Class is meant to *supplement* other training, not as all inclusive training. This session will *not* be recorded, but this PowerPoint can found:

https://medschool.ucla.edu/research/research-infrastructure/administrative-support/department-of-medicine-office-of-research/fund-management-training

Clinical Trials

Pre-Award: OnCore

UCLA DEPARTMENT OF MEDICINE
OFFICE OF RESEARCH ADMINISTRATION
ZOOM TRAINING

Summary

- OnCore - Overview
  - Clinical Trial workflow
  - Notifications for Study Team & Research Administrators
- OnCore – Research Administrator Access & Tasks
  - Configure Invoicing Parameters
  - Verify Milestones
  - Study Team Budget Signoff
  - FAU Entry
  - View Subject Data

CT Key Terminology & Acronyms

- Clinical Research Informatics Systems (CRIS)
- Clinical Trial Agreement (CTA)
- Clinical Trials Management System (CTMS)
- Financial Coverage & Activation (FCA)
- Industry (IND)
- Invoiceable (INVBL or P/Pass Thru)
- Outside Safety Report (OSR)
- Research Quality (RQ)
- Serious Adverse Event (SAE)

OnCore – Overview

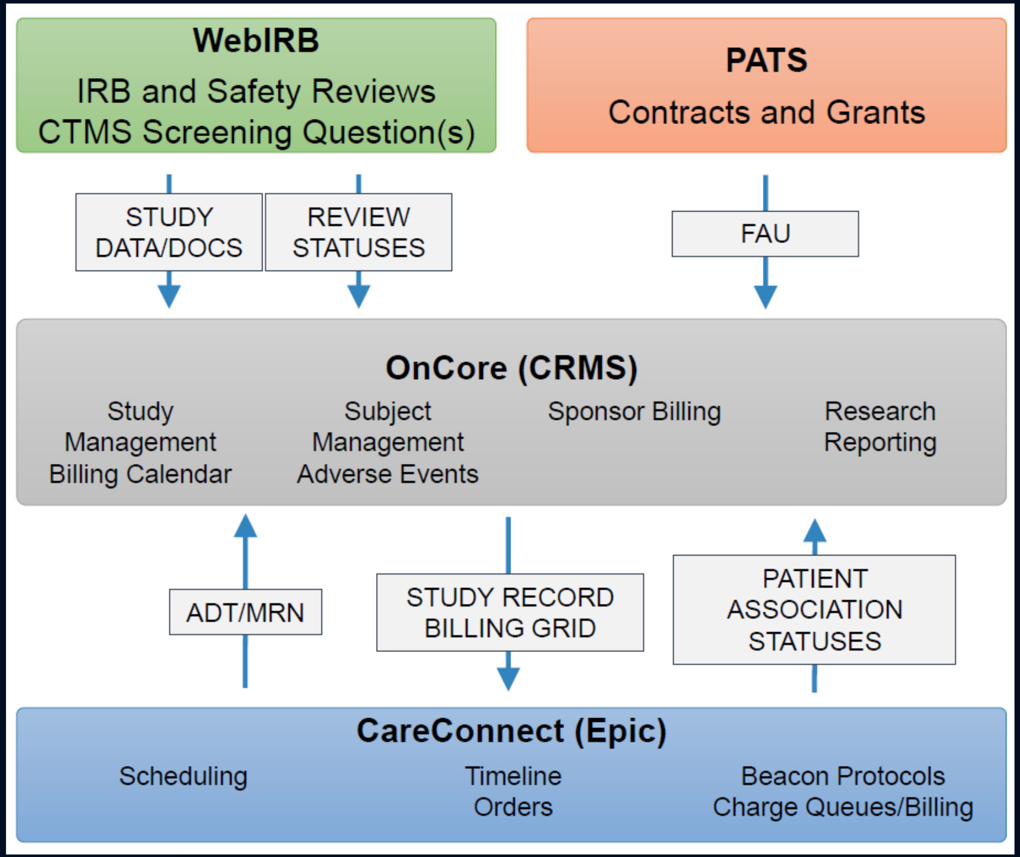
PRE-AWARD

OnCore

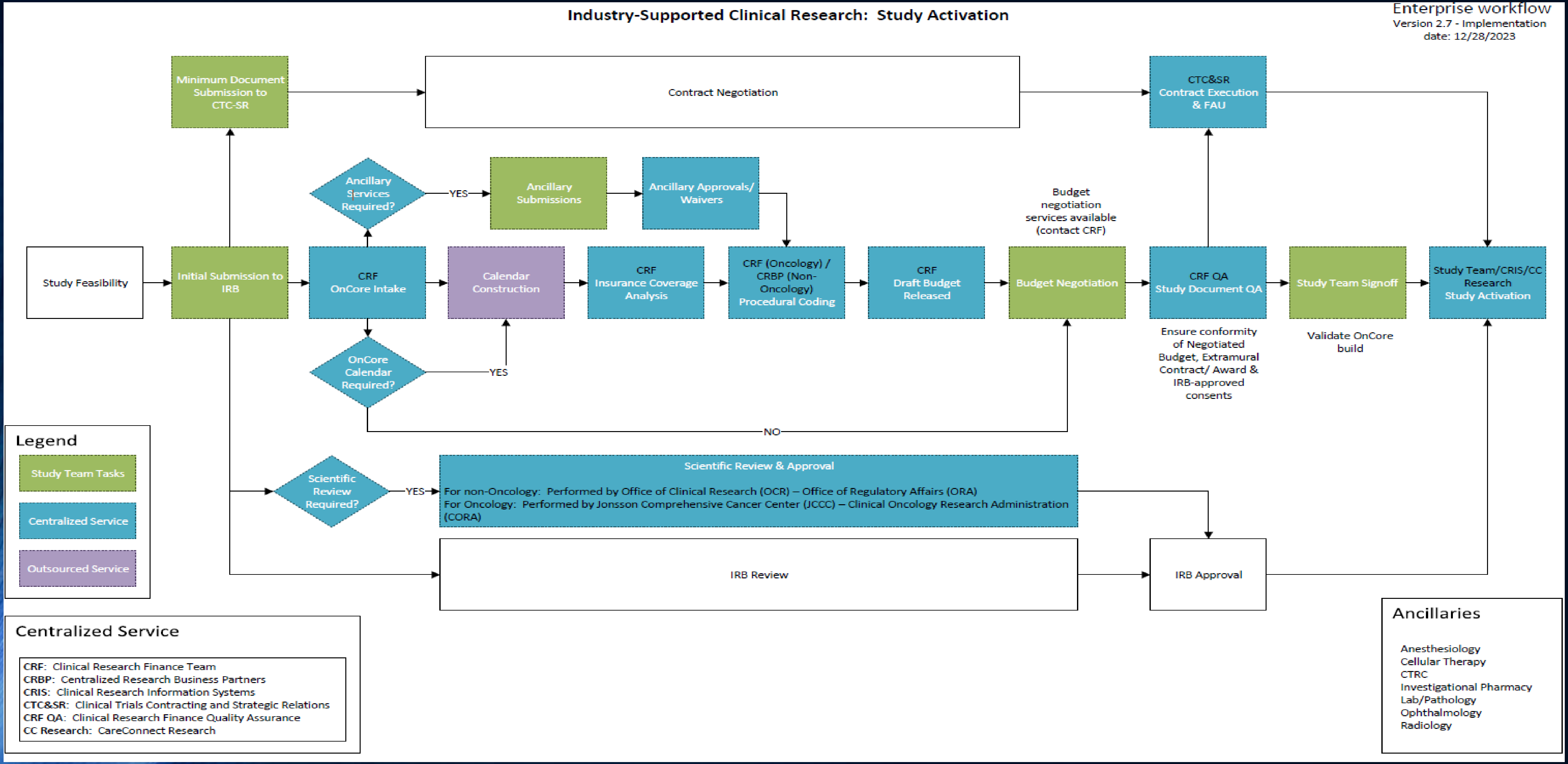
- OnCore allows us to use one program to manage multiple components of clinical trials. It automates the flow of information between UCLA based systems including BruinIRB, PATS and CareConnect.
- Research Administrators have an administrative role with broad access in OnCore.
  - Protocol and subject search
  - Access to subject reports
  - View timeline of specifications
  - subject calendar information, etc
- OnCore users must complete required training before having access to the system.
- Email notifications are triggered by various actions in OnCore when you or someone else performs a specific action.

