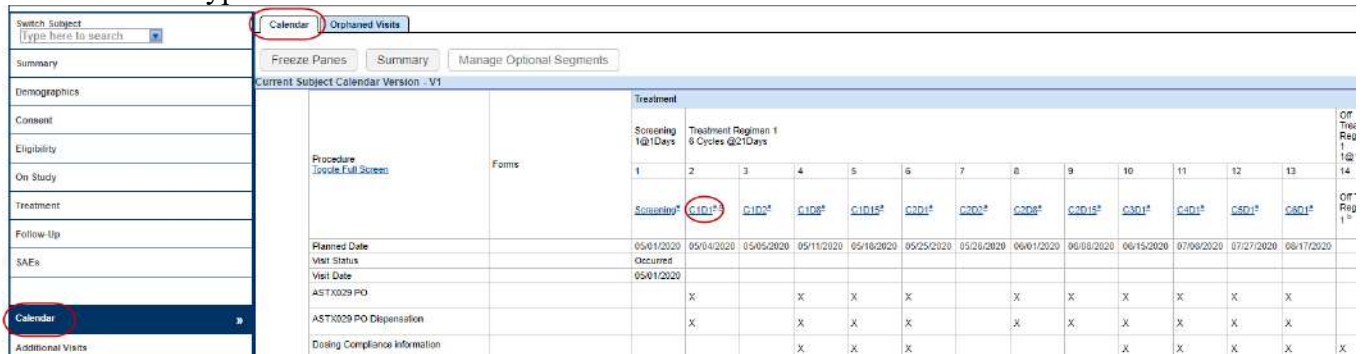
1. Navigate to Subjects-> CRA Console



2. Select a Protocol
3. Click on the Research ID



4. Click on Calendar -> Calendar
5. Click on Visit hyperlink



Subject – Status, Calendar, Visits and Other Events

6. Enter Visit Date
7. Select Occurred
8. Enter Procedure Date (if it's different than the Visit Date)
9. Mark procedure as Missed or NA (if necessary)
10. Select the procedure occurred if there are different types available (if necessary)
11. Click Submit and Close

Subject Visit Update
User: Leslie Chung

Protocol No.: LES-TRAIN
Research ID: 979762
Protocol Status: OPEN TO ACCRUAL
Subject Name: ONE KTESTE
Subject Status: ON TREATMENT
Sequence No.:

Visit Details

Visit Date:

Visit Description:

Data Collection Completed Date:

Collection Location:

Clinical Comments:

Data Comments:

Visit Status: Planned **Occurred** Missed N/A

Visit Tolerance: +/-3

Reset Calendar?:

Submitted Date:

Looked Date:

If one visit occurs off-schedule use the Reset Calendar? field to adjust future visit planned dates

All labs, panels and procedures listed will inherit the Visit Date unless they are marked as Missed or N/A. Only enter a procedure date if it's different than the Visit Date.

If any of these scheduled (expected) procedures did not happen during the visit, mark them Missed or N/A.

Procedures

Procedure	As Needed	Procedure Date	SOC	SOC Modifier	Missed	Missed Count	N/A	Location
Vital Signs	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
ECOG performance status	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Ejection fraction (ECHO/MUGA scan)	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Charge Master Events								
78472-78473 Gated Heart Planar	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	USC
Charge Master Events								
93305 Echo Transthoracic w/ Doppler Complete	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	USC
93306 Echo Transthoracic w/ Doppler Complete (Fac Fee)	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
93306 Echo Transthoracic w/ Doppler Complete (Pro Fee)	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
93321 Doppler Echocardiography Heart	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
93325 Doppler Echocardiography (color flow add-on)	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Study treatment dispensing	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Serum chemistries	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Magnesium ^{AN}	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Uric Acid ^{AN}	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Clinical Trial Unit (CTU) Services	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
CT/MRI	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Biopsy	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
70544-70545 MRI Head w/o & w/ Contrast	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
70551-70553 MRI Brain Stem w/o & w/ Contrast	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
70540-70543 MRI Orbit/Face/Neck w/o & w/ Contrast	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
71550-71552 MRI Chest w/o & w/ Contrast	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
72195-72197 MRI Pelvis w/o & w/ Contrast	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Central Shipping and Handling	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	

Select the procedure that occurred if there are different types of procedures link to an event.

