Indiana University
Office of Clinical Research

Sponsor Guide to Clinical Trial Activation at Indiana University

Thank you for your interest in conducting clinical research with Indiana University (IU) and our affiliated health care systems. Our institutions are committed to working with Sponsors and Contract Research Organizations to efficiently initiate clinical trial startup processes. This document provides the key information most frequently requested by Sponsors regarding site feasibility, study start-up processes, and activation timelines, facilitating the development of a successful partnership.

Sponsor Document Collection and Internal Feasibility must be completed before beginning official start-up activities. These start-up activities, including but not limited to, quote requests, regulatory work, budget negotiations, contracts, and IRB submissions will then proceed in parallel.

Your timely attention to submitting documents and addressing any questions from the study team and budget/contract specialists is critical to ensure the success and timeliness of the activation process.

Sponsor Document Collection

The clinical trial process begins with collection of required information and documents for internal review. When noted, these materials are needed before start-up activities or internal submissions can begin; exceptions require approval from the relevant departments. Required materials may include:

Document Name	Status	Required By
Final Approved Study Protocol	Final	Before start-up
Approved Informed Consent Template(s)	Unlocked draft	Before start-up
Regulatory templates: 1572, FDF, PSP, etc.	Current version	Before start-up
Investigator Brochure/Package Insert	Current version	Before start-up
Patient-facing materials	Current version	Before start-up
Protocol manuals: pharmacy, lab, device, imaging, pathology, EDC/eCRF, etc.	Substantive drafts	Before start-up
CTA, payment terms, budget template	Unlocked draft	Before start-up
FDA documentation: approvals, price exemption, Medicare billing consideration	Final	Before start-up
Device Purchase Agreement	Signed	Before activation
External/Central IRB Study Approval Letter	Final	Before activation
National Clinical Trials (NCT) Number	Final	Before activation

Start-up Activities

Once required documents are collected, many start-up activities may proceed in parallel; however, final approvals may depend on completion of other internal reviews.

Amendments

Protocol amendments during the clinical trial activation start-up window can significantly delay timelines and increase costs. Changes to the protocol often require re-review by regulatory bodies, ethics committees, and site staff, leading to repeated administrative work and postponed site activation.

Industry-Sponsored Clinical Research Fundamental Principles

Our institutions maintain rigorous ethical, legal, and financial standards in industry-sponsored clinical research to safeguard participants, ensure regulatory compliance, and promote consistency across agreements, budgets, and consent documents. Accordingly, the following requirements have been established.

- **Publication Rights:** The University retains the right to publish research results, allowing the Sponsor a limited review period to request removal of confidential information, with publication restrictions only for classified or controlled projects.
- **Intellectual Property:** The University grants the option to exclusively license commercial rights to intellectual property developed in studies though an exclusive option in the agreement; otherwise, the Sponsor may receive a nonexclusive research license for the term of the project, in compliance with Indiana Code (IC) 21-36-5.
- **Confidentiality:** The University accepts confidential information from Sponsors for a standard five-year protection period but does not accept trade secrets or perpetual confidentiality terms.
- **Warranty/Liability:** The University provides no warranties for research results and requires Sponsors to indemnify it for any liability related to the use or commercialization of deliverables.
- **Research-Related Injury (RRI) Responsibility:** Sponsors should fully cover all costs for diagnosis and treatment of research-related injuries, including those caused by investigational products or protocol procedures.
- **Research Billing Compliance:** Payments for protocol-related services must be consistent for all participants, with conditional payment language and sponsor payment of medical co-pays prohibited.
- **Research Billing Compliance Standards (Coverage Analysis):** All clinical services in research studies are billed according to state and federal regulations, with only routine costs billed to patients in qualifying trials; non-qualifying trial costs are Sponsor-funded.
- **Study Document Alignment:** Financial responsibilities for research-related injuries and study costs must be consistent and clearly outlined across all study documents, with amendments required if finalized before coverage analysis.
- **Indirect Cost Rate:** Indiana University applies a 36% indirect cost rate to all industry-sponsored clinical studies, excluding IRB and OCR fees, with project-specific costs negotiated as direct costs.
- **Non-negotiable Administrative Study Fees:** Sponsors must reimburse all required institutional, departmental, and ancillary administrative fees as per the University's fee schedule.
- **Payment Holdback:** Holding back earned clinical trial payments is generally not permitted.
- **Health System Access:** Retrospective research without consent requires review by the Health System's External Data Sharing Subcommittee, and EMR access for research is subject to Health System policies and participant consent.

IU Site Readiness and Activation

Before site activation, Sponsors should provide timely access to all required platforms, systems, and study supplies, including before the SIV, so the study team can complete training and prepare for study conduct. Site activation may occur once the contract is signed, IRB approval is obtained, and all institutional reviews are complete. Timelines depend on study complexity, alignment with IU's fundamental principles, timely final document submission, and Sponsor/CRO responsiveness.

More Information

Additional information is available on our website at https://ocr.iu.edu/. If you have any questions regarding the process to activate a clinical trial, please contact the Office of Clinical Research for Indiana at ocr@iu.edu. We look forward to a successful collaboration.