School of Medicine

Clinical Research

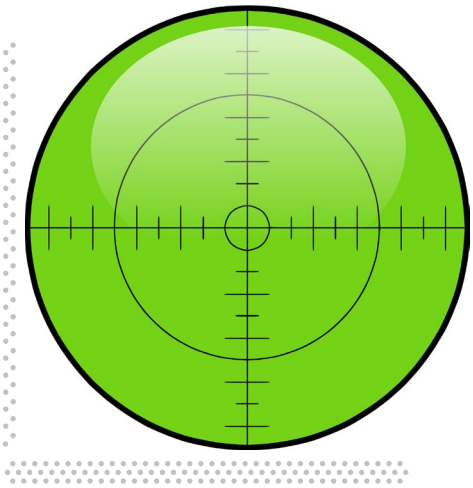
OFFICE OF CLINICAL RESEARCH

May 2025

IMPORTANT

Effective immediately, OCR Contracts now requires a fully executed Confidentiality Agreement (CDA) to accompany all new Clinical Trial Agreement (CTA) submissions. Principal investigators should not be engaged in study-related discussions with third parties unless a CDA is in place. CDA templates can be found *here* on the OCR Contracts page. PIs are not authorized to sign any confidentiality agreements prior to review and negotiation by the appropriate contracting office.

If a CTA is submitted without a fully executed CDA, the submitter will be notified and given one business day to provide the document. If the CDA is not received within that timeframe, or does not exist, the submission will be rejected and must be resubmitted once all necessary documentation is available.



Clinical Study Activation Alignment

Currently, the processes for activating clinical studies through the Office of Clinical Research (OCR) are not optimized or aligned with those of IU Health or the broader IU system. As a result, the OCR has begun the “Clinical Study Activation Alignment” project, which uses Lean Six Sigma methodology. This project is focused on implementing best practices to

- Decrease the time it takes to activate a study
- Maximize communications and activation status transparency
- Substantially reduce duplication and repetition that currently exists in study intake submission and material expedition

The OCR will track processing times for a group of 10 prioritized clinical studies, known as the “Cohort of 10,” to seek out areas of the activation process in need of optimization. Opportunities for improvement include a single, common OCR intake form, an activation status dashboard, enhanced communications, sponsor guidelines, document version control capability, and a standardized workflow.

The outcome of the project could be a basis for a change in OCR processes. For instance, Kelly Denney’s financial compliance team is developing a mechanism to track and report on the Cohort of 10, allowing Denney to seamlessly pull data on the status of each study in the activation process rather than manually check on each individual study, which saves time in the overall process.

For both investigators and the OCR, the project aims to simplify the study activation process.

Cohort of 10

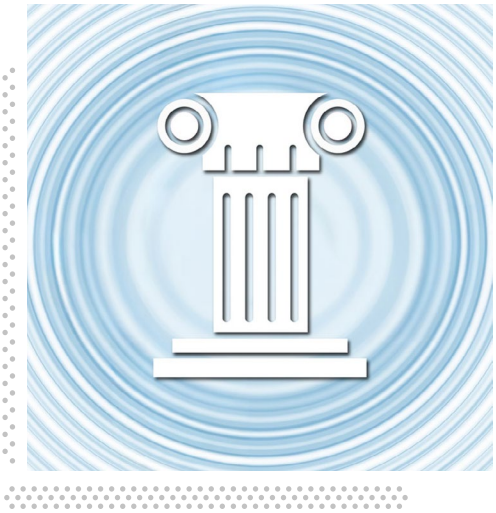
Preparing for and supporting implementation of the Cohort of 10 prioritized clinical studies is of the utmost importance for the OCR.

Establishing the Cohort of 10 not only indicates research priorities but also aims to optimize the processes of clinical research operations at the Office for Research Administration, the OCR, study teams, and all supporting functions.

This Cohort of 10 ties into the Activation Alignment Project, described above. The selected studies' progress through the activation process will be monitored and metrics will be assembled to identify and ultimately eliminate barriers to study activation and to optimize the overall support of the clinical study portfolio.

For these reasons, the groups and functions that support the clinical research operations are expected to prepare for and support implementation of the Cohort of 10 at a highly effective level.

Ensuring that the processes that support execution of the Cohort of 10 are conducted in an efficient, streamlined manner is vital for study progress.



New Hospital Space Pillar

A Clinical Research workgroup has been established to define detailed space options for clinical research at the new hospital.

The goal of the pillar is to ensure adequate preparation for the inclusion of clinical research in the operational design of the new hospital. The work of the pillar workgroup also enables the 10-year enterprise clinical research goal of reaching 6% of IU Health patients consenting to a clinical study.