How is OnCore used in Clinical Trials?

- OnCore is a clinical trials management system (CTMS) used at UCLA for the management of clinical trials in clinical research. The system maintains and manages planning, performing and reporting functions at the study and subject level along with participant contact information, tracking deadlines and milestones.
- OnCore automates the flow of information between UCLA based systems including BruinIRB, PATS and CareConnect.



Pre Award Start-Up



OnCore - Roles & Training

- For system security and compliance, training is required for access to OnCore.
  - OnCore Training Suite
  - OnCore Roles and Responsibilities
- Training Grid for Research Administrator (DOM Non-Hem/Onc)

OnCore Role	RSCH100 Fundamentals	RSCH160 Financials Management	RSCH210 Study Management	RSCH215 Subject/Patient Management
Fund Manager (FM)	Mandatory	Mandatory	Optional	Optional

- Training Grid for Research Administrator (DOM Hem/Onc)

OnCore Role	RSCH100 Fundamentals	RSCH165 Financials Management	RSCH210 Study Management	RSCH216 Subject/Patient Management	RSCH170 Research Billing – Charge Reviewer
Fund Manager (FM)	Mandatory	Mandatory	Optional	Optional	Optional

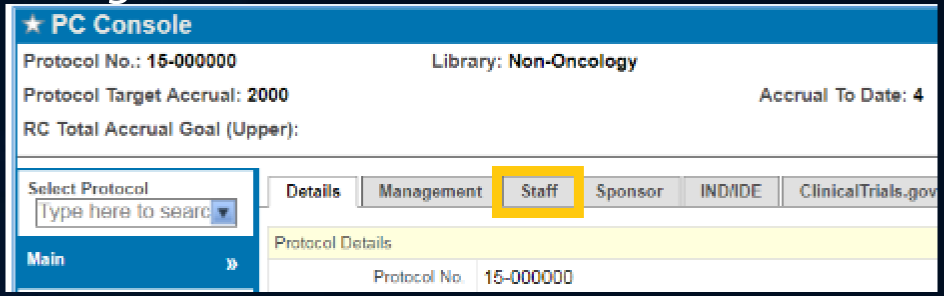
OnCore – Study Team/Protocol Staff

- Who is my Study Team (ST)?
  - Inquire with PI to find out (primary/common roles include Study Coordinator, Regulatory Coordinator, Research Assistant, Data Manager)
  - Tip: Establish an intro meeting to discuss roles and set up regular weekly/biweekly meetings to discuss study updates, including billing/invoice
- If CTSI -CSE services (study support *outside* of DOM), such as Study Activation and Clinical Research Coordinating are being utilized, take the opportunity to facilitate a meeting with them
  - Tip: you may want to check with PI if they have already established meetings so that you may join in on future meetings
  - If PI is unsure of Study Team contacts you may request an introduction by contacting the Office of Clinical Research (OCRCoordinator@mednet.ucla.edu) and CC: Sarahmay Sanchez (SOSanchez@mednet.ucla.edu), Director of CSE, CTSI - Office of Clinical Research

Note: Relationship building is key! Research Administrators should be working *very* closely with Study Teams

OnCore – Study Team/Protocol Staff

- The OnCore Protocol Staff tab displays the Study Team Staff associated with the protocol/study
  - *Navigation: OnCore > Menu > Protocols > PC Console > Horizontal Tab: Staff*



  - Tip: If you are unable to view a Protocol, it most likely means you are not added/assigned to the protocol. You may request that your Regulatory contact add you as staff.
- Study Team (includes Research Administrators) will receive OnCore email notifications based on assigned role
  - OnCore notifications include protocol progress updates and reminders to complete tasks within OnCore

OnCore – Notifications

SENDER / CONTACT(S)	RECIPIENT(S)	EMAIL SUBJECT	ACTION
CRIS Admin crisadmin@mednet.ucla.edu 310-267-2273 (7-CARE)	TO: Study Team	#131: Ancillary Approval or Waiver uploaded - IRB# / PI Name / Division / Sponsor / Protocol	Notification of Ancillary documents (servicing dept – approval/waiver) uploaded
CRIS Admin crisadmin@mednet.ucla.edu 310-267-2273 (7-CARE)	TO: Negotiator CC: Study Team / Research Administrator	#119: Review of Released Budget Document Uploaded - IRB# / PI Name / Division / Sponsor / Protocol	Negotiator to initiate "Budget Out" calendar negotiations with funding agency • Research Administrator- Budget Out Checklist • Financial Management (Non-HemOnc Studies) • Financial Management (HemOnc Studies)
CRIS Admin crisadmin@mednet.ucla.edu 310-267-2273 (7-CARE)	TO: Negotiator CC: Study Team, Research Quality	#133: Financials Budget In Response Uploaded - IRB#	Research Quality reviews and uploads "Budget In" for certification after negotiator uploads & finalizes negotiated budget
CRIS Admin crisadmin@mednet.ucla.edu 310-267-2273 (7-CARE)	To: Negotiator / Research Administrator CC: Research Quality, Study Team	Protocol No.: IRB # - Budget Signoff Notification	Research Administrator to review the OnCore Budget that was entered by FCA and complete the "Study Team" Budget Signoff for All 3: Parameters, Milestones and "Study Team Signoff".
Coverage Analysis *OnCore calendar/budget* *CoverageAnalysis@mednet.ucla.edu*	TO: PI CC: Contract Officer, Research Administrator, Study Team	Final Budget Signoff - IRB# / PI Name / Division / Sponsor / Protocol	Study received Final Budget Signoff (Coverage Analysis releases budget)
CRIS Admin crisadmin@mednet.ucla.edu 310-267-2273 (7-CARE)	TO: PI, Study Team	Protocol No.: IRB # - Protocol Status [OPEN TO ACCRUAL] Notice - Status Date	Study is open for accrual and study team can begin to register subjects • Research Administrator: Enter FAU Specify the FAU in the Internal Account No. field in the Hospital Account No. field. • Access & Attach Ancillary Documents • Study Team: Manage Subjects

