**JUSTIFICATION OF STUDY MANAGEMENT FEES & INVOICEABLES FOR SITE START-UP**

**Contract Review Fee ($**XX **x** XX **hours) $**

Time for principal investigator (PI), financial team and legal team to:

* Review protocol and contract language
* Finalize contract
* Route contract
* Execute contract

**Scientific Committee Review Fee ($**XX **x** XX **hours) $**

Time for the scientific committee to review the protocol for scientific merit and appropriateness to conduct the trial at the institution.

**Study Budget Development Fee ($**XX **x** XX **hours) $**

Time for PI, regulatory team, research coordinator and financial team’s review of estimated costs, budget development, budget negotiations and finalization and CTMS set-up.

**Coverage Analysis Fee ($**XX **x** XX **hours) $**

Time for PI and financial team to develop the coverage analysis and route through institutional approvals.

**Research Team Start-Up Activities ($**XX **x** XX **hours) $**

PI and research coordinator time for review and completion of protocol related documents; feasibility assessment; completion of study-related sponsor feasibility materials; attendance at pre-study, investigator and initiation visits; and local study set-up such as local manuals, source document and order development.

**Study-Specific Training ($**XX **x** XX **hours) $**

Study team’s effort for completing required training per sponsor and regulatory requirements.

**Radiology Set-Up Fee $**

Radiology Services at [LOCATION] charges a $XX administrative fee to review and set up the study.

**Lab Set-Up Fee $**

Study team’s effort to set up lab processes per protocol requirements and cover the per-study administrative fee charged by the lab.

**Neurodevelopmental Services Set-Up Fee $**

Neurodevelopmental Services at [LOCATION] charges a $XX administrative fee to review and set up the study.

**Cardiac Diagnostics Set-Up Fee $**

Cardiac Diagnostics Services at [LOCATION] charges a $XX administrative fee to review and set up the study.

**Clinical Research Center Fee ($**XX **x** XX **hours) $**

The clinical research center at [LOCATION] charges a $XX administrative fee to review and set up the study in electronic medical records (EMRs), and charges $XX/hour to see subjects in its outpatient clinic. Billing for study subjects seen in the clinical research center is part of [LOCATION]’s standard business practices; billing is hourly for all outpatient research visits.

**Ancillary Service Management Fee ($**XX **x** XX **hours) $**

Ancillary services at [LOCATION] charges a $XX administrative fee to review and set up the study.

**Study Financial Management Fee (Finance Office) ($**XX **x** XX **hours) $**

PI and finance team’s effort to manage sponsor and vendor bills and payments and manage correct subject billing/compliance.

**Budget Amendment Fee ($**XX **x** XX **hours) $**

Time for PI and finance team to review protocol/process changes and update the budget and CTMS set-up accordingly.

**Contract Amendment Review Fee ($**XX **x** XX **hours) $**

PI, financial team and legal team’s contract amendment review/finalization, routing and execution.

**Coverage Analysis Amendment Fee ($**XX **x** XX **hours) $**

Time for PI and financial team to update the coverage analysis and route through the institutional approvals.

**Screening/Chart Review Fee ($**XX **x** XX **hours) $**

PI and research coordinator time to review patient records to identify potential subjects and eligibility.

**Study Oversight Fee (PI/CRC/Regulatory) ($**XX **x** XX **hours) $**

Time for PI, research coordinator and regulatory team to maintain the study and provide overall oversight.

**Amendment/Consent Change Fee ($**XX **x** XX **hours) $**

PI and regulatory team time to review protocol, consent amendments or logistical changes that may require consent revisions; update the consent; and submit to IRB.

**Subject Re-Consent Fee ($**XX **x** XX **hours) $**

PI and research coordinator effort to re-consent subjects per sponsor and/or regulatory requirements.

**Serious Adverse Event/Unanticipated Event Management, per event ($**XX **x** XX **hours) $**

PI, regulatory team and research coordinator time to review each event (including follow-ups) and grade and report as per protocol and regulatory requirements.

