Standard Costs and Fees for Sponsored Clinical Trials

Effective: Fiscal Year 2024 (7/1/2023 – 6/30/2024)

Version Date: 08/0/2023

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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 Johns Hopkins Medicine (JHM) IRB 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

IRB Review

The JHM IRBs meet weekly. Applications are typically put on a convened meeting agenda 2-3 weeks from submission. IRB comments are usually received within 1 week of the IRB review date. Any re-review may add an additional 3-4 weeks to the review time.

A Prospective Reimbursement Analysis (Standard of Care Analysis) is completed by JHM ORA, and is typically available 2-3 weeks after submitting the application to the IRB. This analysis is required before a draft budget can be returned to the sponsor.

http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/ora2.html

Contract Execution

The clinical trial agreement cannot be executed until the study has been IRB approved.

Overhead and Indirect Costs

Departmental Administrative Fee: This direct cost with applied overhead varies by department. The departmental administrative fee will be applied to all commercial studies to cover the efforts of the financial manager, research analyst, and grant manager to ensure excellent financial management,

timeliness and compliance. It also pays for a pool of nursing and medical office support, this spread out as an administration fee is a discount to the clinical trials instead of direct charging. Specifically, the fee will be used to cover costs associated with contract administration, financial management and oversight of the agreement, patient care billing compliance, and financial audits. These charges are not covered by the indirect cost which goes to the institution for space, utilities and other non-allocable expenses.

The current **Johns Hopkins University indirect cost rate is 34%**. This rate is applicable to **Off-Campus** (defined as research performed in facilities that are supported by clinical billing) **Commercial Sponsored Research**. This information is also available at the following website:

https://ora.jhmi.edu/faandfringe/

A description of the items that the overhead rate includes is available at the following website:

http://www.hopkinsmedicine.org/research/synergy/ora/handbook/appendixd.html

The above rates are compound rates. These overhead rates are charged to all pharmaceutical companies for all clinical trials. The overhead is taken directly from payments received and is not part of the compensation paid to the Principal Investigator.

Payee Information

Payable to: Johns Hopkins University

Tax ID No: 52-0595110

Address: Johns Hopkins University Central Lockbox
Bank of America
12529 Collections Center Drive
Chicago, IL 60693

Checks must also include the **JHU PI name, Sponsor protocol number,** and **agreement-specific IPN number**. The agreement-specific IPN number will be generated prior to contract execution.

Justification for JHU Costs and Fees

The following sections describe various costs and fees associated with Sponsored Clinical Trials at Johns Hopkins. These costs and fees are mandatory fees required by our institution in order to participate in clinical trials and we provide a detailed description and justification of each item below. These fees are charged to all pharmaceutical companies for all clinical trials. **All fees below vary by department.**

In the event that a clinical trial is terminated or withdrawn prior to full contract execution and/or activation, Johns Hopkins University School of Medicine expects that Sponsors will make good faith efforts to honor all fixed start-up costs and any applicable invoiceable pre-study costs for activities actually undertaken in anticipation of a given study, such as *Initial JHM IRB Review Fee, Pharmacy Start-Up Fee, Clinical Research Finance Fee,* etc. Where appropriate, such fees may be adjusted by mutual agreement to reflect the proportional amounts actually incurred. Where no study contract has been executed, a simple letter agreement is sufficient to document the payment of such costs.

Start-up Costs and Fees

Non-Refundable Start-Up Fees may include the following:

- **Administrative Start-up Fee** varies based on protocol complexity, departmental salaries accounts for an average of 250 hours of combined personnel time for study start up activities

- **Regulatory Start-up Fee up to $2,948:** Varies based on protocol complexity, departmental salaries accounts for an average of 250 hours including 40 hours of Regulatory and QA Review, and IRB review committees.

- **Clinical Research Finance Start-up Fee up to $5,980**: Accounting for an average of 40 hours of research administrative effort to prepare, review, and submit the budget and contract.

- **Nuclear Medicine Set-up Fee up to $737**: Accounting for an average of 10 hours of Nuclear Medicine staff effort to review protocol, complete required study training, and participate in site qualification and/or initiation visits.

