



Clinical Trials Office

Standard Costs and Fees for Sponsored Clinical Trials

Effective: Fiscal Year 2025 (7/1/2024)



Version Date: 7/24/2024

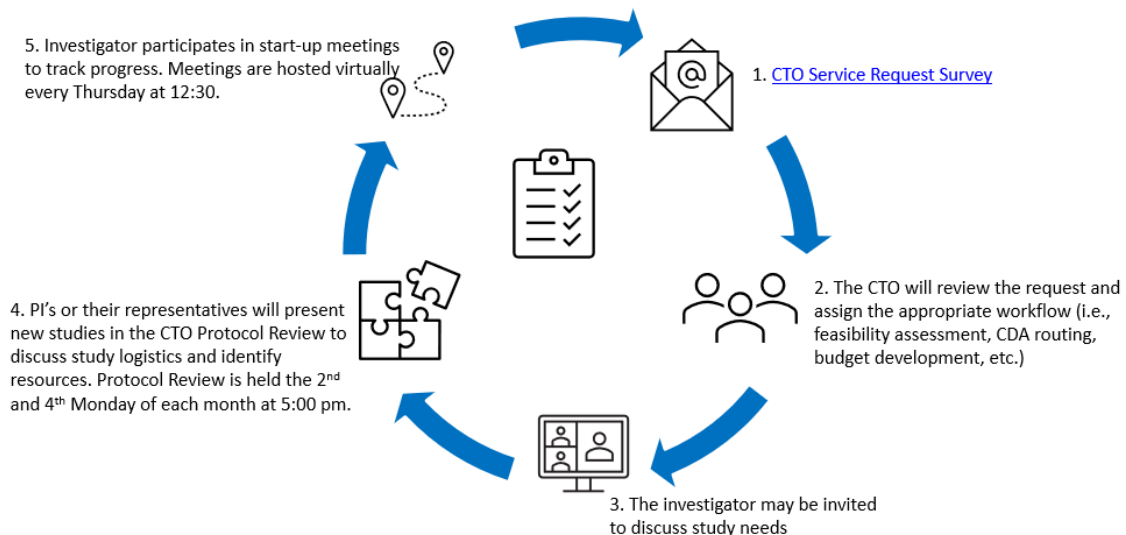
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Contract and Budget Process Overview

The contract and budget review process will occur in parallel with IRB review. Below is an outline of our standard Protocol Review process.



In order to submit the study to the MSM Clinical Trials Office ([CTO Service Request Survey](#) or clinicaltrialsoffice@msm.edu) and develop an accurate budget estimate, we need:

- Final Protocol
- Draft Informed Consent
- Investigator Brochure
- Final Laboratory Manual
- Final Pharmacy Manual
- Other Study Manuals, if applicable
- Patient Handouts, if applicable
- Draft Clinical Trial Agreement
- Draft Budget



Indirect Cost Rates

26% - Industry Sponsored Clinical Trials

46% - Federally Sponsored Clinical Trials

Payee Information

Payable to: Morehouse School of Medicine, Inc.

Tax ID No: 1-581438873-A1

Address: 720 Westview Dr. SW

Atlanta, GA. 30310-1458

Clinical Trials Office Administrative Services

Item	Fee
Start-up Fee	\$1,500
Subsidy Recapture Fee (industry sponsors only)	\$1,250
CTO Coordinator Pool	\$87/hour
CTMS Maintenance Fee	\$495
Protocol Amendment Fee-CTMS Update	\$500
Record Retention (Document Archiving and Storage) Fee	\$1,500
Study Close-out	\$1,500

Start-up Fee (\$1,500) and Subsidy Recapture Fee (\$1,250): One-time, non-refundable fee, includes variable and non-variable fees These fees cover the costs associated with the different processes involved in preparing a study to open, such as:

- Feasibility Review
- Site visits (i.e., Site Selection Visits, Pre-selection Visits, Site initiation visits, etc.)
- Preparation of the regulatory documents (i.e., Form 1572, FDF, DOA, etc.)
- Preparation and entry into the Clinical Trials Management System (CTMS)
- Assessment of the study budget and contract negotiation
- Study account set-up
- Clincard set-up

These fees do not include core research services such as Institutional Review Board (IRB), Regulatory Core, Investigational Drug Services, Clinical Operations Core, Bionutrition Core, and the Engagement Core.



CTO Coordinator Pool (\$87/hr): The Research Coordinator Core provides a wide range of research coordination and management services at an hourly rate. The staff includes licensed nurse research coordinators and experienced research coordinators. We assist with recruitment, screening, consenting, and overall conduct of study visits. This includes facilitating focus groups, interviews, questionnaires, lab processing, and more. Our flexible staffing model allows researchers to increase or decrease usage as needed. Researchers only pay for actual hours that staff spend directly supporting their projects.

CTMS Maintenance Fee (\$495): This fee covers critical functions that enable efficient study management, compliance with regulatory standards, and the protection of sensitive data. It supports system updates and customizations relevant to the study.

