OnCore Support
DEPARTMENT ADVISORY MEETING

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CU Regulatory Compliance
OFFICE OF THE VICE CHANCELLOR FOR RESEARCH
UNIVERSITY OF COLORADO **DENVER | ANSCHUTZ MEDICAL CAMPUS**

STRUCTURE

Review of previous items

Definitions

Review of new items

Reminders and FYIs

Questions

Reminder! Submit agenda items

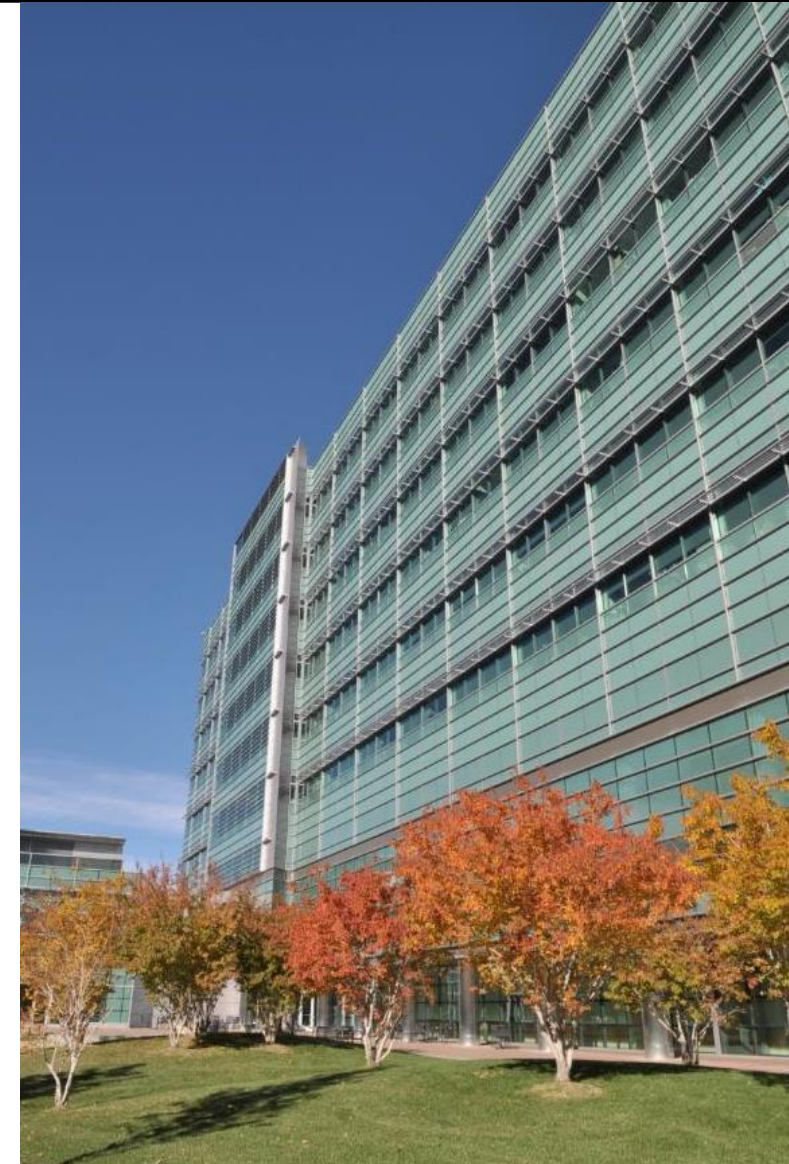## Updated Open to Accrual Notice

- Finance Specialist added as additional recipient to default Open to Accrual notification

- Update to Health Affairs library only

Updated Subject Deviation Notice

- Regulatory Coordinator added as additional recipient to default Subject Deviation notification

