Clinical Trials
Pre-Award: OnCore

UCLA DEPARTMENT OF MEDICINE
OFFICE OF RESEARCH ADMINISTRATION
ZOOM TRAINING

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Enter your Participant ID followed by #.

This session will not be recorded, but this PowerPoint can be found https://medschool.ucla.edu/ora/fund-management-training
Summary

• OnCore - Overview
  • Clinical Trial workflow
  • Notifications for Study Team & Fund Managers

• OnCore – Fund Manager 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 WebIRB, PATS and CareConnect.
- Fund Managers 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 WebIRB, PATS and CareConnect.
Pre Award Start-Up

New Study Activation Workflow

- **Minimum Documents Submission to Contracting**
- **Contract Negotiation**
- **Study Team Tasks**
- **Centralized Service**

Legend:
- **FOA**: Financial Coverage & Activation Team
- **CRBF**: Centralized Research Business Partners
- **CRIS**: Clinical Research Information Systems
- **QA**: Quality Assurance
- **RD**/BR**: OnCore Interface (RD/BR CaresConnect)**
OnCore - Roles & Training

• For system security and compliance, training is **required** for access to **OnCore**.
• Tipsheet: **OnCore roles/job titles, functions & course registration**

**Training Grid for Fund Manager (DOM Non-Hem/Onc) (pg. 9)**

<table>
<thead>
<tr>
<th>OnCore Role</th>
<th>RSCH100 Fundamentals</th>
<th>RSCH160 Financials Management</th>
<th>RSCH210 Study Management</th>
<th>RSCH215 Subject/Patient Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fund Manager (FM)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>Optional</td>
<td>Optional</td>
</tr>
</tbody>
</table>

**Training Grid for Fund Manager (DOM Hem/Onc) (pg. 10)**

<table>
<thead>
<tr>
<th>OnCore Role</th>
<th>RSCH100 Fundamentals</th>
<th>RSCH165 Financials Management</th>
<th>RSCH210 Study Management</th>
<th>RSCH216 Subject/Patient Management</th>
<th>RSCH170 Research Billing – Charge Reviewer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fund Manager (FM)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
</tbody>
</table>
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 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 (OCRCordinator@mednet.ucla.edu) and CC: Sarahmay Sanchez (SOSanchez@mednet.ucla.edu), Director of CSE, CTSI - Office of Clinical Research

