
Office of Clinical Research

January 2023

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CLINICAL RESEARCH EDUCATIONAL SERIES (CRES)

Clinical Research Billing Compliance: The Rules & Regulations

Monday, January, 23 from 2:00 - 3:00 pm

Speaker: *Kelly Denney CCRP, Senior Coverage Analyst, Office of Clinical Research*

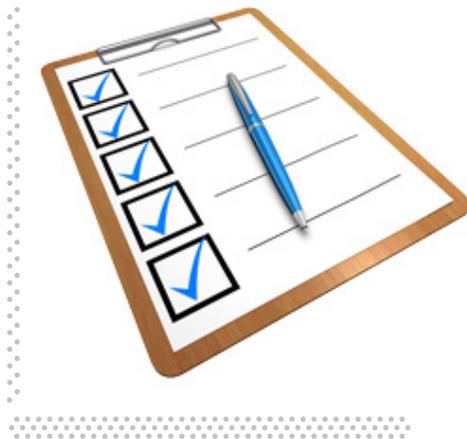
CME: 1.0

Meeting ID: 850 4262 6645

Password: 727942

In this presentation, we'll define key research billing compliance terms and review the regulations that help us determine when billing is allowable within the context of clinical research protocols. We'll review the process of Coverage Analysis and how this is utilized to improve compliant patient billing. We'll briefly discuss why conditional billing arrangements should be avoided, and finally we'll look at how we individually contribute to compliant billing as an institution.

[Zoom Link](#)



Managing discrepant subjects in OnCore

A crucial task for research

Interventional research studies conducted at IU Health study sites require that information about the protocol and enrolled subjects be included in the Cerner Electronic Medical Record (PowerChart) for patient safety purposes. The protocol and subject information entered in OnCore is sent electronically to PowerTrials and available for clinicians to view in PowerChart.

Study subjects automatically cross to PowerTrials once they achieve the On Study status in OnCore as long as the protocol is Open to Accrual in PowerTrials. Although this process is automatic, research staff need to check to make sure that subject updates are successful. The IS Clinical Research Support team recommends researchers check for discrepant subjects each time a subject is enrolled or an update is made to a subject's status.

Subjects whose updates fail to cross into PowerTrials from OnCore will show up as discrepant subjects in the RPE Console-Protocols section. To see why a subject failed to cross into PowerTrials, click on the Subjects hyperlink at the end of the row to see the History. Click on the word Failure next to the status that failed to see the reason. Many problems can be corrected by the research staff; however some will need to be referred to the OnCore team or the IS Clinical Research Support team.

A job aid for managing discrepant subjects can be found on the [Office of Clinical Research](#) website under the PowerTrials/OnCore RPE section. This section can be found by clicking on the IU Health Research Info tab on the home page, and then on the Cerner Training: PowerChart & PowerTrials subtab.



Eskenazi Health Research News

Eskenazi Health launches new webpage and research stations for researchers

Researchers Webpage

This new webpage welcomes visitors with an introduction to Research at Eskenazi Health and provides focused content on how to conduct research at the organization.

The webpage can be accessed by visiting www.eskenazihealth.edu and clicking on “Researchers” at the top of the main page or by clicking [here](#).

Research Stations at Eskenazi Health

New Research Stations are located on the Eskenazi Health main campus in the waiting rooms of OCC3, OCC4, OCC5, and OCC6. The frosted glass enclosures are wheelchair accessible and have sliding glass doors to provide for privacy. Each Station is equipped with a table, two chairs, an electrical connection, and wireless access. These Stations will provide research teams a space to meet with research participants to conduct non-clinical research activities.

Ideally the Research Stations CAN be used for informed consent discussions; research interviews, surveys, or education with participants or caregivers (both Eskenazi Health patients and non-patients); and recruitment activities such as study explanations.

Research Stations CANNOT be used for clinical care such as billable appointments; specimen collection (e.g., blood, urine, swabs) or procedures, and researcher office space.

All Research Station appointments MUST be scheduled in Epic by the research team. Scheduling education is available via the Manage Research Study Patients Tip Sheet that contains screen shots and instructions for Research Station scheduling, or through personal Webex training with our Epic Research Trainer. To receive a Tip Sheet or more

information related to Research Station scheduling please contact researchtraining@eskenazihealth.edu.

For additional Information related to either the Eskenazi Health Webpage for Researchers or the New Research Stations, please contact [Patti Noblet](#).



Advarra webinars

Advarra offers regular webinars that may be of interest to our research community. These webinars are available for on-demand viewing and may qualify for continuing education credits; check with your certifying organization(s).

Recent webinars include the following:

Budget Negotiation 101

“Clinical trial costs vary from each site, and a prolonged budget negotiation process can affect the startup timeline.”

Addressing Decentralized Pre-Enrollment Challenges for Sites and Site Networks

“Explore key processes and tools your teams should use to show sponsors your organization operates at peak performance.”

Your Guide to sIRB Mandates

“This webinar offers insights to your pressing questions related to single IRBs and explores the key features of federal sIRB mandates.”

[On-Demand Webinars at Advarra >](#)

News from the ICBI

ICBI member company Early is Good raises \$4 million

Early is Good (EIG) recently closed a \$4 million seed round from Social Capital, the Silicon Valley-based technology investment firm managed by venture capitalist Chamath Palihapitiya. EIG, a cancer diagnostic company, will use the funds to complete clinical trials for an early detection test for bladder cancer. The company's BC diagnostic assay quantifies a panel of biomarkers from urine to diagnose bladder cancer and identify the stage of cancer. Early is Good is co-founded by Dr. Thakshila Liyanage and Asel Liyanage.

[Read more >](#)

Connecting our Clinical Research Community

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