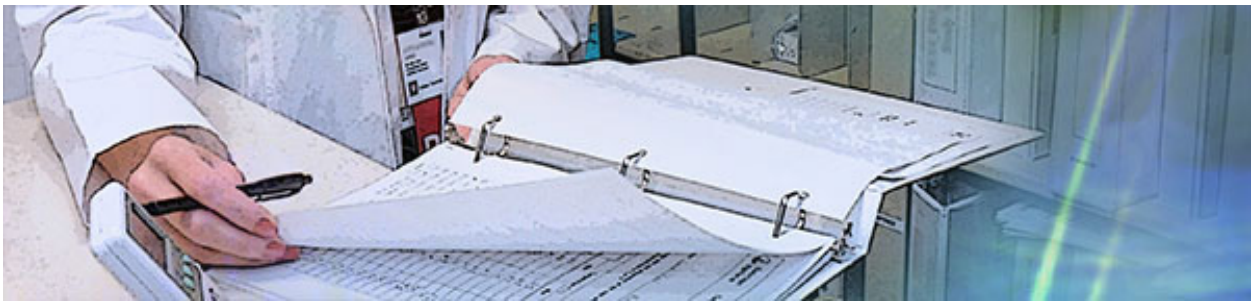
Office of Clinical Research Updates

February 2020



OnCore & KC IRB are in a relationship

The Office of Clinical Research (OCR) and the Office of Research Compliance (ORC) are pleased to announce the launching of a partial integration between OnCore and KC IRB on February 27, 2020.

Why the transition?

Integrating OnCore and KC IRB is the first step in reducing complex and redundant processes between clinical research systems at Indiana University. We will expand the integration as the transition and need arise.

How will this help you?

- **Alleviates the need for duplicate data entry:** Information regarding Initial IRB Approvals, Amendments, Renewals, Reportable Events, and Closeouts will all flow seamlessly from KC IRB into OnCore.
- **Improves efficiency and productivity:** Data is transferred automatically and in real-time allowing research staff to focus their attention elsewhere.
- **Reduces data entry errors:** IRB review information is provided from the source and is more consistent between clinical research systems.
- **Improves data accessibility and communication:** Allows clinical research staff and services to access IRB data without the need for extraneous e-mails or phone calls.

What if you have questions?

We will be sending updates and information regarding documentation and webinars as we approach February 27, 2020.

If you have questions or encounter issues that require assistance from the Office of Clinical Research, please notify the OCR Research Systems Support Team.

E-mail: *oncore@iu.edu*
Phone: 317-278-2600

Be sure to use the updated IU Health Revenue Cycle forms

IU Health Revenue Cycle has updated 2 forms to remove an inactive email address. Both **"Research Billing Packet Form 3: Research Supplies, Implants, and IDE"** and **"Investigational Device Coverage (Time of Service)"** have new email links for form submissions. The updated versions are posted *here* on our OCR website. Please download and begin using them immediately.

Please note that completed forms should be sent to *clinicaltrials@iuhealth.org* and *chargehelp@iuhealth.org*. Emails sent to the previous IDENotification email address will NOT be received.

Does standard of care = routine care

In the world of Clinical Research Billing Compliance, coverage analysis is a systematic review of the planned events in a research protocol to determine whether the items or services required in the protocol are billable to the Centers for Medicare and Medicaid Services (CMS). The first step is to make sure that the study itself qualifies. If it does, then we review each procedure, item, or service within the protocol to determine whether these costs are only required for research purposes or whether they are routine costs.

Wait. You mean routine care, right? Also known as standard of care? No, not exactly.

Standard of care is actually a legal term used to define the degree of care (watchfulness, attention, caution, and prudence) that a reasonable person should exercise under a given set of circumstances *(Cornell Law School, 2020)*. This term, also called best practice, standard medical care, or standard therapy, is widely used in discussions regarding the typical course of treatment for a particular diagnosis or patient population.

