Today's call will be recorded, and a copy of the slides and other materials referenced will be emailed to all who attended.

Microphones have been disabled. If you have questions during the presentation portion, please place them in the chat which will be monitored.

During our Q&A session at the end of the call, please raise your hand if you would like to ask a question.

Revised Clinical Study Activation Process

A clearer path through study startup

Kelly Denney, CCRP
Director of Financial Operations, OCR

July 2026

Revised Process Begins August 1

Submit earlier.
Submit completely.
Activate more efficiently.

Why are these changes necessary?

- Activating a clinical research study is complex, requiring close collaboration across IU and IU Health offices — IRB, contracts, budgets, billing, ancillary services, and study teams. Reviews can often happen in parallel but require careful coordination to ensure alignment before documents are finalized.
- Startup often involves duplicate requests, separate follow-ups, and late discovery of review needs.
- The revised process aims to eliminate duplication where feasible and collects critical information earlier so that the OCR and other reviewers can get to work sooner.
- Our goal is to clear the path, leading to fewer incomplete submissions, better coordination, and clearer activation status.

Improving Activation Coordination

We are improving activation coordination so studies can move through startup with fewer avoidable delays.

Reduce delays

Incomplete or unclear submissions can slow down review and require repeated follow-up.

Minimize duplicate requests

Information submitted through OCR intake can support participating review groups and ancillary partners.

Improve visibility

Study teams need clearer expectations and better insight into activation progress and key milestones.

