OnCore Department Advisory Meeting

February 14, 2023

Structure

- Definitions
- Review of previous items
- Review of new items
- Questions
- Reminder! Submit agenda items

Definitions – Changes vs. Proposals

Change

- Study team approval not required

- Will be implemented immediately

- Affected parties are notified prior to and after implementation
  - Newsletter
  - Department advisory meeting

Proposal

- Planned change

- Requires review and approval from one or a combination of:
  - Study teams
  - Research administration staff
  - Change control board

Change: Compliance Signoff Removed

- **CHANGE**
  - Compliance Sign off removed before upgrade as upgrade has taken longer than initially expected. It is not needed since we added Quality Assurance Sign Off.

- **IMPACT**
  - Compliance Sign off will no longer be needed during Initial Calendar/Specifications signoffs. The signoff order will now be:
    - Quality Assurance > Pre Award > CRM Calendar > PI

- **FUTURE CONSIDERATIONS**
  - Updates might be needed to guidance documents

Change: Updated Task List Viewing Permissions

- **CHANGE**
  - FC-PRE, FC-POST, FinMan, CRA, PI, Manager, and REG roles all updated to have appropriate viewability of task lists
  - Updated as of 1/12/2023

- **IMPACT**
  - Staff with those roles that are listed in the staff tab of a protocol will be able to **view** all task lists pertaining to the study (examples: Initial Calendar Build, Amendment Calendar Build, UCHealth Approval/Activation Review, HSR Portal, OnCore Access and Training).
  - This way they can also see detailed current status and next steps for study.

Task List

Name	Status	Previous Task	Completed Date	Current Task	Target Date
HSR Portal_V17 -	Complete	HP170: HSR Portal Process Complete	03/04/2022		
Budget Task List V3 -	New			B20: Draft Budget approved by PI/Study Team and sent to Sponsor	03/21/2022
CHCO Contracts_V1 -	Complete	C120: Contract terms finalized	06/15/2022	C122: Executable contract received from sponsor	04/03/2022
CHCO Contracts V3 -	Complete	C190: Request complete/fully executed	10/24/2022		
Regulatory Task List -	In Progress	R70: Regulatory Documents (FDF, 1572, etc) sent to Sponsor	12/21/2022		
CHCO Study Activation V2 -	In Progress	SC14: Study Team Action: Epic Use Plan PI Signoff	04/27/2022		
Initial Calendar Build V2.6 -	In Progress	S020: Project Analyst Action: Started working on build	06/16/2022	S100: Study Team Action: Sent finalized financial documents (or confirmed no budget applicable) to OnCoreSupport@ucdenver.edu	09/25/2022
Initial Calendar Build V2.4 -	Complete	amendment submitted	06/15/2022		

- Current task lists will either be **New** (meaning none of the tasks on that list have been started yet) or **In Progress** (meaning at least one task has been completed on that task list)

- **Previous Task** & **Completed Date** indicates the last task that was taken care of and when it was done

- **Current Task** is the next task that needs to be performed. The **Target Date** is calculated based on time allotted to perform each task and does not update after the task list is started. This means the date could be far in the future (if previous tasks were completed expediently/ahead of schedule) or in the past (if previous tasks were completed late).

Task List

- Some Task Lists are for study teams (Budget Task List & Regulatory Task List) to fill out if useful. Most are updated by research administration personnel.

- If the "Current Task" says "Study Team Action" that means that we are waiting on the Study Team to perform that action. OnCore Support will update the task list when that action has been performed.

- You can click on the blue hyperlink of the task list to see current progress of all tasks on that list

Change: E-Consent Document Type Added

- **CHANGE**
  - Under types of consent forms in the IRB Review tab, a new document type "Electronic Consent (E-Consent)" is available as of 1/25/2023

- **IMPACT**
  - Study teams can now choose this document type for e-consents.
  - This will permit tracking of studies approved to use e-consent platforms

Change: New Sites

- **CHANGE**
  - 1/11/23 Added two new sites as options in OnCore (visible in Institution tab under PC Console):
  - "Department Specific Study Site - North" added under UCHealth – North institution
  - "Department Specific Study Site - South" added under UCHealth – South institution

- **IMPACT**
  - This will allow Northern and Southern Colorado to register participants that are not patients (e.g. caregiver studies).
    - **Caregivers should not be in Epic**: Studies that are enrolling caregivers or health care providers in research studies where they are not seen clinically for their own personal UCHealth encounter should not submit research informed consents into UCHealth's EHR. These classes of participants are not UCHealth patients and their consents should be retained by the study team.

Change: Cost Center Added

- **CHANGE**
  - UCH-ASC cost center added

- **IMPACT**
  - UCHealth has multiple ASC locations. The cost center has been added to accurately capture research pricing structure at ASCs.

- **FUTURE CONSIDERATIONS**
  - Based on requested surgical event and location, UCHealth CRCAs will add the UCH-ASC cost center when applicable.

