FAQ: OCR Clinical Study Activation Workflow

For clinical research coordinators, study teams, budget contacts, regulatory staff, and others involved in study startup and activation.

How to use this guide: Use the table of contents or search keywords such as activation, intake form, OnCore, IRB number, billing, coverage analysis, budget, ancillary services, kickoff meeting, amendments, or expanded access to quickly find related questions.

Purpose and Process Summary

The Office of Clinical Research revised the Clinical Study Activation Process effective August 1, 2026, to reduce incomplete submissions, minimize duplicate requests, improve activation visibility, and move key reviews earlier in startup.

1. Before Submission: Understand the Process

Why is the clinical study activation process being revised?

The revised process identifies key reviews, documents, system identifiers, and ancillary service needs earlier to reduce activation delays and improve coordination across OCR, IU Health, ancillary services, and other review groups.

When does the revised process begin?

The revised process begins August 1, 2026.

Which studies are affected by the revised process?

This workflow applies to studies that meet OnCore registration requirements or require OCR or IU Health review, including new submissions, amendments, expanded access protocols, and non-routed legal agreements such as CDAs or other industry legal documents.

What is not changing about the process?

Required IRB, contract, financial compliance, ancillary, regulatory, and institutional reviews remain in place. Studies must receive all required approvals before activation and enrollment.

What is changing?

Study teams will use the OCR Study Activation Portal as the single-entry point for applicable submissions. Key changes include:

- The portal will accept additional OCR non-routed legal agreements, including CDAs.
- The prior Form 1/Form 2 model is replaced by one more complete intake form.
- A required study startup sequence has been established.
- More complete information is required earlier in the process.
- CRC service requests and IU Health device supply research charge code requests are incorporated into intake.
- Research billing questions will help determine whether financial compliance review is required.
- When financial compliance review is not required, study teams, contract officers, and the IRB own CTA, ICF, budget, and related language alignment.
- Budget contacts may need to participate in OCR OnCore task lists when financial compliance review and budget alignment are required.

2. Before Submission: Prepare the Study

What should I complete before submitting a new clinical study?

Before submitting your new study through the revised OCR intake form, complete the following as applicable:

- Obtain a completed CDA.

- Complete internal feasibility review and decision to move forward.
- Collect current sponsor documents and study materials.
- Obtain an IU IRB number generated in Kuali Protocols (This does not require submission to the IRB at this timepoint.)
- Route draft funding agreements, including the draft CTA and budget in KC Grants, when applicable.
- Gather required documents and study information for the submission form, including:
    - Draft budget (if not included in routing), final protocol, and draft consent documents.
    - Planned locations, services, recruitment goals, investigational drugs or devices, IND/IDE numbers, billing expectations, participant costs, and sponsor-paid services.
    - Ancillary service needs, including CRC, IDS, ORI, SRC, IU Health device and supply charge code implications.
    - Primary contacts for regulatory, budget, contract, recruitment, and general study follow-up.
    - Input from the PI, budget contact, contract officer, regulatory staff, and applicable health system or ancillary partners.

Once these items are confirmed, complete the OCR study submission through the revised intake form.

What documents should I gather before starting the portal submission?

Commonly needed documents include:

- Protocol
- Informed consent form
- Draft clinical trial agreement or other funding agreement, if applicable
- Draft sponsor or internal budget, as applicable, if not included in proposal routing
- Investigator brochure, if applicable
- Pharmacy manual, if applicable
- Lab manual, if applicable
- Imaging manual, if applicable
- Device manual, if applicable
- Other sponsor manuals or study-specific documents, if applicable

The specific documents needed may vary by study type and required services.
OCR may request additional materials later, such as investigator brochures, manuals, FDA letters, or CMS approval letters, and may require them before review or signoff is complete.

Why is an IU IRB number required before OCR submission?

The IU IRB number provides a consistent study identifier that can be entered into OnCore early. This supports integration between Kuali Protocols and OnCore, improves study tracking, and helps OCR connect records across systems for activation status, metrics, and reporting.

Does obtaining the IU IRB number mean the IRB submission must be complete?

No. The study team only needs to generate the IU IRB number by completing a few initial fields. The full IRB submission can be completed later when the team has all materials needed for submission.

Why should draft funding agreements be routed before submitting the OCR intake form?

Early routing helps OCR and related reviewers align contract, budget, consent, coverage analysis, and activation requirements before documents are finalized, reducing later amendments or rework.

Should routing begin with draft or incomplete budget and contract information, or should OCR submission wait until the budget is final?

For externally funded studies, route the draft CTA and budget before OCR portal submission so routing identifiers are available. Budget negotiations may continue, but the budget and contract should not be finalized until aligned with coverage analysis findings, when applicable. If required, discuss concerns during activation and notify Financial Compliance when the budget is ready for final review.

