INSTITUTE FOR ADVANCED CLINICAL TRIALS FOR CHILDREN

9211 Corporate Blvd, Suite 250
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Industry Sponsored Clinical Trial Start Up and Other Fees

Sample Definitions

Pharmacy Review Fee: Costs associated with review of IB and protocol, meeting with monitors and research staff throughout the course of the study, initial set up, drug accountability and study closeout. *(Check with your Investigational Pharmacist as they may individual costs for initial set up, drug accountability, drug management/maintenance and closeout)*

Regulatory Document Preparation and Routing: Costs associated with preparation and routing for signatures of 1572, Financial Disclosures, CVs, licenses, lab certifications, W9. This fee also includes maintenance a nd updating as needed throughout the course of the study for change in personnel or expiration of any documents.

Archive Fee: Costs charged to institution to store study related documents onsite or offsite.

Lab Manual Review Fee: Cost associated with lab manual review, meeting with PI to review labs, lab supply set up, inventory, maintenance of lab supplies and return or destruction of supplies.

Administrative Fees: Costs associated with administrative fees include budget preparation, negotiation, contract review, account management, study invoicing, stipend payments, travel reimbursements, account reconciliation and account closeout.

Study Start Up and Closeout: Costs associated with study start up include protocol review and feasibility, completion of site questionnaires, investigator meeting time, site initiation meeting, internal in-servicing and educational meetings regarding the study. Costs associated with study closeout include, IRB documentation, preparation of archiving study materials, queries and time involved with monitor closeout visit.

Study Specific Training: If the sponsor requires annual study specific training or annual GCP training, this fee will assist with offsetting the time for the training.

Additional Monitoring Visits: If additional monitoring visits are performed due to study monitor turnover and the frequency is more that 4-6 weeks, site is requesting to be compensated for the additional time for CRA to acclimate the new monitor. *(Similar language is usually put into the contract to reflect frequent monitoring visits)*

Dry Ice Fee: If lab specimens are to be shipped to a central laboratory on dry ice, Site is requesting to be reimbursed for the cost.

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IRB Fees

Initial IRB Preparation and Review: Preparation of Initial IRB Application and consent for submission to the IRB for review**.** Time and effort for changes needed by Industry and the IRB prior to final approval.

Annual IRB Preparation and Review: Preparation of Annual IRB report for IRB approval. Review of all study participants, SAEs, AEs and other relevant information to be submitted for IRB review.

Amendment Preparation and Review: Preparation of amendments for IRB review and approval. Completion of amendment applications for IRB review.

Safety Report Preparation and Review: Preparation of Safety reports for IRB submission. Review of information and sign off by PI. Submission to IRB for review and approval.