Proposal: Deviation Notifications

- **PROPOSAL**
  - Update "Subject Deviation Notice" default notification to include Regulatory Coordinators.
  - Current Default:

Subject Deviation Notice				Defa
Reply To	OnCoreSupport2@ucdenver.edu; OnCoreSupport@ucdenver.edu			
To	OnCoreSupport2@ucdenver.edu			
Cc			CC Sending User?	N

Additional Recipients			
Role Scope	Staff Role		Recipient Type
Protocol	Clinical Research Coordinator		To
Protocol	Clinical Research Manager		To
Protocol	Study Monitor		To

Subject	Subject Deviation Notice		
Text	This is a Subject Deviation Notice		
Enabled?	Y	Include Participating Affiliates	Y

- **IMPACT**
  - Would not need to customize the notification to add this role for each individual study
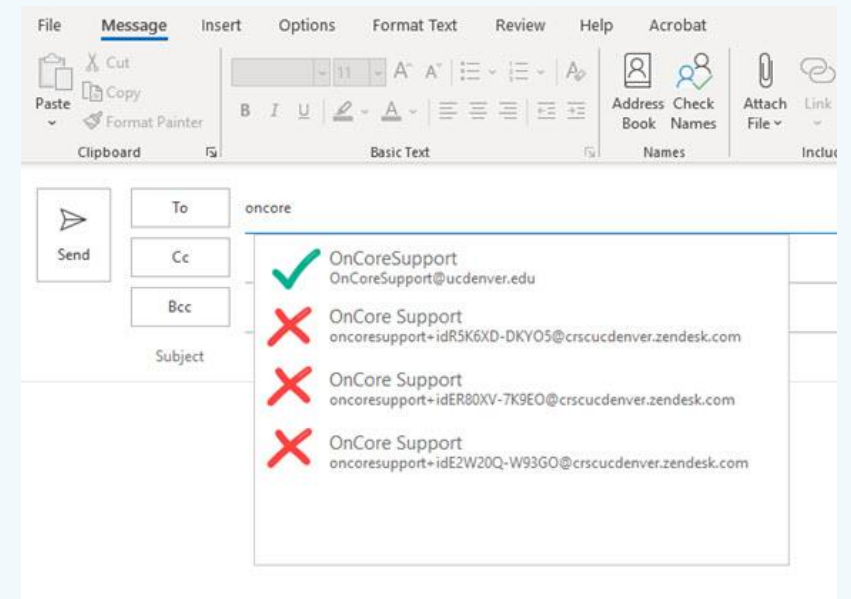
Reminders and FYIs – OnCore Upgrade

- **OnCore Upgrade Plans – Tentative**
  - Current OnCore version: 2020R3
  - Upgrade to: 2022R3
  - Timeline pushed out due to an Advarra identified bug. Patch was received by OIT on 01/19/23.
  - Non-production OnCore environments: RSS and DEV upgraded. DEV UAT testing began 01/30/23 and concluded 02/10/23. Currently awaiting additional security testing by OIT and will prepare to upgrade TEST shortly.
  - We plan to do yearly upgrades with the intention of going live with a new OnCore version every February.
  - Yearly upgrades will decrease the burden of testing and ensure new features are more readily available.

Reminders and FYIs – Emailing OnCore Support

- When sending a new email to OnCore Support, please ensure the correct email address is being utilized – OnCoreSupport@ucdenver.edu. If you send a new email to an address with the format oncoresupport+id123456@crscucdenver.zendesk.com, that will not create a new ticket, but will instead thread your email into an existing ticket. This can lead to confusion and delays in responses.

Reminders and FYIs – Financial Documents

- In order for the Project Analyst to begin financial entry, the study team needs to send the necessary financial documents to OnCoreSupport@ucdenver.edu. OnCore Support is not automatically notified if you upload the documents into OnCore (e.g. uploading the FE CTA under the Financials Console > Attachments). To ensure timely financial entry, email all needed documents to OnCoreSupport@ucdenver.edu. If you have an unfunded study with no financial documents (including no internal budget), OnCore needs to know that before proceeding forward.

- Industry or other: finalized budget and fully executed contract (FE CTA)

- Federally funded studies: grant or subaward notice including budget (and any additional financial documents that provide information)
  - CHCO studies: Work order

- Non-federal funded studies (IIT, grant, foundation, department): Any award notice and internal final budget
  - CHCO studies: Work order

- CTRC budget, if applicable

Questions?

Review of Previous Items

- **ITEM 1**
  - Details and updates
- **ITEM 2**
  - Details and updates
- **ITEM 3**
  - Details and updates

Change: Title of Change

- **CHANGE**
  - Details of change

- **IMPACT**
  - Impacted parties, downstream effects, etc.

- **FUTURE CONSIDERATIONS**
  - If applicable

Proposal: Title of Proposal

- **PROPOSAL**
  - Proposal details

- **IMPACT**
  - Impacted parties, downstream effects, etc.

- **FUTURE CONSIDERATIONS**
  - If applicable

Reminders and FYIs

- **REMINDER!**
  - List any reminders as applicable