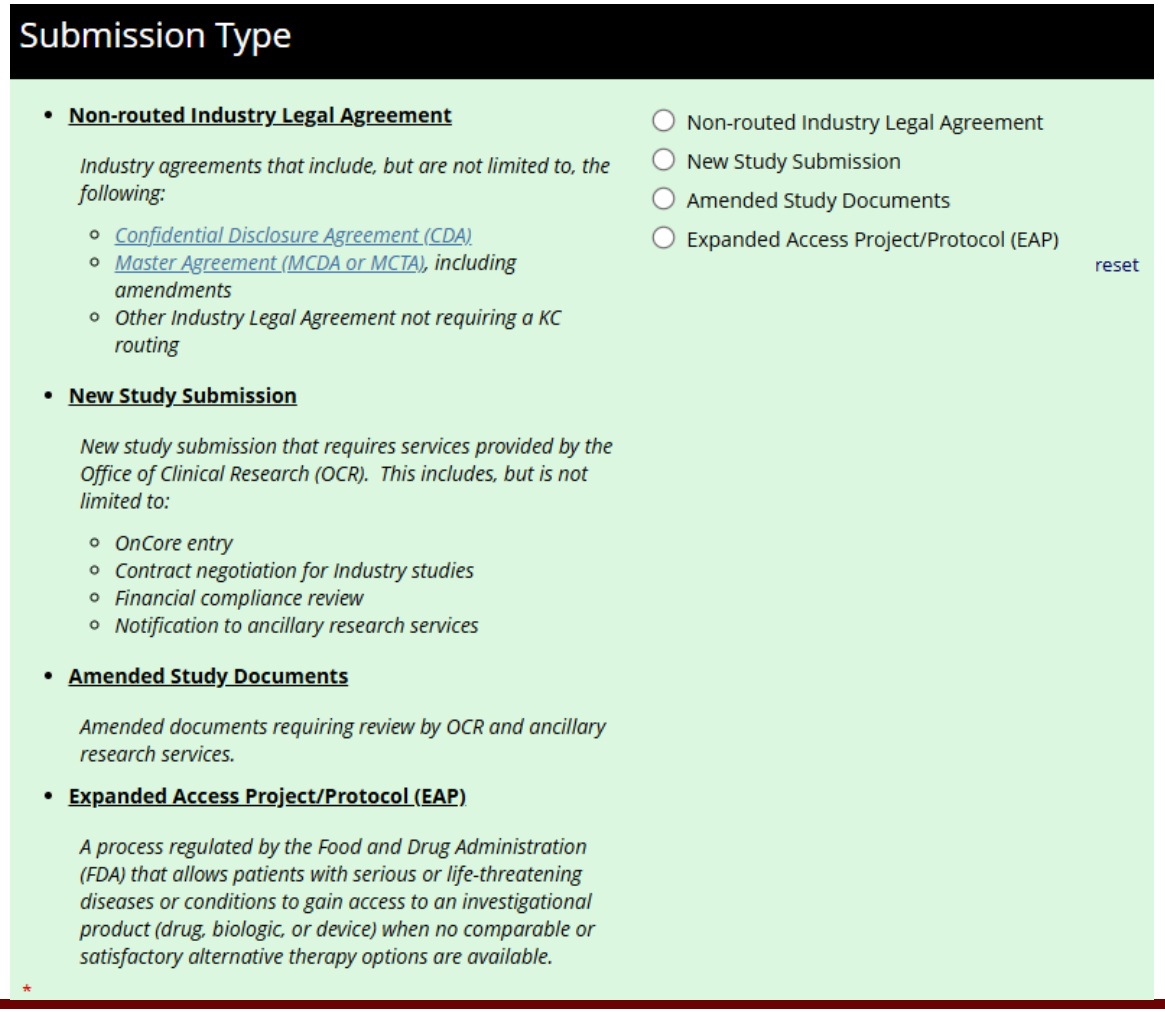
Coordinate earlier

Billing, budget, contract, ancillary, and system needs should be identified earlier in the process.

This is more than a form update - it is a coordinated activation model.

Scope – Which studies does this apply to?

- Aspects of this process change may apply to any study that meets **OnCore Registration Requirements** or must be submitted to the OCR or IU Health for review.
- This includes:
  - Non-routed legal agreements for OCR Contracts
  - New Study Submissions
  - Amendments
  - EAPs
- And would apply **regardless of funding type/status**



What is changing - and what is staying the same

What is changing

- The Study Activation Portal now accepts additional OCR Non-Routed Legal Agreements for Contracts Review (Replaces CDA submission form and separate email processes)
- OCR Intake Submission is now one single form – Form 2 process removed.
- **A required study start-up sequence has been developed,** and more complete information is required at the start
- Ancillary and health system requirements are flagged sooner, and CRC Services and IU Health Device/Supply Research Charge code requests are now integrated into the OCR submission form.
- Research Billing Analysis Questions now direct the financial compliance pathway and studies with no billing implications now skip Financial Compliance review
- Study teams and contract officers own CTA / ICF / budget alignment when financial compliance review is not required
- In some cases, the study Budget Contact will be required to participate in OCR OnCore Task Lists to confirm budget ready and financials build complete.

