THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

MEMORANDUM

TO: **University Deans, Chairs, Faculty, & Staff**

FROM: **Christopher S. Brown, PhD**
Vice President for Research

DATE: **January 12, 2026**

SUBJECT: **Institutional Fees for Industry-Funded Clinical Trials**

This memorandum communicates the University-wide fees associated with industry-funded clinical trials. There are no UAB fees for trials funded by federal, non-profit, or UAB/Internal sources. The fees below are direct costs. Facilities and Administration (F&A) fees will be added at the appropriate rate.

All industry-funded clinical trials are required to include an Institutional Study Start-up Fee of $7,500 (+F&A). This fee is separate from the study start-up costs applicable to individual research units.

For each year of the study, an Institutional Annual Maintenance Fee of $2,750 (+F&A) will be assessed. The fee will be applied one year after the date of the fully executed Clinical Trial Agreement and each subsequent year until study close-out. Trials initiated prior to January 1, 2024 will maintain their original Annual Maintenance Fee.

An Institutional Close-out Fee of $250 (+F&A) will be applied at the conclusion of the trial and is exclusive of any costs required by the individual research units.

All of these amounts are exclusive of applicable F&A (indirect costs) because indirect cost rates vary based on contractual language.

The Institutional Fees for Industry-Funded Clinical Trials reflect a portion of the costs associated with supporting operations related to the conduct of clinical trials on campus. These essential operations include:

- The **Office of Clinical Trials Contracting** is responsible for the oversight, development, and execution of all contractual agreements related to clinical trials conducted within the institution. This team ensures that all clinical trial agreements (CTAs), confidentiality disclosure agreements (CDAs), and related contracts are negotiated, drafted, and executed in a timely manner, while safeguarding the institution's legal, financial, and intellectual property interests. The team includes contracting officers who serve as key experts and liaisons for internal and external stakeholders regarding clinical trial contractual matters.

- The **Office of Clinical Trials Financial Services** develops, implements, and maintains robust financial policies, procedures, and systems to ensure the accurate budgeting, invoicing, payment reconciliation, and financial reporting of clinical trials. The team serves a critical role in optimizing financial performance, ensuring compliance with institutional policies, sponsor requirements, and federal regulations, while also providing strategic financial guidance to the University's leadership, investigators, and research teams.

- The **Office of Accrual Strategy** is responsible for ensuring the attainment of the UAB's clinical trial patient accrual goals. This department is responsible for development and oversight of all aspects related to increasing clinical trial accruals, including investigator awareness, study staff training, report development and patient recruitment and retention.

- The **Office of Clinical Trials Regulatory Affairs** oversees all regulatory aspects of clinical research conducted within the University. This team ensures institutional and investigator compliance with all applicable federal, state, and local regulations, Good Clinical Practice (GCP) guidelines, and institutional policies governing human subjects' research. The team is responsible for the development, implementation, and maintenance of robust regulatory processes, provides expert guidance to research teams, and serves as the responsible party for oversight of Investigational New Drug and Investigational Device Exemptions.
- **The Office of Clinical Billing Review (CBR)** is responsible for conducting a Medicare coverage analysis for all clinical trials per UAB policy. This analysis provides an approved billing plan based on an objective determination of items/services that are billable to third party payers using Medicare and local payer coverage rules along with clinical care billing guidelines. The CBR also evaluates any subsequent protocol amendments that modify the items/services required by the study and amends the approved billing plan as needed. The approved billing plan is used to facilitate an accurate and appropriate clinical trial billing process.
- **OnCore Enterprise** is the University's Clinical Trial Management System (CTMS) designed for clinical research operations and data management at both the participant and study level. OnCore serves as the system of record for all clinical research studies with clinical billable services, serves as the source by which study and participant information flows to the health system's electronic health record, and is managed and maintained by the UAB OnCore team. The team supports calendar building, reporting, education and training.
- The **Office of the Human Research Protection Program (HRPP)** performs a pre-review of the protocol for institutional and commercial IRB requirements to include coordination of ancillary reviews (conflict of interest (COI), pharmacy, radiation safety, biosafety, etc.) and key personnel training and qualifications. It also stores, maintains, and updates the file through the life of the protocol at UAB. If applicable, the UAB HRPP will conduct an expedited or full review.
- The **Office of Research Conflicts of Interest (RCOI)** reviews the responsible personnel on the project and their associated financial interests to ensure any potential conflicts are managed. These reviews occur as needed throughout the life of the protocol at UAB.
- **PowerTrials** integrates the clinical trial information into the workflow of the electronic health record to enhance both patient safety at the point of care through Research Study Summaries and appropriate billing practices for the University through the development of PowerPlans.

If you have any questions, you may contact Mike Matthews at mimatt@uab.edu .