Foot Notes

c Visit Procedure Footnote
AN As Needed

Subject – Status, Calendar, Visits and Other Events

Entering Additional (unscheduled) Procedures

Sometimes during research visit, additional procedures that are not part of the schedule of events are performed based on the physician’s judgement.

Steps:

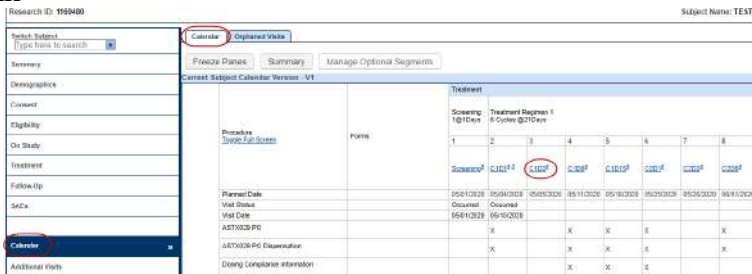
1. Navigate to Subjects-> CRA Console



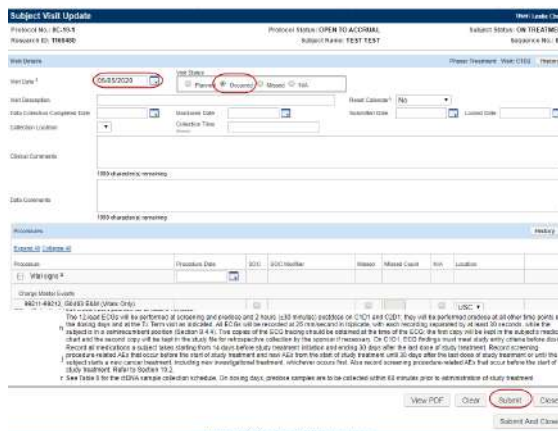
2. Select a Protocol
3. Click on the Research ID



4. Click on Calendar -> Calendar
5. Click on Visit hyperlink



6. Enter Visit Date
7. Select Occurred
8. Click Submit



Subject – Status, Calendar, Visits and Other Events

9. Click Additional Procedures
10. Select Procedure to add
11. Click Submit

Event Code	Additional Event ID	Event Description	Forms	Select?
		12-lead ECG		<input type="checkbox"/>
		Additional blood pressure (BP) and heart rate		<input checked="" type="checkbox"/>
		Adverse Events		<input type="checkbox"/>
		ASTX029 PO		<input type="checkbox"/>
		ASTX029 PO Dispensation		<input type="checkbox"/>
		Bone Scan (Conventional Care)		<input type="checkbox"/>
		Bone Scan (research)		<input type="checkbox"/>
		CBC w/ differential (local lab)		<input type="checkbox"/>
		Central Lab Blood Draw		<input type="checkbox"/>

Buttons: Additional Procedures, Billing Slip, View PDF, Delete, Clear, Submit, Close, Submit And Close

12. Enter Reason for adding
13. Click OK

Additional Procedure: Additional blood pressure (BP) and heart rate

Reason for adding: Request by physician

Buttons: OK, Cancel

14. Click Submit and Close

Buttons: Additional Procedures, Billing Slip, View PDF, Delete, Clear, Submit, Close, Submit And Close

Subject – Status, Calendar, Visits and Other Events

Deleting Visit

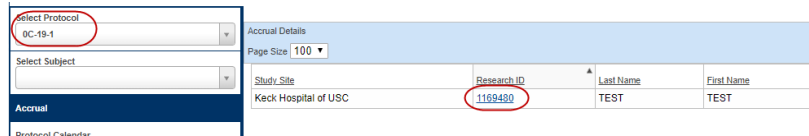
Deleting a visit removes all information and returns the visit to a Planned status. A visit cannot be deleted if the visit has been added to an Invoice.

