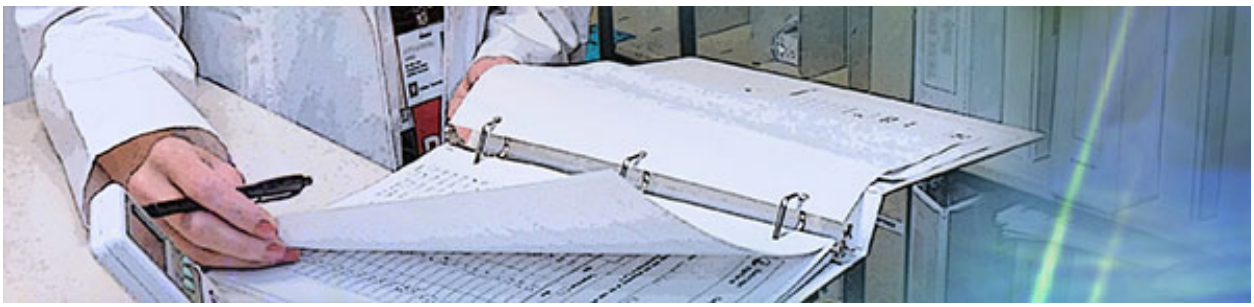
Office of Clinical Research Updates

September 2019



Building a better billing workflow

September 9th marked the beginning of an exciting new development in clinical research billing for our enterprise—a new paperless process. Instead of using paper grant charge forms, the IU School of Medicine and IU Health have begun using OnCore to notify IU Health Revenue Cycle Services (RCS) of patients participating in a research study. OnCore prompts a global bill hold for each patient and provides direction for how items and services should be billed. This new process, developed jointly by OCR and IU Health RCS with input from the research community, will reduce patient billing errors, improve research billing compliance, and lessen the burden on researchers.

Currently in the pilot phase, the OCR Coverage Analysis and OnCore teams have been actively collaborating with the division of Gastroenterology and Hepatology, Neuroscience Clinical Research Services, and Enterprise Clinical Research Operations to transition studies into the new paperless process. *Learn more and read the FAQs for the new research billing process*

What's on your calendar?

The core of any clinical trial management system (CTMS) is the protocol calendar that contains a patient's schedule of procedures, treatments, and tests throughout the study. Built into that

framework are other processes like coverage analysis, research billing, and biospecimen management. Why is that important? Errors in the calendar can result in missed visits and inaccurate treatments, creating safety concerns for patients and regulatory compliance concerns for the site and sponsor. Calendar errors can also lead to incorrect coverage analysis, billing, and other mistakes in interrelated systems.

We need YOU!

Because a protocol can be interpreted differently, the calendar builder is forced to make judgment calls throughout the build process. However, the calendar analysts have a systems background, not a clinical background, so we need the clinical study team to be engaged before the calendar is completed.

Read more

New OnCore eLearning modules

The OCR Systems & Support Team is providing real-time access to eLearning content for OnCore's 800+ users. If you're stuck in a clinic, sick at home, or don't like to attend classroom training, don't worry, we've got you covered! You can learn how to manage a protocol, find and create new patients, and/or track patient visits anywhere at any time.

Study teams must register research subjects in OnCore within 24 hours of patient consent and also document subject visits in OnCore within 24 hours of the visit to ensure that patient charges are correctly identified and appropriately invoiced for research-related charges, services, and procedures. Two new eLearning modules will help you understand the new billing initiative and the impact it has on OnCore's protocol and subject management:

Module 3 — Subject Registration: Learn how to search for existing subject records, create new subjects, and add subjects to the protocol.

Module 4 — Subject Management: Learn how to manage and track subject visits from consent through off-study status.

To access the learning modules, click on the blue buttons below and follow the prompts.

- You will be asked are you "part of Indiana University?" Click Continue.
- You may need to complete the IU Login if you are not already logged in.
- At the "Leaving Box" page, click Continue to proceed to the module.
- The links to these modules can also be found on the *OCR Training and Support webpage*.

OCR Contracts team at your service!

Headed by Caren Geppert, the “small but mighty” contracts team reviews, negotiates, and executes all industry-sponsored research contracts for Indiana University and, yes, even IU Health. At any given time, we have about 140 open negotiations! Unlike the Office of Research Administration (ORA), all the contracts we negotiate are with industry sponsors (no government funding) for studies involving human research subjects (no bench research). We negotiate terms such as the following:

- Indemnification (allocation of risk)
- Subject injury reimbursement (who is financially responsible in the case of a subject injury)
- Publications
- Inventions
- Confidentiality terms
- Termination causes and procedures

IU Health contracts and Statewide Research. Although the relationship between IU and IU Health is highly collaborative, they are separate legal entities requiring additional considerations. Whether a trial involves one IU Health site or is statewide, our team is here to help navigate the sometimes complicated legal aspects of research, including identifying the appropriate parties to the contract, determining the correct contract type, negotiating terms, and assisting with contract execution.

Additional Resources

View our most common contract templates

Visit us for more information on industry sponsored research, the “big orange button” for CDA requests, and the “big red button” for study initiation as well as the standard pricing schedule of recommended fees for industry sponsored trials.

Feel free to *contact us* if you have questions regarding research contracting.

Help with listing trials and connecting with patients

All IN for Health is a site designed to attract volunteers for clinical studies and connect them to research opportunities. This site uses iConnect, an online platform by TrialX that went “live” for research studies in December and was up and running with the volunteer registry a few months later. Since then, several members of the initial training cohort have reported improved efficiencies and shortened recruitment times.

To list your clinical studies on the searchable website or request iConnect training, contact *Keier Dante*.

iConnect training

Training sessions as well as the opportunity to identify future system enhancements will continue throughout the next several months. Currently, iConnect training consists of a video approximately 90 minutes long. The training is geared towards principal investigators, study coordinators and their study teams.

The initial part of the training video details what the participants/volunteers will encounter while navigating through the website.

The second part of the training video details the management/administrative use of the iConnect application from the study team's perspective and covers these topics:

1. Communicating with prospective participants and tracking email referrals using an automated tracker
2. Filtering out false leads using a pre-screener
3. Setting up and managing recruitment campaigns for a variety of outreach tactics like flyers or online ads
4. Measuring ROI across different outreach channels using trackable phone numbers, links, and emails.

New guidelines for pager use

The IU School of Medicine plans to move away from the use of pagers since the technology is impossible to secure and poses a critical privacy risk. IU Health has accelerated its transition to Diagnotes and is asking physicians and other team members who have not yet done so to make the change immediately.

What this means for Research

Many investigators and their research teams conduct research across multiple hospitals in different health systems, and the exclusive use of Diagnotes is currently not feasible for all users. As we work with partner hospitals to resolve these challenges, the use of pagers remains an option. However, please adhere to the paging guidelines to ensure the protection and privacy of our patients' data:

1. **Everyone must immediately cease sending any patient or case information via pages or text.** This is in alignment with previous guidance. Pages may only include a call-back number or numerical contact information and, if helpful, the unit involved. IU Health team members are being notified of this change, and the IU School of Medicine will work with other health system partners to ensure similar safeguards are in place.

2. **Pages and texts should not include a patient's name, initials, room numbers or any other identifying information.** Use of Diagnotes is strongly encouraged if your clinical assignment is limited to IU Health hospitals and clinics.

The IU School of Medicine continues to explore how to integrate Diagnotes and is working with IU Health to address other technical issues that have been raised. Please do not hesitate to reach out to OCR at *ocr@iu.edu* with any questions.

Connecting our Clinical Research Community

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