THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

MEMORANDUM

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

FROM: **Anupam Agarwal, MD**
Senior Vice President for Medicine and Dean of Heersink School of Medicine

Christopher S. Brown, PhD
Vice President for Research

Robert P. Kimberly, MD
Senior Associate Dean for Clinical and Translational Research

DATE: **November 1, 2023**

SUBJECT: **Institutional Fees for Industry-Funded Clinical Trial Budgets**

This memorandum communicates the updated University-wide fee schedule for industry-funded clinical trial budgets.

All new industry-funded clinical trial budgets must include a Study Management Fee of $7,500 as of January 1, 2024. This fee is separate from the study start-up costs required by the individual research units.

After the initial year of each study, an Annual Maintenance Fee of $2,750 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.

A Close-out Fee of $250 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 indirect costs that will be added.

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 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. 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 Institutional Review Board (IRB)** performs a pre-review of the protocol for institutional and commercial IRB requirements to include coordination of ancillary reviews (COI, pharmacy, radiation safety, biosafety, etc.) and key personal training and qualifications, as well as stores, maintains, and updates the file through the life of the protocol at UAB. If applicable, the UAB IRB will conduct an expedited or full review.

- **The Office of the Conflict of Interest Review Board (CIRB)** reviews the responsible personnel on the project and their associated financial interests to ensure any 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 and appropriate billing practices for the University. Power Trials ensures availability of Research Study Summaries at the point of care to enhance patient safety and the development of PowerPlans to provide the foundation for appropriate billing practices.

If you have any questions, you may contact Mark Marchant, Director of the Clinical Trials Administrative Office, at 205-934-2098 or marchant@uab.edu.