OnCore – Budget in / Study Team sign off Notification

- There are 4 action items to complete when receiving these email notification that Research Administrator must complete for OnCore to trigger the next action item.
  - Parameters
  - Milestones
  - Specifications - Study Team Sign-Off
  - FAU Entry
- After a budget has been negotiated or finalized, you can define the Parameters and Milestones for which the sponsor has agreed to pay receiving the notification "Specification Status: Budget Signoff".
  - The first step is to retain copy of the contract that is considered final and may be in route. Be sure to ask the negotiating party (may be contract officer or negotiator of budget) for final draft (prior to signatures) of contract.
  - Secondly, set parameters in the Financials Console which affect the protocol's budget reports and sponsor invoices.
  - Then set Milestones which define specific protocol- or subject-related event/s that can be invoiced according to a study payment schedule.
  - Lastly, Study Team Sign Off indicates the calendar is awaiting your approval.
  - After receipt of another OnCore notification to enter the Fund Accounting Unit (FAU) in OnCore and also receiving the FAU from ORDM, Research Administrators are required to ensure a research guarantor is applied to the research encounter in CareConnect when a research visit occurs.

OnCore – Parameters

PRE-AWARD

Configure Invoicing Parameters

- Invoice Parameters are used for data to reflect on your invoices sent to sponsor. Entering data here should be captured from the (final proposed) contract information.

- Financial Coordinators can set budget parameters for details such as the study's rate base for charge master events, indirect withholding amounts, and rules for invoicing screen failures and SAEs, as agreed upon in the CTA. Predetermined costs can be programmed for milestone events such as consents, enrollments, cycle/visit completions, and SAEs to allow efficient invoicing after the event is logged by the research team.

- 3 sections
  1. Budget Related
  2. Invoice Related
  3. Remit To / Bill To

- *Navigation: OnCore > Menu > Financials > Financials Console > Parameters tab*

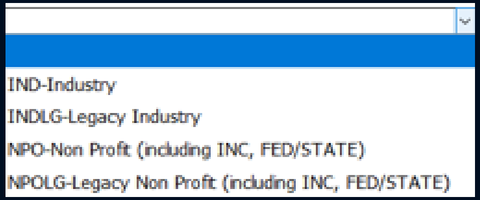
Parameters – Section 1: Budget Related

Navigation: OnCore > Menu > Financials > Financials Console > Parameters tab

1. Click on Update located on bottom right

2. Select Protocol by entering IRB#

3. For Rate Base, select applicable agency

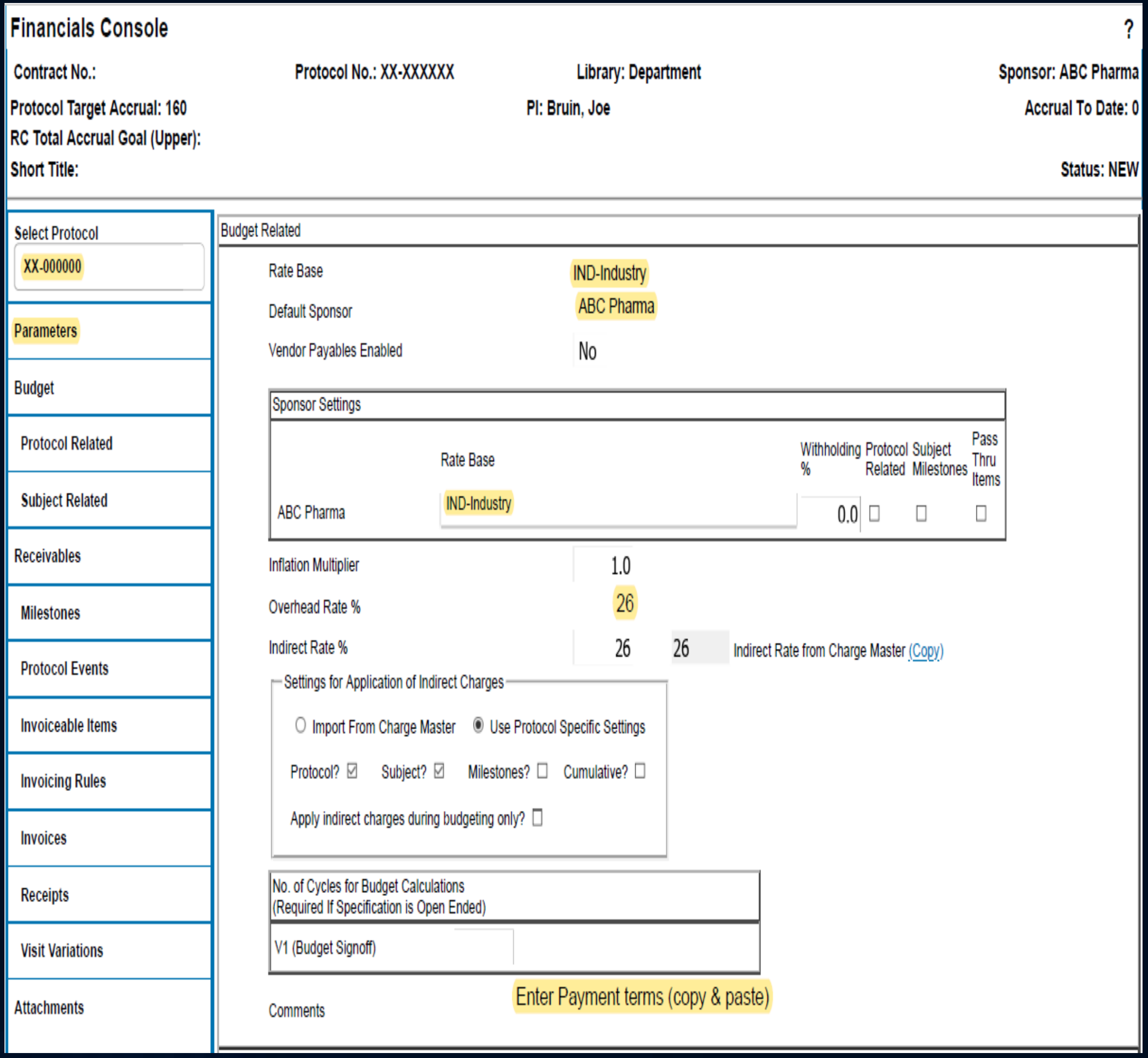


4. Default Sponsor – select sponsor

5. Rate Base – select agency again

6. Overhead Rate – enter rate – now 33%

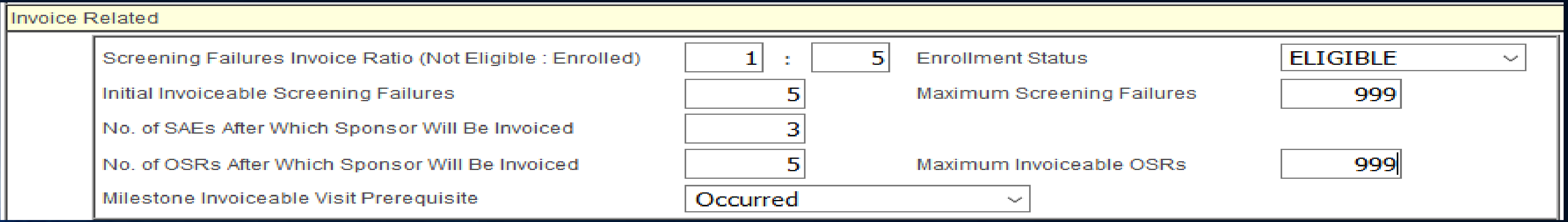
7. Comments (optional) – enter payment terms (copy & paste) from CTA



