CLINICAL TRIALS – INDUSTRY BUDGET (INVOICEABLE SALARY RELATED COSTS)

Revised July 12, 2024

Administrative Item	Description	Note
Start-Up & Study Approval Process: Application Preparation & Submission to: IRB and Pharmacy (includes ISPRC&/ MRSC)	• Preparation and submission of applicable pre-study approvals completed by Regulatory for start-up • Review of Case Report Forms (CRFs), laboratory & specimen collection manual, source document preparation and coordination, and training on applicable EDC system(s) and e-CRF completion procedures. • Maintenance of study-specific in-service and staff training • Budget preparation, development, and negotiation	Study Team - Regulatory
Site Initiation Visit: Time & Effort	• Sponsor Required Visit that pertains to the time and effort conducted by study team to clarify the Study Start-up Process from protocol development through site initiation and activation	Study Team - PI, Regulatory, Coordinator, Data Manager
Study Closure including IRB Closure	• Staff time and effort in preparing study closure that consist of: IRB submission of study closure application, correspondence through approval, and routing of IRB closure notice, clinical trial management system all appropriate Departments notified as well as study team.	Study Team - Regulatory, Coordinator, Data Manager
Study Re-Open Process: Application preparation and submission to IRB, IMV	• Time and effort conducted by research staff to reopen study by resubmitting IRB approval and notification to the appropriate parties involved.	Study Team - Regulatory, Coordinator
Annual Committee Renewals	• Staff time and effort required to: correspond with applicable regulatory committees, sponsor and/or CRO, answer questions, resolve queries, obtain necessary approval(s), and provide documentation to applicable parties in accordance with federal, state, and local laws and regulations	Study Team - Regulatory
Protocol Amendment/Investigator Brochure (IB)	• Staff time and effort in preparing, completing and submitting the required documentation and application(s) upon the receipt of sponsor protocol amendment	Study Team - Regulatory
ICF Change	• Staff time and effort in preparing, completing and submitting the required documentation and application(s) triggered by sponsor initiated amended protocol	Study Team – Regulatory
Sub-study ICF (or any other additional consenting)	• Time and effort conducted by research staff to submit separate approval for sub study IRB consent form.	Study Team – Regulatory, Coordinator
Re-Consent per participant	• Time and effort conducted by research staff to go over revised/amended consent for study. Review sponsor requested changes in potential or actual risks or benefits to subjects.	Study Team - Coordinator

Remote Monitoring	• Remote or on-site monitoring visit fee (applicable if UCLA faculty and/or staff visit participation is required)	Study Team – Coordinator or Regulatory
Telephone Lost to Follow-Up/Survival	• Time and effort of clinical team to make calls to subjects to provide an update on status	Study Team - Coordinator
Pre-Screening Log, Cost Per Patient	• Time and effort for study team to review chart and history for potential study accrual, obtaining subject's prior history and prior chemotherapy detail	Study Team* – PI *or* Coordinator
Medwatch Reports/IND Safety/SAE Reporting "Per report"	• Report that are submitted to UCLA for study team review. This review is performed by PI and allotted for PI time and effort.	Study Team - PI
Serious Adverse Event (SAE) (Initial/Follow-Up/Resolution) Per Event	• Subjects being hospitalized during study due to an SAE outpatient visit, this fee is coverage for staff time and effort for research related outpatient visits.	Study Team* – PI, Coordinator, Data Manager (*split rates for each staff; request rates from negotiating party)
Adverse Event (AE)	• Research staff time and effort working on reviewing entire chart, enters data in log for AEs and preps for monitor review. AEs (assessing the patient's condition) are difficult to pinpoint time, different patients will vary when checking the patient's conditions.	Study Team – PI, Coordinator, Data Manager (*split rates for each staff; request rates from negotiating party)
Unscheduled Visits (staff fees)	• Time and effort for subjects coming in for an unscheduled visit, this fee is coverage for staff time and effort for research related visits	Study Team* – PI, Coordinator, Data Manager (*split rates for each staff; request rates from negotiating party)
Hospitalization Research Staff	• Subjects being hospitalized during study due to an SAE inpatient visit, this fee is coverage for staff time and effort for research related inpatient visits.	Study Team – PI, Coordinator, Data Manager
Survival Follow-up (per contact)	• Time and effort performed by study staff for subjects provide sponsor with the appropriate data and in effort to collect information regarding patient status, this may not just occur over one call. Sometimes it may take several calls to get a hold of a patient and or several follow-ups are made to retain status	Study Team – PI, Coordinator, Data Manager
Monitoring Change Fee Monitor visit if beyond protocol/contract determined visits	• Time and effort conducted by study staff for Monitor Change (only applicable if new monitor requires study staff to review data) or unpredicted visits over and beyond what was determined regular practice.	Study Team – Coordinator, Data Manager
Sponsor Budget Template Creation	• Sponsor's budget template is used as a source document for the Sponsor's internal purposes only. Therefore, if sponsor has negotiator complete budget	Study Team - Negotiator/CTP

	on sponsor template this is a cost that is used for study team time and effort.	

Audit Item	Description	Note
Preparation Fee	• Time and Effort conducted by Study Team (Principal Investigator, Sub-Investigator, Study Coordinator, Project Manager, Clinical Research Staff) during the inspection. • Facility spaces/rooms for conduct of inspection. FDA Investigator office space to work provided. • Assigning tasks to specific staff to assist in preparation for the inspection.	Study Team – PI, Regulatory, Coordinator, Data Manager
Performance	• Study procedures, Protocol, Patient information sheet and informed consent forms, Case report forms and queries, Source data including medical records, Serious adverse events (SAEs), Adverse Events (AEs), SUSAR Reports, Site files (patient's notes and diaries, home health records, pharmacy and drug records, signed financial documents/receipts, pharmacy agreements, documentation relating to doses/dispensing, etc.). • Review qualifications and training of the trial team members (etc.). • Meet with the support team to monitor audit preparation, identify issues to address, and take corrective actions as required (etc.). • Legal and administrative documents: Annual safety report, end of study letter and/or protocol amendments regulatory authority and ethics committee (etc.). • Essential documents: Structure and content of files, Archiving facilities, Document retention (etc.). • Case Report Form (CRF): Timeliness of completion (etc.). • Informed consent form (ICF) procedures: ICF availability, Copies of ICF provided to patient (etc.). • Source data: Location of source data documents, Records of patient participation, Confirmation of patient eligibility by investigator (etc.). • Conduct of the trial: Patients eligibility criteria, Patient visits per protocol, Protocol amendments (etc.). • Organization and personnel: Reviewed Delegation log, clinical trials Curriculum Vitae (CV), GCP training, CV (etc.). • Investigational Medicinal Product (IMP) handling: Accountability, Inventory, The storage area security, The temperature log (etc.). • Laboratory: Equipment used, Calibration of equipment, SOPs on receipt of samples or specimens, calibration, documentation of samples (etc.).	Study Team - PI, Regulatory, Coordinator, Data Manager

	• Monitoring: The monitoring plan, follow–up, Monitor rooms (etc.). (Data reviewed for previously monitored data from 2017 based on sponsor-initiated monitor changes resulted study team additional time and effort.) • UCLA to provide U.S. Food and Drug Administration (FDA) required Corrective Action Plan with strict deadline.	