Although the terms standard of care and routine care are often used interchangeably, they are not entirely synonymous when used in the context of a coverage analysis review. We are specifically looking to see that these procedures, items or services meet the CMS definition of routine costs as defined in *Medicare's Clinical Trial Policy NCD 310.1.*

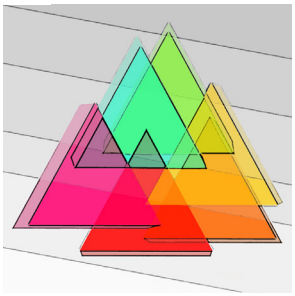
Routine costs include conventional care—procedures, items or services that are typically provided absent the trial. However, they also include the following:

- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.

Additionally, CMS provides some general exclusions to routine costs:

- The investigational item or service itself, unless otherwise covered outside the clinical trial.
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan).
- Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

A coverage analysis review does not determine whether any given procedure or treatment is the appropriate course of care, nor whether it would be covered by CMS or other 3rd-party payers if done as part of a patient's clinical care. Our review ensures compliant billing by confirming that claims for these services, when done in the context of a research study, will meet the requirements set forth by CMS.



Is your research trial exceeding expectations?

To help research teams assess the performance of their trials, the OCR provides semi-annual accrual reports. The accrual ratios provided in these reports are based on the Common Metrics Initiative—part of the Clinical Translational Science Award (CTSA) Program that standardizes the way efficiency is measured. These accrual ratios provide the ability to measure the progress of individual trials as well as performance across the entire enterprise.

The Accrual Ratio metric is calculated using the accrual goal for the study (RC Total Accrual Goal, lower) and the estimated study duration (Accrual Duration, months) in OnCore, which is then converted into a percentage. The interpretation of the metric is straightforward.

Ratio	Interpretation
close to 100	Study is accruing patients at expected rate & is aligned with projected time to complete enrollment
> 100	Accrual is faster than anticipated
< 100	Accrual is slower than anticipated

Key pieces of information, which are all part of the required minimum footprint in OnCore, are essential to create the accrual reports and calculate the Accrual Ratio. Proper accrual ratios rely on these data points:

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

Learn more about accrual ratio metrics and report types

Boost your study recruitment

Meeting research recruitment targets can be a challenge, but through the Indiana Clinical and Translational Science Institute, IU has made that easier by maintaining a volunteer registry. Currently, about 9,000 full and partial individual profiles populate the *ALL IN for Health volunteer registry*. Community members who have expressed a willingness to be contacted (and participate) in research projects for which they may be eligible have given their informed consent and entered their individual health information into the registry.

Researchers can request that the CTSI query the registry for those individuals who are eligible for their studies. The current listing has 500 studies open for recruitment to the public. People who are interested in participating in research can review the categorized studies to find one that interests them and contact the study team. The online platform that streamlines the study recruitment process is called iConnect.

With iConnect, prospective participants can

- Access a centralized up-to-date portal to learn about and match with ongoing studies at IU and IU Health
- Self-screen to determine if they pre-qualify for studies
- Communicate with study teams directly
- Sign up to receive alerts for future studies
- Engage in educational online presentations that showcase our clinical research enterprise

iConnect enables researchers to

- Create participant-friendly study pages
- Setup and manage recruitment campaigns for a variety of outreach tactics like flyers or online ads
- Filter out false leads using pre-screeners
- Communicate with prospective participants
- Track referrals using an automated tracker
- Measure ROI across different outreach channels using trackable phone numbers, links and emails
- Query for matching prospective participants in the volunteer registry

Training to maximize your team's study information page is easy. Please contact *Keier Dante* for assistance. Querying the volunteer database for individuals who may be eligible can be done by email: *ctsirro@iu.edu.*

You've asked, we've answered: A new subscribe button

Subscribe to OCR newsletter

For our friends in the research community who have not been receiving our OCR newsletter but who have been wanting to know how to subscribe, we have an easy solution. We now have a subscribe button on the OCR website! Look for it on the *OCR homepage*.

Question or topic for the OCR newsletter?

Don't be shy. Maybe you have an idea for a training module. Maybe you have a burning question about OnCore but haven't gotten around to asking anyone about it yet. Maybe you just want to know more about a clinical research topic. Maybe you have an upcoming research-related event to publicize. Or maybe you yourself have a wealth of information that you want to share with the clinical research community.

We're here for you!

Send your topic requests, questions, event announcements, short articles, or other newsletter items to *clinresearchops@iuhealth.org*, and we'll be in touch!

Connecting our Clinical Research Community

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