	GUIDANCE CLINICAL TRIAL FEES FOR INDUSTRY-SPONSORED RESEARCH	
<b>LSU Health</b> New Orleans		
Health Sciences Center &	EFFECTIVE DATE	PAGE
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## **Overhead Rate**

Industry-Sponsored Trials	35%

## **Start-Up Costs** (one time, non-refundable)

Administrative Start-Up Fee, including overhead Start Up Fee includes CDA Review, Protocol Review, CTA Review and Negotiation, Coverage Analysis, Budget Review and Negotiation, Regulatory Submission, Subcontracting, Protocol Build, and Administration.	\$10,800
Clinical Trial Management System (LSUHN Only) Our CTMS is a purpose-built platform that is designed to be used at the point of care, enabling our clinical research team to focus on our patients while achieving our research goals. The system further empowers us to optimize research management through workflow, dashboard and analytic tools. Nonnegotiable and nonrefundable.	\$1,000
<b>eRegulatory System (LSUHN Only)</b> In order to improve study start-up timelines, centralize, standardize and optimize regulatory documents and processes and provide remote monitoring functionality, we utilize an e-regulatory system. Sponsors have direct access to the investigative site file (ISF). The sponsor pays an annual fee for the utilization of the e-regulatory system. Nonnegotiable and nonrefundable.	\$500
LSUHSC IRB Initial Review	See IRB Fee Schedule
LSUHSC IBC Initial Review	\$500

## **Invoiceable Costs** (invoiced per occurrence)

Protocol Amendment with Consent Changes	\$500
Protocol Amendment without Consent Changes	\$250
Budget or Contract Amendment	\$450
LSUHSC IRB Amendment Review	See IRB Fee Schedule
LSUHSC IRB Renewal/Continuing Review	See IRB Fee Schedule
LSUHSC IBC Renewal/Continuing Review	\$300
Monitoring Visit (Remote or On Site), Half Day	\$500
Monitoring Visit (Remote or On Site), Full Day	\$1,000
Monitor Change Fee	\$500
Sponsor-Directed Audit, per day	\$1,000
FDA-Directed Audit, per day	\$2,000
SAE Reporting, per event	\$250
Document Storage Fee	\$750
Administrative Close-Out and Visit	\$1,000
Reconsent	\$100
Lab Set-Up/Specimen Storage Fee	\$750
Clinical Trial Management System (LSUHN Only)	\$1,000
eRegulatory System (LSUHN Only)	\$500
LSUHN Clinic Room Rate, per visit	\$130

## Study Staff Non-CPT Coded Service Rate

Clinical Research Nurse Coordinator, per hour	\$100
Clinical Research Coordinator, per hour	\$75