- Update to Health Affairs and Oncology libraries only

Added CHCO Research Non-Patient Site

- Site added for CHCO to use when patients are enrolled but there is no reason to create a patient record (such as parent surveys)
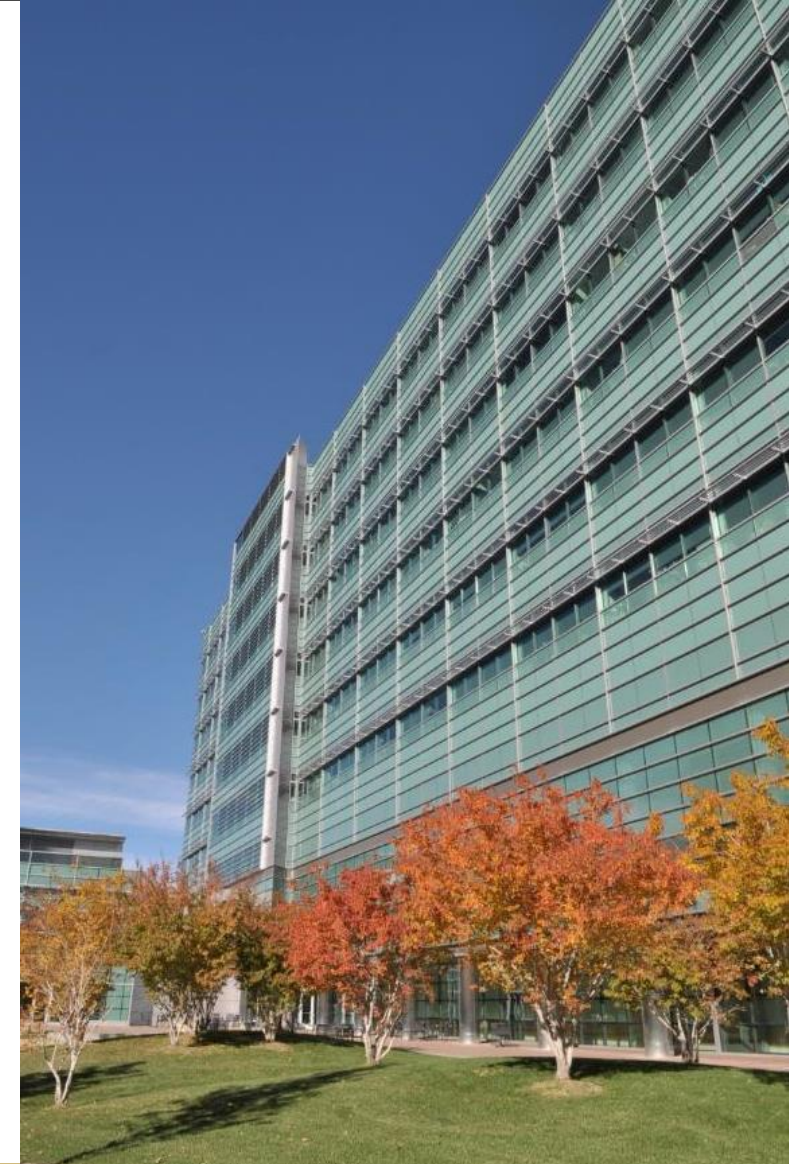
Added UCHealth Reference Lab

- Institution added to assist in billing compliance and overall study management/activation at UCHealth
- Institution will have no study site and subjects will not be registered to this institution
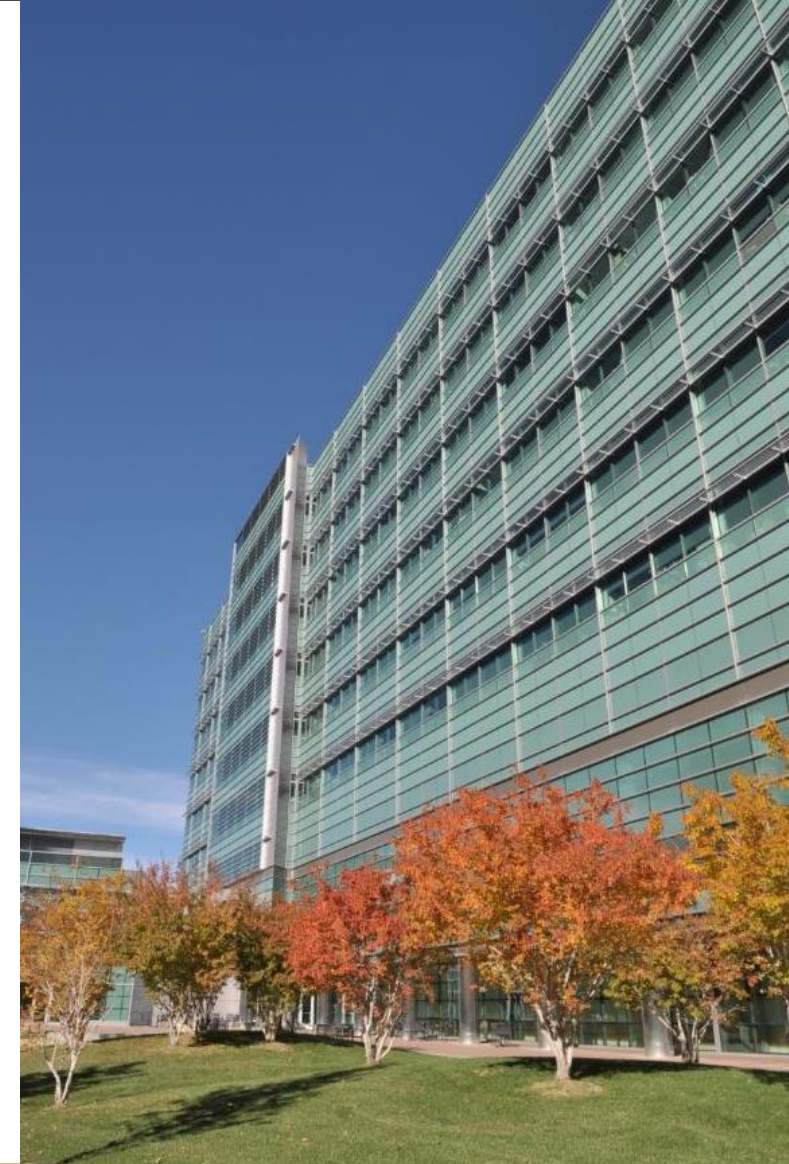
Removed SOM-Medicine Department