Protocol Amendment Fee (\$500): Amendments may or may not be required in the course of the study. However, in the event they are required or requested by the sponsor, these are our site’s standard fees. Amendments include, but are not limited to modifications to research which require board review, such as protocol amendments, revised protocols, updates to consent forms, and new recruitment or retention materials, which covers the cost of reviewing the materials, any updates to the CTMS system and associated calendar and the related administrative responsibilities of preparing review documents and updating the investigator file.

Record Retention Fee (\$1,500): Accounting for a minimal of 7 years of study document retention at Iron Mountain and/or other MSM-contracted facility.

Study Closeout Fee (\$1,500): Accounting for an average of 20 hours of study team and research administrative effort to prepare, review, and participate in study close-out activities.

Regulatory Core

The Regulatory Core works in partnership with study team members to successfully navigate the clinical research regulatory landscape throughout the lifecycle of a study.

Item	Fee
Regulatory Document/Administrative Preparation Fee-INITIAL Submission (One-time fee)	\$1,500
Regulatory Document Preparation Fee-Annual Review	\$500
Regulatory Document Preparation Fee-Amendments/Modifications involving more than Minor Revisions	\$500
Regulatory Document Preparation Fee-Amendments/Modifications with Minor Revisions	\$250
Regulatory Documentation Preparation Fee-AEs	\$100
Regulatory Documentation Preparation Fee-SAEs	\$500
Regulatory Document Preparation Fee-Study Closeout	\$500
Audit Fee (As requested)	\$500
Sponsor monitoring visit assistance	\$150/hr



Investigational Drug Services

The Investigational Drug Service (IDS) of the Morehouse School of Medicine is responsible for the consistent and centralized management of pharmaceutical/investigational drug protocols used in human subject research, at all sites under the Clinical Research Center (CRC). The Investigational Drug Service serves as the management unit for the storage, dispensing and disposal of study medication for many clinical trials. It ensures standardization of procedures within each protocol, and further protects human subjects who participate in research protocols, through improved drug safety and accountability measures.

Investigational Drug Services	Rate	Comments
Study Initiation		See below*
<ul style="list-style-type: none"> • Simple 	\$3000	<ul style="list-style-type: none"> • Simple studies are defined as studies in which investigational products (IP) are utilized in the outpatient setting and do not meet specific criteria for complex studies.
<ul style="list-style-type: none"> • Complex 	\$4500	<ul style="list-style-type: none"> • Complex studies are defined as studies in which IP are requiring non-sterile/sterile manipulation or special handling. • Example: Reduced dosing due to impaired kidney function
Study Maintenance	\$250/mo	See below*
Study Closeout	\$500	See below*
Dispensing Fee		<ul style="list-style-type: none"> • Fees are charged at the time of dispense of medications
<ul style="list-style-type: none"> • Simple 	\$60	
<ul style="list-style-type: none"> • Complex 	\$200	
<ul style="list-style-type: none"> • IV Infusion 	\$200	
<ul style="list-style-type: none"> • IV Bolus 	\$75	
Patient Return Fee	\$45	<ul style="list-style-type: none"> • Unused medications should be returned to the Midpoint and End of dosing (EOD) visit
Monitoring Visits	\$100/hr	<ul style="list-style-type: none"> • The purpose is to determine compliance with protocol and regulatory requirements and with study policies and procedures

Description of Services

Study Initiation:

- **Fees are charged for the work of setting up a study and of performing necessary staff training which include:**
 - Review protocol and prepare budget
 - Drug Build and Reviews
 - Orderset reviews
 - Meet with sponsor or investigator
 - Receive and process initial shipment of study drug
 - In-service staff (as needed)
 - Prepare study fact sheet and drug information fact sheet for pharmacy staff and nursing staff (as needed)

Study Maintenance:



- Maintain appropriate inventory storage, study records
- Update ordersets/review based on amendments
- Order and receive inventory
- Process expired inventory and patient returns
- Store patient returns
- Periodic study billing

Study Closeout:

- Process study records to archive
- Meet with participant for closeout visit
- Final billing
 - Additional cost: Process study drug for Return to sponsor/ destroy on-site

Clinical Operations Core

The Clinical Operations Core consists of experienced, skilled nurses and laboratory technicians who demonstrate a high level of clinical expertise, critical thinking, and complex decision-making skills. They are responsible for protecting the study participant and administering clinical services according to IRB-approved study protocols.