After submission, OCR will notify the study team whether coverage analysis is required. If not, the team may finalize the budget and contract without further Financial Compliance review.

3. During Submission: Complete the Intake Form

What submission types are included in the revised intake form?

- Non-routed industry legal agreements, including CDAs, master agreements, and other Industry Legal Agreement not requiring a KC routing.
- New study submissions for OnCore entry and applicable OCR, IU Health, ancillary services, and other reviews.
- Amended study documents when OCR notification or review is needed.
- Expanded access protocols for OnCore entry, with legal agreements emailed directly to OCR contracts at ocr@iu.edu.

Can the intake form be paused and completed later?

Yes. Teams may pause and return to the form while they wait for additional documents or identifiers, or while consulting with other stakeholders.

To save a REDCap survey and return later:

1. Click **“Save & Return Later”** at the bottom of the survey.
2. A pop-up window will display the **return code**.
3. Copy or save the **return code** provided.

How can I return to the form once I have saved to complete later?

To return to a saved REDCap survey:

1. Open the original OCR Study Activation Portal link.
2. Select **“Returning?”** in the top right corner.

3. Enter the **return code** you received when you saved the survey.
4. Continue where you left off.

What happens if my submission is incomplete?

OCR or a participating review group may request missing information, clarification, or documents. Submissions with placeholder documents or identifiers may be returned to the study team for corrections.

What should I include in the Additional Notes/Comments section at the bottom of the form?

Although not required, this field can be used to communicate any additional relevant information to the OCR.

What does the attestation at the end of the intake form mean?

The attestation confirms the submitter completed due diligence, consulted appropriate stakeholders, and provided accurate information to the best of their knowledge. Incomplete, placeholder, or clearly inaccurate submissions may be returned.

4. During Submission: Identify Ancillary Services and Partner Reviews

Why does the portal ask about ancillary services?

The portal identifies ancillary service needs earlier so the appropriate groups can be notified, duplicate requests reduced, and operational issues addressed before activation. Responses may support OCR coverage analysis and research billing review, CRC notification and review, or early notification to IDS, ORI, and CTSL when their services may be needed.

Will I still need to submit separate requests to ancillary groups?

Separate submissions are no longer required for CRC or IU Health research device/supply charge code requests. Other ancillary service requirements may vary, so follow the portal instructions and any follow-up guidance. The portal submission does not replace the existing IDS, ORI, or CTSL service request processes.

Where do the IU Health External Data Sharing Subcommittee, IT Risk Assessment and AI/ML Committee reviews fit into the activation timeline?

IU Health Office of Research Compliance and Acceleration (ORCA) has begun reviewing IRB submissions for potential External Data Sharing Subcommittee, IT Risk Assessment or AI/ML Committee review needs outside of the OCR intake process. The OCR intake form includes questions that may help notify ORCA or flag these reviews if not already identified.

5. After Submission: Review, Follow-Up, and Activation Activities

What happens after I submit through the portal?

After submission, OCR and participating review groups use the information collected in the more robust intake form to determine which activation activities apply. Depending on the submission type, study requirements, and services involved, this may include OnCore registration, financial compliance or coverage analysis review, legal document review, ancillary or IU Health service coordination, kickoff meeting scheduling, or additional follow-up.

How will I know what I need to do after submission?

Study teams may receive follow-up questions, task list items, meeting requests, or instructions from OCR or partner groups. Monitor communications and respond promptly.

What can delay activation after submission?

- Missing or outdated documents.
- Incomplete portal responses.
- Incorrect billing-related responses.
- Inconsistent CTA, budget, or ICF language.
- Failure to enter external IRB approvals in OnCore.
- Delayed responses to follow-up questions or task list items.

6. After Submission: Financial Compliance, Billing, and Budget Alignment

How will the revised intake form determine whether financial compliance review is needed?

The form asks whether the study will use affiliated health system facilities, equipment, personnel, or services for protocol-related activities that may generate charges. A “Yes” response to either question indicates that Financial Compliance review is needed. Study teams should answer carefully and contact IU Health or Eskenazi Health if they are unsure.

What are the key research billing questions study teams should be prepared to answer?

- Will protocol-related items, procedures, or services be ordered or performed in an affiliated health system facility that generates charges to the study, participant, or participant insurance?
- Will affiliated health system equipment or personnel be used to perform protocol-required activities?

What should a study team do if they are unsure how to answer the billing questions?

Consult the appropriate health system or ancillary service contacts before submitting. For IU Health or Eskenazi questions, seek guidance from the relevant clinical trial or research contact before attesting.

My study is all standard of care; does it require financial compliance review?