Note: Relationship building is key! Fund Managers 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*
  ![OnCore PC Console](image.png)
  • Tip: If you are unable to view a Protocol, it most likely means you are not added/assigned to the protocol. Request to be added to Protocol Staff by emailing [DOMCTP@mednet.ucla.edu](mailto:DOMCTP@mednet.ucla.edu).
  • Study Team (includes Fund Managers) will receive OnCore email notifications based on assigned role
  • **OnCore notifications** include protocol progress updates and reminders to complete tasks within OnCore
<table>
<thead>
<tr>
<th>SENDER / CONTACT(S)</th>
<th>RECIPIENT(S)</th>
<th>EMAIL SUBJECT</th>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRIS Admin</td>
<td>TO: Study Team</td>
<td>#131: Ancillary Approval or Waiver uploaded - IRB# / PI Name / Division / Sponsor / Protocol</td>
<td>Notification of Ancillary documents (servicing dept – approval/waiver) uploaded</td>
</tr>
<tr>
<td><a href="mailto:crisadmin@mednet.ucla.edu">crisadmin@mednet.ucla.edu</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>310-267-2273 (7-CARE)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRIS Admin</td>
<td>TO: Negotiator</td>
<td>#119: Review of Released Budget Document Uploaded - IRB# / PI Name / Division / Sponsor / Protocol</td>
<td>Negotiator to initiate “Budget Out” calendar negotiations with funding agency  [Fund Managers: Budget Out Checklist]  [Financial Management (Non-HemOnc Studies)]  [Financial Management (HemOnc Studies)]</td>
</tr>
<tr>
<td><a href="mailto:crisadmin@mednet.ucla.edu">crisadmin@mednet.ucla.edu</a></td>
<td>CC: Study Team / Fund Manager</td>
<td></td>
<td></td>
</tr>
<tr>
<td>310-267-2273 (7-CARE)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRIS Admin</td>
<td>TO: Negotiator</td>
<td>#133: Financials Budget In Response Uploaded - IRB#</td>
<td>Research Quality reviews and uploads “Budget In” for certification after negotiator uploads &amp; finalizes negotiated budget</td>
</tr>
<tr>
<td><a href="mailto:crisadmin@mednet.ucla.edu">crisadmin@mednet.ucla.edu</a></td>
<td>CC: Study Team, Research Quality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>310-267-2273 (7-CARE)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRIS Admin</td>
<td>To: Negotiator / Fund Manager</td>
<td>Protocol No.: IRB # - Budget Signoff Notification</td>
<td>Review of “Budget In” entered by FCA, enter/verify Parameters and Milestones to complete “Study Team Signoff” confirmed by Study Team / Fund Manager or DOM CTP.</td>
</tr>
<tr>
<td><a href="mailto:crisadmin@mednet.ucla.edu">crisadmin@mednet.ucla.edu</a></td>
<td>CC: Research Quality, Study Team</td>
<td></td>
<td></td>
</tr>
<tr>
<td>310-267-2273 (7-CARE)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research Quality</td>
<td>TO: PI</td>
<td>Final Budget Signoff - IRB# / PI Name / Division / Sponsor / Protocol</td>
<td>Study received Final Budget Signoff (Coverage Analysis releases budget)</td>
</tr>
<tr>
<td><a href="mailto:ResearchQuality@mednet.ucla.edu">ResearchQuality@mednet.ucla.edu</a></td>
<td>CC: Contract Officer, Fund Manager, Study Team</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Add’tl Support:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• OnCore calendar/budget</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><a href="mailto:CoverageAnalysis@mednet.ucla.edu">CoverageAnalysis@mednet.ucla.edu</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRIS Admin</td>
<td>TO: PI</td>
<td>Protocol No.: IRB # - Protocol Status [OPEN TO ACCRUAL] Notice - Status Date</td>
<td>Study is open for accrual and study team can begin to register subjects  [Fund Managers: Enter FAT]  [Access &amp; Attach Ancillary Documents]  [Study Team: Manage Subjects]</td>
</tr>
<tr>
<td><a href="mailto:crisadmin@mednet.ucla.edu">crisadmin@mednet.ucla.edu</a></td>
<td>CC: Study Team</td>
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<td></td>
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OnCore – Budget in / Study Team sign off Notification

• There are 3 steps when receiving this email notification that Fund Manager must complete for OnCore to trigger the next action item.
  • Parameters
  • Milestones
  • Specifications - Study Team Sign-Off

• After a budget has been negotiated or finalized, you can define the Parameters and Milestones for which the sponsor has agreed to pay.
  • 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.
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

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](image)

UCLA Department of Medicine - Office of Research Administration
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

- If you wish to modify who this notification goes to and what it says, check the Adding Notifications tip sheet
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
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

**TIP** – Open Final Budget to reference during reviewing/entering of Milestones
OnCore – Study Team Signoff

PRE-AWARD
Study Team Signoff

• After the Fund Manager 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

 This step should be completed only after all Pre-Award tasks are completed.
OnCore – FAU Entry

POST-AWARD
**FAU Entry**

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

- Fund Managers 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

• This is a “New Access”

• Fund managers (FM) 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: FMs 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: Fund Manager (FM) access does not permit FMs 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’
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
  - Fund Manager training support including OnCore navigation
  - Assistance with Study Team/Fund Manager 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 Courses & Registration: [Cornerstone Learning Management System](#)
  - Tipsheet: [OnCore Notifications](#)
  - Tipsheet: [Personalize Your OnCore Favorites Bar](#)
  - TIP: [Recommended Favorites](#) for Fund Managers
    - Reports
    - My Console
    - Protocols > PC Console
    - Subjects > CRA Console
    - Financials > Financials Console
    - Financials > Coverage Analysis Console
    - eCRFs/Calendars > Specifications

- **DOM Clinical Trials Fund Manager Manual Chapters**
  - [CT Acronyms & Key Terminology](#)
  - OnCore
    - [Roles & Job Duties](#)
    - Tip Sheets:
      - Parameters
      - Milestones
      - Study Team Signoff
      - FAU Entry
      - CRA and Subject Console
Survey Link
https://forms.gle/QaMyquTmKtNDEj1k8

We appreciate if you would take a few moments to complete a short 5 question anonymous survey to help us improve your training experience. Thank you!