Office of Clinical Research

September 2023

OCR Community Call

Thursday, Oct 26th from 2:00 - 3:00 pm

OCR Community Calls

The OCR held a community call on August 29th, 2023. Topics discussed during this call included Advarra eReg implementation, IU Health research access, reporting of RCS billing errors, and new and revised clinical research fees. Slides are available here. Login with your IU Single Sign-On (SSO) may be required to access this information.

Our next call is scheduled for **Thursday, October 26th from 2-3pm**. If you would like to attend, you can access the calendar invitation above, or email *ocrfin@iu.edu* to be added. The agenda for the October call will be provided one week prior to the meeting. Questions or topic suggestions should be directed to *ocrfin@iu.edu*.

IU & IU Health Clinical Research Billing Compliance Training

The OCR has scheduled an educational presentation on the IU & IU Health OnCore Research Billing Notification process and other clinical research billing compliance requirements. For anyone in a study coordinator role, this presentation should be considered required training and will likely provide new information even for those actively using these processes.

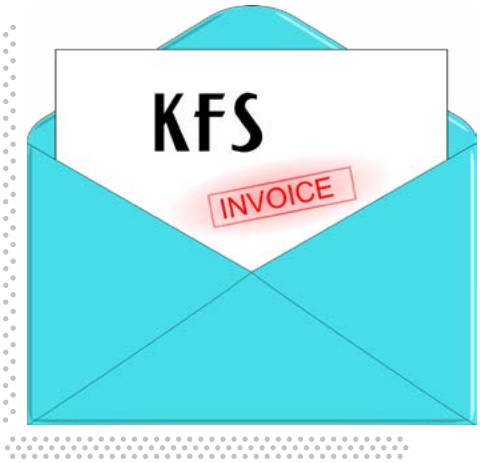
Two training dates have been scheduled. These will be identical presentations. To register for this training, please click on the registration link below for the date that fits your schedule.

IU Health Clinical Research Billing Compliance Training (choose 1)

Register for training Tuesday, Nov. 7th 9:30 - 11:00 AM

Register for training Wednesday, Nov. 15th 2:30 - 4:00 PM

After registering, you will receive a confirmation email containing information about joining the meeting. If you have questions, please contact our team at *ocrfin@iu.edu*.



Invoicing for Clinical Trials Under the UA-CTIN Billing

When initiating a Customer Invoice document (INV), the Processing Organization and Billing Organization information automatically populate based on the initiator's User Role information in KFS.

As per standard operating procedures that went into effect 5/1/2020, the Office of the University Controller (UCO) requires all clinical trials to be invoiced under the UA-CTIN Billing and Processing Organizations. To change the Billing Org and Processing Org information on a new KFS invoice, the initiator has to first be added to the biller role for each Billing Organization they will be invoicing for in the KFS AR module, including UA-CTIN. Your fiscal officer will need to request proper role access.

Additional guidance provided to the Office of Clinical Research by the UCO can be found here. Please contact Non-Student Accounts Receivable at *nonstdar@iu.edu* for any questions.

New OCR Fees

The OCR provides our Indiana University & IU Health investigators, administrators, and study coordinators with a schedule of required and recommended fees for industry-sponsored clinical trials.

The fee schedule is intended to assist in the development of budgets for industry sponsored clinical trials by providing a consistent starting point for budget negotiations with industry sponsors; ensuring clinical trial teams more accurately estimate time/resources required for clinical trial activities; and creating tangible documentation of research related costs for industry sponsors.

Beginning January 1, 2024, all industry-sponsored clinical study agreements will be assessed a one-time, non-negotiable OCR Study Initiation Fee; as well as CTA Amendment Fees for each amendment to the clinical study agreement that will impact the study's overall budget. These fees are included in the current OCR Industry Fee Schedule, which can be dowloaded below, and are addressed in a *letter to our industry partners*.

OCR Industry Fee Schedule v.4

OCR Industry Fee Schedule v.4 DT (with line-item detail)

Common questions about the OCR's new fees have been addressed in this frequently asked questions document: *OCR fees FAQ*.

For additional questions – please contact the OCR Financial Compliance Team at *ocrfin@iu.edu*.

Summary Accrual Reporting in OnCore for Clinical Research Studies

Summary Accrual refers to an OnCore function that ***reports the total number of participants enrolled in a clinical study using periodic updates****. This function differs from typical subject entry, which involves collecting detailed data about individual participants and completing calendar information to log visit history and procedure coverage.*

Since OnCore serves as an enterprise system, all clinical research investigators within IU and IU Health are required to record and store their human subjects data in the OnCore database. In almost all cases, investigators must keep comprehensive information about their protocols, subjects, and study calendars, with timely data input (within 48 hours) after every research visit to ensure IU Health billing compliance.