- **Clinical Engineering Initial Fee up to $737:** Accounting for an average of 10 hours of Clinical Engineering Services (CES) effort to review protocol, inspect sponsor-provided equipment, and pertinent documentation.
  http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/clinical_engineeringservices.html

- **Initial JHM IRB Review Fee up to $4,422**: Direct charge by JHM IRB for initial review of convened, commercially funded human subject research studies.
  http://www.hopkinsmedicine.org/institutional_review_board/about/fees.html

- **IDS Pharmacy Set-Up Fee (FY '24)** varies based on protocol complexity: accounting for an average of 40 hours of IDS pharmacy effort to review protocol, prepare budget, participate in site qualification and/or initiation meetings, set-up of electronic inventory management system, and review of order sets.

- **Rheumatic Diseases Research Core Center (RDRCC) Initial Review Initial Fee up to $3,685:** (The Rheumatic Disease Research Core Center - Human Subject's Core D provides infrastructure and resources to facilitate multidisciplinary translational research in rheumatic disease. The Core works with the Investigator and study team to monitor and assist with IRB submissions, responses, renewals, subject recruitment, enrollment, internal audits, retention and any other aspects of clinical research from initiation to completion to improve the research process and enhance quality of research.) Mandatory expense - All studies in the division of rheumatology are under the supervision of the RDRCC.

- **Radiology Imaging Set-Up Fee up to $2,425**: Accounting for an average of 10 hours of Radiology staff effort to review protocol, complete required study training, and participate in site qualification and/or initiation visits.

- **Nutrition Start-Up Fee**: Fee varies based on the requirements in the protocol.

- **ICTR Clinical Research Unit Start-Up Fee up to $1,843.**

- **ICTR Clinical Research Unit Room (Utilization) Fee up to $68 per hour.**

- **Standard Lab Start-Up Fee up to $2,948.**

IRB Costs and Fees

- **IRB Annual Continuing Review Fee up to $2,580**: Direct charge by JHM IRB for annual review of convened, commercially funded human subject research studies.

  IRB Guidelines on Changes in Research (Change in Research = Amendment): https://www.hopkinsmedicine.org/institutional_review_board/about/fees.html

  - **IRB Change in Research with consent change, up to $1,769 each**: Direct charge by JHM IRB for convened review of a change in research application without consent form revisions.

  - **IRB Change in Research without consent change, up to $1,474 each**: Direct charge by JHM IRB for convened review of a change in research application without consent form revisions.

- **IRB Monitoring Fee for Commercially funded studies, up to $553**: Where the Johns Hopkins Principal Investigator holds the IND/IDE, first year, invoice if applicable
- **IRB Monitoring Fee for Commercially funded studies, up to $995 annually**: Where the Johns Hopkins Principal Investigator holds the IND/IDE, years two and beyond, invoice if applicable
- **IRB Monitoring Fee for Commercially funded studies, up to $553:** That require High Risk Review Committee review, first year, invoice if applicable
- **IRB Monitoring Fee for Commercially funded studies, up to $995 annually**: That require High Risk Review Committee review, years two and beyond, invoice if applicable
- **IRB Monitoring Fee for Commercially funded studies, up to $332**: Where the Johns Hopkins relies on an external IRB, first year, invoice if applicable
- **IRB Monitoring Fee for Commercially funded studies, up to $553 annually**: Where the Johns Hopkins relies on an external IRB, additional years
- **IRB Monitoring Fee for Commercially funded studies, up to $332**: That qualify as expedited but involve drugs/devices, first year, invoice if applicable$302
- **IRB Monitoring Fee for Commercially funded studies, up to $553 annually**: That qualify as expedited but involve drugs/devices, years two and beyond, invoice if applicable$

Pharmacy Start-up Costs and Fees

- **Monthly Drug Storage Fee, up to $170 per month**: Covers inventory management, drug storage, and supplies.
- **Monitoring Visit Fee, up to $160 per on-site visit**: Covers preparation for the visit and time spent assisting the monitor while on-site or remote.
- **Dispensing Fees, included in Per Subject Cost:** Based on intensity/time required for preparation and dispensing of study drug(s), and use of IVRS/IWRS systems.
- **Supplies**: Varies based on protocol.
- **Pharmacy amendment management fee up to $1,618 per amendment.**
- **Shipping or Transfer Fees up to $211:** Shipping study drug to Study Subject.

