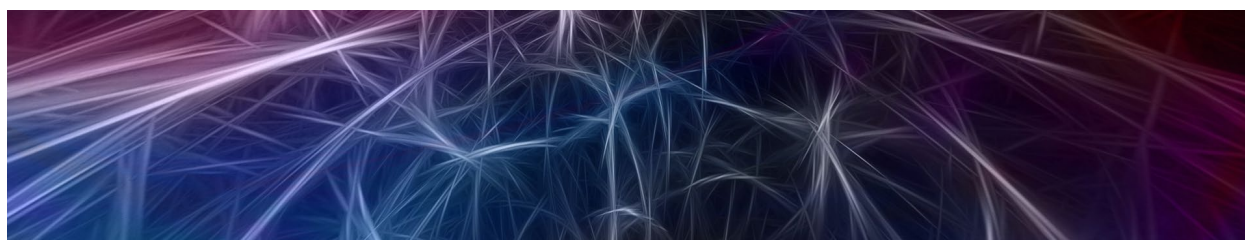

Office of Clinical Research

May 2023

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OCR Community Call

Thursday, May 18th from 2:00 - 3:00 pm

**The Office of Clinical Research
holds first OCR Community Call
Thursday, May 18th from 2-3 pm**

The purpose of this call is to share information and education from the OCR, as well as other clinical research offices or service areas across the enterprise; and to establish an open forum for communication, collaboration and sharing of best practices across all clinical research teams. This meeting will be held roughly 6 times per year on a rotating schedule with the Clinical Research Educational Series (CRES) and replaces the previous OCR Extended Lead Team meeting series. The first meeting will be recorded and available upon request.

Topics for our first meeting will include:

- *Introduction to the OCR's new look!*
- *Updates to the IU Health Research Policies*
- *Research Billing Compliance Updates*



Multi-Factor Authenticator changes

IU Health replaces Duo with Microsoft Authenticator

IU Health is replacing DUO with Microsoft Authenticator as the Multi-Factor Authenticator (MFA) for access to IU Health applications such as Works Web (IUH workspace). If you use DUO to authenticate for IU Health applications, please take steps to prepare for the switch to Microsoft (MS) Authenticator. To ensure a smooth transition, consider setting up MS Authenticator as soon as possible. IU Health applications will require MS Authenticator instead of DUO to access applications beginning in May of 2023.

Instructions for setting up MS Authenticator are also available on the Office of Clinical Research website in the IU Health Research Info section under IU Health Access – Remote.

Please note that you will need to be on an IU Health workstation to do this set-up. An IU Health workstation is an IU Health-issued computer or Virtual Desktop (VDI). You will need access to the same device e.g., cell phone, currently using DUO authentication.

Key Points

1. If you use DUO today to access any IU Health applications, you need to prepare for the switch to Microsoft Authenticator.
2. IU Health applications will require MS Authenticator instead of DUO to access applications beginning in May of 2023
3. There will be no change to the use of DUO for any IU applications. This only applies to IU Health applications.

Questions or issues with setting up authenticator should be directed to the IU Health help desk at (317) 962-2828. Select option #5 to speak with the project team directly.

Registering MS Authenticator BEFORE Location Launch

If you are setting up authenticator after your location's Go-Live date, you will receive the More Information Required notification and will need to follow the instructions in the Job Aid below:

Registering MS Authenticator AFTER Location Launch



PowerPlans now linked to specific studies in PowerTrials

New research study PowerPlans in Cerner will now be linked to the study in PowerTrials. This is a safety measure to avoid entering a PowerPlan on non-study patients. A user will receive a warning if they attempt to order a PowerPlan for a subject that is not enrolled in a study.

If a user clicks to add a research PowerPlan, and that subject isn't enrolled in the study in PowerTrials, they will see a warning/soft stop:

Add Plan

To order the plan IRB# 1710369 Shaanxi Micot MT1002- Screening the patient must be enrolled in the BALL-SHAANXI-MT1002 clinical trial/study and the patient is not enrolled. Would you like to continue ordering this plan?

[Contact Information](#)

Override Reason:

Comment:

Tstclinres, Bettie - 38122329

There are instances in which a subject truly is enrolled in study, but there is an error or a delay in their enrollment in OnCore and/or PowerTrials. If that is the case, the user should select override reason, enter comment if necessary and click OK:

Add Plan

To order the plan IRB# 1710369 Shaanxi Micot MT1002- Screening the patient must be enrolled in the BALL-SHAANXI-MT1002 clinical trial/study and the patient is not enrolled. Would you like to continue ordering this plan?

