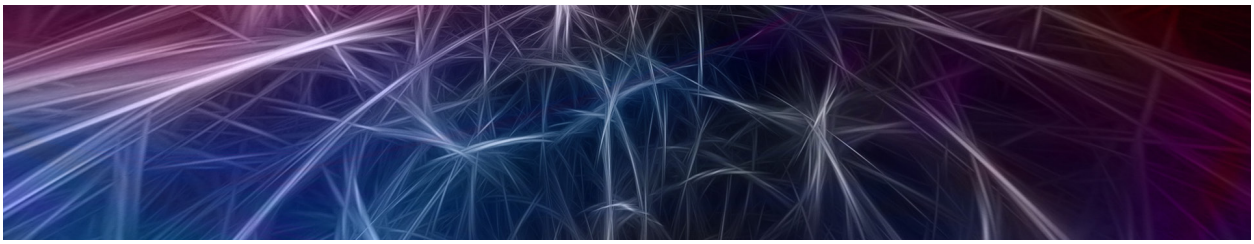
Office of Clinical Research

September 2021



OCR indirect rates & contract renegotiation

Indiana University continues to see strong growth in industry-funded clinical research. Similarly, our internal costs of conducting this research has also increased.

On December 1, 2019, the Office of Clinical Research (OCR) increased the indirect rate to 36%, which is consistent with most academic medical centers. At that time, studies that were negotiated before that date could remain at the 30% rate until December 1, 2021.

As December 1, 2021 approaches, we are requesting all departments to work with their industry partners to renegotiate all contracts at 30% to the current 36% rate. These amendments will need to be routed through KC, so accounts may be adjusted. Our office is ready to handle your amendments in an efficient manner, and we look forward to working with you!

Need an ITRA?

An Information Technology Risk Assessment (ITRA) is triggered if a third-party vendor is capable of housing protected health information (PHI) or other proprietary data and is connected to the IU Health network.

If you need an ITRA or are unsure if an ITRA is required for a solution, please email *ITRA@iuhealth.org*. You will be sent a pre-assessment questionnaire to complete. An ITRA analyst will determine if the solution needs to be assessed and contact you regarding next steps.

In today's technology-driven world, healthcare institutions find themselves at increased risk for cyber-attacks. The protection of patient information is a priority of IU Health, especially in the field of research. The HIPAA Security rule sets national standards to protect the electronic personal health information of individuals that is created, received, used, or maintained by a covered entity. Current IU Health policy requires a risk assessment be performed for any third-party vendor solution.

The assessment will identify areas of risk and receive vendor confirmation that IS standards and policies are followed. A few examples of scenarios that would require an assessment:

- Studies using phone applications for subjects or researchers
- Web-based platforms outside of a typical electronic data capture (EDC) system that exchange electronic protected health information
- Sponsor-provided iPad or other devices that connect to the IU Health network

FAQs: Order set

I have an inpatient study coming up. How do I get assistance with my Cerner order set?

You can contact Kate Buckley by filling out this RedCap form. Kate is our Clinical IS Analyst who assists with Adult, Non-Oncology Research Order Sets.

I'm not sure if my study will require an order set.

Most inpatient studies will require an order set. Kate will be happy to review your protocol with you and help you determine next steps. If you have any questions, please email Kate at *kbuckley@iuhealth.org.*

New PowerTrials functionality

On October 24, 2021 Cerner will be upgraded to a new code level which provides new PowerTrials functionality.

Researchers will see the following key changes to PowerTrials when IU Health upgrades Cerner on October 24, 2021:

1. On Treatment subject status now crossing to PowerTrials

When a subject is moved to on treatment after on study, the on treatment status and date will be sent to PowerTrials and will be available in PowerChart. It will be easier to tell if a subject failed to cross to Cerner at on study because the on treatment status will also fail, causing the subject to show as discrepant in the RPE Console.

2. Expanded Demographic/Banner Bar Clinical Trial Subject Statuses

The Clinical Trial indicator contains information about the patient's current participation status in clinical research trials. The details are being expanded to include the current research treatment status for interventional trials.

The 5 possible statuses are defined below:

- **Clinical Trial: No data available**
  Never shown in a clinical trial in PowerTrials
- **Clinical Trial: On Study**
  Currently enrolled (on study) in a clinical trial
- **Clinical Trial: On Treatment**
  Currently on treatment in a clinical trial
- **Clinical Trial: Off Treatment**
  Currently off treatment in a clinical trial
- **Clinical Trial: Off Study**
  Currently off study for all clinical trials in PowerTrials

3. Arms descriptions in PowerChart

OnCore will begin sending information about which arm a subject is currently enrolled in to PowerTrials. The information will be able to be seen in the Clinical Research page by all clinicians. If the information is in OnCore, it will come to PowerTrials. There is no way to prevent it from crossing over into PowerTrials and being seen in PowerChart. PowerTrials can only take one stratum or arm at a time. The RPE will process any subsequent arm changes as an update and overwrite any existing data.