Parameters – Section 2: Invoice Related

Based on the CTA, enter Screening Failure (SF) details, if applicable. A screen failure occurs when a subject is marked as ineligible in the Subject Console. Screen failures will appear in the Invoiceable Items tab if Screen Failed is set up as a milestone.

- The SF Invoice Ratio (Not Eligible: Enrolled) indicates the sponsor can be billed for x number of subjects deemed ineligible, for every y number of eligible subjects.
  - Enrollment Status
    - Eligible: indicates the number of subjects that must be considered "enrolled" in order for you to bill the sponsor for the number of screen failures indicated in the "Not Eligible" field
    - Not Eligible: indicates the number of screen failures
  - This ratio applies only after the value set in the Initial Invoiceable Screening Failures field is reached, and up until the Maximum Screening Failures is met
- No. of SAEs indicates the first Serious Adverse Event on the protocol for which the sponsor will receive an invoice
- No. of OSRs indicates the first Outside Safety Report/external SAE on the protocol for which the sponsor will receive an invoice


Invoice Related

Screening Failures Invoice Ratio (Not Eligible : Enrolled)	1 : 5	Enrollment Status	ELIGIBLE
Initial Invoiceable Screening Failures	5	Maximum Screening Failures	999
No. of SAEs After Which Sponsor Will Be Invoiced	3		
No. of OSRs After Which Sponsor Will Be Invoiced	5	Maximum Invoiceable OSRs	999
Milestone Invoiceable Visit Prerequisite	Occurred		

Parameters – Section 2: Invoice Related (cont.)

If you want automated Invoicing Reminders, enter the following details:

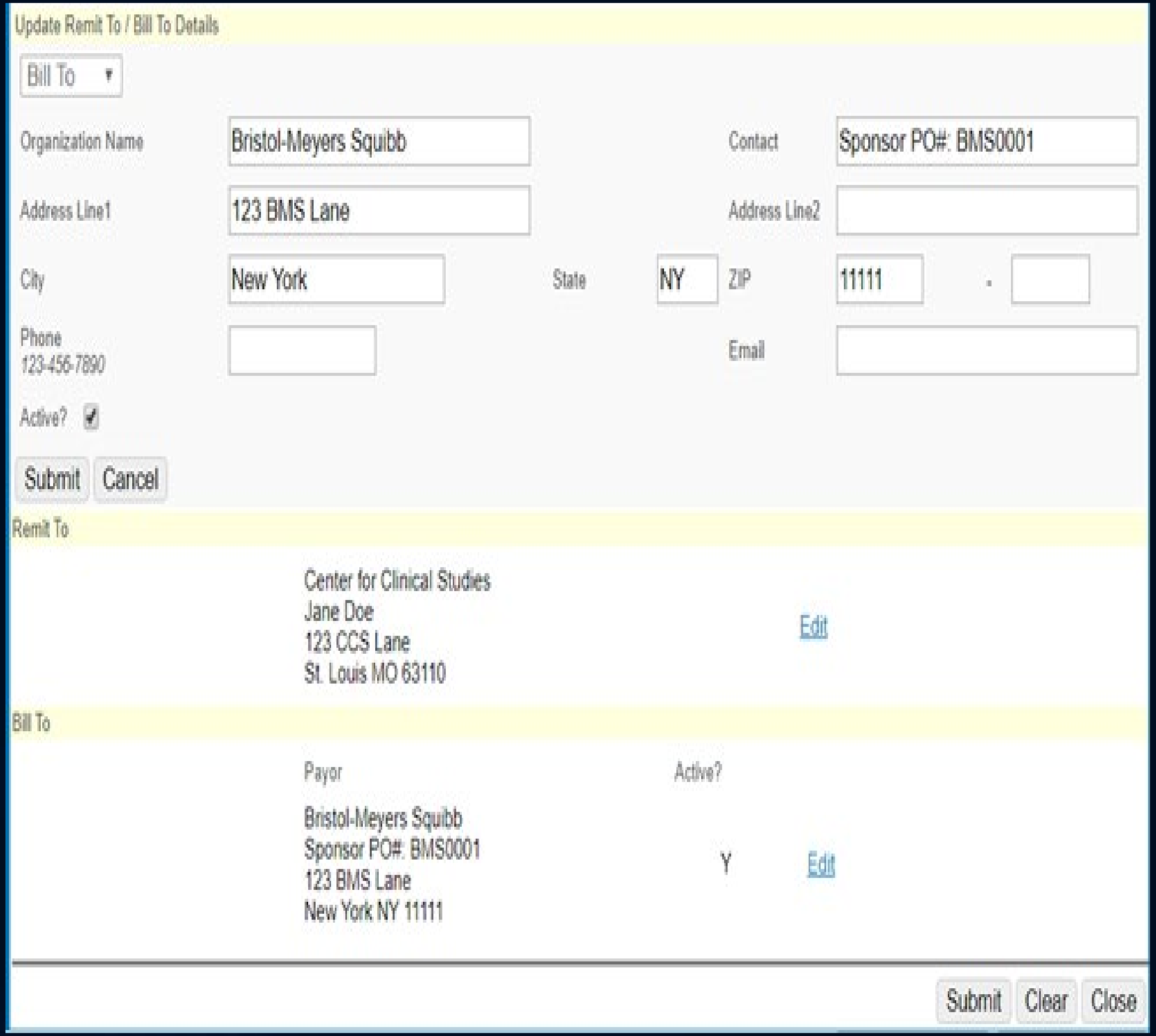
- Notification Frequency (Months) Reminder of your choice. Example, if Entering 3 here. Setting a notification frequency of every 3 months (Jan 1, Apr 1, June 1, Oct 1)
- Number of Invoice reminders to send after study closure Number of reminders sent once protocol has a completed status (Abandoned, Terminated, or IRB Study Closure)
- Notification Start Date The date on which notifications are activated. If you enter 4/15/2020 in here, for example, your first notification will occur on 6/1/2020
- Notification Comments: Any other information you wish to add regarding the notifications

The invoicing reminder notification is an email that will go to the Financial Billing Contact and the Financial Coordinator listed on the protocol. This function is currently being used by DOM

Invoicing Reminder	
Notification Frequency (Months)	3
Number of invoice reminders to send after study closure	1
Notification Start Date (MM/DD/YYYY)	04/01/2020
Notification Comments	Invoicing Reminder is set for the 1st of the month of Jan, Apr, June, and Oct.