**IND Safety Report Processing ($**XX **x** XX **hours) $**

PI and regulatory team time to review each IND report (including follow ups) and report per regulatory requirements.

**Monitor Visit Fee ($**XX **x** XX **hours) $**

Costs involved for the PI, regulatory team and research coordinator to set up, prepare and be available for study monitor for length of visit.

**Monitor Change Fee ($**XX **x** XX **hours) $**

Costs involved for research team to set up processes for the new monitor and revisit items covered by the prior monitor.

**Sponsor Audit Fee ($**XX **x** XX **hours) $**

Costs involved for the PI, regulatory team, research coordinator and QA team to set up, prepare and be available for study auditor for length of visits.

**Regulatory Agency Audit (not for cause) Fee ($**XX **x** XX **hours) $**

Costs involved for the PI, regulatory team, research coordinator and QA team to set up, prepare and be available for auditor for length of visits.

**IRB Review Fee - Initial Submission $**

Institutional IRB fee of $XX is charged for initial review. The commercial IRB fees are paid directly to commercial IRB by sponsor or CRO.

**IRB Review Fee - Continuing Review $**

Institutional IRB fee of $XX is charged for continuing review. The commercial IRB fees are paid directly to commercial IRB by sponsor or CRO.

**IRB Review Fee - Amendment or Change in Research $**

Institutional IRB fee of $XX is charged for amendment or change in research review. The commercial IRB fees are paid directly to commercial IRB by sponsor or CRO.

**Study Document Translation Fee $ Per Invoice**

This is typically by word count so will depend on the length of the consent or other document.

The commercial IRB translation fees are paid directly to commercial IRB by sponsor or CRO.

**Local IRB Review/Waiver Fee - Initial Submission ($**XX **x** XX **hours) $**

**Local IRB Review/Waiver Fee - Renewal ($**XX **x** XX **hours) $**

**Pharmacy Start-Up Activities $**

For pharmacy study start-up and study maintenance for one year. Pharmacy fees are determined by the investigational pharmacy per protocol and are non-negotiable.

**Pharmacy Maintenance Fee $**

For pharmacy maintenance after one year. Pharmacy fees are determined by the investigational pharmacy per protocol and are non-negotiable.

**Monitor Visit Fee (Pharmacy/Investigational Drug Services) ($**XX **x** XX **hours) $**

For pharmacy scheduling and time spent reviewing drug service during visit.

**Product Management/Return/Destruction ($**XX **x** XX **hours) $**

For pharmacy management/return/destruction of study products. Pharmacy fees are determined by the investigational pharmacy per protocol and are non-negotiable.

**Pharmacy Close Out Fee ($**XX **x** XX **hours) $**

For pharmacy close out. Pharmacy fees are determined by the investigational pharmacy per protocol and are non-negotiable.

**Greenphire ClinCard Management Fee ($**XX **x** XX **hours) $**

Financial team time for Greenphire ClinCard set up and management.

**Final Study Reconciliation Research Team ($**XX **x** XX **hours) $**

PI, regulatory team and research coordinator time for close-out activities.

**Final Study Financial and Accounting Reconciliation ($**XX **x** XX **hours) $**

PI and financial team time for close-out activities.

**Study Record Archival and Storage Fee < 10 years ($**XX **x** XX **hours) $**

Long-term storage fee for institutional and off-site storage per site policies.

**Study Record Archival and Storage Fee ≥ 10 years ($**XX **x** XX **hours) $**

Long-term storage fee for institutional and off-site storage per site policies.

**These start-up fees are NON-REFUNDABLE and are required for our institution to participate as a site in an industry-sponsored clinical trial.** They are not connected to recruitment or enrollment of a specific subject and therefore are not a part of the per-subject budget.

**All industry-sponsored studies are subject to an institutional overhead rate of XX%. These rates are standard and will be applied to all start-up fees and invoiceable items.**

The fees above are effective as of [DAY/MONTH/YEAR (XX/XX/XXXX)].

Signature Date

Title