In special circumstances where OnCore workflows are not required for billing or regulatory compliance, Summary Accrual may be requested. However, the following CANNOT apply:

- Study requires safety flags in the EMR (i.e., PowerTrials)
- Study requires monitor access to patient data in Cerner
- Study requires a full Medicare Coverage Analysis
- Study requires Research Billing tools in OnCore
- Study is categorized as Interventional
- Study requires IU specimen storage services
- Study utilizes Advarra Participant Payments

Additional considerations may be taken into account such as current status of the study or operational needs. Summary Accrual requests can be *submitted to the Office of Clinical Research*. For more information regarding Summary Accrual, please contact *oncore@iupui.edu.*

IU Health University Hospital CRC Moves to AAHC

The University Hospital Clinical Research Center will be moving to the new Adult Academic Health Center (AAHC) in the 4th quarter of 2027. Click on the link below to view a recorded powerpoint presentation which provides an overview of the AAHC and reviews the CRC design. The recording is about 9 minutes long.

Plans for New CRC

In case you missed it:

Advarra Participant Payments – Accounts Payable Update

Please use the new card order form that became available several months ago, which can be found *here* or on the OCR website under the System Support navigation tab > Participant Payments. Below is important information about the new form.

Account Numbers

Account numbers must be entered into the “Financial Reference Number” field of each protocol in the Participant Payments System using only numbers with no hashes, dasher, or other marks The Account number is the 7-digit, IU Account number (the same as the “Internal Account Number” in OnCore). Sub account numbers may be entered directly after the account number in the same field.

It is also necessary to track the accuracy of the account numbers placed in the Participant Payments System. Often account numbers, especially Grant Accounts, will expire or close as required by the parameters of the contract or grant agreement. When the study account is closed and a new account number is issued, replace the new study account number in the Participant Payments System as soon as possible. If your study does not get a new account number, finding an internal account to cover any remaining charges will be necessary; this can be an account of your choosing in which you have authority to incur charges.

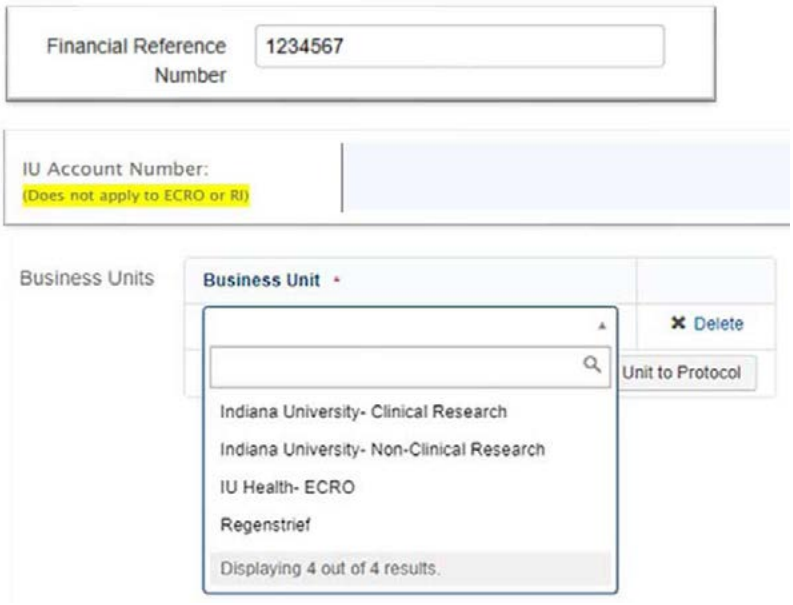
Card Ordering

Please use the new order form and follow the instructions for submitting it to Advarra. The new "IU Account Number" field allows us to process payment for these cards when they appear on the monthly report from Advarra, reducing the time spent reaching out to study teams to get the number when payment is due. Advarra, and the System Support team, will deny the order form if this field is not completed.

Business Unit

Completing the Business Unit field is important when entering a new study. Some of our Affiliates, including IU Health, Regenstrief, and our Non-Clinical Research Partners in Bloomington have begun using the Advarra Participant Payment System to pay their research participants. These Affiliate studies currently need to be handled a bit differently. The Business Unit is what flags these individual studies to differentiate the study needing special attention. If the Business Unit field is not completed, additional work is needed to find out where the study belongs and how it is handled.

See examples from the Advarra Payments System below:



News from the ICBI

2023 Innovation Series

The Indiana Center for Biomedical Innovation released the first in its Innovation Series: The Researcher Spotlight. This story features the work of Mark Heiman, the Chief Scientific Officer for Scioto Biosciences, an ICBI company since 2018.

Learn about Dr. Heiman's background, his current studies, and the role the ICBI has played in his research.

View the story ❭

Connecting our Clinical Research Community

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