Parameters – Section 3: Remit to / Bill to

- Refer to the CTA to locate payment terms and enter sponsor billing information, as well as UCLA remit payment information
- The Remit To / Bill To Details should match the contract
  - This allows you to keep a record of all relevant addresses
  - If you need to add the Sponsor # or PO #, add it to the Contact line
- Once all information has been entered, click Add just left of section and the information will populate into the appropriate section below
- The Bill To sponsor is required to facilitate sponsor invoicing and payment reconciliation



OnCore – Milestones

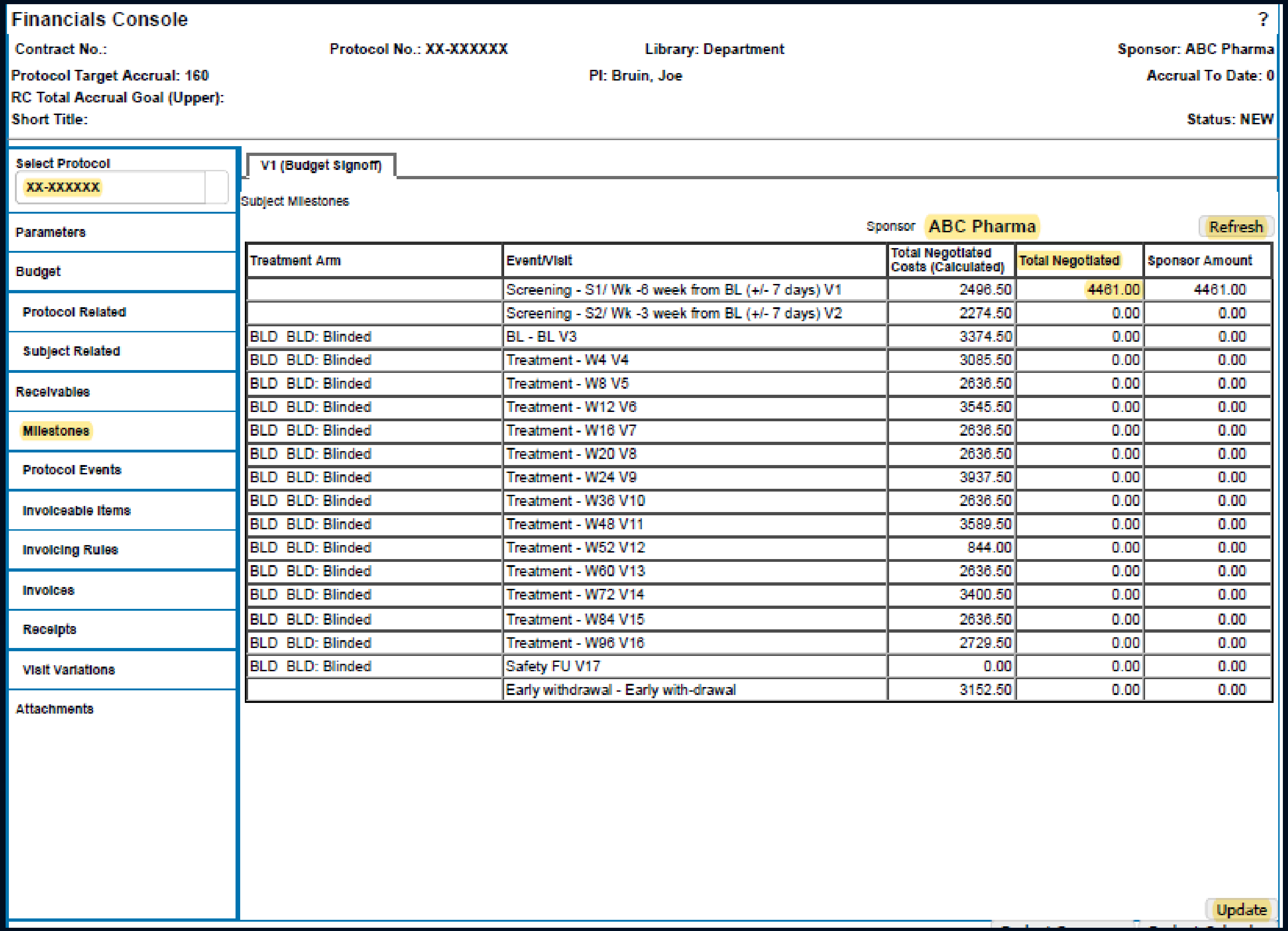
PRE-AWARD

Setting up Protocol Budget to Verify billable Milestones

- After a budget has been negotiated or finalized, you can define the milestones for which the sponsor has agreed to pay. A milestone defines a specific protocol or subject related event that can be invoiced according to a study payment schedule. Tabs will appear across the top of the Milestones page indicating the subject/protocol calendar version and the latest budget version date in parentheses next to the version.
  - Invoiceable items are based on the milestones and pass thru procedures defined for a version of the calendar with which the visit was created.
- Enter the data from agreed negotiated budget between both UCLA and funding agency & enter total costs inclusive of overhead. This function is important for review so that invoice can be sent for patient visits.
- *Navigation: OnCore > Menu > Financials > Financials Console > Milestones tab*

Milestones

- *Navigation: OnCore > Menu > Financials > Financials Console > Milestones tab*
- Refer to the CTA to enter milestone information
  1. In the Financials Console, select the Milestones vertical tab
  2. Click Update
  3. A new window for Protocol Events/Visits will open
  4. Select only those visits that have amounts reflected on your budget. Do not enter amounts for items separate from schedule.
  5. Click Submit and then Close



Treatment Arm	Event/Visit	Total Negotiated Costs (Calculated)	Total Negotiated	Sponsor Amount
	Screening - S1/ Wk -6 week from BL (+/- 7 days) V1	2496.50	4461.00	4461.00
	Screening - S2/ Wk -3 week from BL (+/- 7 days) V2	2274.50	0.00	0.00
BLD BLD: Blinded	BL - BL V3	3374.50	0.00	0.00
BLD BLD: Blinded	Treatment - W4 V4	3085.50	0.00	0.00
BLD BLD: Blinded	Treatment - W8 V5	2636.50	0.00	0.00
BLD BLD: Blinded	Treatment - W12 V6	3545.50	0.00	0.00
BLD BLD: Blinded	Treatment - W16 V7	2636.50	0.00	0.00
BLD BLD: Blinded	Treatment - W20 V8	2636.50	0.00	0.00
BLD BLD: Blinded	Treatment - W24 V9	3937.50	0.00	0.00
BLD BLD: Blinded	Treatment - W36 V10	2636.50	0.00	0.00
BLD BLD: Blinded	Treatment - W48 V11	3589.50	0.00	0.00
BLD BLD: Blinded	Treatment - W52 V12	844.00	0.00	0.00
BLD BLD: Blinded	Treatment - W60 V13	2636.50	0.00	0.00
BLD BLD: Blinded	Treatment - W72 V14	3400.50	0.00	0.00
BLD BLD: Blinded	Treatment - W84 V15	2636.50	0.00	0.00
BLD BLD: Blinded	Treatment - W96 V16	2729.50	0.00	0.00
BLD BLD: Blinded	Safety FU V17	0.00	0.00	0.00
	Early withdrawal - Early with-drawal	3152.50	0.00	0.00

