RESEARCH STUDY FEE SCHEDULE

This schedule describes the fixed fees associated with Seattle Children’s participation in clinical research studies. The fees are set by the hospital service areas based on the costs required to provide the associated services and are considered non-negotiable. The charges are only incurred when the specified service is required by the study (e.g., if no investigational drug is required, neither IDS charge applies).

F&A RATE

Our F&A (i.e. indirect cost or overhead) rate for industry sponsored clinical trials is 27%. The prices listed in this schedule of costs are our total costs and include of our F&A rate.

FIXED START-UP & CLOSEOUT COSTS

Investigational Drug Service (IDS) Administration Start-up $3,332
Includes pharmacy services such as: Research Pharmacist and Research Pharmacy Technicians, randomization, accountability, administration costs, start-up and closeout services. Note: Cost may differ if the IDS needs to prepare a placebo, or the study drug is a Class I drug, etc.

Investigational Drug Service (IDS) Hematology/Oncology Administration Start-up $3,204
Includes pharmacy services such as: Research Pharmacist and Research Pharmacy Technicians, randomization, accountability, start-up and closeout services.

Investigational Drug Service (IDS) Administration Quarterly Maintenance $320
Includes pharmacy services such as: blind study maintenance, dispensing oversight, drug preparation, accountability, administration costs, and compliance program services. Note: Cost may differ if the IDS needs to prepare a placebo, or the study drug is a Class I drug, etc.

Radiology Setup
Includes study start-up, study-specific requisitioning, maintenance and closeout.

Level I: Simple clinical imaging exams in DX, DEXA, US during regular business hours. $793

Level II: Clinical DX and DEXA (complex), Nuclear Med, PET, CT, regular and after-hours; large numbers of subjects enrolled. $2,178

Level III: MRI, drug studies, multiple modality studies with anesthesia - sedation component, non-clinical research studies regular and after-hours, combination research/clinical studies. $3,501

Clinical Lab Setup
For studies involving the local lab, this cost includes study start-up, study-specific lab requisitioning, study maintenance and study close-out. The clinical lab provides an array of laboratory and pathology-related services to support clinical and translational research at Seattle Children’s, including histology, tissue microarrays, DNA and RNA isolation, electron microscopy, providing local results.

$621

Research Lab Services (RLS) Setup
For studies involving a central lab, this cost includes study start-up, maintenance and study close-out for the research lab. The RLS provides an array of laboratory and pathology-related services to support clinical and translational research at Seattle Children’s, including histology, tissue microarrays, DNA and RNA isolation, electron microscopy, short and long-term specimen storage and shipping of specimens to other core facilities.

Level I: Application review, processing and/or moderate pathology consult $119

Level II: Application review, processing and/or complex pathology consult $305
Pediatric Clinical Research Center (PCRC) Setup $1,922
Includes study start-up, maintenance and study closeout. The PCRC offers inpatient and outpatient nursing support, study coordinators, nutritional consultation and psychometric testing specialists through the adult and pediatric clinical research units.

PCRC Prep $1,281
Includes research coordinator’s effort for completion of the initial application to the PCRC, which approves the study for feasibility and ultimately for the use of the PCRC.

Study Initiation / Institutional Review Board (IRB) Prep
Includes research coordinator’s effort for initial IRB document preparation, completion of site feasibility questionnaire, protocol implementation meetings, inventory of study supplies, preparation of regulatory binders, prescreening activities, etc. *Note: These prices do not include IRB fees from a third party, such as the Western Institutional Review Board (WIRB). Such fees may be paid directly by the sponsor, or the invoices may be paid on a pass-through basis by Seattle Children’s. F&A will be charged for all pass-through costs.*

- Initial Application $2,563
- Closeout $641

Document Storage $641
Includes document storage for a period of 5 years.

**INVOICEABLE COSTS**

Site Initiation Visit $1,922
Includes study team’s and associated hospital service area’s time for a site initiation visit with the sponsor; price is per day.

Investigator Meeting – Time $1,922
Includes the time and effort for the principal investigator and other required study team members to attend an investigator meeting; price is per day.

Investigator Meeting – Travel (invoice)
Travel expenses will be paid upon submission of an invoice and receipts.

Closeout Visit $961
Includes research coordinator’s time for a close out visit with the sponsor; price is per day.

FDA Audit $6,407
Includes the significant study team time and study site resources required to accommodate FDA auditors and comply with FDA audit requirements for the study, should an audit occur; price is per audit.
IRB Modifications and Renewals
Includes research coordinator’s effort to complete IRB documents, correspond with IRB and ongoing maintenance of the study. Note: These prices do not include IRB fees from a third party, such as the Western Institutional Review Board (WIRB). Such fees may be paid directly by the sponsor, or the invoices may be paid on a pass-through basis by Seattle Children’s. F&A will be charged for all pass-through costs.
- Modifications/Renewals (price is per submission) $1,602

Serious Adverse Event (SAE) Reports & Submissions $256
Serious Adverse Event (SAE) Reports & Submissions Hematology/Oncology $320
Includes completing, reviewing and submitting SAE reports to the IRB and sponsor; price is per submission.

MedWatch / Investigational New Drug (IND) Reports & Submissions $26
Includes completing, reviewing and/or submitting MedWatch and/or IND reports; price is per submission.

Safety Reports $320
Includes completing, reviewing and submitting safety reports to hematology/oncology regulatory officials; price is per submission.

Translations $2,563
Includes a certified translation of consent/assent or other minor study documents (diary, etc.); price is per translated document. Note: This cost only applies to studies if the Sponsor does not provide certified translated documents.

Monitoring Visits
Includes study team’s time for monitoring visits that is not included in per subject payments; price is hourly rate plus indirect costs and is paid upon submission of an invoice.
- Level I: Research Coordinator $64
- Level II: Registered Nurse $90
- Level III: Research Coordinator and Registered Nurse $154

Contract/Budget Amendments $641
Includes study team’s time and administrative costs to prepare and execute contract and budget amendments.