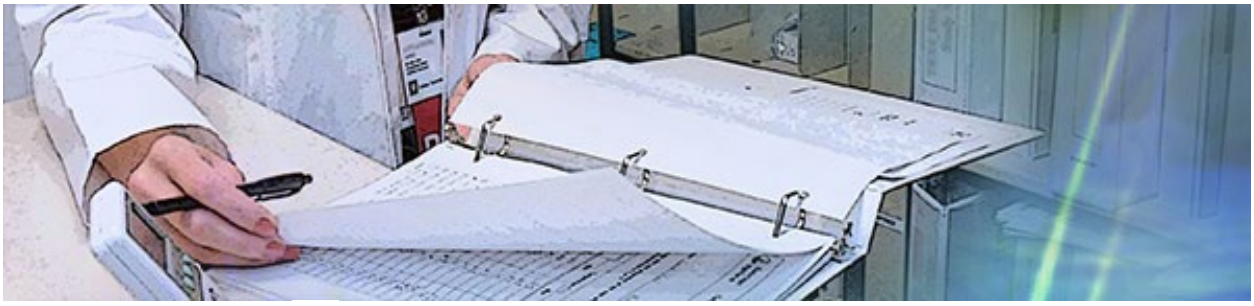
Office of Clinical Research Updates

August 2019



Welcome

OCR was created 5 years ago to provide support services to Indiana University clinical researchers and to make our enterprise more attractive to sponsors. Starting with the Contracts group, which focused on executing contracts with commercial sponsors, the scope of OCR has expanded to include implementing a clinical research management system (OnCore); conducting coverage analyses for research billing; and, adding a clinical research operations group that conducts studies at the IU Health Academic Health Center as well as establishing a network with IU Health regional hospitals.

While OCR has collaborated intensively with many research groups, not all researchers are fully aware of what OCR can offer, and their needs for new services have not been included in OCR's initiatives.

We hope this newsletter will help to better inform our research community of the many initiatives and programs we've undertaken to facilitate your research efforts and enable OCR to serve as a more effective partner to you.

We welcome your feedback and ideas.

Ken Carlson
Director
Office of Clinical Research

Naga Chalasani, MD
Associate Dean for Clinical Research
IU School of Medicine

Need to access IU Health systems?

Changes are here. As of August 15, 2019 we have a new electronic process for requesting research-related access to IU Health systems—including Cerner. Most access requests will be approved with no expiration date except for view only access, which will be granted for the life of the project. This new process replaces existing paper access requests.

All existing users will be contacted between August 15 and December 31 with the request to individually reapply for research access. The access level will be standardized for all research positions and aligned with the Cerner model. While this may result in some changes to the way you view information in the electronic medical record, it does not change the availability of that information.

Additional information concerning access to IU Health systems will be distributed in the form of FAQs and job aids in the near future. Questions can be sent to *IUHealthResearchAccess@iuhealth.org*.

Chart Access for Research Monitors

New electronic processes will also go into effect August 15th for research monitor-related access to IU Health systems.

To help facilitate monitor review of pertinent research information within the electronic medical record (EMR), IU Health will begin using a dynamic patient list created from information in PowerTrials that is already required for both patient safety and compliance. PowerTrials' security configuration allows a view-only monitor workflow that restricts access to only charts of patients enrolled on the protocol to be monitored. These access requests will be granted for the life of the study. Please note that this new

process replaces the existing paper research access requests. Users in existing monitor roles will be transitioned between August 15 and December 31, 2019.

When patient enrollment is tracked using PowerTrials, the Clinical Research: Auditor/ Monitor role minimizes the impact of monitor site visits on ongoing activities. Without PowerTrials, more time intensive preparation and supervision of the visit is required. PowerTrials eliminates the need to manually create and maintain patient lists and also removes the need to constantly supervise the monitor's use of EMR to prevent access to unauthorized patient charts.

If something's wrong and OnCore's down, who ya gonna call?

The OCR Systems Support Team.