TIP – Open Final Budget to reference during reviewing/entering of Milestones

OnCore – Study Team Signoff

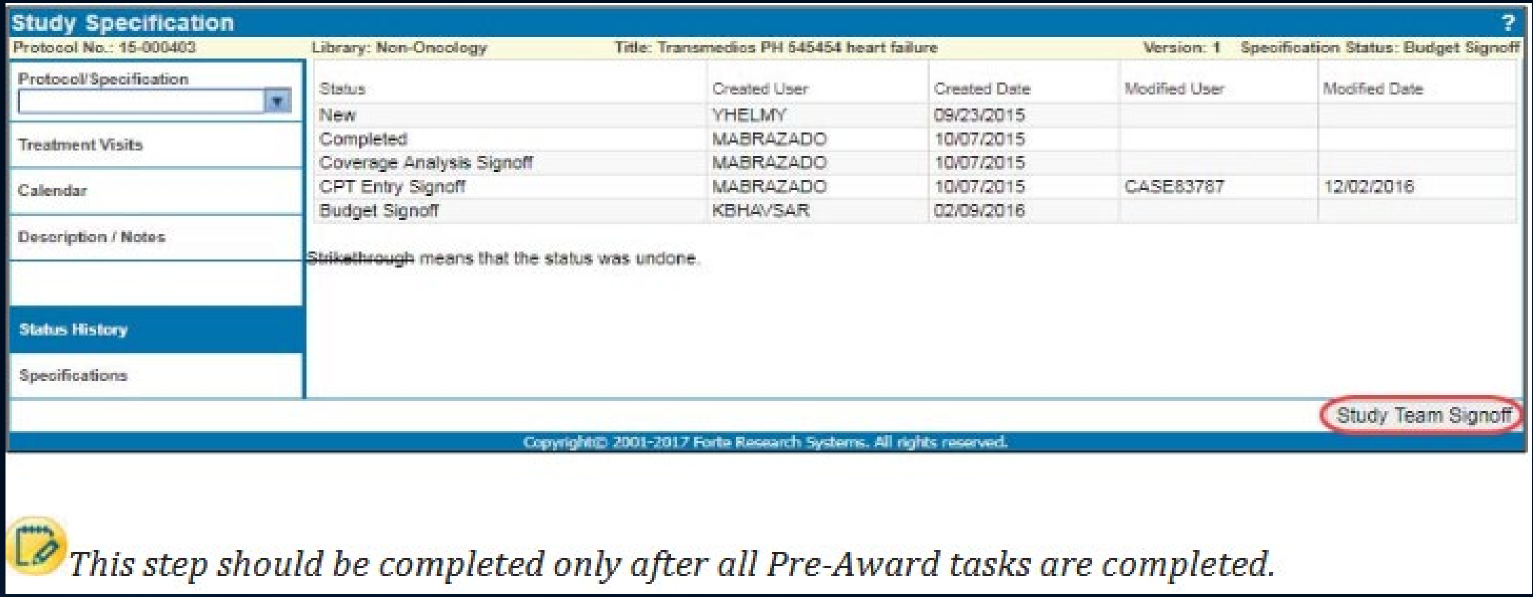
PRE-AWARD

Study Team Signoff

- After the Research Administrator has verified the Principal Sponsor, configure Invoicing Parameters and billable Milestones, they are to complete a final signoff of the Budget. This will allow the Centralized Teams to move the process forward.

- TIP - Good to send Research Quality a follow-up email to let the team know that sign off has been completed.

- *Navigation:*
  OnCore > Menu
  > eCRFs/Calendars
  > Specifications
  > Status History tab
  > Study Team Signoff



OnCore – FAU Entry

POST-AWARD

To assure appropriate billing –FAU Entry

- Once an email notification from Office of Research Data Management /ORA is received by RA with assigned FAU, this should trigger the RA to enter FAU into OnCore.

- Research Administrator and/or Regulatory Coordinators must enter the FAU in OnCore prior to opening the study for accrual. This is one of the *mandatory* tasks that are required in the study activation process, and is required to ensure a research guarantor is applied to the research encounter in CareConnect when a research visit occurs.
  - Tip: *Note*: Only one FAU is allowed in the Internal Account No. field. Any changes made to the FAU will send a notifications to the CareConnect, CRIS or CSI team, and any applicable ancillary departments to route charges to the correct guarantor and ensure proper billing occurs.

