Office of Clinical Research Updates

August 2020

PI approval of coverage analysis beginning 9/1

Effective September 1st, the criteria for completing the Research Unit Signoff in OnCore will be expanded—the Principal Investigator (PI) or his or her delegate will need to review and approve the completed Coverage Analysis.

The PI is ultimately responsible for all aspects of a clinical study, including the coverage determinations. These decisions made during the Coverage Analysis (CA) process are used by billing entities (e.g., IU Health Revenue Cycle Services) to allocate charges to third-party payers, including Medicare. As part of the CA process, the Coverage Analysis Team (CAT) communicates questions and decisions through emails or meetings with the study team (as delegates of the PI). These communications are archived by the CAT, and the results of the CA are available to the study team in OnCore. Previously, no formal procedure existed for documenting a PI's approval of the CA prior to their study opening to accrual.

Upon completion of the CA, and along with the OCR Signoff/Account Signoff process, the Coverage Analyst will provide a summary of key outcomes of the CA to the study team for

review by the PI or their delegate. The OnCore system includes a Research Unit Signoff, and completion of this signoff will indicate that the PI (or assigned delegate) has approved the Coverage Analysis.

Please review the updated OnCore Status Workflow guides and direct any questions to *ocrfin@iu.edu*.

OnCore Status Workflows

IU Health research billing

In September 2019, the OCR and IU Health began the pilot phase of a new process to communicate research billing information through OnCore. Fourteen research groups have used this paperless process since then, and we are grateful for their help in working through early phase implementation. Based upon the success we have seen so far, we are implementing the process across all research units, effective December 1, 2020.

So, what does this mean for you?

Beginning 12/1, all NEW studies opened in OnCore that contain any billing through IU Health Revenue Cycle Services (RCS) will use the OnCore process for research billing notification. (Please note, laboratory tests processed through research lab requisition do not generate charges through RCS.)

For these new studies, “IU Health Revenue Cycle Services” management group will be appended in OnCore, and study teams will be required to keep subject and protocol statuses current and track subject visits within 24 hours.

While new studies will open into this process on or after 12/1, the OCR Coverage Analysis Team will work with research teams to transition existing studies with billing through IU Health RCS throughout 2021.

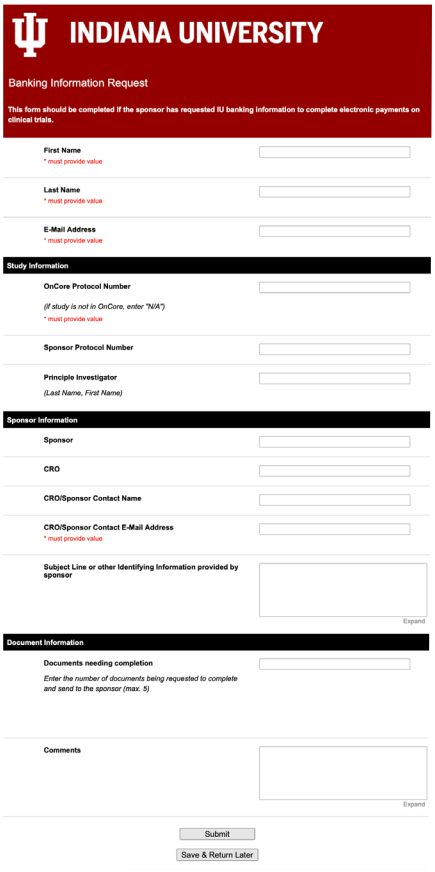
Over the next few months, the OCR will be providing training and resources to help you prepare for the 12/1 change. Questions or comments can be directed to the OCR Coverage Analysis Team at *ocrfin@iu.edu*.

New process for banking information requests

In early 2018, Indiana University Treasury and Accounts Receivable contacted the Office of Clinical Research for help in controlling the way that IU's Bank Account Information was being distributed. These departments had specific examples of Research Staff either providing incorrect information or sending the information in non-secure emails. This created many issues that had to be corrected. To alleviate the problem, the Office of Clinical Research's Finance team was made responsible for sending banking information when it's requested by a sponsor.

The originally implemented process was as follows:

1. Sponsor informed IU staff that a form needed to be completed and sent back to them.
2. IU Employee emailed form to ocrfin@iu.edu to be completed.
3. The OCR Finance Staff completed and sent the form securely to the sponsor.


INDIANA UNIVERSITY

Banking Information Request

This form should be completed if the sponsor has requested IU banking information to complete electronic payments on clinical trials.