Steps:

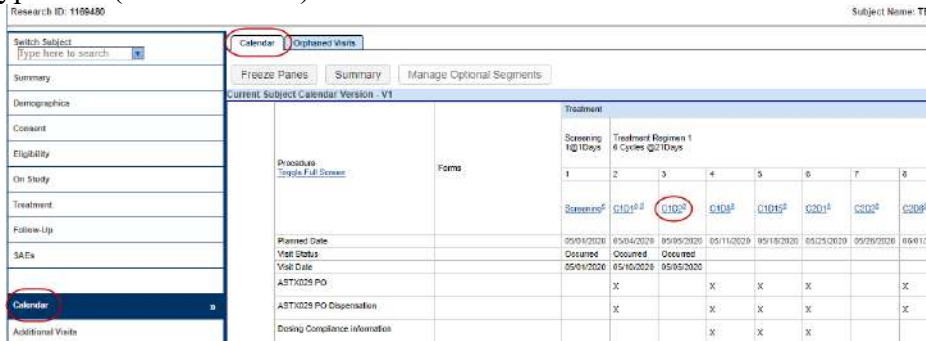
1. Navigate to Subjects-> CRA Console



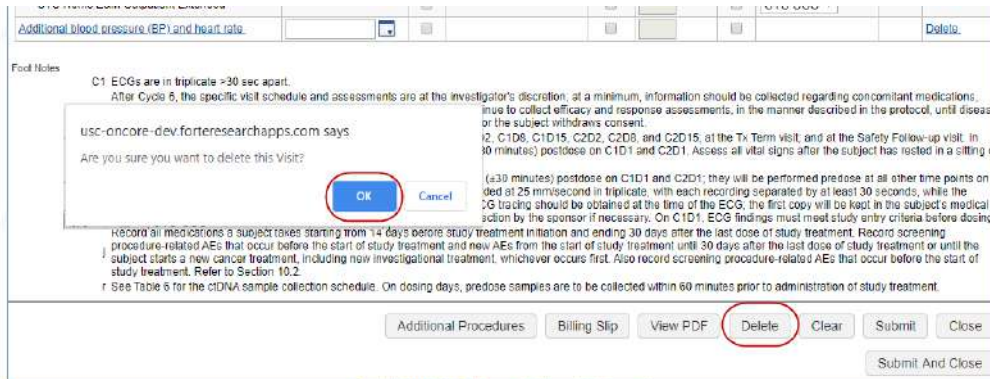
2. Select a Protocol
3. Click on the Research ID



4. Click on Calendar -> Calendar
5. Click on Visit hyperlink (wish to delete)



6. Click Delete
7. Click OK



Subject – Status, Calendar, Visits and Other Events

Adding Additional (unscheduled) Visit

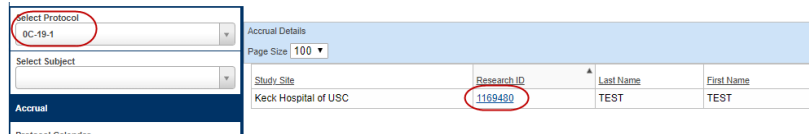
Subjects participating on clinical trials might require additional unscheduled visits during the study. Additional visits are not visible in the subject calendar.

Steps:

1. Navigate to Subjects-> CRA Console



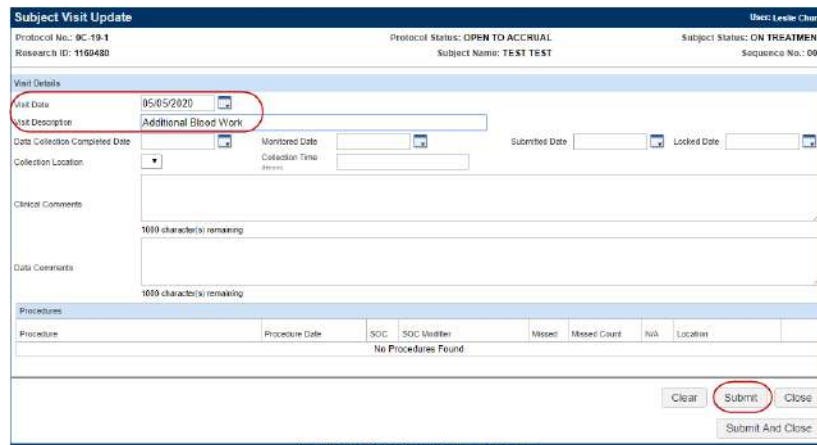
2. Select a Protocol
3. Click on the Research ID



4. Click on Additional Visits
5. Click New



6. Enter Visit Date
7. Enter Visit Description
8. Click Submit



Subject – Status, Calendar, Visits and Other Events

9. Click Additional Procedures
10. Select Procedure to add
11. Click Submit

Procedure Add - Google Chrome
 usc-oncore-dev.forteresearchapps.com/smrs/SubjectStudyDataControlServlet?hdn_function=ADDITIONAL_EVALUAT...