- *Navigation: OnCore > Menu > Protocols > PC Console > Management tab*

FAU Entry

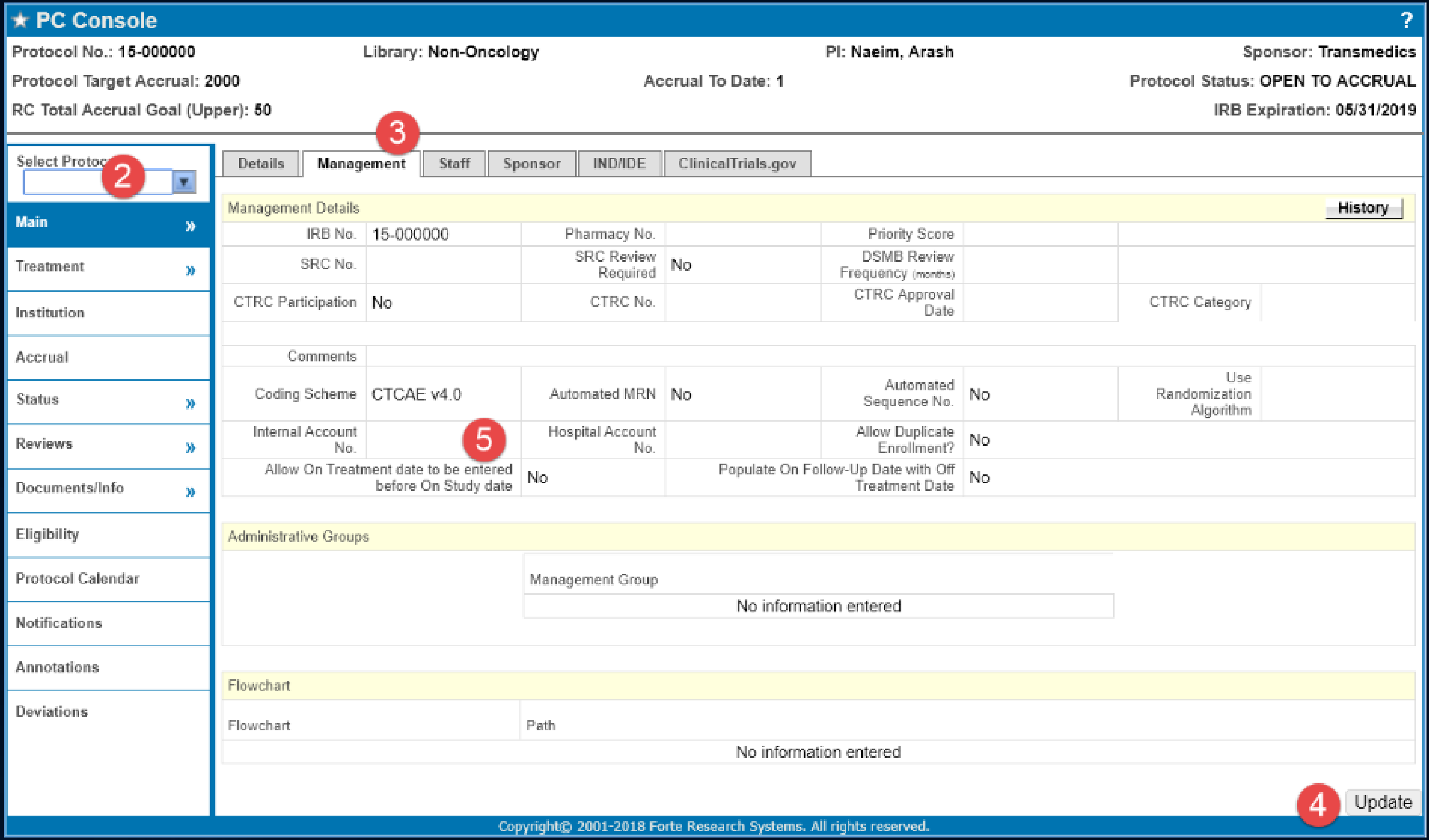
1. *Navigation: OnCore > Menu > Protocols > PC Console*

2. Select Protocol by entering IRB#

3. Select horizontal Management tab

4. Click Update

5. Enter the FAU number into the Internal Account No. field



OnCore – Subject Data

POST-AWARD

OnCore - Subject Data in CRA Console

After contract execution and study team has open study to accrual in OnCore, Research Administrator Managers can review study activity.

- Research Administrators (RA) have access to View Subject Data in CRA and Subject Console for studies that they are listed as protocol staff
- For this to work, check with your study team to ensure subject visit data has been updated in OnCore and is also updated regularly.
  - Study teams should be providing regular updates to subject visit data to avoid delays on invoicing and projected receivables to PI's CT accounts.
- Note: RAs are not responsible for subject management but subject data and visit reports are needed for financial management (i.e. update Calc sheets and invoicing)
- *Navigation: OnCore > Menu > Subjects > CRA Console or Subject Console*

View Subject Data in CRA and Subject Console

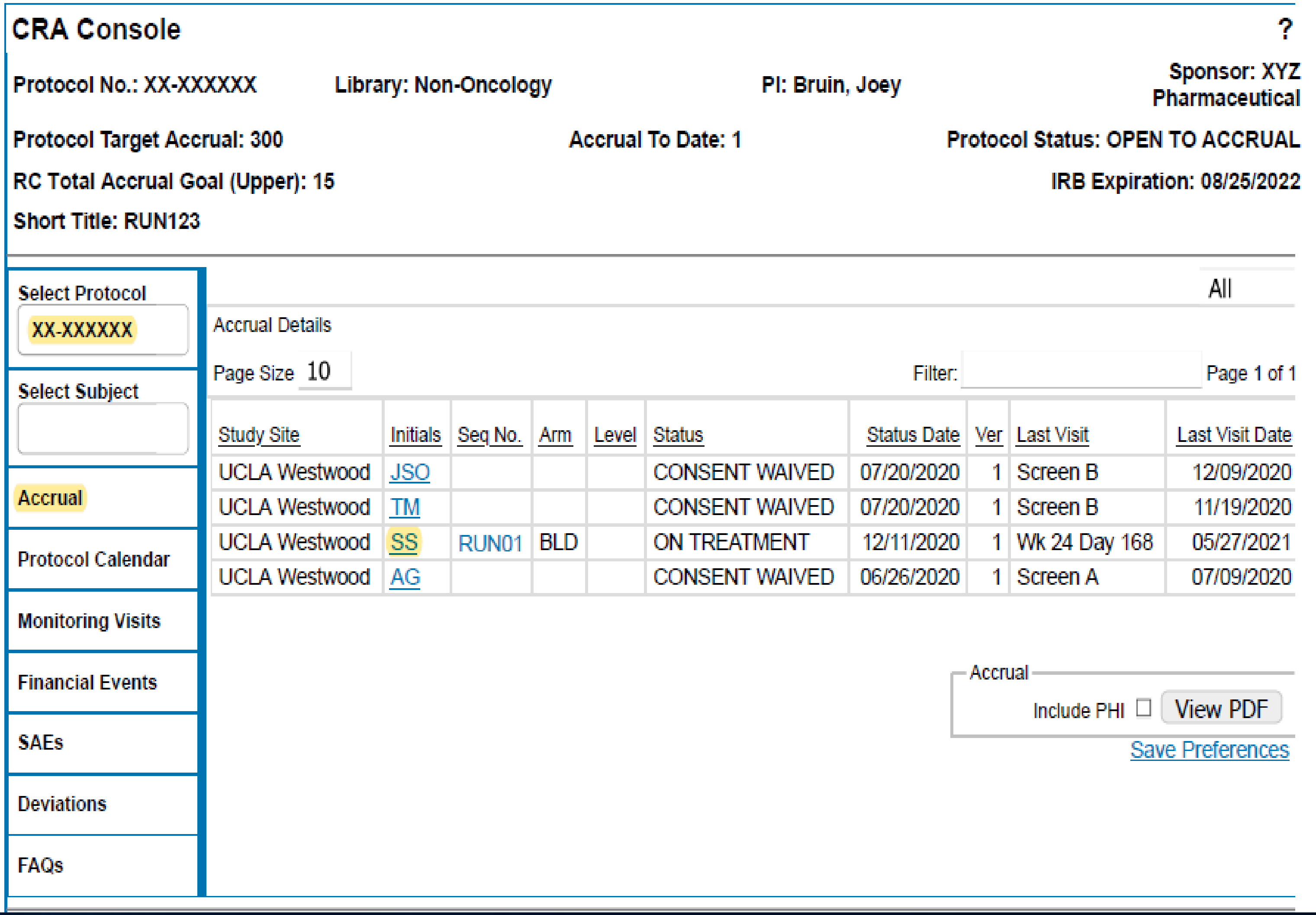
1. *Navigation: OnCore > Menu > Subjects > CRA Console*