First Name
* must provide value

Last Name
* must provide value

E-Mail Address
* must provide value

Study Information

OnCore Protocol Number

(If study is not in OnCore, enter "N/A")
* must provide value

Sponsor Protocol Number

Principle Investigator
(Last Name, First Name)

Sponsor Information

Sponsor

CRO

CRO/Sponsor Contact Name

CRO/Sponsor Contact E-Mail Address
* must provide value

Subject Line or other Identifying Information provided by sponsor

Expand

Document Information

Documents needing completion

Enter the number of documents being requested to complete and send to the sponsor (max. 5)

Comments

Expand

Submit

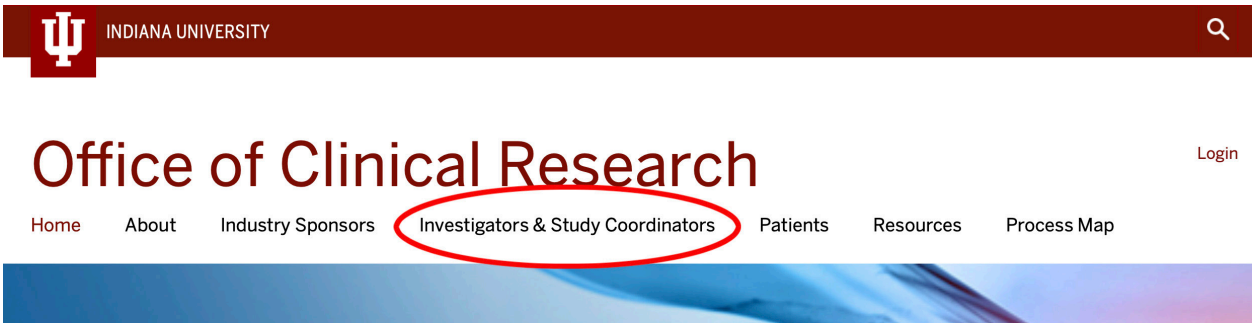
Save & Return Later

These requests often included separate documents requesting specific information about the study, investigator, and IU. Many of these requests did not identify the study, PI, or much of the information needed to properly send this material, which led to a substantial amount of communication back-and-forth between OCR and the Study Team. As you can imagine, this flooded our inbox, increasing the probability that some emails would be accidentally overlooked.

Recently, in an effort to streamline the process, we created a REDCap form that asks all the necessary questions to help ensure that these requests have the correct information and can be sent in a timely manner.

The documents will be completed and sent from Secure email. The person who completes the REDCap submission form will be copied on the communication from the sponsor.

The form is available on the “Investigator & Study Coordinators” page of the *ocr.iu.edu* website: (see below for navigation).



The new form is also directly accessible by clicking on the green button on the right, which matches the button you will see on the Investigators & Study Coordinators web page.

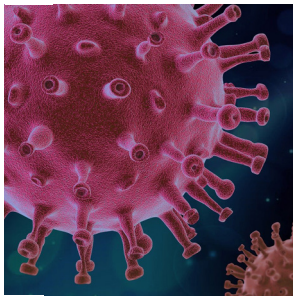
If you have any questions, please contact *ocfin@iu.edu*.

Process update: How do you request a clinical research order set?

The manual request for a clinical research order set has changed to a new standardized electronic format.

To request that an order set be built in Cerner, complete this *REDCap Survey* that asks for details related to the study. The survey can also be found on the Office of Clinical Research website by clicking on the IU Health Clinical Research Information link under the Quick Links section on the home page. Once on the IU Health Clinical Research Information page, you will find the heading IU Health Cerner Research Order Sets and under that will be the link “Request for Cerner Research Order Sets,” which is the REDCap survey. When the document is completed, an email with the study information will be sent to the Clinical Research Analyst to continue the discussion and fact gathering.

Along with this updated process, research order sets will be reviewed for Cerner build approval on an on-demand basis, instead of monthly. This will aid in turnaround and allow for the order set to be active and ready by the time the study starts enrolling.



Indiana Biobank creates COVID-19 repository

The Indiana Biobank, in partnership with IU Health and IU School of Medicine, has created a COVID-19 repository as a resource to researchers who are leading the way in developing diagnostic tools and treatments for COVID-19. The Indiana Biobank's collection protocol allows the collection of de-identified samples, linked to the electronic medical record, which can be distributed for broad research use to approved researchers. The Indiana Biobank's COVID-19 repository has a variety of samples including serum, plasma, RNA, DNA, PBMC, and urine collected from patients during active infection.

At this time, second samples from recovered patients are being sought at the Academic Health Center while samples of COVID positive patients are being collected at IU Health Ball and IU Health Bloomington locations. In addition, through its recovered patient donation program, patients are being sampled during recovery. The Biobank is also asking recovered patients (sampled as inpatients) to come back serially to allow for longitudinal sampling studies. For more information, contact Brooke Patz at *bpatz@iu.edu*.

What metrics tell us about clinical trials

Because of OnCore, there is a single repository of data for all industry-sponsored clinical trials across the system. This common denominator sparked the creation of OCR's analytics program, which gives us a way to measure and evaluate our clinical trial processes. Providing senior leaders with these metrics establishes a clear account of research activities, and is also helpful

information for PIs and study coordinators. The reports either confirm that objectives are being met or identify delays and create the opportunity to introduce possible remedies.

A variety of accrual reports are used to assess the progress of enrollment into interventional clinical trials. These are created and distributed semi-annually, based on the data in OnCore as of January 1st and July 1st.
Key pieces of information in OnCore are essential for creating these accrual reports are part of the required minimum footprint:

- Estimated study duration time: Accrual duration (Months)
- Target accrual (lower): RC Total Accrual Goal (Lower)

Learn more about accrual ratio metrics and report types

Connecting our Clinical Research Community

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