What is staying the same

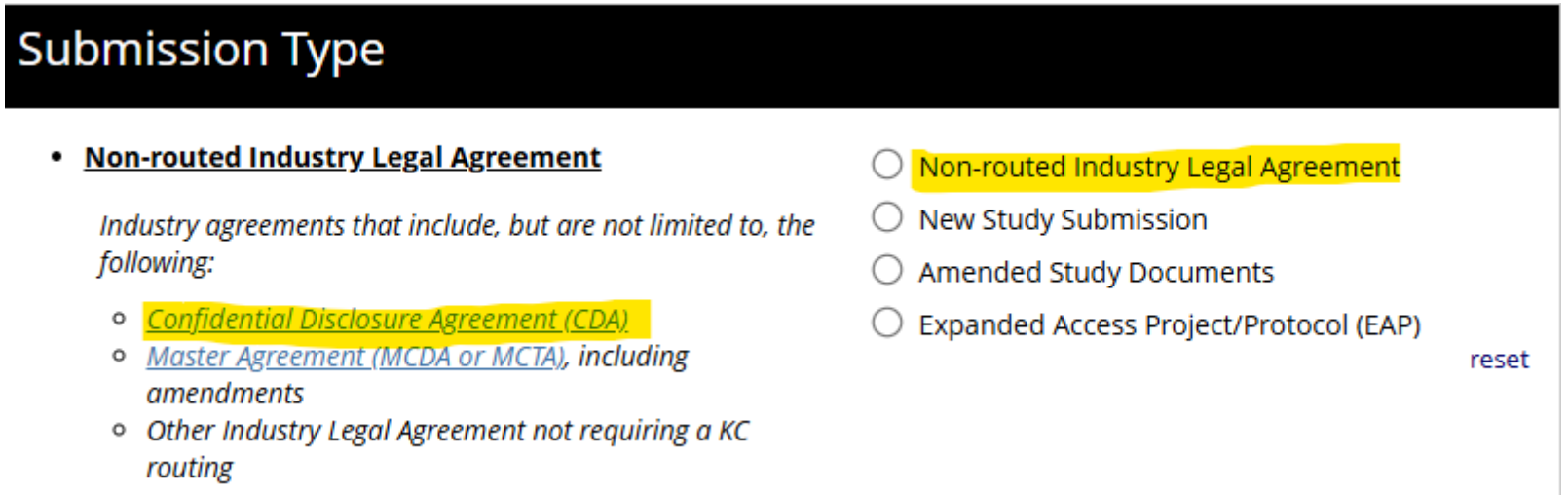
- All required reviews by IRB, contracts, financial compliance and other ancillary or health system groups remain
- Accurate and timely study team responses remain essential to timely activation
- Studies still need to receive these necessary approvals before activation/enrollment

Before You Submit: Study Startup Sequence

1. **CDA** (Industry)
2. **Complete Internal Feasibility**
3. **Sponsor Document Collection**
4. **Obtain an IU IRB # in KP** – submission is not required at this point
5. **Route any *draft* funding agreements** and note your IPID or PDD
6. **Gather all necessary documents and study information**
7. **Complete the OCR Study Submission Portal** intake form

A completed CDA for Industry

- For Industry sponsored studies negotiated by the OCR, a CDA must be completed. Do this step by using the first option on the new OCR Study Submission Portal for Non-routed Industry Legal Agreements.



Internal Feasibility & Document Collection

- As your study team is collecting study documents and performing your internal feasibility review, a new **Industry Sponsor Intro Letter has been created**. This should be provided to Sponsors interested in conducting clinical research with IU and IU Health. This letter will be provided along with these slides.

Obtain an IU IRB

- Please note, your submission to the OCR does not require an IRB *submission*. Just a few pieces of information are required to **generate the IU IRB number** in Kuali Protocols. You may then return to it later when you are ready to complete your IRB application.
- Requiring an IRB number for submission into OnCore ensures that the connection between Kuali Protocols and OnCore works to automatically feed IU IRB status updates.