2. Enter/Select Protocol

3. Select vertical tab Accrual

4. Click on Subject Initials

Note: Research Administrator (RA) access does not permit RAs to view MRNs or Subject Names. Please refer to the Patient Initials or Seq. No, which is used for the subject ID to identify a patient on a study

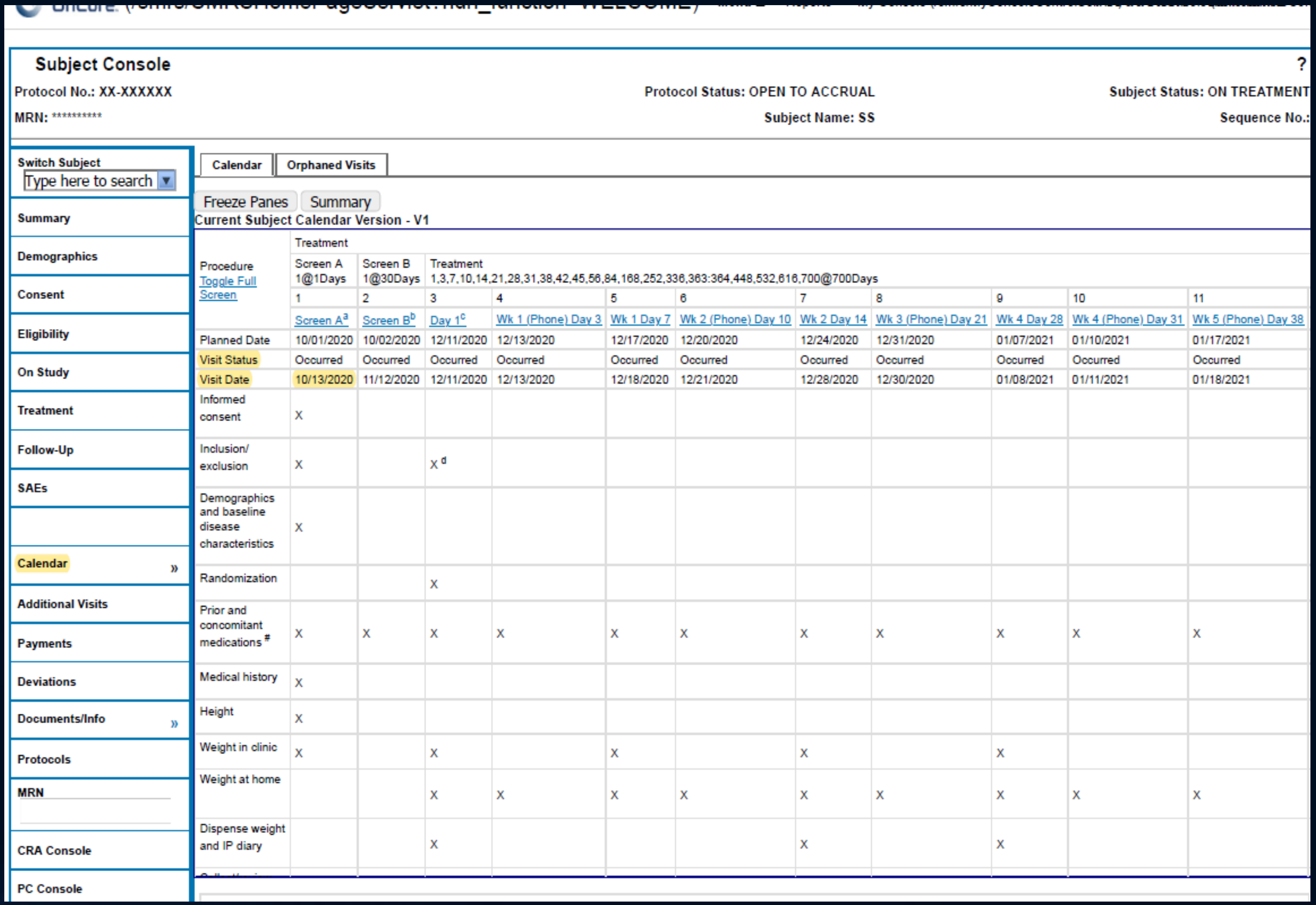


View Subject Data in CRA and Subject Console

5. After clicking subject initials, you will be redirected to Subject Console

6. Click on horizontal tab Calendar to view subject data

Note: Completed visits will be indicated by Visit Status: Occurred & completed procedures will be marked with an 'X'



Procedure	Treatment: Screen A 1@1Days	Screen B 1@30Days	Treatment 1,3,7,10,14,21,28,31,38,42,45,56,84,168,252,336,363:364,448,532,616,700@700Days								
Toggle Full Screen	1	2	3	4	5	6	7	8	9	10	11
	Screen A[a]	Screen B[b]	Day 1[c]	Wk 1 (Phone) Day 3	Wk 1 Day 7	Wk 2 (Phone) Day 10	Wk 2 Day 14	Wk 3 (Phone) Day 21	Wk 4 Day 28	Wk 4 (Phone) Day 31	Wk 5 (Phone) Day 38
Planned Date	10/01/2020	10/02/2020	12/11/2020	12/13/2020	12/17/2020	12/20/2020	12/24/2020	12/31/2020	01/07/2021	01/10/2021	01/17/2021
Visit Status	Occurred	Occurred	Occurred	Occurred	Occurred	Occurred	Occurred	Occurred	Occurred	Occurred	Occurred
Visit Date	10/13/2020	11/12/2020	12/11/2020	12/13/2020	12/18/2020	12/21/2020	12/28/2020	12/30/2020	01/08/2021	01/11/2021	01/18/2021
Informed consent	X										
Inclusion/ exclusion	X		X[d]								
Demographics and baseline disease characteristics	X										
Randomization			X								
Prior and concomitant medications[#]	X	X	X	X	X	X	X	X	X	X	X
Medical history	X										
Height	X										
Weight in clinic	X		X		X		X		X		
Weight at home			X	X	X	X	X	X	X	X	X
Dispense weight and IP diary			X				X		X		

Who do I Contact if I have a CT OnCore Inquiry?

- DOM Clinical Trial Program (DOMCTP@mednet.ucla.edu)
  - Add/assign OnCore staff user to protocol
  - Research Administrator training support including OnCore navigation
  - Assistance with Study Team/Research Administrator Task List and invoice management
  - Other general inquiries
- CRIS Admin (CrisAdmin@mednet.ucla.edu; 310-267-2273)
  - Technical support for OnCore access & training

Links from Today's Class

- OnCore
  - Training Request Courses
  - Tipsheet: OnCore Notifications
  - Tipsheet: Personalize Your OnCore Favorites Bar
    - TIP: Recommended Favorites for Research Administrators
      - Reports
      - My Console
      - Protocols > PC Console
      - Subjects > CRA Console
      - Financials > Financials Console
      - Financials > Coverage Analysis Console
      - eCRFs/Calendars > Specifications
  - OnCore Knowledge Base

Survey Link
https://forms.gle/QaMyquTmKtNDEj1k8

We appreciate if you would take a few moments to complete a short 7 question anonymous survey to help us improve your training experience. Thank you!