- **Shipping to Other Facility up to $317 per shipment.**

Clinical Engineering Costs and Fees

- **Clinical Engineering Annual Maintenance Fee up to $737 per year**: Accounts for an average of 8 hours of CES effort to maintain and conduct required inspection(s) annually for study provided equipment. http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/clinical_engineeringservices.html

Rheumatic Diseases Research Core Center (RDRCC) Costs and Fees

- **Rheumatic Diseases Research Core Center (RDRCC) Initial Review Annual Fee up to $3,685**: (The Rheumatic Disease Research Core Center - Human Subject's Core D provides infrastructure and resources to facilitate multidisciplinary translational research in rheumatic disease. The Core works with the Investigator and study team to monitor and assist with IRB submissions, responses, renewals, subject recruitment, enrollment, internal audits, retention and any other aspects of clinical research from initiation to completion to improve the research process and enhance quality of research.) Mandatory expense - All studies in the division of rheumatology are under the supervision of the RDRCC.

Extended Archiving Fee

- **Extended Archiving Fee up to $737 per year:** If the study is extended and/ or the requirement for archiving records is changed the sponsor agrees to pay an additional $737 per year the study archiving is extended. All future archiving payments will be collected at the close of the study.

Monthly Meal Inventory Management Fee

For all meal studies:

- **Nutrition Inventory Management Fee, monthly:** Meals vary dependent on the protocol. This includes going through all expired foods/products, forecasting and ordering new products for these meals. It also includes ordering supplies for the packaging and/or getting specialized foods outside of Hopkins. Maintaining a par level to ensure all foods are on hand for special patients.

- **Nutrition Monitor Visits, up to $111 per visit**: Monitor fees per site visit.

- **Nutrition General Protocol Services**: Fee varies on protocol development, protocol management, consultation, training, supplies, etc.
- **Nutrition Food Services Fee**: Fee varies on the type of food required per the protocol.
- **Nutrition Food Challenges Fee**: Fee based on the food challenge tier required per the protocol.
- **Nutrition Clinical Assessment**: Fee varies on the assessment required per the protocol.
- **Nutrition Dietary Assessment**: Fee varies on the assessment required per the protocol.
- **Nutrition Staff Time Fee**: Fee varies based on time/labor hourly.
- **Nutrition Body Composition Fee**: Fee varies based on anthropometric measurement required.

Personnel Effort Fees

These administrative fees are charged to compensate for study team effort, and do not include the actual review fees.

- **Annual Administrative Fee, up to $4,422 per year**: Staff effort to prepare, review, and submit the continuing review report, including study progress, prepare reports for institutional clinical research management system report, annual review of financial accounting status and overall annual review of study
- **Amendment Processing Fee for All Sponsor Initiated changes, up to $1,474 each**: Accounting for staff effort to review, prepare, and submit study amendments to JHM IRB, including but not limited to dissemination to all study team members, institutional submissions as well as education/training when applicable. Rate is determined by the intensity-level of the amendment.
- **Pre-Screen Chart Review Fee up to $2,948:** Staff effort to search EPIC to locate potential patients, reviewing the potential patients charts for eligibility to participate in the clinical trial. This is done in order to minimize screen failures as well as identifies patients who may want to participate in the study which increases enrollment numbers.
- **Advertising/recruitment Fee**: Based on what is needed i.e., inter Hopkins TV, newspaper, letters to outside physicians.
- **Patient Parking Fee of up to $90**: For ten parking vouchers.

- **Serious Adverse Event Submission Fee, up to $516 per report**: PI and study coordinator effort to prepare, review, and submit study Serious Adverse Events per protocol to the sponsor, accounting for an average of 4 to 6 hours of effort per report.

- **IND Safety Report Processing Fee, up to $244 each**: PI and study coordinator effort to review, file, and submit when applicable each IND safety report received per sponsor, accounting for an average of 0.25 hour of effort.

- **Query Fee on previously monitored data, up to $74 each.**

- **Re-consenting Fee, up to $148 each**: Accounts for staff effort to familiarize patient with consent changes, answer any questions, and document the re-consent process.