Browse Results

Protocol Calendar Procedures/ Labs

Event Code	Additional Event ID	Event Description	Forms	Select?
		12-lead ECG		<input type="checkbox"/>
		Additional blood pressure (BP) and heart rate		<input type="checkbox"/>
		Adverse Events		<input type="checkbox"/>
		ASTX029 PO		<input type="checkbox"/>
		ASTX029 PO Dispensation		<input type="checkbox"/>
		Bone Scan (Conventional Care)		<input type="checkbox"/>
		Bone Scan (research)		<input type="checkbox"/>
		CBC w/ differential (local lab)		<input type="checkbox"/>
		Central Lab Blood Draw		<input checked="" type="checkbox"/>

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

Submit Clear Close

Additional Procedures Billing Slip View PDF Delete Clear Submit Close Submit And Close

12. Enter Reason for adding
13. Click OK

Additional Procedure Reason for adding
 Central Lab Blood Draw Request by physician

OK Cancel

14. Click Submit and Close

Subject Visit Update
 Protocol No.: OC-19-1 Research ID: 1169480
 Protocol Status: OPEN TO ACCRUAL Subject Name: TEST TEST
 Subject Status: ON TREATMENT Sequence No.: 001

Visit Date: 05/05/2020
 Visit Description: Additional Blood Work

Procedures

Procedure	Procedure Date	SOC	SOC Modifier	Missed	Missed Count	N/A	Location	Delete
Central Lab Blood Draw								

Submit And Close

Subject – Status, Calendar, Visits and Other Events

Switch Calendar Version

New calendar version is created during amendments or changes need to be made to an existing version due to some errors or missing information. Subjects are not automatically upgraded to a new calendar version, and subjects are not required to be upgraded. Depending on the protocol amendment, the schedule of events might change for new subjects enrolled on the study, but existing subjects might be allowed to continue treatment and finish on their original schedule.

Steps:

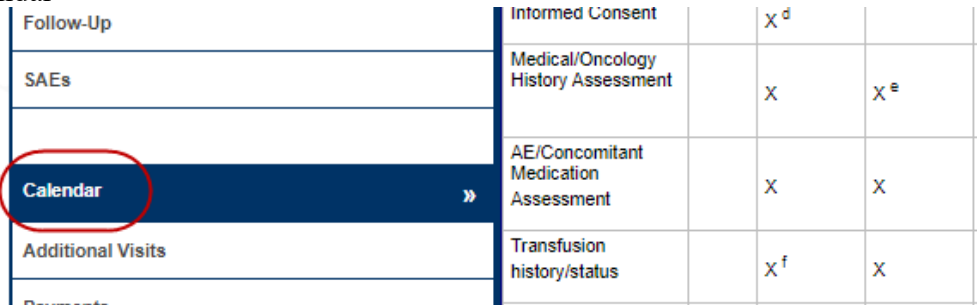
1. Navigate to Subjects-> CRA Console



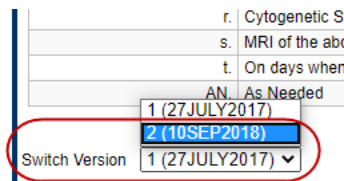
2. Select a Protocol
3. Click on the Research ID



4. Click on Calendar

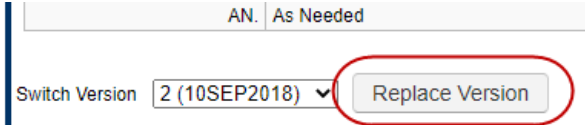


5. Scroll all down the page
6. Select the calendar version to switch



Subject – Status, Calendar, Visits and Other Events

7. Click Replace Version



8. Click Orphaned Visits

These visits are from a previous calendar version and are not associated with any visits on the subject’s current calendar version. These may be due to the change of visit name or the visit is no longer valid on the current calendar. These visits are retained under the Orphaned Visits and can’t be viewed on the main calendar.

