

OnCore Department Advisory Meeting

September 12th, 2023

Structure



Review of previous items



Definitions



Review of new items



Reminders and FYIs



Questions



Reminder! [Submit agenda items](#)

Review of Previous Items

- **HRH - CU Medicine Clinic Added**

- HRH – CU Medicine will be visible in the PC Console’s Institutions tab if applicable for a study (it occurs at CU Medicine clinics at UHealth Highlands Ranch Hospital).

- **Proposal: Health Affairs OTA Notice – updated**

- Will review in proposal section; Finance Specialist & Affiliate Finance Specialist were added to OTA notice.

- **Proposal: Subject Deviation Notice – updated**

- Will review in proposal section; Regulatory Coordinators now included in default notice.

- **Proposal: Protocol Versioning in Footnote Process not updated**

- We did not receive many votes and the ones we did receive were split.

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

Proposal: Updated Health Affairs OTA Notice

- **Add Finance Specialist as an additional recipient to default Open to Accrual Notice**
 - This would only be for protocols in the Health Affairs library. These protocols utilize UCH or CU or BDC but are not required to be in the Oncology library (cancer studies).
 - The only library that does not have Finance Specialist listed for OTA is the CHCO library. If CHCO would like this updated, please [submit a change request form](#).
 - This change went into effect 8/23/2023 after receiving mostly positive study team votes.
- **IMPACT**
 - Anyone listed as a Finance Specialist or Affiliate Finance Specialist in the staff tab for the specific protocol will receive a notification when the Protocol Status is changed to Open to Accrual. Study teams would not need to customize the notification to add these personnel.
 - Receiving this notification would indicate to the Finance Specialist that they can invoice the startup/initial fees out of OnCore.
 - Any notifications that are already customized would not be affected by this update.

Proposal: Updated Subject Deviation Notice

- **Add Regulatory Coordinator to Default Subject Deviation Notice**

- This was updated in HA and Onc libraries only. CHCO was not part of discussion when this was originally discussed and voted on, so their default notification has not been affected. If CHCO would like this applied to their library as well, please submit to please [submit a change request form](#).
- This change went into effect 8/23/2023 after receiving mostly positive study team votes.

- **IMPACT**

- Now Regulatory Coordinators do not need to manually notified by their CRMs or coordinators when a subject deviation occurred in order to facilitate faster reporting.
- For HA library, those notified are: CRM, Affiliate CRM, Regulatory Coordinator
- For Onc library, those notified are: CRM, CRC, Study Monitor, Regulatory Coordinator

Changes: Update to CHCO Site

- **CHANGES**

- CHCO Research Non-Patient site added for CHCO
- This went into effect 8/3/23

- **IMPACT**

- This site was added for CHCO to use when patients are enrolled but there is no reason to create a patient record (such as parent surveys)

Change: Renamed Research Imaging Center site

- **CHANGES**

- CT-RIC renamed to CU-RIC for accuracy
- This went into effect 8/23/23

- **IMPACT**

- This site will be visible when indicated under CU Anschutz Free Standing Clinic

Changes: Added UCHealth Reference Lab

- **CHANGES**

- UCHealth Reference Lab added as an institution.
- This went into effect 8/14/23

- **IMPACT**

- UCHealth will manage addition of this site at the time of coverage analysis.
- This will assist with reporting for billing compliance and overall study management/activation at UCHealth.
- This institution will not have a study site.
- Subjects will not be registered to this institution.

Changes: SOM-Medicine Dept Removed

- **CHANGES**

- SOM-Medicine Department removed from options to select.
- This went into effect 8/15/23

- **IMPACT**

- This will facilitate more accurate reporting of the department conducting the research and should match the department in which the PI has a faculty appointment.

Changes: Update to Protocol Shell Notification

- **CHANGES**

- When a protocol shell is built in OnCore, those listed in the submitter and additional submitter fields will be notified.
- The notification will include instructions on how to update and maintain the staff tab in OnCore.

- **IMPACT**

- Once the shell is built, Regulatory coordinators and CRMs may
 - update the staff tab
 - enter the Initial IRB approval
 - begin PC Console required signoff actions

Reminders and FYIs – Oncore User Agreement

- Please read the [UCD APS 6001 - Providing and Using Information Technology policy document](#) and sign the updated OnCore User Agreement at [this link](#) as soon as possible.
- All active OnCore users must complete the OnCore Updated User Agreement by 9/26/2023.

Questions?