Route your Funding Agreement

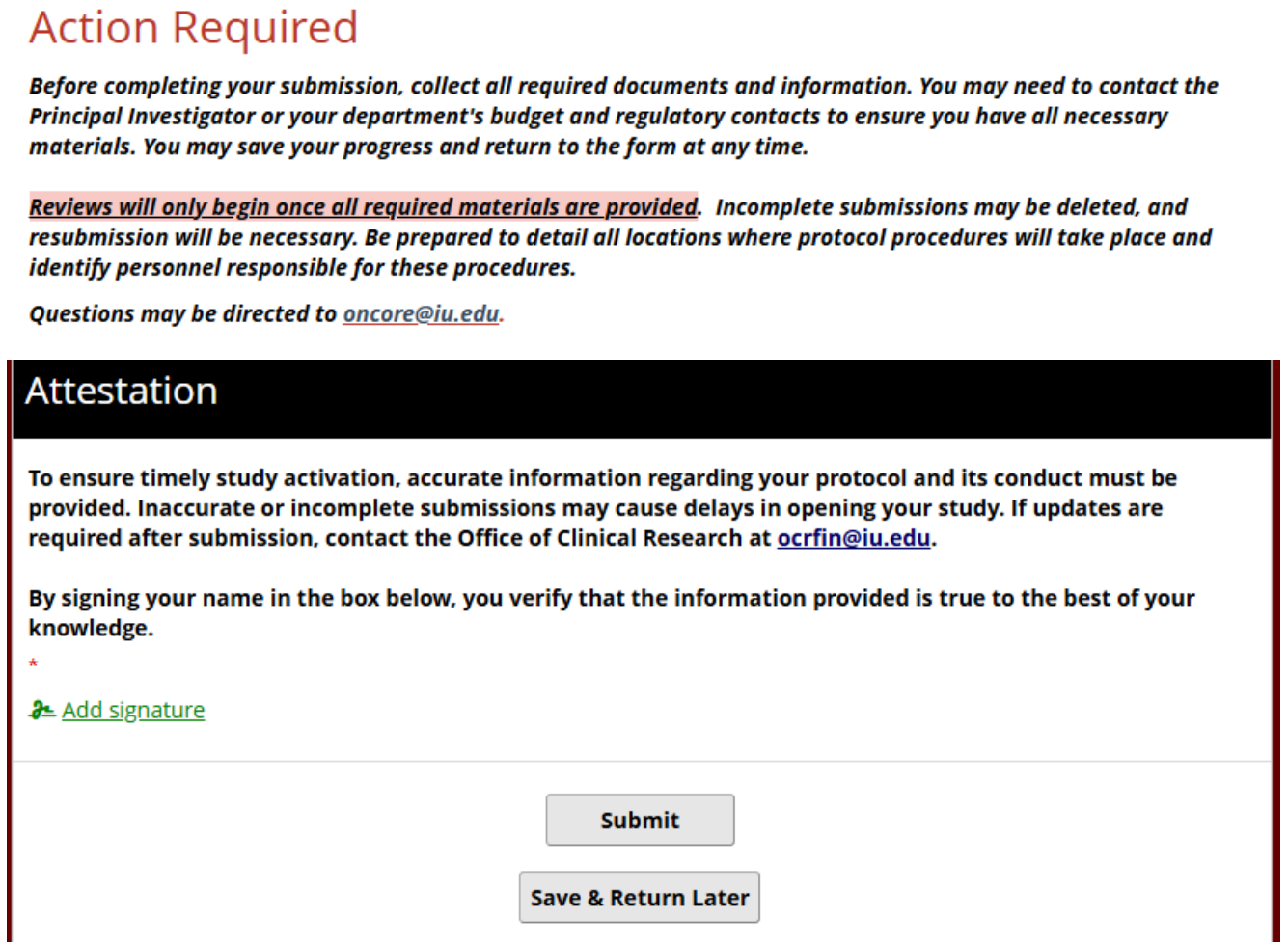
- For Industry-sponsored studies reviewed by the OCR, a complete routing must have all of the following documents included:
  - Completed CDA
  - Editable ***Draft*** CTA Template
  - ***Draft*** Budget
  - Protocol
  - ***Draft*** cIRB Approved ICF(s)
- For IU department study teams, submitting through the OCR Submission Portal requires an IPID or PDD number from Kuali Coeus; your department grants and finance staff can help you locate this information. Providing these numbers assists with improved metrics and activation visibility for study teams.
- IU Health Affiliate Teams will continue to "route" contracts to the OCR through the OCR Contract Intake Form and will not be required to provide KC identifiers.
- Additionally, effective Monday 7/13/2026, the OCR Contracts team will no longer require study teams to reroute proposals due to aging negotiations. Again, this change is implemented to improve our overall ability to track and share activation metrics across industry sponsors and study types.