We're available to help Monday through Friday from 8 am to 5 pm. We can be contacted by e-mail at *oncore@iu.edu* or by phone at 317-278-2600.

Our team supports OnCore Enterprise Research, Advarra Participant Payments, Supported Integrations (OnCore Cerner PowerTrials, INPCR, and KC IRB), and iConnect.

Learn more about our supported systems

How we can help

Our support services include, but are not limited to, the following:

- **OnCore initial protocol entry:** The first step to managing your study and research subjects. Contact us for any technical issues concerning the *Study Initiation Form*.
- **OnCore calendar builds:** Reflects the protocol schedule of events and supports Coverage Analysis, Research Billing, use of OnCore as an EDC and Biospecimen Management. This includes initial versions as well as updates/amendments.
- **Training for all systems:** Available in classroom settings, eLearning modules or 1:1 assistance. Click *here* for OnCore system access and *here* for Advarra Participant Payments system access and training. *Contact us* for *information and training on iConnect.*
- **Education and Documentation:** We are available for 1:1 consultation or can also work with research groups to explain how our systems can best work for you. We can assist with anything from process creation to end user support. We also provide a multitude of documentation and online resources that can be accessed from the *OCR website*.

- **Reporting and Data Extraction:** OnCore can quickly generate meaningful reports that support decision-making for individuals, administrative leaders, and finance staff. Custom searches provide accrual data and insight into your research study portfolio, while available reports provide data on financials, participant safety, staff workload, and a wide range of other metrics.

Helpful hints from Systems Training & Support

Are you searching for guides that will assist you with OnCore protocol and subject entry?

This *link* will direct you to the OnCore Training & Support page for the following information:

OnCore Training Calendar
Protocol & Subject Managment
Subject and Calendar Visit Tracking
eLearning Modules
Frequently Asked Questions
Minimum Standard Requirements (Footprints)

Please use your IUSOM credentials to sign in to SharePoint when prompted.

Are you looking for OnCore Training and Access?

These classes are currently enrolling: Protocol & Subject Management
Calendar & Subject Visit Tracking

To learn more, go to the *Training & Support page* on the OCR website, or to sign up for training, click *here*.

For any questions or concerns, call us at 317-278-2600 or email us at *oncore@iu.edu*.

Coverage analysts have you covered

A financial review of clinical research studies is mandated by federal policy. Lucky for all of our researchers, the OCR Coverage Analysis Team knows what you need and are enthusiastic about taking on those compliance tasks that some might find burdensome. How great is that?

Our team of analysists are gathered under one roof to provide an efficient, consistent approach to identifying and recording financial accountability. Likewise, tapping into the centralized system of OnCore provides expediency, allowing coverage analysis to be readily available to IU Health Revenue Cycle Services, which in turn improves billing accuracy for patients participating in

Revenue Cycle Services, which in turn improves billing accuracy for patients participating in clinical trials.

The process of coverage analysis is multifaceted and requires a team effort, but the process starts with the research unit. We need your help. If you are the research coordinator, or a designee, please submit accurate, up-to-date information for new studies in the online submission form: *IU Office of Clinical Research Study Initiation Form*

The Power of the Click

Clicking on the submit button at the bottom of the study initiation form initiates a cascade of activities.

What happens after the Study Initiation Form is submitted?

1. ***The Study Record is created.*** The submission is routed to the Calendar Analysts who use the information in the first section of the form to create a study record in OnCore. This record, also referred to as the "OnCore Shell," may be used for effort tracking, pipeline review, and other initial study management tasks within OnCore.

2. ***The Study Calendar is created.*** If coverage analysis is necessary, the Calendar Analysts begin building a study calendar in OnCore.

