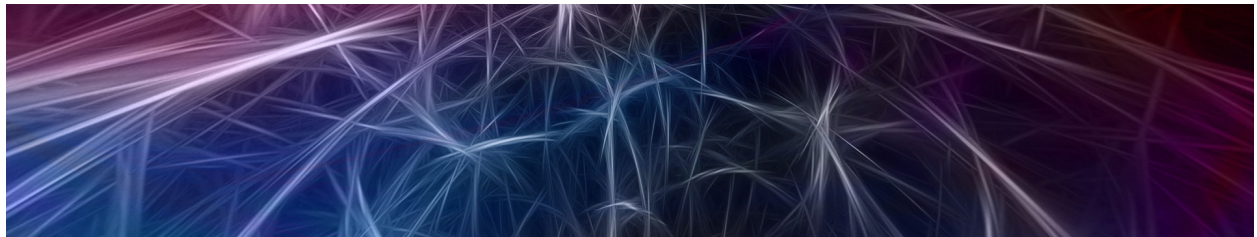


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# Office of Clinical Research

*September 2022*

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## Welcome to our new director

**Carmel Egan, PhD**



Join us in welcoming Carmel Egan, PhD, as the new director for the Office of Clinical Research (OCR). Egan brings a wealth of research and senior leadership experience to the OCR family, after serving in a series of leadership positions at Lilly, IU School of Medicine, and CTSI.

[Learn more](#)

## REMINDER

If your industry-sponsored clinical trial has not yet increased the indirect rate to 36%, please amend your contracts before October 1, 2022. Otherwise, the F&A rate will still be adjusted, your study costs will be impacted, and any overdrafts will need to be covered through departmental/discretionary resources.



## Help us reduce study enrollment delays

Staffing shortages and a high volume of study submissions has created a significant backlog of studies awaiting Coverage Analysis review. The Coverage Analysis Team is working as quickly as possible and the OCR is actively recruiting to fill vacant positions; however, you may experience long wait times.

As a completed Coverage Analysis is **required prior to enrollment** for any protocol with items or services potentially billing through any healthcare partner, please ensure your research teams are following these best practice recommendations to reduce the likelihood of a delay in enrollment:

- Submit to the OCR early, with your final protocol, draft informed consent(s), and draft budget/CTA, award or other funding agreement. Studies cannot be assigned for review until all required documents are received.
- Respond to Coverage Analyst communication and meeting requests in a timely manner
- Ensure OnCore IRB status is up to date and all necessary billing fields are complete when applicable (internal account number, NCT#, PO numbers, etc.)

Study teams should not begin enrollment until the OnCore status is "Open to Accrual." If you have questions, email [ocrfin@iu.edu](mailto:ocrfin@iu.edu).



## Participant Payment changes

Several suggestions have been made to help improve the accuracy and timeliness of reimbursing Advarra for the funds they use to pay research subjects in the Participant Payment System. OCR staff have been working with IU Accounts Payable to develop a new, less cumbersome and time-consuming process that takes the responsibility away from study team finance personnel, while also making timely and accurate payments to Advarra.

In late August a process was developed and placed in the testing phase, which allows centralized staff to manage the invoices due, make one lump sum payment to Advarra, and direct funds from the appropriate research account for the payment. The testing of this process has gone well, and a tentative rollout of December 1, 2022, has been set.

Training will be scheduled shortly with the finance personnel from each team to provide an explanation of the new process. In the meantime, there are a couple data fields within the payment system that need to be updated, or confirmed, to help confirm the testing:

1. Business Unit – This field will need to be completed for every study to differentiate IU studies from Affiliate studies.
2. IU Internal Account Number – This number will need to be placed in the “Internal Reference Number” field and not include any characters, just numbers (i.e., 5923459).

Please confirm and/or update these fields in your studies ASAP. Information about training dates and times will be emailed to the designated finance person on each team.



## REMINDER

### Collaborative Engagement Day with Community Health Partnerships

Tuesday, September 27, from 9:00 - 4:00 am

Fort Harrison State Park  
6000 N Post Rd, Indianapolis, IN 46216

For those who have already signed up, set your reminder for Tuesday! Hear from Indiana partners and share your own experiences on establishing and evaluating trustworthiness in science and research as well as strategies for building partnerships.

This event will bring together partners from across the state including *Trailblazer and Planning Grant Awardees* and those who have worked with *Connections IN Health, All IN for Health, Research Jam, WISE Indiana*, and *Global Health*.

Registration for this event is now closed, but for more information, please email [chep@iu.edu](mailto:chep@iu.edu).

## News from the ICBI

### 2021 Data Results



The Indiana Center for Biomedical Innovation is excited to share the immense scientific, societal, and economic impact of our member companies! Of the \$43.5 million in total funding, \$40.1M was from private sources, 2.7M was from federal grants, and 150K was from non-federal grants.

## **ICBI member company Monon Bioventures, awarded nearly \$400,000 from National Cancer Institute!**

Monon Bioventures is collaborating with fellow ICBI company, Genezen Labs, and Purdue University College of Pharmacy to study the feasibility of manufacturing a glioblastoma therapeutic using human immune natural killer (NK) cells. The therapeutic was created at the Purdue University College of Pharmacy.

[Read more about this partnership >](#)

### **Connecting our Clinical Research Community**

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*Office of Clinical Research* is a program of

Indiana CTSI

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