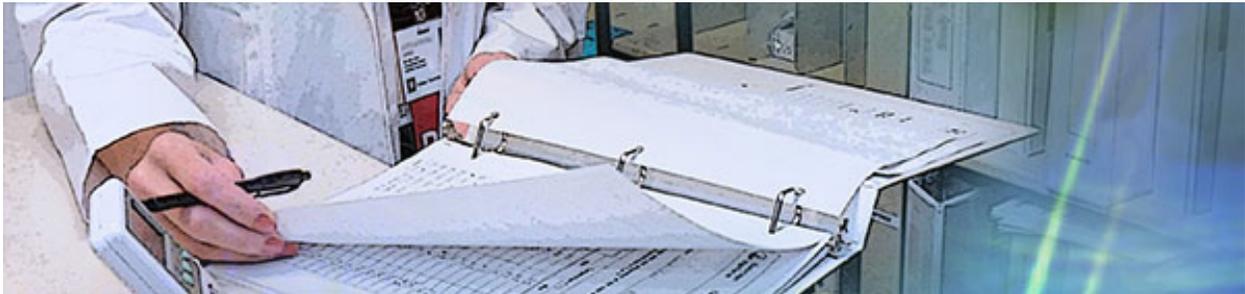


# Office of Clinical Research Updates

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March 2021

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**It's almost here!**

A complete redesign of the OCR website is on it's way. We have been working behind the scenes to bring you a more user friendly site with improved navigation and a cleaner look. The major update will launch within the next few weeks.

Be on the lookout!

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## Cerner access changes for non-IU Health employees and study monitors

The Clinical Research Systems (CRS) team is implementing a transition period between March 1 and June 30, 2021 for transitioning responsibility for Cerner research access to IU Health employee sponsors. During this time, the CRS team will maintain a streamlined access process for both research staff and study monitors using REDCap to gather demographic information from the requester along with the name and contact information for the IU Health employee sponsor.

More information can be found in the updated documents on the [OCR website](#) under the Cerner Access tab or by clicking on the buttons below.

[Research Related Systems Access Overview](#)

[Job Aid Research Access](#)

[Job Aid Research Monitor Access](#)



## Ready to make the switch?

***Are you . . .***

- *Tired of carrying around the large and bulky regulatory binder wherever you go?*
- *Running out of physical space and have nowhere to keep your paper binders?*
- *Sending binders to a storage facility, only having to retrieve them again later for audits?*

Want something that will help you save time, keep an electronic audit trail, improve your workflows and enhance your regulatory processes across Indiana University and other institutions? Think beyond the binder.

## *Try the Advarra eRegulatory Management System*

Replace your current regulatory binder system with eReg, an electronic system that is validated as 21 CFR Part 11 Compliant. It allows you to store all your essential protocol documents, tracks owners and expiration dates, and integrates with OnCore (IU's clinical research management system). You can boost efficiency by quickly routing documents and managing electronic signatures, including the Delegation of Authority. With eReg, you can also leverage multi-site management, allowing you to view and manage essential documents for participating sites.

Currently, the Office of Clinical Research (OCR) is piloting eReg with several research groups before we roll it out enterprise-wide. We are delighted to open the pilot up to additional research areas if there is an interest. If your team would like to be included in the pilot, please email us at [oncore@iu.edu](mailto:oncore@iu.edu).

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## Tax time tip for research teams

One of the many benefits to using the Advarra Participant Payment program to pay stipends and reimburse research participants is the ability to run a single report to review the tax consequence of paying research participants. ***The United States Internal Revenue Service (IRS) requires Indiana University to report amounts paid to research participants in excess of \$600 per calendar year in stipends.*** The participant total is a collective amount from any number of studies in which an individual participant is enrolled.

The Advarra Participant Payment system is equipped with a resource, called the “10-99 Report,” that helps calculate the total amount each participant receives in taxable income. The Indiana University Tax Office runs the 10-99 report directly from the Participant Payments Program, which provides the total stipend amount that each participant received regardless of research study. While this report is very beneficial to the Tax Office in assisting with IRS compliance, it is only as effective as the data entered into the Participant Payments System.

The best way to ensure that the Tax Compliance Officers have what they need at the end of the year is to enter the participant's Social Security Number into the Participant Payment System at the time of study enrollment. With this information, if the participant does receive \$600 or more in stipends, the Office of the University Controller can quickly and easily complete their step of the process. ***If the Social Security Number has not been entered when the Tax Preparer runs the 10-99 report in January of each year, the Research Team will be responsible for reaching out to the participant to enter the Social Security Number into the Payments System.***

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## New! OnCore billing annotations tab

With the new IU/IU Health research billing notification process, a new Billing Annotations tab has been added in the PC Console in OnCore. On this tab, the Coverage Analysis Team will document our responses to 2 questions about the protocol's status with regard to billable items and services:

1

### **Does the study contain any items or services that are billable through a healthcare billing partner?**

If yes, a coverage analysis will likely be completed.

If the answer is no, this protocol may receive only an abbreviated document alignment review.

2

### **Will the study use the IU/IU Health OnCore research billing notification process?**

For new studies opening to accrual after 12/1/20, this will be answered yes when protocol required items or services are billed through IU Health Revenue Cycle Services, regardless of whether those items or services are billed to the study or the patient. If this question is answered as yes, an RCS management group will be added to the protocol in OnCore to trigger the notification process.

Following this assessment to determine a protocol's billable status, there is now a dedicated place to store the purchase order information for your study. If the IU Health OnCore research billing notification process is used for a study that will bill items or services back to a research account, an IU Health RCS patient care purchase order is required to be added here. However, additional PO vendors are also available in this list and should be added as applicable. These

other billing partners include Eskenazi, Advarra (Forte) Participant Payments, Investigational Drug Services (IDS), and WIRB. Having all applicable purchase orders listed within OnCore makes them quickly accessible to study team members as well as the billing partners who can access OnCore. Additional vendors can be added to this list at any time by emailing our [OnCore support team](#).

The billing annotations tab is completed by the OCR Coverage Analysis Team in partnership with the study's coordinator or budget contact and should be completed as applicable prior to a study receiving the Open to Accrual status in OnCore. If you have any questions about the billing annotations tab or its use in the coverage analysis process, please contact [ocrfin@iu.edu](mailto:ocrfin@iu.edu).

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## Connecting our Clinical Research Community

Please credit OCR when referring to or using information in this publication.

[Office of Clinical Research](#) is a program of

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