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

Updated Protocol Shell Notification

- When a protocol shell is built in OnCore, submitter and additional submitter fields from HSRP submission will be notified with instruction on how to update and maintain staff tab

- Once shell is built, Regulatory coordinators and CRMs may

  - update the staff tab

  - enter IRB approval

  - begin PC Console required signoff actions

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
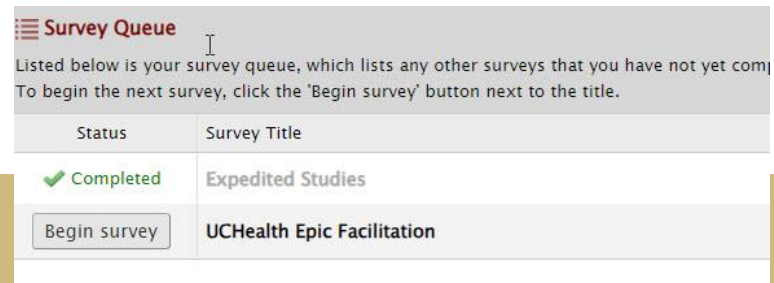 - Research Administration Staff
  - Change Control Board

UCHealth Questions Moved In HSR Portal

- UCHealth-specific questions related to management of the study in Epic and to Clinical Services and Ancillary Services have been moved to a different survey instrument.

Impact

- This will allow submitters to submit the HSR Portal form while still seeking answers for Epic-related and UCHealth-service related questions.

- Based on the study, submitters will still be prompted to answer these questions if required. If required to complete, these surveys need to be completed prior to UCHealth issuance of approval or Open to Accrual in OnCore.

- The survey(s) will show in the survey queue once the HSR Portal application is submitted. Provided is an example screenshot for UCHealth Epic Facilitation survey still outstanding:

Patient Interaction Questions Replaced in HSR Portal

- To streamline portal submissions a few questions regarding patient interaction have been updated. This will allow branching logic to function more efficiently.

Does this study require prospective....	Yes	No
Clinical interactions such as blood draws, exams, administration of any drug, device, or biologic	○	○
Focus groups, surveys, or questionnaires	○	○
Collection of discarded samples	○	○

Impact

- Prior submissions do not need to be updated. These questions will assist in determining if the study needs to be in OnCore and if it needs a calendar.

Future Considerations

- Please send any questions regarding HSR portal questions and branching to clinicalresearchsupportcenter@ucdenver.edu

UCHealth – Parkview Medical Center added

- This is available as an institution & its own site in the Institutions Tab in the PC Console

Impact

- Future and current studies that occur at Parkview Medical center will have this institution & site listed in the PC Console

Information Sheet/Postcard Consent added as a Consent Tpe

- Information Sheet/Postcard Consent added as a consent document type that can be uploaded to IRB Reviews.

Impact

- When updating for IRB reviews, study staff can now add the specific document type "Information Sheet/Postcard Consent" and this will also be able to be associated as a signed consent for a patient in the Subject Console.

Cancer Center – Other Department Currently Being Removed from OnCore

- This has already been removed from the HSR Portal. It has not yet been deleted entirely from OnCore as still working through protocols that have it associated.

Impact

- This is being removed to facilitate more accurate reporting of department conducting the research and should now match the department in which the PI has a faculty appointment.

Amendment Budget Task List

- Similar to the Budget Task List in PC Console that is available at study start up, study teams have requested an amendment budget task list for amendments in order to pull metrics and track that process.

Impact

- Current plan would be for study teams to ask for this to be added to a protocol as needed and not be added by default each time there is an amendment. This is because not all amendments have budget updates and sometimes multiple amendments are processed together over time before final changes are released.

- Request by study team could be performed after they are notified of amendment MCA/calender update review.

- This would be a task list available for study teams to update and would not be actively managed by OnCore administrative staff.

Current Tasks Requested for Amendment Budget Task List:

- Date amend received
- Date draft budget received
- HSR portal submission
- MCA/billing grid review e-mail received
- Date Budget Specialist sent budget to CRO/sponsor
- Final budget submitted to Oncore for financial attachment
- CRM signoff
- Calendar release

Future Considerations
- Please email OnCoreSupport@ucdenver.edu if you have any further ideas or comments on this task list and its process.

QUESTIONS?

THANK YOU

OnCore Support