Yes. If the protocol requires specific procedures to be performed at specific timepoints, those services are still considered protocol-related, even when they are part of the participant's routine care and billed to the patient or insurance. Financial Compliance review is needed to determine whether research billing codes or modifiers are required and to support compliant billing.

Will financial compliance review document alignment for every study?

No. Financial Compliance aligns documents only when full coverage analysis is required. When coverage analysis or research billing setup is not required, the study team, contract officer, and IRB remain responsible for aligning financial language across the CTA, ICF, budget, and related documents.

When does the budget contact need to participate in OCR task lists?

The budget contact participates in OCR task list when a study has a budget and requires financial compliance review. As applicable, only the budget contact should use the OCR task list to indicate that the budget is ready for final review and that OnCore Financials setup is complete.

Can budget negotiations begin before coverage analysis is complete?

Yes. Budget negotiations may begin, but the budget should not be finalized until alignment with coverage analysis findings and financial compliance requirements is confirmed.

What does OCR review when looking at the budget?

OCR reviews financial compliance alignment, not financial sustainability, or negotiated adequacy. The review focuses on whether the budget aligns with the coverage analysis, consent form, and billing plan.

What does CTA, budget, and ICF consistency mean?

CTA, budget, and ICF consistency means these documents align on key financial and participant-facing terms, including participant costs, sponsor-paid services, subject compensation, and research-related injury language.

7. After Submission: Study Kickoff Meetings

What is a study kickoff meeting?

A study kickoff meeting will be scheduled early for studies requiring financial compliance review to align startup partners, identify barriers, clarify documents or services, and support efficient activation planning.

Which studies will have a study kickoff meeting?

Study kickoff meetings will be scheduled for studies requiring OCR financial compliance review. A simplified calendar review meeting may be scheduled when a calendar is requested for studies that do not require Financial Compliance review.

Who should attend the study kickoff meeting?

Attendees may include any members of the study team, including study coordinators, budget, and regulatory contacts, as well as internal OCR team members such as the CRMS Project Specialist, Coverage Analyst, and Activation Project Manager.

Does the PI need to attend the study kickoff meeting?

The Principal Investigator may attend the study kickoff meeting but will be invited only if listed as the Study Site Contact on the OCR Protocol Activation submission or if the study team requests their participation.

8. After Submission: Activation Project Management and OnCore Tasks

What is the role of the Activation Project Manager?

For studies requiring financial compliance review by the OCR, the Activation Project Manager helps to identify activation requirements, tracks milestones, supports communication, identifies barriers, and leads an earlier kickoff meeting. They also serve as subject matter experts for research billing compliance, providing the final review and approval of the coverage analysis and research billing setup.

Does the Activation Project Manager replace the study coordinator?

No. The study team remains responsible for study-specific decisions, document preparation, sponsor communication, and responding to activation-related questions or tasks.

What are OnCore task lists?

OnCore task lists track activation milestones and required study team actions, improving visibility and coordination across OCR, partner teams, and study teams.

9. Special Submission Types: Amendments and Expanded Access

Do all amendments need to be submitted to OCR?

No. Submit amendments through the intake form when they affect the OnCore calendar, coverage analysis, billing review, OnCore Financials, budget alignment, or ancillary service notification.

Will every amendment require the same level of review?

No. Review level depends on the amendment type and whether it affects billing, budget, contract, OnCore, ancillary services, or other activation elements.

How do I know whether an amendment needs to be routed, submitted, or both?

Route CTA amendments through KC Grants when they increase the overall budget or change the Principal Investigator; submit through the OCR Study Activation Portal when they affect the study calendar, OnCore Financials, coverage analysis or billing, ancillary review notification,

OCR Contracts or Financial Compliance review, or study record updates. Some amendments may require both.

What amendment-related questions should teams expect?

- Does the amendment change the schedule of events in a way that affects the OnCore calendar?
- Does the amendment change the budget in a way that could affect OnCore Financials or coverage analysis?
- Does the protocol change require billing re-review?
- Do ancillary services such as CRC, IDS, ORI, or others need to be notified?

How should expanded access protocol agreements be managed?

Submit expanded access protocols through the intake form for OnCore entry. Email related legal agreements directly to OCR contracts at ocr@iu.edu because these agreements are time sensitive.

10. Help and Additional Guidance

Where can I find more guidance?

Study teams should use the most current OCR training materials, portal instructions, quick start guides, checklists, amendment guidance, and website resources.

Who should I contact with questions?

Questions about OCR Activation Alignment and revised OCR Study Activation Portal should be directed to ocrfin@iu.edu.

What is the most important thing study teams can do to avoid delays?

Prepare earlier, submit completely, and respond promptly to follow-up requests.