Item	Fee (Industry/Non-Industry)
Start-up Fee	\$1,500
Nursing Level 1	\$101/\$91 per hour
Nursing Level 2	\$187/\$168 per hour
Nursing Level 3	\$278/\$250 per hour
Nursing Level 4	\$410/\$368 per hour
Nursing Level 5	\$560/\$504 per hour
Laboratory: Whole blood processing 1 unit 1-2 aliquots	\$14/\$12 per unit
Laboratory: Buffy coat processing 1 unit 1-5 aliquots	\$15/\$13 per unit
Laboratory: Plasma or serum processing 1 unit each 1-5 aliquots per unit	\$19/\$17 per unit
Laboratory: Urine processing including urine pregnancy testing	\$14/\$12 per unit
Laboratory: Saliva/Stool processing 1 unit each – 1-2 aliquots	\$15/\$13 per unit
Laboratory: PBMC processing 1 unit 1-2 aliquots	\$40/\$36 per unit
Laboratory: Sample Storage Service	\$35/\$30 per month

Nursing Level 1: Minimal intensity: vital signs, weight, height, pulse oximetry, 6-minute walk test, specimen collection- 1 timepoint

Nursing Level 2: Minor intensity: 12-lead ECG. IV Placement, all medication administration, post administration monitoring <1 hour, specimen collection- multiple time points <3 hours between collection. Vision testing.



Nursing Level 3: Moderate intensity: IV infusion, post administration monitoring >1 hour

Nursing Level 4: Moderate intensity: Glucose tolerance test, testing requiring the skills of an Advanced Practice Provider, complex sample processing

Nursing Level 5: High intensity: Multiple IV infusions, biopsy (fat, muscle), procedures requiring multiple nurses

Bionutrition Core

The Bionutrition Core is comprised of a Metabolic Research Kitchen and Body Composition Lab and provides the following services:

Item	Fee
Menu Development	\$109 per hour
Research Meal Production	\$15 per meal, base price*
Dietary Assessment <ul style="list-style-type: none"> • 24-hour Dietary Recall Administration & Analysis • Harvard Food Frequency Questionnaire Administration & Analysis • 3-Day OR 7-Day Food Record Instruction & Analysis 	\$100 per hour, billed in 15-minute increments \$15.25 per questionnaire** \$30 per instruction session plus data entry and analysis fee of \$100 per hour, billed in 15- minute increments
Body Composition Analysis <ul style="list-style-type: none"> • Anthropometric Assessment (e.g., measurement of weight, height, and waist & hip circumferences) • Dual Energy X-Ray Absorptiometry (DXA) Scan • Bioelectrical Impedance Analysis 	\$30 per assessment \$100 per scan \$50 per analysis
Indirect Calorimetry	\$100 per assessment



Nutrition Education Materials Development	\$60 per hour***
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*Fee per meal may increase based on protocol intensity.

**Administration and analysis fees are based on current rates published by Harvard University.

***Price does not include printing fees for printed materials

Engagement Core

Engagement Core offers a comprehensive suite of services that aim to support programs and studies in the field of clinical research. These services encompass a wide range of activities that are critical to the success of research projects.

Service Fees



Service Name	Hours	Quantity	Cost Per	Total Cost	Details
Planning	5	1	\$100	\$500	Develop recruitment strategy, budget, and timeline for study or project.
Training	2	1	\$60	\$120	2 Engagement Training
Support	48	1	\$60	\$2,880	Program Manager for 6 months
SMS (Mobile Text MSG) Campaign	2	1	\$225.00		Up to 2500 sent Mobile messages per campaign
Email Marketing Campaign	2	1	\$100	\$200	Up to 2500 sent Email messages per campaign
Online Forms/Surveys	1	1	\$100	\$100	
Reporting and Analytics Support	2	1	\$100	\$200	Creation of an Engagement Dashboard for Reporting
Virtual Event Planning and Support	24	1	\$200	\$4,800	Per Virtual Event. Includes: SMS + Email Campaigns, Microsite, Online Registration Form
Event Planning and Support	24	1	\$200	\$4,800	Per Virtual Event. Includes: SMS + Email Campaigns, Microsite, Online Registration Form
Landing Page/Microsite	2	1	\$100	\$200	
Marketing Assets	1	1	\$150	\$150	Cost per asset includes flyers, postcards, posters, etc.
Engagement Specialists	1	1	\$40	\$40	Per Engagement Specialist per Engagement Activity
Mobile Fleet	1	1	\$1,500	\$1,500	Includes cost of driver, maintenance, and gas. Up to 50 miles



Engagement Tiers

Level 1	Planning	1	\$500	\$500
	Training	1	\$120	\$120
	Support	1	\$2,880	\$2,880
	Email Marketing Campaign	1	\$200	\$200
	Online Forms/Surveys	1	\$100	\$100
	Reprint and Analytics Support	1	\$200	\$200
	Landing Page/Microsite	1	\$200	\$200
	Marketing Assets	3	\$150	\$450
			Total Cost	\$4,650
Level 2 Enhanced Engagement				
	Tier 1	1		\$4,650
	SMS (Mobile Text MSG) Campaign	1	\$225.00	\$225.00
	Event Planning	1	\$4,800	\$4,800.00
	Engagement Specialists	60	\$40	\$2,400.00
			Total Cost	\$12,075
Level 3 Mobile Outreach				
	Tier 1 + 2	1		\$12,075
	Mobile Sprinter	4	\$1,500	\$6,000
			Total Cost	\$18,075