Nearly Parallel Processing

- The Study Startup Sequence of events is required to ensure that required information and study identifiers are available for the OCR Study Submission Portal.
- Both the IU IRB # and the KC Grants Proposal Routing ID(s) are required fields so that we can tie data together for important metrics projects that will display status updates on your studies as they move through the activation process.
- This also allows key study reviews to happen nearly in parallel, with communication and coordination that ensures alignment and avoids unnecessary rework and delays.
- **It is imperative that study teams follow this sequence of submissions as soon as the required documents and information are gathered.**

The Revised Intake Form

- The OCR Study Submission portal is robust, and more complex studies will take more time to submit.
- It now folds in the CRC Services Request and the IU Health IDE/Device Research Charge Code Request as well as additional questions to ensure studies are receiving the reviews they truly need.
- The added upfront effort cuts later rework that can lead to enrollment delays.
- Teams must coordinate with all study stakeholders to provide complete and accurate information, and they will attest to this upon submitting the form.



Required Documents

- A complete submission requires the following, when applicable:
  - **Final Protocol**
  - ***Draft* cIRB Approved Informed Consent Template(s), and**
  - ***Draft* CTA/Budget or other funding agreement**
- As applicable, additional documents should be submitted when available and may be requested and required prior to receiving OCR Signoff in OnCore.

Required Documents and Info	Version	When Needed
★ Final Study Protocol	Final	At submission
★ Informed Consent/Assent Templates	Unlocked draft	At submission
★ Clinical Trial Agreement (CTA), Payment Terms, Budget Template	Unlocked draft	At submission
FDA & CMS Approval Documentation, as applicable	Most current version	At submission, if available
Investigator Brochure or Package Insert	Most current version	At submission, if available
Study Manuals (Pharmacy, Lab, Device, Imaging, Pathology, EDC, eCRF, etc...)	Substantive draft	At submission, if available

Gather Necessary Items & Information

To avoid delays, study teams should gather necessary documents and information before beginning the intake form. Document and information requirements will vary by study! Do not submit placeholders in your submission.

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
- FDA and CMS approval letters

Information to have ready.

- Planned study locations and services
- Investigational drugs or devices
- Recruitment goals
- 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, recruitment and study team follow-up

Consult key stakeholders before submitting the intake.
Complete the OCR Study Activation Portal submission only when required information and documents are ready. This may require input from your PI, regulatory, budget, and other study team members.

OCR Levels of Study Review

One Link for most OCR Submissions

- Non-routed legal agreements for OCR Contracts team only.
- No more Form 2s — all in one new study submission. Pause and return until ready to submit.
- CTO-managed studies will complete an abbreviated intake form
- Intelligent form logic ensures studies receive the services they require

Additional Intake Activation Triggers

- IU Health Device Charge Code Request
- Request CRC Services
- Notifications for IDS, ORI
- Epic Integrations (future state)

	Contracts Only	OnCore Entry Only	Financial Compliance Review Required	CTO – Managed Protocols	Amendments	Expanded Access Protocols
Description/ Submission Type Examples	CDA, Master CDA, Master CTA, etc.	Meets OnCore Reg Requirements and does not have research billing implications.	Meets OnCore Reg Requirements and has research billing implications. Receives CA/Billing Setup.	An abbreviated intake for Ancillary/IU Health Reviews.	Amended study documents impacting the OnCore Calendar or Coverage Analysis.	**EAP agreements will be emailed to OCR contracts**, while the intake is completed for OnCore Entry.

Changes in Financial Compliance Reviews

Key Change: Studies (funded or unfunded) that do not have protocol-related items or services planned as billable through an affiliated health system will no longer be reviewed by the Financial Compliance Team.

Document Alignment

When a full coverage analysis is not required, it is now the responsibility of the study team and the assigned contract officers in OCR or ORA to ensure alignment between the ICF and CTA regarding research injury, subject compensation, and participant cost language. Guidance will be available on the OCR Financial Compliance website, but the OCR will not be performing only Document Alignment reviews when coverage analysis is not required.

