Office of Clinical Research Updates

November 2020

OCR Finance Open Office Hours via Zoom

Begins Tuesday December 1st

The Finance group in the Office of Clinical Research is excited to announce that we will be conducting Open Office Hours online every Tuesday beginning December 1st from 3:00 pm - 4:00 pm. These sessions will be hosted by Senior Coverage Analysts Kelly Denney and Eric Borchardt for any clinical research finance inquiries including but not limited to:

- OCR Intake Process
- Coverage Analysis Study Reviews
- Research Billing
- Participant Payments

To add the OCR Finance Open Office Hours to your Outlook Calendar, click on the image below to be routed to the OCR webpage with the calendar link.

OCR Finance Open Office Hours.ics

We look forward to assisting you. If you have any questions, please contact *ocrfin@iu.edu*.

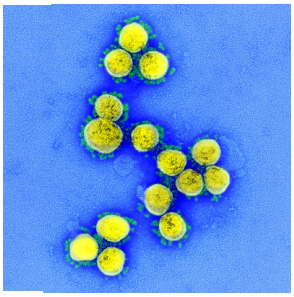
NEW OnCore Billing Process for IU Health Facilities→ Still Time for Training

As noted in our last newsletter, beginning December 1st, all NEW clinical research studies opened in OnCore that contain any billing through IU Health Revenue Cycle Services (RCS) will begin using the OnCore process for research billing notification. For now, existing studies may continue to use the paper Grant Charge Form process (when applicable). Study teams that wish to transition an existing study into the revised process, should email ocrfin@iu.edu.

If you manage Clinical Research studies that use IU Health facilities and services, please be sure you are familiar with this new process and the new requirements for billing account setup, research patient registration, and OnCore subject and visit tracking.

Follow the link below to register for our final planned IU/IU Health OnCore Research Billing Training session before the 12/1 implementation.

Training – Friday, November 20th 1:00 - 2:30 pm



IU School of Medicine Enrolling Volunteers for COVID-19 Vaccine Trial

IU School of Medicine, in partnership with IU Health, is now enrolling volunteers in a late-stage clinical study of an investigational COVID-19 vaccine known as AZD1222. The trial is sponsored by pharmaceutical company AstraZeneca and the University of Oxford. The overall goal is to enroll 30,000 volunteers across several countries. The local study team plans to enroll more than 1,000 volunteers over the next several weeks. The IU School of Medicine site, housed within the Indiana Clinical and Translational Sciences Institute's Clinical Research Center at IU Health University Hospital, is the only site in Indiana for the study. If you have questions or are interested in learning more, email *inhealth@iu.edu.*

How the HRPP & OCR CAT Work Together in Reviewing Clinical Research

By Eric Borchardt, OCR Coverage Analysis Team, and Beth Johnson, Human Subjects Protection Program

Before a clinical research study can begin to accrue subjects, the study must be submitted to a number of offices who complete varying level of reviews and approvals. The HRPP and the Office of Clinical Research Coverage Analysis Team (CAT) review many of the same documents, with a different focus. The HRPP focuses on human subject protections and IRB compliance, where the CAT is focused on clinical research billing and finance compliance.

CAT Process and Responsibilities

When a study is submitted for entry into OnCore (the Clinical Research Management System required by IU since 2016), the CAT receives the information provided and focuses on reviewing the billing plan and financial responsibility language within the budget, contract or award, and informed consent documents.

When reviewing the billing plan and budget, the CAT is responsible for documenting the separation of allowable costs and validating that all procedures planned as billable to the patient/patient insurance are allowable by Medicare standards and regulations. In some cases, this is confirmed by reviewing Medicare National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), national treatment guidelines (NCCN, AHA, etc.) and peer reviewed journals to help determine if the procedure is part of the nationally recognized routine treatment for the condition indicated in the protocol. This review is documented in OnCore under the ‘Coverage Analysis Console,’ inside the Billing Grid, and is used to inform hospital billing in the OnCore Research Billing Process, which expands to all departments beginning December 1, 2020.

The CAT also completes a document alignment review to ensure that the financial responsibility language is consistent across study documents and complies with regulations governing clinical research billing compliance, such as NCD 310.1 and Medicare’s Secondary Payer rules. Financial responsibility language can include the costs of care, subject stipends and reimbursements, and also subject injury language. Since subject injury language should also be addressed within the contract or research agreement, the CAT is also assisted by the Office of Clinical Research Contracts Team, who review the subject injury language within the informed

consent in order to negotiate proper language into the contracts with industry sponsored studies.

It is best to submit for entry into OnCore and start the Coverage Analysis Review as early as possible. Ideally, the CAT reviews should take place with draft documents. Reviewing the draft documents will allow the CAT to provide feedback and direction on how to negotiate the documents, and allow for changes to take place prior to finalizing, and removing the need to amend the documents after approval.

IRB Process and HRPP Responsibilities

Compared to the CAT process, the IRB review process has more breadth but less depth. The IRB's primary role is protection of human subjects. To this end, the IRB reviews risks and benefits, recruitment procedures, consent forms and processes, safety monitoring, and protection for vulnerable populations, among other details. The IRB's review of billing information is limited. The IRB does not review the CAT's determinations regarding who will be billed for clinical procedures conducted during the course of a research study nor does the IRB compare billing information to the budget or the contract. Those responsibilities are managed solely by the CAT. The IRB's role is limited to ensuring the informed consent is clear and understandable regarding what costs the subject may incur as a result of participating in the research.

When an external (non-IU) IRB is used, the study must still be submitted in KC IRB, but typically, the HRPP does not review the consent form. Responsibility for review of the consent form is deferred to the reviewing (external) IRB. In these cases, any request by the CAT to revise language in the consent to align to the coverage analysis, budget, or contract language must be submitted to the external IRB for review and approval. The HRPP is always willing to assist in communications with the external IRB regarding these types of changes.

Summary

While the IRB and CAT provide review and approval based upon different areas of focus and responsibility, these two offices have worked closely to ensure the IU studies meet the highest standard of compliance. While your study is undergoing review by each of these offices, it is important to remember that approvals do need to come from each office prior to a study opening to accrual, and keeping open communication during the reviews will be of the utmost importance to get your study opened in a timely manner.

Connecting our Clinical Research Community

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