

UAB Standard Non-Negotiable Fee Schedule for Industry-Sponsored and/or Industry-Funded Clinical Trials

As a part of the University's commitment to a systematic approach transforming how clinical trials are conducted at the University of Alabama at Birmingham, the University has embarked on its Clinical Trials Initiative. This program embodies principles governing the overall conduct of clinical trials¹ and reflects national efforts such as the Clinical Trials Transformation Initiative (CTTI). One component of the initiative is the financial management of trials from start to finish. Below you will find the schedule of activities and fees which must be applied to trial budgets and which will be invoiced throughout the trial lifecycle. These are direct costs and the applicable F&A rate for industry-sponsored and/or industry-funded clinical trials will still apply. These are required activities and non-negotiable rates and do not include study personnel, laboratory tests, SAE reports, IND safety reports, consent translation and other costs, which are part of the necessary conduct of the trial.

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Upfront Activities and Fees				
Activity	Fee	Occurrence	Notes	
Departmental Study Start-up	Based on trial complexity	One time	The total cost varies depending on the trial complexity and includes: Protocol Review & Feasibility, Site Selection Visit, Regulatory Processing, Budget Processing, Contract Processing, Scientific Review Committee, EDC Training, Source Documentation, and Site Initiation Visit. Study start-up costs are payable upon invoicing.	
Pediatric Research ²	Based on special approvals and trial complexity	One time	For pediatric studies, the total cost is determined by the Department of Pediatrics.	
Study Management	\$7,500	One time	IRB, CIRB, OnCore, PowerTrials, and Medicare Coverage Analysis.	
UAB/COA Pharmacy ²	Based on trial specifics	One time	Pharmacy review and assessment, as applicable. Additional fees (storage, dispensing, shipment, etc.) may apply for recurrent activities.	
Radiology ²	\$1000 or \$2000	One time	Radiology review and assessment, as applicable depending on complexity.	
	Recurrent	Annual Activi		
Activity	Fee	Occurrence	Notes	
Study Maintenance	\$2,750	Annual	IRB, CIRB, and CTMS	
UAB/COA Pharmacy ²	Based on trial specifics	Annual	When Applicable	

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Regulatory Preparation	Based on trial complexity	Annual	IRB report preparation and submission
Laboratory ²	Based on trial specifics	Annual	Laboratory re-assessment and review
Administrative Maintenance	Based on trial complexity	Annual	Study activity reconciliation
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Activity	Fee	Occurrence	Notes
PI/Study Team Time	Based on trial complexity	One time	Trial closure includes summary financials, contracts, preparation of source documents and data for archival storage, etc.
IRB / CIRB	\$250	One time	Review and approval of IRB close-out materials
Pharmacy Close-out ²	TBD	One time	When Applicable
Document Archival	Based on study	One time	Document storage

¹Based on the institutional definition found here:

https://www.uab.edu/research/administration/offices/OSP/Guidance/Pages/Clinical-Trials.aspx

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²Fees are based on service unit fee schedule and subject to change without notice.