3. ***The Billing Grid is used to document coverage analysis.*** Coverage analysis is completed within the Coverage Analysis Console, which may be found in the "Financial" drop down from the menu in OnCore. Inside the Coverage Analysis Console, the Billing Grid is used to provide the documentation of the Coverage Analysis. The Billing Grid includes a version of the study calendar that designates each procedure as being billed to the study "R," or billed to the subject "S." Additionally, the Billing Grid includes a comments section, this is where you will find justifications for the procedures designated to be billed to the patient/patient insurance. These justifications come from Medicare National and/or Local Coverage Determinations, National Guidelines (i.e. NCCN, American Heart Association), and Peer Reviewed Journals.

4. ***The Study Documents are aligned.*** Additionally, and of equal importance to the billing grid, is the piece of Coverage Analysis referred to as a Document Alignment. This procedure consists of reviewing the Protocol, Informed Consent, and funding documents (i.e. Sponsor or department Budget, Clinical Trial Agreement, or Grant Approval Document) to ensure consistency of Subject Injury Language and Subject Stipend/Reimbursement.The patient injury language needs to align with Medicare "Payer of Last Resort" rules. Specifically, these documents need to state that either the patient or patient's insurance is responsible for the cost of the procedures if a patient is injured while on the study, or the Study or Study Sponsor is covering all of those costs. An

example of unacceptable language is, “Sponsor will pay for any costs not covered by patient insurance, if injured while on this study.” This language indicates that the sponsor will pay copays and deductibles and this cannot be allowed.

5. ***The study information is reviewed.*** After receiving notice of completion of the coverage analysis, PIs, coordinators, and other members of the research unit are responsible for reviewing the Billing Grid and the communication from the Coverage Analysis team. If there are questions, comments or concerns on the part of the Research Unit, it should be discussed with the Coverage Analysis Team for clarification.

What metrics tell us about clinical trials

For the first time, thanks to enterprise-wide adoption of OnCore as the Clinical Research Management System (CRMS), 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.

The key pieces of information in OnCore that 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

Hitting your stride statewide

Researchers operating within a large research enterprise face a common challenge: How do I find resources to maximize research outcomes, improve efficiency, and increase subject recruitment?

In a nutshell, contact the *Statewide Research Network*.

Our team can help expand your protocol from a single site to a multi-site collaboration among IU Health Hospitals, including IU Health Arnett, Ball, Bloomington, North, Saxony, and West. We can help with any protocol type, whether it is investigator-initiated, sponsored, or a cooperative group trial. We can help whether you are currently in preliminary protocol discussions or if your protocol is currently open to enrollment.

What are the major benefits from opening your trial statewide?

Recruiting from multiple locations will expand your patient demographics and provide a more robust sample. This is particularly helpful if your protocol has restrictive inclusion/ exclusion criteria, or if you require more rare disease groups. Each site in the statewide network has an experienced research team who is intimately familiar with their region's demographics. Working with their coordinators and recruiters can help you target difficult-to-track populations. **By going statewide, you will benefit from collective bargaining and learn how much sponsors have paid other groups for the same procedure**. Negotiating strong budgets to support your operations can be difficult when working with sponsors and funding sources. We have discovered that sponsors might not always pay each group equally for certain procedures or study-related costs. Our budget and financial team will ensure your group will get the maximum reimbursement during negotiations. In addition, working with other sites allows IRB and administrative fees to be split equality, ensuring lowered costs than if operating independently.

Collaborating gives your team new insight into protocol development, best practices, regulatory management, quality, and more. Each site within our Statewide Research Network has an experienced research team that is uniquely equipped to support certain specialties. We host a monthly meeting to exchange ideas, share upcoming protocols, and provide research guidance. The Statewide Research Network focuses on both improving research across the enterprise and ensuring that our patient population has access to new and innovative trials in their own area. Whether you have a protocol ready to open, or if you are just interested in learning more, you are invited to attend!

To learn more about our monthly meetings or for general questions:
Please contact *Ian SerVaas*, Statewide Regulatory Quality Compliance Coordinator.

To learn more about how opening your trials statewide will benefit your protocols or patients, or if you are an investigator interested in joining a study team:
Please contact *Mona Geinosky,* Statewide Research Program Manager.

Connecting our Clinical Research Community

Office of Clinical Research is a program of
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