Ultimately, this is an IU Health hospital goal that ties into the IU School of Medicine's tripartite mission of clinical care, education, and research. The new hospital and clinics will support our research efforts for inpatient and outpatient participation in clinical studies. Clinical research considerations for the new hospital include on-site monitors, clinical research staff, equipment storage, and biospecimen sample processing space.

Among the workgroup's priorities are identifying clinical research space and infrastructure requirements and integrating patient-facing systems for inpatient and outpatient flexible platforms of care to increase synergy.

Additional key focus areas in the pillar include resolving the plan for patient and sample transportation and refreshing the CRC strategic plan.

The group is currently focused on clarifying unplaced programs, developing draft plans (including a financial plan) by the end of June for these programs. The unplaced program plan recommendations will be submitted to a formal IU Health review process by the end of August 2025.

Detailed clinical research operations planning, in the context of the Flexible Platform of Care paradigm, will begin in September (approximately).

Changes to the Advarra Suite of Applications

Advarra eClinical applications (eReg, eSource + EDC, and EVAL) are now enabled with Advarra Single Sign-On (SSO) for user authentication. Advarra's single sign-on (SSO) capabilities for user authentication allow users to access SSO-enabled Advarra products in one place using just one set of credentials.

After logging in with Advarra SSO, you will see the Advarra One homepage containing tiles for your SSO-enabled Advarra applications. You can then click an application's tile to access it. Note that there is a separate tile for each application instance. If you have access to a prod and a staging/test instance, you will see two tiles. Production and non-production tiles are separated by a filter at the top of the Advarra One homepage.

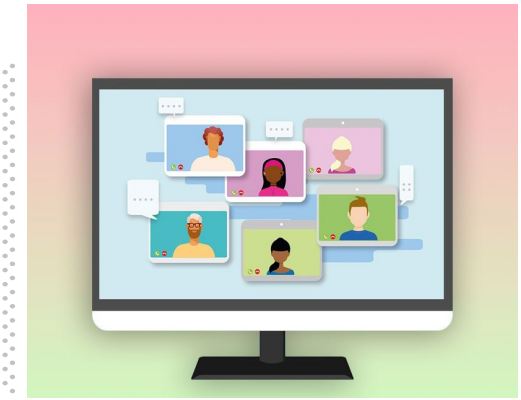
What do I need to do?

In the next few weeks, you will receive an email invitation from no-reply@advarracloud.com. After you receive the email invitation, you can complete your one-time Advarra SSO account setup. After successfully registering, you will login to the Advarra eClinical applications using your IU/IU Health credentials.

If you are logging in via Advarra SSO currently, then you will receive an email from no-reply@advarracloud.com informing you have access to another tile. No action is needed.

What resources are available if I need help?

In the Learning Portal on the Advarra SSO page, you can find step-by-step instructions for setting up your Advarra SSO account. You can also refer to the SSO Help Center, linked on the Advarra One login page, for additional support.



May 1 Community Call

Introducing the new OCR Clinical Research Roadmap

On the May 1st OCR Community Call, we introduced the new OCR Clinical Research Roadmap. As seen below, the roadmap is a tool to guide IU and IU Health research teams through the steps required to activate clinical research studies in the IU Health System.

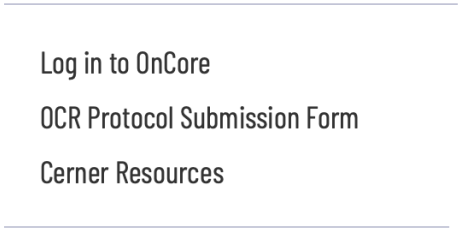
This *roadmap* can be accessed by clicking the Getting Started button located on the top left of the OCR Homepage:

The slides and a recording of the call are available on the *OCR Community Call archive* page.

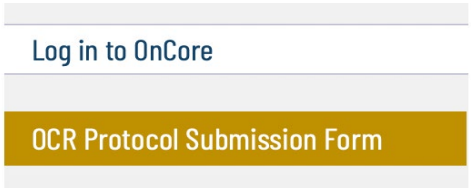
Once you have had a chance to review the tiles and try out the roadmap a bit, we would greatly appreciate your feedback, which can be submitted *here* or through the Feedback button at the top of the roadmap page. Your input will help us to further refine the content and format to meet the needs of the research community.

Already, we have incorporated feedback that requested a more visible link to submit a new or amended protocol to the OCR. You will now find links to the "*OCR Protocol Submission Form*" to submit your study to the OCR for OnCore entry and financial compliance review in the following new locations:

In the side bar, on the OCR homepage



- In the side bar, on the OCR homepage



- And on the Complete OCR Protocol Submission page

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