Indiana University
Office of Clinical Research

Revised Clinical Study Activation Process

A Quick Start Guide for Study Teams

Bottom line

Submit earlier. Submit completely. Activate more efficiently.

The Office of Clinical Research is revising the clinical study activation process to make startup more coordinated, transparent, and efficient. This guide outlines what study teams need to prepare and what to expect when submitting through the OCR Study Activation Portal. The new intake form will be available beginning August 1.

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Submit earlier	**Submit completely**	**Activate more efficiently**
Submit to OCR as soon as the required study information and documents are ready—do not wait for other approvals to be completed.	You may save your progress and return to the OCR Study Activation Portal before final submission. Please submit only when the survey has been carefully reviewed and completed.	Respond to follow-up, task list items, and kickoff meeting requests promptly.

Who should use this guide?

This guide applies to clinical research studies that meet the OnCore entry requirements and must be submitted to the Office of Clinical Research.

What is changing?

Study teams will use one OCR Study Activation Portal for new study submissions, amendments, and other OCR submission types.

The updated process is designed to:

- Reduce incomplete submissions.
- Minimize duplicate requests for information.
- Improve coordination across review groups.
- Help study teams understand where their study is in the activation process.
- Support earlier planning for billing, ancillary services, or other startup needs

What is staying the same:

- Existing regulatory, contracting, budget, compliance, IRB, and institutional requirements still apply.
- Studies must still receive all required approvals before activation or enrollment.
- Required reviews are not being removed; the process is being coordinated earlier

This is more than a form change.

Study teams will be asked to gather key information and documents earlier so the appropriate reviews and services can begin with fewer delays.

Before you submit: Study Startup Sequence

1. Complete OCR Contracting CDA review, if applicable.
2. Conduct internal feasibility discussions.
3. Collect sponsor documents and required study materials.
4. Obtain an IU IRB number in Kuali Protocols.
5. Route any funding agreement, draft clinical trial agreement, or draft budget, if applicable.
6. Note the associated IPID or Proposal Development Document number.
7. Gather all required documents and study information.
8. Submit the study through the OCR Study Activation Portal.

Gather these items before starting the portal submission.

To avoid delays, study teams should gather applicable documents and information before beginning the intake form. The intake form may ask different questions depending on the study type and services needed.

Commonly required documents and identifiers

- ***Protocol*** (***required***)
- ***Draft Informed consent form (required)***
- ***IU IRB number (required)***
- IPID or Proposal Development Document number (required if externally funded)
- Draft budget, if not included in KC Proposal routing
- Investigator brochure, pharmacy manual, lab manual, imaging manual, or other study manuals, if applicable

Information to have ready.

- Planned study locations and services
- Investigational drugs or devices
- Billing, participant cost, and sponsor-paid service details
- Ancillary service needs, such as CRC services, IDS, ORI, or IU Health device and supply charge code requests
- Primary contacts for regulatory, budget, contract, and study team follow-up

Consult Key Stakeholders

Complete the OCR Study Activation Portal Submission only when required information and documents are ready. This may require input from various stakeholders.

All OnCore studies must be submitted through the OCR Study Activation Portal, which supports new studies, amendments, some CTO-managed studies, and other OCR-supported submissions. Study teams may save their progress and return later but should submit only when required information and documents are ready.

Answer research billing questions carefully.

The portal includes questions that help determine whether Financial Compliance review is needed. Study teams should answer carefully and accurately, as responses guide routing and identify whether additional review, coverage analysis, or billing support is required.

Important

Studies without protocol-related billable items or services through an affiliated health system may not require full Financial Compliance review. In those cases, the study team and contract officer must ensure the informed consent form, clinical trial agreement, and budget align on participant costs, subject compensation, and research-related injury language.

What happens after submission?

After the study is submitted, OCR and participating review groups will use the information provided to begin applicable activation activities.

Depending on the Submission, this may include:	Study teams may be asked to:
• OnCore registration • Coverage analysis review • OnCore Calendar Build • Ancillary service coordination • IU Health service coordination • Study document review. • Activation tracking	• Provide clarifications. • Provide additional documentation. • Participate in a study kickoff meeting • Confirm budget readiness or financial build information when assigned • Respond promptly to follow-up requests

OnCore task lists and study team signoff

OnCore task lists may be used to track key activation milestones and provide visibility into study startup progress. Prompt completion of assigned study team tasks helps reduce activation delays.

Study team action is limited and specific.
Study teams may be asked to complete two assigned task list items, when applicable: Budget Ready for Final Review and Financials Console Build Complete. Other task list items may be visible for OCR or partner team tracking and may not require study team action.

Study kickoff meetings and Activation Project Managers

Studies requiring Financial Compliance review will be assigned to an Activation Project Manager. The Activation Project Manager coordinates selected studies by tracking key milestones, organizing startup support, and connecting the study team with OCR and partner review groups. They work closely with the study team to keep activation moving by identifying barriers, supporting communication, and following up on outstanding items.

For these studies, a kickoff meeting will be scheduled early in activation to align the study team and partners, identify barriers, clarify needed documents or services, and support more efficient startup planning. Study teams should be prepared to discuss logistics, billing considerations, ancillary service needs, budget questions, and known startup concerns.

Before you submit: review and attest.

Before submitting, complete a final review and attest that the submission is accurate, complete, and ready for OCR review. Complete and accurate submissions help reduce delays.

Where to get help

OCR will provide training materials and supporting documentation on its website. Questions may be directed to the OCR Financial Compliance Team at ocrfin@iu.edu.