Calendar	Orphaned Visits				
Orphaned Visits					
Visit	Event	Source	Visit Date	Visit Status	Calendar Version
Visit 1 (D1)	Treatment	Treatment	03/15/2018	Occurred	2
Visit 1 (D1)	Treatment	Treatment	03/21/2018	Occurred	2
Visit 2 (D1)	Treatment	Treatment	03/13/2018	Occurred	2
Visit 2 (D1)	Treatment	Treatment	03/29/2018	Occurred	2
Visit 3 (D1)	Treatment	Treatment	04/12/2018	Occurred	2
Visit 4 (D1)	Treatment	Treatment	05/18/2018	Occurred	2
Visit 5 (D1)	Treatment	Treatment	06/07/2018	Occurred	2
Visit 6 (D1)	Treatment	Treatment	06/21/2018	Occurred	2
Visit 8 (D1)	Treatment	Treatment	07/05/2018	Occurred	2
Visit 7 (D1)	Treatment	Treatment	08/02/2018	Occurred	2

Subject – Status, Calendar, Visits and Other Events

Protocol Financial Events (Fees)

Add Protocol-Related Events that occurred like “Office Monitoring Visit”, “Remote Monitoring Visit”, “Protocol Amendment Re-Consent Fee”, and “IND Safety Reporting Fee”. Once an event is added, it will create an Invoiceable Item to invoice sponsor.

Steps:

1. Navigate to Subjects-> CRA Console



2. Select a Protocol No
3. Click on Financial Events
4. Click Update

Occurred Date	Event	Protocol Related Comments	Submitted By	Comments
No events submitted				
0 Total Records				

Update

5. Select Financial Event from the drop down
6. Enter Occurred Date
7. Enter Count (multiple instances can be created at the same time)
8. Enter Comments (if needed) – for “Protocol Amendment Re-Consent Fee”, please enter subject Seq No
9. Click Add

Occurred Date	Event	Protocol Related Comments	Submitted By	Comments	Delete?
No events submitted					
0 Total Records					

Submit Close

10. Click Close

Occurred Date	Event	Protocol Related Comments	Submitted By	Comments	Delete?
02/22/2022	Office Monitoring Visit	Per Visit	Chung, Leslie		<input type="checkbox"/>
02/22/2022	Office Monitoring Visit	Per Visit	Chung, Leslie		<input type="checkbox"/>
2 Total Records					

Submit Close

Subject – Status, Calendar, Visits and Other Events

SAE's

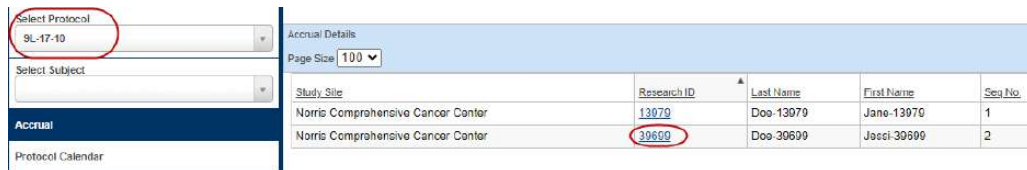
SAEs entered will create an Invoiceable Item to invoice sponsor.

Steps:

1. Navigate to Subjects-> CRA Console



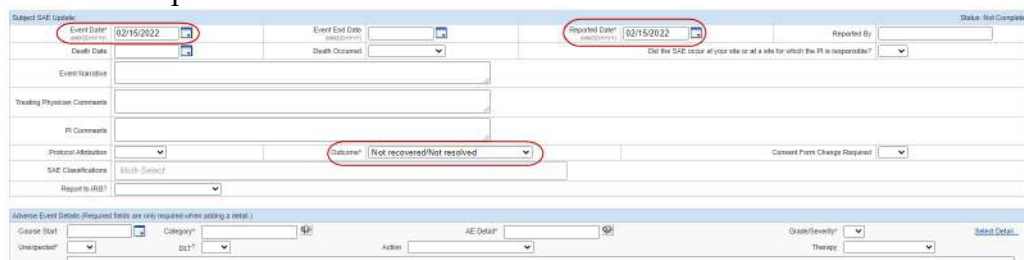
2. Select a Protocol
3. Click on the Research ID



4. Click on SAEs
5. Click New



6. Enter Event Date
7. Enter Reported Date
8. Select Outcome from drop down



9. Click Submit
10. Click Close