Research Billing Analysis Questions

Study Team responses in the submission portal will guide the level of review required. **These questions must be answered carefully and correctly to ensure proper routing.**

Kick-Off Meetings And APMs

Studies requiring a Financial Compliance Review will be assigned a Coverage Analyst and an **Activation Project Manager** and a kick-off meeting will be scheduled within 3 weeks of submission.

Answering the Research Billing Questions

*Indicate if your study uses any **protocol-related services, procedures, or resources** from an affiliated health system.*

- *Protocol-related activities are those directed or required by the study, either for research or conventional care.*
- *Health system facilities include hospitals, outpatient centers, and clinics where services are billed through the health system.*
- *Resources may cover staff, space, equipment, and supplies.*

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

IMPORTANT!

If you are uncertain whether your study involves the use of health system facilities or resources, contact clinicaltrials@iuhealth.org or research1@eskenazihealth.edu for guidance. At the conclusion of this form, you will be required to attest that the information provided regarding study protocol implementation at Indiana University and its affiliated hospitals is accurate.

Additional support for Financial Compliance review

Activation Project Manager

- Helps coordinate activation activities
- Supports communication and tracking
- Identifies barriers and follow-up needs

Study Kickoff Meeting

- Scheduled for studies requiring financial compliance review
- Clarifies documents, services, and startup risks and dependencies
- Aligns study team and review partners early

Earlier Planning

- Billing, budget, contract, and service needs identified earlier
- Fewer surprises later in activation
- More predictable handoffs

Budget Contact Responsibilities

- When financial compliance review is required, the study team can build the budget and begin negotiations, but they should not finalize the budget until the Activation Project Manager has confirmed its alignment with the Coverage Analysis and other Research Billing Compliance rules.

Tasks

#	Name	NA	Target Date	Completed Date	Owner
6	Budget Document Ready for Review	☐			Budget Contact
7	All Final Documents Collected (Trigger Task - Enter Completed Date in both Target and Completed Fields)	☐			Activation Project Manager
8	OnCore Financials Build Complete	☐			Budget Contact

Key Change: For studies that receive a Coverage Analysis and Billing Review, the study Budget Contact will be required to participate in the OCR Activation Task List.

Amendments

- If you will answer yes to any of these questions, then an amendment should be submitted to the OCR Intake form using the ***Amended Study Documents*** option.

	Yes	No
Has the protocol had changes to the Schedule of Events (SOE) that could potentially affect the OnCore Calendar? *	○	○
Has the study had changes to the budget that could potentially affect OnCore Financials or the Coverage Analysis? *	○	○
Has the protocol had changes to the procedures that might require a billing review? *	○	○
Do you need to notify any ancillary services of changes to the study?	○	○

What Study Teams Should Do Now

- The current OCR Intake Button shuts off end of day 7/24.
- **Review your studies already submitted to the OCR**
  - Finish any Form 2 detail request before July 24th or resubmit the study as new after August 1st.
  - For studies not moving forward, notify ocrfin@iu.edu and mark them abandoned in OnCore.
  - Submissions complete by 7/24 will not require resubmission through the new intake.
- **Review your upcoming study pipeline**
  - Gather protocols, consents, sponsor materials, funding identifiers, and ancillary details.
- Review the provided resources and prepare for the new intake on August 1.

Resources Provided

- Revised Clinical Study Activation Process – A Quick Start Study Guide
- Final RRI and Conditional Language Guidance
- Are You Ready to Submit? A Checklist and Portal Resource Guide
- Sponsor Guide to Clinical Trial Activation at Indiana University

A Final Reminder

Submit earlier.
Submit completely.
Activate more efficiently.

The updated process is intended to reduce delays, minimize duplicate requests, and improve coordination across activation partners.

Questions?

Contact

Direct Questions to:

OCR Financial Compliance Team
ocrfin@iu.edu

Thank you!