- **Monitoring Fee On site visit per day up to $737**: Accounts for the time and effort of staff to stay with Monitors while reviewing and adjudicating patient records

- **Remote Monitoring Visit with Sponsor Monitor per teleconference, up to $737 each during COVID-19**: Accounts for the time and effort of staff to pull documents from patient binders, scan, redact and sit on calls with the monitors.

- **Additional Monitor Fee, up to $1,474 per day**: Accounts for additional study coordinator effort to accommodate space for, and address comments and queries from, more than one monitor per day.

- **Change in Monitor Fee, up to $1,474 each**: Accounts for the additional staff effort required to familiarize the new monitor with our medical records system/study charts, and our site's policies, procedures, and various departments (PI office, pharmacy, SAC lab, or other facilities, as needed).

- **Audit Fee, up to $5,159**: If selected for audit (FDA or sponsor-initiated), this accounts for staff effort to prepare for and facilitate an audit up to 7 days.

Invoiceable Subject Costs

Port Access Fee up to $422.

Imaging submission/copy up to $211.

Cardiology Fees:

- **Single ECG (sponsor or JHH machine) up to $211.**
- **Triplicate ECG up to $422.**

Laboratory Fees: Based on protocol and budgets prepared by laboratory.
https://grcf.jhmi.edu/clinical-trial-support/

The Specimen Accessioning Lab (SAC) provides a centralized resource for the collection and processing of samples from patients. The SAC Lab facilitates and supports the ongoing laboratory and clinical research within Johns Hopkins University, School of Medicine. In addition, the SAC provides rigorous quality assurance and quality control for the processing and storage of clinical samples. Thus, the specific services of the lab are:

1) Centralize accessioning of patient specimens,

2) Process patient specimens and tissue samples utilizing good laboratory practices (GLP) procedures,

3) Store specimens in a well-controlled and monitored environment in order to ensure sample integrity,

4) Fairly and equitably distribute accessioned samples to investigators with IRB-approved research questions.

5) Maintain a secure relational database that includes detailed information on the handling and processing of the samples along with pertinent clinical and demographic data that correlate to the specimen.

6) Provide expertise and support to investigators in the planning of sample collection for the development of correlative biologic tests for clinical trials and for pharmacokinetic/pharmacodynamics analysis

Subject Travel

Subject lodging and travel reimbursement costs will be included per study provision. Patient reimbursement costs may vary by department. Based on consent language and contract. A one-time **Patient Travel Reimbursement Admin Fee of $120 per subject** will be charged to the sponsor, to cover staff effort to set up and manage the service, and to provide details for Sponsor records. May use third party vendors.

If using sponsor vendors, the same **Patient Travel Reimbursement Admin Fee of $120** will be charged per subject, to cover staff effort to train and assist the subject on using the service.

Physical Therapy Fees

- **Training up to $111 per hour:** Required training for study start-up and reviewing the protocol.
- **Re-Certification Training up to $89 per hour:** Re-certification is required per year for the duration of the study.

Close-Out Fees

One-time administrative fees required at study completion include:

- **Administrative Close-Out Fee up to $2,211**: Accounting for an average of 20 hours of study team and research administrative effort to prepare, review, and participate in study close-out activities.
- **IDS Pharmacy Close-Out Fee up to $737**: Accounting for 10-15 hours of IDS pharmacy effort for closeout meetings, drug return/destruction, final records review, and final accounting.
- **IRB Close-Out Fee of up to $1,106**: Direct charge by JHM IRB for study close out.
- **Long-term Record Retention Fee up to $2,211**: Accounting for a minimal of 7 years of study document retention at Iron Mountain and/or other JHU-contracted facility.
- **Nutrition Close-Out Fee up to $737**: All studies will be utilizing nutrition will have a one-time close out fee.

Invoice Support Documents

There are internal procedures in place to prevent billing a patient's insurance if a test or procedure is to be billed to the research study. **Individual departments (i.e., pathology, radiology, etc.) at JHU do not provide invoices for each test performed on subjects that go on clinical trials.** Therefore, a summary invoice will be compiled based off of completed tests and procedures on each study subject as recorded on the CRFs. These tests and procedures will be billed at the total rates as agreed upon in the study budget. **No additional departmental statements will be provided**.