[Contact Information](#)

Override Reason: Imminent Enrollment

Comment:
Patient enrolled but error in interface with OnCore

Tstclinres, Bettie - 38122329

OK Cancel

The plan will now be ordered and able to be initiated and signed. If you have questions about this process, please email ISClinicalResearchSupport@iuhealth.org.



Participant Payment users:

A new card order form is available for download on the OCR website. Please begin using this new form, which became available on April 14th. (Note: The date on the new form is December 15, 2021, which is the date of Advarra's last update. The OCR made new changes to the form but kept Advarra's original date.)

Here is what's changed:

1. The 7-digit Indiana University Account number, which should be the same as the "Internal Account Number" in OnCore, must be entered into the "Financial Reference Number" field of each protocol in the Participant Payments System. The order form will be denied if the field is not completed.
2. The new form has a field to identify the person receiving the card order.
3. Completing the Business Unit dropdown for every study has taken on increased importance. Our Affiliates are now using the Advarra Payment System, and their studies are handled differently. The business unit entry flags studies needing special attention.

Additional important information

In December 2022, a new process for using the Participant Payments System was put into place. The latest process centralizes and streamlines payment due to Advarra monthly, to ensure Indiana University stays in good standing by minimizing the occurrence of past due charges.

Upon implementation and usage over the past few months, the new process revealed some common issues that with your help will make this process smoother.

Account Numbers: Account numbers must be entered into the “Financial Reference Number” field of each protocol in the Participant Payments System. The Account number is the 7-digit, Indiana University Account number, and should be the same Account number that is entered into the “Internal Account Number” field in OnCore. The account number should be entered with numbers only, no hashes, dashes, or other marks. Sub account numbers may be entered directly after the account number in the same field. Most existing studies have been updated but be sure to include this for all future studies. See below an example in the Advarra Payments System.

Financial Reference Number	1234567
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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. In the instance where the study account is closed, and a new account number is issued, it is necessary to 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, it will be necessary to find an internal account that can be used to cover any remaining charges, this can be an account of your choosing that you have authority to incur charges.

Card Ordering: A new card order form is available on the OCR.iu.edu website, for all future card orders please use the new order form and follow the instruction on submitting it to Advarra. The change to the form that effects the process of paying Advarra is the addition of the “IU Account Number:” field. Adding this field allows us to process the payment for these cards when they show up on the monthly report from Advarra. Reducing the time spent reach 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. See below an example in the Advarra Payments System.

IU Account Number: (Does not apply to ECRO or RI)	
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Business Unit: The Business Unit has increased in importance to complete with every 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. In the new way of paying Advarra, these Affiliate studies 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 to research the study is necessary to find out where it belongs and how it is handled. Most existing studies have been updated, but it is important that this field be completed when entering a new study. See below an example in the Advarra Payments System.



The new card order form can be found [here](#) or on the OCR website under the Research Systems navigation tab > Participant Payments. The form is located under the Support section at the bottom of the page within the Internal Shared Documents dropdown.

Support

- > Guidance Documents
- ▼ Internal Shared Documents
 - ➔ Payments Card Order Form and Instructions
 - Participant Payments Checking Account (or Paper Check)
- > Support for Participants



Advarra webinars

Advarra offers regular webinars that may be of interest to our research community. The topics below have been recently added for on-demand viewing and may qualify for continuing education credits; check with your certifying organization(s).

Privacy and Confidentiality in the Age of Mobile Apps and Connected Devices

“Discover how to protect participant privacy in mobile-app-based clinical research. Learn about risks and what IRBs need to consider in protocol review.”

Full Board vs Expedited vs Exempt: Why IRBs do That

“A discussion on what IRBs must consider, what might tip the scales for a study that could go either way, and what “expedited review” means.”

Rare and Orphan Diseases in Regulated Development

“In this webinar, gain an in-depth understanding of regulatory and clinical development challenges for rare/orphan diseases.”

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

News from the ICBI

2022 Annual Report

The Indiana Center for Biomedical Innovation released its 2022 Annual Report earlier in the year and is pleased to share it with our IU and IU Health family.

[View the report >](#)



If you are an IU Health physician, clinician, nurse, technician, or other health professional who may have a potential innovation, solution or entrepreneurial idea, the staff of the ICBI is eager to help you on the path to entrepreneurship. Reach out to us at infoicbi@iu.edu.

Connecting our Clinical Research Community

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Office of Clinical Research

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