Office of Clinical Research Updates

October 2019

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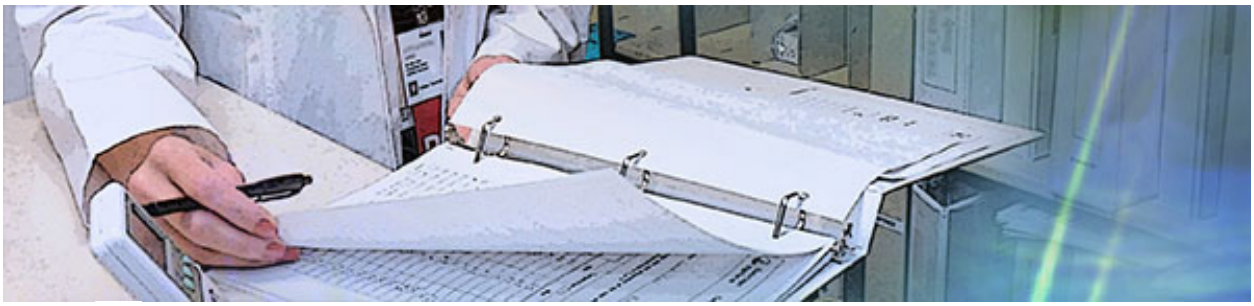

Indirect rate changes for industry-sponsored studies

While Indiana University has endeavored to minimize internal costs for supporting our clinical research programs, these costs have continued to increase, especially those associated with mitigating our risks for clinical research billing compliance.

To help underwrite a portion of these costs, IU will be increasing our indirect (facilities and administrative/F&A) rate for industry-sponsored clinical research studies from the current 30% to 36% effective December 1, 2019.

Our initial plan was to recover these expenses by levying an administrative fee on industry

studies—but, we were overwhelmingly advised by our investigators that adjusting our indirect rate would be a better approach.

IU's current indirect rate of 30% is far below the mean and median of indirect rates for industry studies at our peer academic research institutions. A recent survey of 30 peer institutions showed that their median and mean indirect rates are 36%.

The increased rate will be applied to new studies that initiate contract routing after December 1, 2019. Studies routed before then and ongoing studies that were executed at the 30% rate will remain at 30% for the next 2 years.

The OCR Contracts team will inform our industry sponsors of this change over the coming weeks. Please contact the Office of Clinical Research *ocr@iu.edu* if you have questions.

Help align study documents with parallel submissions

When study teams submit final contracts or IRB-approved documents to the coverage analysis team, inconsistencies in those documents could require amendments that delay study enrollment.

To reduce or eliminate these delays, a parallel workflow for document review has been created to ensure that initial document alignment is performed on draft documents. The OCR encourages parallel submissions to the IRB, the contracts team, and the coverage analysis team. Study teams can complete the OCR Study Initiation Form (Form 1) once they have a final protocol. Then, when the draft clinical trial agreement (CTA), budget, and informed consent forms (ICF) become available, they can route the CTA and ICF through KC grants and complete the OCR Study Activation Form (Form 2).

See the diagram outlining the document review process

Learn more about document alignment

Who pays for research-related injury?

The Office of Clinical Research has increased its focus on language regarding research-related injury. The informed consent (ICF) and clinical trial contract (CTA) are required to address the issue of who bears financial responsibility for costs incurred in diagnosing and treating study-related injuries. The ICF and CTA should be in alignment in content and scope of language. The Coverage Analysis Team reviews both draft documents to ensure that they mirror each other and contain no conditional language.

Sometimes, industry sponsors will propose language that indicates the sponsor will pay for study-related injuries only if the patient's insurance denies payment. The Institution will not accept such language or similar language that requires that Institution to bill the third-party insurance companies or the research subjects in lieu of recovery of such costs from the sponsor. In such cases, the conditional language must be removed.

Read examples of unacceptable and acceptable language in clinical trial documents

New eLearning module available

With so many processes in place, it's easy to be confused about who does what or even what comes next. Module 2, the third installment of four eLearning modules, will provide guidance on how to manage the protocol after it has been opened to accrual.

Routine costs denied by 3rd-party payer?

Private insurers will typically follow the Centers for Medicare & Medicaid Services (CMS) for rules in paying routine costs in clinical trials. However, in rare situations, 3rd party payors have denied claims for routine costs in clinical trials.
If any of your study participants experience this problem, please contact Kathryn Box, IU Health Revenue Cycle Services manager at 317.963.0382. She will direct you, based on the denial reason, to the appropriate RCS team member .

If your PI or treating physician have questions, please contact the RCS team of Physician Advisors for physician-to-physician discussions of claim denials.

Contact:

Joseph Fox
RCS Medical Director
317.963.5619
Jfox10@iuhealth.org

Jeff Amodeo
RCS Associate Medical Director
765.346.1063
jamodeo@iuhealth.org

How are electronic health records validated?

When opening a new industry trial, the sponsor might ask how our Electronic Health Records are validated or if they comply with FDA 21 CFR 11. This request may be a simple question or a complicated questionnaire requesting details of IU Health and Cerner's compliance.

To reduce the burden on your study team, the IU Health Privacy and Security Council prepared a document that you can download from the OCR website and send to the sponsor or CRO. This document, titled 21 CFR 11 Compliance Information, can be accessed from the IU Health Research Information page, which has a link at the bottom of the OCR home page.

If there are any areas of concern that the prepared information does not address, please contact the team at IU Health Information Services Clinical Research.

Latest news from the IU Health Clinical Research team

The Cerner upgrade to version 2018.01.10 is coming on December 8, 2019 This upgrade will include changes to the platform that Cerner uses to create and run pre-screening rules for research studies. If you have a current prescreening rule, you may be contacted about options to move the rule to the new platform. Future prescreening builds will occur in the new platform, allowing faster searching. In addition, the new package will contain the building blocks for the new CRPC (billing grid) integration between On-Core and PowerTrials. Plans are to do extensive build and functionality testing after the first of the year.

PowerChart for Researchers Web Based Training (WBT) will be available again soon through a direct link on the OCR website. It has taken some months to reformat the existing presentation for use on a new platform. Plans for 2020 include a project to revamp and update the education to reflect current workflows.

Patient ethnicity results are being added to the Patient Information tab in Power-Chart on 12.16.19. Researchers and monitors have been asking for an easy way to view this information, which is collected at the time of registration for our patients.

4 The new process for research system access is in place for new users and is being rolled out to existing users over the next 6-8 weeks. Some users have already received REDCap links to complete and should have those completed by the end of October. Users who have not received a link will receive one in the near future. Monitors will also be provisioned during this process. Please make sure that all protocol and subject information is up to date and synced between OnCore and PowerTrials.

5 An IU Health response statement on 21 CFR 11 compliance has been posted on the OCR Website under the IU Health System Access section. Researchers are asked to provide this statement to sponsors in lieu of submitting EMR questionnaires to IU Health data security.

Questions about any of these updates can be directed to *Cheryl Yacone*.

Connecting our Clinical Research Community

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

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