Office of Clinical Research

November 2026

1. South Region Research Council accelerates statewide clinical research growth
2. Details defined for enterprise study accrual metric and staged implementation
3. New guidance for research contract routing at Indiana University
4. Team effort enables patients to receive breakthrough treatment early
5. Zero accrual, shared responsibility: Keeping OnCore data current
6. Study intake form revised
7. Get your clinical study PRIMED for success
8. New downtown hospital planning moves into next phase



South Region Research Council accelerates statewide clinical research growth

The South Region has rapidly expanded clinical research. Since October 2025, participation has grown from seven to 21 physician investigators and from two to 16 advanced practice providers (APPs). This growth gives more patients access to research close to home and creates more opportunities for providers to participate.

A simple idea that sparked rapid growth

A key driver of this success is the South Region Research Council, the first council of its kind in the system. Meeting every other month, the council provides a central

forum to:

- Share active and upcoming research studies
- Show providers how to begin participating in research
- Clarify training, onboarding and other requirements
- Provide updates on systemwide efforts, including the Lilly initiative

The council also uses a point-of-contact model, with a physician champion in several medical specialties who shares updates and identifies interested providers.

Making research more approachable

Because many providers are new to clinical trials, the council emphasizes a simple, supportive process. Leaders meet with providers individually or in small groups to explain what to expect.

New participants are encouraged to start as sub-investigators, allowing them to gain experience with full support from the research team.

APPs have been central to the region's growth. Already integrated into clinic workflows, they can help screen, enroll and follow up with trial participants.

What's ahead in the research pipeline

The South Region expects to launch five studies before year-end. It is also expanding into oncology and exploring other specialties. With support from South Region leaders, IU Health Enterprise Clinical Research Operations (ECRO) and the IU School of Medicine, the council anticipates opportunities will continue to grow.

A model for other regions

The South Region Research Council is emerging as a model for other regions. Many clinicians want to participate in research but need clear guidance to get started. By simplifying the process, providing strong support and promoting transparency, the South Region is demonstrating what is possible.



Details defined for enterprise study accrual metric and staged implementation

The metric will measure study-level performance against the approved accrual plan using the Accrual Ratio: The percentage of the accrual target achieved divided by the percentage of the planned accrual period elapsed. A ratio of 100% indicates that a study is accruing on schedule; below 100% indicates it is behind plan, and above 100% indicates it is ahead of plan. The calculation assumes a linear accrual rate over the planned enrollment period.

2027: The metric will be applied to the Tier 1 clinical study portfolio, with an initial target of 85% and red/yellow/green reporting against the planned enrollment timeline.

2028: The metric will expand to Tier 2 and Tier 3 clinical study portfolios.

This phased approach provides a practice period while recognizing the potential impact on research of the new downtown hospital and Goodman Hall transitions.

An important consideration is the quality of the underlying accrual targets. The metric will only be meaningful if study teams use rigorous, realistic recruitment and enrollment plans. Multi-site studies will also require clear, standardized guidance on site-specific versus enterprise-wide targets. Work is underway to meet these goals.supports the integration between OnCore and the electronic health record, for discrepancies.

Epic transition: The IU Health Epic team will review OnCore information and study team spreadsheet updates to support the transition into Epic. This review is expected to continue through December 2026.



New guidance for research contract routing at Indiana University

The Office of Clinical Research (OCR) and the Office of Research Administration (ORA) have collaborated to develop new guidance to help departments determine the appropriate office for processing research-related agreements.

The Guidelines to Determine the Appropriate Contracting Office at Indiana University are intended to promote consistency, reduce confusion and minimize delays caused by agreements routed to the incorrect office.

Guidelines →

The guidance includes:

- Quick Reference Guide: An at-a-glance overview of contracting responsibilities based on study type and funding source.
- Detailed Guidance: Additional information regarding funding distinctions, Kuali Coeus routing requirements and unfunded agreements.
- Decision Flowchart: A visual tool to help departments identify the appropriate contracting office.

The document also clarifies responsibilities involving IU Health and provides specific routing instructions for industry-funded prospective observational studies.

What if an agreement doesn't clearly fit the guidance?

We anticipate these guidelines will address approximately 90% of research-related agreements. However, exceptions and unique circumstances will arise. When an agreement does not clearly fall within the guidance, OCR and ORA leaders will work together to determine the appropriate contracting office. **Departments are**

encouraged to contact either office before routing an agreement if they are uncertain where it belongs. This can help avoid unnecessary delays and rerouting.

We encourage departments and research teams to consult this guidance before submitting agreements for review. Our goal is to make the contracting process more efficient, consistent and transparent for everyone involved.

With questions or for assistance, please contact OCR at ocr@iu.edu or ORA at oraresco@iu.edu.



