**Start-Up**

The start-up fee is a one-time, non-refundable fee which represents costs associated with the time and effort for all start-up related activities completed by the Regulatory, Finance and Clinical Operations staff.

Regulatory activities may include, but are not limited to, attendance at intake meeting, preparation of all documents for submission to the Institutional Review Board (IRB) and other regulatory committees as needed, regulatory binder development, regulatory packet preparation, and attendance at the Site Initiation Visit.

Finance activities may include, but are not limited to, understanding of the study protocol, attendance at the intake meeting, preparation and negotiation of the sponsor budget and completion of all internally required forms and signatures. The Finance team will also liaise with the University's Office of Sponsored Projects Administration as they negotiate the clinical trial agreement.

Clinical Operations activities may include, but are not limited to, attendance at the intake meeting, understanding of the protocol, meeting with the Principal Investigator (PI) to understand subject identification, evaluate study drugs or devices, review clinical best practices, study flow, study training for all appropriate personnel, source document creation, and attendance at the Site Initiation Visit.

**Investigational Drug Service (IDS) Start-Up**

The IDS start-up fee is a one-time, non-refundable, non-negotiable fee which represents costs associated with the time and effort for the investigational pharmacy staff to prepare for a clinical trial. Activities include, but are not limited to, staff in-service, storage space identification and preparation, protocol file set-up, and electronic health record build. The IDS staff will also meet with the PI and study team as needed to understand study flow and specific study needs.

**ORI**

The Office of Research Integrity (ORI) fee is charged to commercial/industry sponsors of clinical trials for IRB-related expenses. This is a flat-rate, one-time, non-refundable, non-negotiable fee of $3,000 for the ORI's initial review. ORI sends a separate invoice at contract execution to the sponsor for this fee. No overhead will be charged on this fee.

**Coverage Analysis**

The Clinical Research Support Office (CRSO) charges a flat-rate one-time, non-refundable, non-negotiable fee of $3,200 for all pharmaceutical industry-sponsored clinical trials that require a full coverage analysis. Coverage Analysis (CA) is a prospective review of all items and services provided in an NIH-defined clinical trial, to determine how each item should be funded. The process involves a detailed review and application of Medicare's National and Local Coverage Determinations (NCDs and LCDs), as well as specialty guidelines. The

process informs the study team of which items can be billed to the patient/their insurance, and which will need to be funded by the study. No overhead will be charged on this fee.

**IRB Continuation Review**

This non-refundable fee covers time and effort for preparation and submission of the annual continuation review to the local Institutional Review Board (IRB). This may include, but is not limited to, collecting the following: enrollment numbers including ethnicity, AEs/SAEs, withdrawals, deviations/violations, DSMB reports (if applicable), funding updates (if applicable), key personnel updates and summary of progress.

**Protocol Amendment**

This non-refundable fee covers time and effort for review, preparation, administration and submission of a sponsor-driven protocol amendment to the local IRB. Each protocol submission varies widely so details of work done will be protocol amendment specific.

**Contract Amendment**

The Contract Amendment Fee is a non-refundable fee that will be charged for each sponsor-initiated contract amendment. The fee covers the costs associated with the time and effort to process a contract amendment. This may include, but is not limited to, review of the amendment and any changes to the protocol that triggered the contract amendment, an assessment of the dollar change resulting from the amendment, completion of internally required documentation as well as liaising with our Office of Sponsored Projects Administration as they review the legal language and provide official University signature.

**Coverage Analysis Amendment**

This fee covers any significant sponsor-driven protocol amendments that alter the study visits, procedures, or study visit calendar. The CRSO Coverage Analysis fee is a non-refundable, non-negotiable $1,000 per occurrence. No overhead will be charged on this fee.

**Any Other Sponsor Driven Modification**

This fee covers any sponsor-initiated changes to the study that are not included in a protocol amendment. This may include, but is not limited to, changes to the Investigator Brochure, changes to the number of trial subjects, changes to recruitment plans, and study advertisement.

**Monitor Visits**

This fee covers the time and effort for the Principal Investigator, Clinical Operations and Regulatory staff to prepare for and participate in Monitor Visits. This fee will cover remote or on-site monitor visits and will be invoiced for each day of the monitor visit.

**SAE Reporting**

This is a non-refundable fee for the reimbursement of time and effort for documenting, completing and submitting the internal safety report to the IRB and other regulatory committees as needed. Activities involved in this process may include, but are not limited to, documentation of the SAE by

the coordinator, PI's review of the SAE and determination of the cause and possible association with the study treatment, decide if the safety item requires a change to the informed consent, determine if re-consenting of subjects is needed, communication with PI and sponsor as needed, submit the report to the local IRB and other regulatory committees as needed as well as addressing feedback and concerns raised by the IRB and other regulatory committees as needed.

**IND Safety Reporting**

This non-refundable fee covers time and effort to review the external safety report and submit to the IRB. Activities involved in this process may include, but are not limited to, consult with the PI, decide if the safety event requires a change to the informed consent, if re-consenting of subjects is necessary, submit the report to the local IRB and other regulatory committees as needed, as well as addressing feedback and concerns raised by the IRB and other regulatory committees.

**Long Term Storage/Archiving**

This is a non-refundable, one-time fee for the reimbursement of costs of storing study documents and materials for future reference, protection, and audit purposes.

**FDA Inspection**

This non-refundable fee covers time and effort to prepare for, participate in and provide follow-up for an FDA Inspection. Internal parties involved in an FDA Inspection may include the Principal and Co-Investigators and the Clinical Operations, Regulatory and Finance teams. Preparation activities may include, but are not limited to, review of all ICFs and HIPAA forms, source documents, adverse event logs, notes to file, Electronic Data Capture (EDC) and any outstanding queries. In addition, all regulatory and IRB documents will be reviewed such as the protocol along with all amendments, Investigational Drug Brochures (if applicable), 1572/1571 (if applicable), CVs, financial disclosures, licenses, trainings, IRB submissions/approvals, other regulatory committees as needed, all communications and corresponding logs. Lastly, the Finance team will review the internal account, all invoices and corresponding cash receipts and compare those to the fully executed contract and budget. During the inspection, all appropriate parties will attend as necessary as well as provide follow-up to any questions.

**Study Closeout**

The Study Closeout Fee is a one-time, non-refundable fee that covers the costs associated with the time and effort to close out the study. This may include, but is not limited to, review of all regulatory documents and submission of the closeout with the IRB and other regulatory committees if necessary. It also includes a final review of all financial data and communication of that data to the PI's departmental administrators.

**Pharmacy Closeout**

The Pharmacy Closeout is a non-refundable, non-negotiable, one-time fee that covers the time and effort of the Investigational Pharmacy staff to review drug accountability records as well as any investigational product remaining, prepare remaining investigational product for return, answer all sponsor questions and closeout all internal study files.