MEMORANDUM

TO: University Deans
FROM: Richard B. Marchase
Vice President for Research and Economic Development
DATE: January 21, 2015
SUBJECT: Name Change/Clarification for Fees for Industry-Initiated and Sponsored Protocols

Effective immediately, the UAB Administrative Fee which is assessed by the UAB Clinical Trials Office to industry-initiated and sponsored protocols has been renamed as the UAB Human Subjects Review Fee. The previous name created some confusion among our industry sponsors. The fee continues to be subject to the applicable F&A rate and is separate from the fee charged for review of the project by any independent IRB (currently WIRB). As a reminder, the fee structure is as follows:

- $2,000 for “convened” reviews of industry-initiated and sponsored protocols by any independent IRB (currently WIRB) or “expedited review” by UAB IRB
- $3,000 for “convened” review by UAB IRB of industry-initiated and sponsored protocols

This amount is used to offset costs associated with reviews of industry-initiated and sponsored protocols by several areas involved in the activation process, including:

- The Office of the IRB (OIRB) conducts a pre-review of the protocol for institutional and WIRB requirements and 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 (OCIRB) conducts a review of the responsible personnel on the project and their associated financial interests to ensure any conflicts that may exist are managed appropriately. These reviews occur as needed throughout the life of the protocol at UAB.
- The Clinical Billing Review (CBR) unit of the Clinical Trials Office is responsible for conducting a 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 can and cannot be billed to third party payers using Medicare and local payer coverage rules along with clinical care billing guidelines. The CBR is also responsible for conducting reviews of any subsequent protocol amendments that modify the items/services required by the protocol and modifying the approved billing plan as needed. The approved billing plan is used to facilitate an accurate and compliant clinical trial billing process.

Please note: this fee is only applicable to industry-initiated and sponsored clinical trials and research studies and is not applicable to (1) investigator-initiated clinical trials or (2) those supported by non-profit foundations or government sponsors.

The Clinical Trials Office will invoice the PI for this amount and payment to the CTO should be made from the study account. The PI/study team is responsible for invoicing the study sponsor for funds to cover this fee. Remember to include the applicable F&A amount when invoicing the sponsor.

Please contact Carolyn Whitmire at 975-0699 if you have any questions.