Team effort enables patients to receive breakthrough treatment early

Collaboration among the IU Simon Comprehensive Cancer Center, IU Health and the Indiana CTSI helped bring a promising new treatment option to Indiana patients with metastatic pancreatic cancer months before it became commercially available.



Zero accrual, shared responsibility: Keeping OnCore data current

What research staff need to know

- **Study teams remain responsible for maintaining accurate study status and accrual information, including monthly summary accrual updates.** Reminder: If you have not accrued a participant for your study in 11 months or more and you are still listed as “Open to Accrual,” you will receive an alert and be asked to respond.
- Reviews will continue quarterly into 2027. Previously, study notices were sent directly to study teams; however, moving forward flagged studies will be sent to the department’s point of contacts for resolution.
- Beginning in Q1 2027, points of contact will receive alerts on studies that have remained in other OnCore statuses longer than expected. A list of the OnCore statuses and when an alert will be triggered can be found here. A link to this list can also be found on the OnCore page of the OCR website under the Training Guides heading (under Protocol & Subject Management).
- Studies experiencing recruitment difficulties will be referred to Indiana CTSI’s PRIMED for Success for evaluation and recommendations.

The OnCore team reviews OnCore recruitment reporting **every quarter** to ensure study information is current.

Results of the most recent review

The September review identified 177 studies listed as “Open to Accrual” in OnCore with no reported recruitment for 11 months or more. Of these, 108 were included in previous outreach and still need resolution, while 69 were newly identified.

Follow-up on the flagged studies will determine whether each record needs an OnCore status or accrual update or whether the study team may benefit from recruitment support.

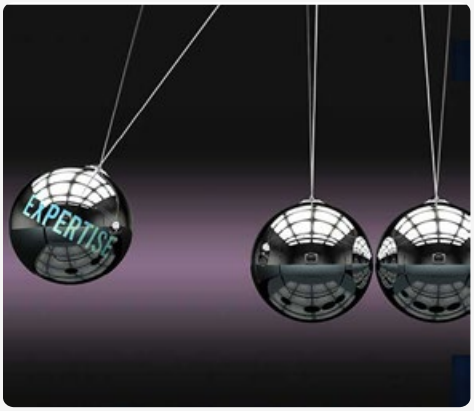
Criteria for receiving an alert: The “zero accruing” review flags non-cancer center studies that have remained “Open to Accrual” for at least 11 months with no documented enrollment during that period.

Reminder: Studies that report individual enrollment must enter participants within 24 hours of enrollment to remain compliant with Epic. Studies approved for summary accrual must report enrollment monthly.



Study intake form revised

On Aug. 1, OCR implemented a revised study intake form and process to create a more coordinated, streamlined pathway for new clinical research study activation. Feedback from the study teams has been consistently positive with the majority of comments focused on the thoroughness and ease of the new intake form, increased transparency and expedited processing. With the new form and process, OCR staff have appreciated the increase in document material completeness and reduced delays in activation processing, partially due to the use of task lists. Further enhancements to the intake form and workflow have been shared; some have been implemented and others will be considered at a future date. Email your thoughts and comments to ocrfin@iu.edu.



Get your clinical study PRIMED for success

Leverage Indiana CTSI expertise to identify barriers early and keep your clinical research on track.

Clinical trial studies often face unexpected challenges that can delay participant recruitment and impede project momentum. PRIMED for Success introduces a proactive solution designed to help investigators launch or maintain their clinical studies more efficiently.

The program is a comprehensive consultation service designed to help investigators accelerate the startup of newly funded studies or meet ongoing challenges. By bringing together expertise from across the research enterprise, PRIMED helps researchers identify and address potential barriers before they become costly delays.

Through a multidisciplinary review, investigators receive guidance on protocol development, recruitment planning, regulatory strategies, multi-site startup, community and outreach engagement, data management, and more. The program also connects researchers with key Indiana CTSI resources and collaborators to support successful study implementation.

Who is eligible?

If you have received notice of funding but have not yet begun participant recruitment, or if you are experiencing delays in recruitment, take advantage of this valuable service.

Request advice from the PRIMED team ⟶



New downtown hospital planning moves into next phase

The new downtown hospital clinical research transition planning effort has reached an important milestone with the first version of the comprehensive planning document now finalized and locked.

Leads have been designated for each component of the plan, with initial individual component plans due Nov. 13. These plans should capture key milestones, dependencies, decisions, risks and immediate next steps.

A first working session with department and component leads has been completed, and a follow-up session is scheduled for Nov. 16. These sessions are helping teams identify immediate priorities, address additional considerations and interdependencies, close planning gaps, and ensure action items are moving forward. Through year-end, the focus will be on finalizing key milestones, adding greater detail to each component, further developing the integrated transition plan and defining key details to enable effective execution of ongoing studies and onboarding of the new studies during the transition period.

Indiana CTSI
410 W. 10th Street Ste. 1000
Indianapolis, IN 46202