4. Availability of quick prescreening

Offers another tool that the IS Clinical Research team can use for leveraging the Cerner EMR to assist with patient recruitment.

The IS Clinical Research Support team will host four Zoom sessions in October to review this new PowerTrials functionality and answer any questions. You will only need to attend one session, as same content will be repeated. No registration needed.

FRIDAY	**October 1 - 09:00-10:00 AM**	Meeting ID 849 6945 3423
WEDNESDAY	**October 6 - 12:00-01:00 PM**	Meeting ID 841 2635 2220
THURSDAY	**October 7 - 07:30-08:30 AM**	Meeting ID 835 7256 3946
MONDAY	**October 11 - 03:00-04:00 PM**	Meeting ID 840 1808 3928

Transitioning studies

The OCR Coverage Analysis Team will soon begin the process of transitioning studies that are actively using the IU Health RCS Grant Charge Form to the OnCore Research Billing Notification Process.

Studies that use the U Health RCS grant charge form will transition to the OnCore Research Billing Notification Process in one of 2 ways:

1. When a protocol amendment is submitted through the OCR intake form – the assigned Coverage Analyst will assess the billing scenario and transition Grant Charge Form studies as part of their amendment review.

2. The Coverage Analysis Team will begin reaching out to study teams to initiate the transition for protocols that have been identified by IU Health Revenue Cycle Services as actively using a paper Grant Charge Form.

Studies nearing completion may not be transitioned ,and this will be discussed on a case-by-case basis. If you have any questions regarding IU Health RCS Research Billing, please contact *ocrfin@iu.edu* or *clinicaltrials@iuhealth.org*.

Tracking subject visits

To avoid billing errors, please remember that patient visits that use the IU Health RCS OnCore Research Billing Notification process must be tracked in OnCore within 24 hours.

This step triggers the global bill hold that routes all of that patient's IUH RCS charges to a research charge review tool.

Additional information must be provided to confirm the billing plan for each visit. The research charge review team uses OnCore coverage analysis as well as the individual subject calendar, the additional visits screen, and the electronic medical record to match visit and procedure

dates. If the visit has not been tracked with appropriate dates in the patient calendar in OnCore, and the eMR does not contain additional notes that indicate the visit/procedure was conducted as part of the protocol, these charges will be released to the patient as unrelated to the study.

Study Coordinator's responsibility in tracking Subject Visits:

- Track the subject's individual calendar in OnCore to confirm the date of service(s) for all procedures are accurate.
    - Update the date visit occurred if different from the planned date.
    - Review procedures for accuracy.
        - Mark procedures as missed or N/A as appropriate and , if necessary, document why.
        - If procedures occur on a different date, add that date in the procedure date section.
        - In the rare instance that an additional procedure is required to be billed to research, add the additional procedure to the visit.
    - If there is additional information that could be helpful for the charge review team, document in the clinical comments of the Subject Visit page.
- If a screening procedure occurs PRIOR to the actual screening visit, add an additional visit in OnCore and add the procedure to the visit. The Additional Visit could also be used throughout the study as needed.

Human subjects audits include research billing compliance

By Beth Johnson, University Director, Human Research Protection Program

Historically, the Office of Research Compliance monitored research billing compliance for human subjects research conducted in clinical settings. Compliance activities have been paused in recent years while the Office of Clinical Research (OCR) developed centralized policies and procedures around coverage analysis and research billing. Because centralized policies and procedures are now in place, the Office of Research Compliance is resuming research billing compliance activities.

Rather than conducting dedicated billing audits, however, the billing review will instead be incorporated into the existing not-for-cause and for-cause audits conducted by the Quality Improvement Office (QIO). During these audits, QIO auditors will review billing-related actions for which the study team is responsible.

The audit process will include confirmation of the following key elements:

- The study was registered in OnCore and submitted for coverage analysis as required
- Applicable protocol amendment documents were provided to the Office of Clinical Research (OCR) for the purposes of study calendar and billing grid updates
- Unit and OCR sign off were completed prior to enrollment of the first subject
- Subjects were registered in OnCore as consented within one day of consent being obtained
- Subject visit dates were accurately recorded on the OnCore protocol calendar within one day of visit occurrence
- Other subject statuses, specifically withdrawn, not eligible, and off study, were entered in OnCore within one day of occurrence

Only studies that are subject to the OCR/IU Health research billing policies, and for which initial IRB approval was granted December 1, 2020 or later, will be reviewed for compliance.

Connecting our Clinical Research Community

Office of Clinical Research is a program of
Indiana CTSI
410 W. 10th Street Ste. 1000
Indianapolis, IN 46202