



# TRENDING IN TRIALS

Essential Information for Principle Investigators

March 2020

## Updates & More to Improve Your Research

### Return to Research Updates:

- Reentry Guidelines during COVID are [HERE](#).
- [FAQs](#) from Coffee --Kent Keyser list.
- Join Thursday's [CCTS Forum Zoom call](#): *Conducting Clinical and Translational Research in the Time of COVID: Local and National Perspectives with Panel Discussion*.

### CCTS Enterprise Protocol Initiative

Through the joint efforts of the CCTS, Department of Pathol

For questions, please contact:

- **Tissues:** Arianne Jones, Tissue Procurement Coordinator - (205) 934-6071
- **Fluid/other specimens:** Jeffrey Edberg, Director, CCTS SPAN - (205) 934-0894

**COVID-19 Specimen Update:** Dr. Paul Goepfert in the Division of Infectious Diseases is spearheading the UAB effort for biospecimen collection from persons with COVID 19. Procedures for collection and proper handling of specimens are currently being finalized.

## Updates from the UAB Office of Institutional Review Board

The Office of Human Research Protections, a division within the U.S. Department of Health and Human Services, revised the Common Rule in 2018 and instituted a Single IRB policy effective January 20, 2020. All new cooperative multi-site research projects governed by the revised Common Rule, approved on or after the effective date, will be required to be reviewed by a single IRB of record. The UAB Office of the Institutional Review Board (IRB) has developed guidance on the UAB single IRB review process and how it may affect your study. Please visit the UAB Single IRB webpage (<https://go.uab.edu/sIRB>) for more information. If you have additional questions, please contact the UAB Office of the IRB at [irb@uab.edu](mailto:irb@uab.edu).

### Streamlining OIRB and CIRB Submissions

Beginning March 1, 2020, The Office of the Institutional Review Board (OIRB) and the

Office of the Conflict of Interest Review Board (OCIRB) will begin coordinating efforts regarding training and disclosures of financial interests. These changes will reduce administrative burden and improve turnaround times, while also ensuring a robust review process and compliance with federal requirements.

Protocols will be reviewed to verify current Financial Conflict of Interest training for any responsible personnel listed on the IRB protocol in IRAP and to ensure that all responsible personnel have a current disclosure of financial interests on file. Protocols not meeting one or both of these requirements will be returned to the investigator and may be resubmitted once training and disclosures have been completed.

Detailed instructions for checking conflict of interest training and disclosure status in IRAP may be found here or under the “IRB/Human Subjects” training tab on the IRAP Training webpage. If you have any questions, please contact the OCIRB at [cirb@uab.edu](mailto:cirb@uab.edu).

## OnCore: Helpful Tips for Managing Your Trial Data

*In the OnCore section of Trending in Trials, we share useful knowledge for getting the most out of OnCore, and showcase achievements of study teams and OnCore users. **Note about the current limited business model:** OnCore support is still being provided through the normal channels, (205) 934-8888 and by email: [oncore@uabmc.edu](mailto:oncore@uabmc.edu).*

### Reminder: Keep Study Details Current

**What should be updated?** A best practice is to identify a staff member who is responsible for updating study-related information by keeping the following areas updated in a timely manner, you maintain an accurate record of your team’s study activity and you avoid increasing the workload of other areas that rely on this information downstream.

1. **IRB Reviews** - Initial approvals, Annual reviews, Amendments
2. **Study Staff** - Coordinating staff often changes. Update study staff by adding a Stop Date on the Staff tab for the former staff member. Do NOT delete former staff. Add the new staff member and enter the Start Date.
3. **Protocol Status** - Protocols have various stages of life in OnCore: OPEN to Accrual, CLOSED to Accrual, IRB Study Closure. Or was your protocol Terminated? Abandoned? Each status tells a specific story about the protocol, which is important for reporting.
4. **Study Closure** - When your study has completed its activity, don’t forget to tell OnCore – update the protocol status to Close to Accrual when you are no longer enrolling subjects. Click IRB Study Closure when the IRB has closed it out. Confirm all subject statuses have been entered correctly, all subject visits have been managed appropriately (Occurred, Missed, or N/A), and all subjects are in the Off Study Status.

### Clearing Up a Misunderstanding: OnCore Billing

Occurring each visit in OnCore within 24-48 hours of the actual visit is essential for appropriate billing of both the research study and third party insurers. This is how we get paid and support our salaries!

Here’s what happens when you “occur” in OnCore a visit which has taken place:

- A visit with a clinical billable item creates a document called a Clinical Trial Billing Notice (CTBN).
- The CTBN provides the information to the billing office on how to direct the study charges (either to the patient’s insurance or to the research study account).

If the visit happens but is not “occurred” in OnCore,

- The UAB Health System (via IDX or HealthQuest) doesn't know that research is involved.
- It generates an insurance bill as if all activities are standard of care.
- In some cases, the patient may get a bill for services not covered by their insurance.

Without an occurred visit the research study sponsor can't be charged and salary expenses can't be covered. Even more importantly, charging research expenses to third party insurance is not just inappropriate, it's illegal. And reversing these charges adds more work for the study team, the OnCore team and the billing offices.

**Please occur each visit in OnCore as it happens!**

### Upcoming Events:

### On The Up & Up:

- **CCTS Research Seminar Series (Online): Building Better Budgets: Tips for Best Practices and the Art of Negotiating** - Thursday, March 26th, 12-1pm [Learn more.](#)
- **CCTS Forum (Online): Conducting Clinical and Translational Research in the Time of COVID: Local and National Perspectives with Panel Discussion** - Thursday, March 26th, 3 - 4:30pm [Learn more.](#)
- Clinical Research Career Ladder project is concluding: [Learn more.](#)
- **Keep it up!** There are 569 active protocols in OnCore, 419 active OnCore users, and an average of 222 unique users log in to OnCore each week!

**(205) 934-7442**

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