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
Review of Previous Items

- **Compliance Sign off Removal**
  - 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.
  - 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 (PI for Initial Builds only)

- **Updated Task List Viewing Permissions**
  - FC-PRE, FC-POST, FinMan, CRA, PI, Manager, and REG roles all updated to have appropriate viewability of task lists.
  - 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) in order to keep up with current study status.
Task List

- 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).
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.
Review of Previous Items

- **E-Consent Document Type Added**
  - Under types of consent forms in the IRB Review tab, a new document type “Electronic Consent (E-Consent)” is available. This will permit tracking of studies approved to use e-consent platforms.

- **New Sites Added**
  - “Department Specific Study Site - North” added under UCHealth – North institution
  - “Department Specific Study Site - South” added under UCHealth – South institution
  - This will allow Northern and Southern Colorado to register participants that are not patients (e.g. caregiver studies). **Caregivers should not be in Epic. These classes of participants are not UCHealth patients and their consents should be retained by the study team.**
Review of Previous Items

- **UCH-ASC cost center added**
  - UCHealth has multiple ASC locations. The cost center has been added to accurately capture research pricing structure at ASCs. Based on requested surgical event and location, UCHealth CRCAs will add the UCH-ASC cost center when applicable.

- **Proposal: Deviation Notifications**
  - Update “Subject Deviation Notice” default notification to include Regulatory Coordinators.
  - We haven’t received many responses on the Form. Please vote [here](#).
Reminders and FYIs – Signoff Status

- Before OTA, two sets of OnCore Signoffs must be completed: PC Console & Specifications.
  - PC Console Signoffs:
    - Regulatory Admin >> Research Manager
    - Before Regulatory Admin can be completed, the IRB Initial Approval needs to be added under PC Console >> Reviews >> IRB
  - Specification Signoffs:
    - Quality Assurance >> Pre Award >> CRM Calendar >> PI

- You can find out which of these have been completed/what signoffs are needed next within OnCore.
For PC Console Signoffs status, go to Menu >> PC Console then select the tab on the left “Status” and its sub-tab “Status.” You will also see the current status in the top right under PC Console labeled “Protocol Status:”

For Specifications Signoffs status, we recommend you get to the Protocol in PC Console first before navigating to Specifications Console as it takes longer to load in the Specifications Console. Once there, go to Menu >> eCRFs/Calendars >> Specifications. Once in Specifications Console, click the “Status History” tab on the left. You will also see the current status in the top right under Specifications Console labeled “Specification Status:”

Highlighted in green are the Console Names & the tasks the study team is responsible for.
Reminders and FYIs – OnCore Upgrade

- **OnCore Upgrade Plans – Tentative**
  - On hold until internal discussions are held on 04/28.
Signoffs

• If status is in “New” that means no tasks have been completed yet.
• If Specification Status is “Completed” that means the signoffs have been initiated by the Project Analyst. If the calendar has not been reviewed by the study team and/or OnCore Support has not received financial documents and completed financial entry, the signoffs will not have been initiated.
• Please also review the Initial or Amendment Calendar Build Task List in the PC Console in order to see what action is needed from the study team if you do not know why signoffs have not been started in the Specifications Console.
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