

CLINICAL RESEARCH INSTITUTIONAL FEE SCHEDULE

SUPPLEMENT A – COST STRUCTURE RATIONALE

The scope and purpose of this SOP is to set forth requirements for the conduct of industry sponsored *clinical trials* within the University of Utah. This SOP may be used to guide the conduct of other types of clinical research studies to promote standardization and proper clinical research billing compliance practices.

Introduction and Purpose

The Clinical Research Institutional Fee Schedule (UUSOP-13) is set forth as a standardized cost structure to be utilized when participating in industry sponsored research. Fee standardization within the University of Utah promotes consistency and assists in adhering to proper research billing compliance. Information in this document outlines the rationale for the cost structure to allow proper oversight of research at the University of Utah.

Definitions and Acronyms

Clinical Research: Clinical research includes all research involving human participants. It does not include secondary studies using existing biological specimens or data collected without identifiers or data that are publicly available.

Clinical Trial: Clinical trials are clinical research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome.

CMS:	Centers for Medicare & Medicaid Services
CRF:	Case Report Form
CTO:	Clinical Trials Office
CTSI:	Clinical & Translational Science Institute
eCRF:	Electronic Case Report Form
GCP:	Good Clinical Practice
HIPAA:	Health Insurance Portability and Accountability Act
IB:	Investigator's Brochure
ICF:	Informed Consent Form
IDDF:	Investigational Drug Data Form
IDE:	Investigational Device Exemption
IDS:	Investigational Drug Services
IND:	Investigational New Drug
IRB:	Institutional Review Board
PI:	Principal Investigator

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SAE:	Serious Adverse Event
SIV:	Site Initiation Visit
SOP:	Standard Operating Procedure
SUSAR:	Suspected Unexpected Serious Adverse Reaction

1. Administrative Start-up. Fee will be assessed based upon the specifics of the protocol and will include, but is not limited to the following (as applicable):

1.1. Internal Study Review

- Meeting with research staff: Principal Investigator, Sub-investigators, study coordinators, lab personnel, finance personnel, contract personnel and Investigational pharmacy
- Familiarization with the study protocol and review IB
- Determine logistics of study execution (working with ancillary services in additional to outpatient/inpatient locations)
- Preparation for Sponsor visit (site initiation)

1.2. Study Preparation

- Training on sponsor specific Data Capture Systems (eCRF)
- Training on sponsor protocol
- Training on sponsor specific equipment, rating scales, GCP
- Creation of source templates based on the study protocol
- Creation of subject charts, logs, trackers
- Provide training to support staff on study procedures as applicable: back-up study coordinator, lab, investigational pharmacy, clinic/floor nurses
- Investigator Meeting (travel time & attendance)

1.3. Imaging/Testing Preparation

- Determine scope of service and requisite space
- Staff training on the study protocol and lab manual
- Inventory and store adequate supplies and ensure receipt of necessary items
- Local Equipment accountability and calibration logs (i.e., BP monitors, ECG's, etc.)

1.4. Investigational Pharmacy Preparation

- Determine supplies required for study drug administration
- Logistics of study drug dispensing

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- Accountability documentation/CRF requirements
- Collecting previous and current temperature logs
- Planning for study drug retrieval/disposal
- Associated fees will be passed on to sponsor via line-item costs

1.5. Research Location Assessment and Procurement

- Evaluation of trial needs in terms of space and personnel
- Application for use of space and personnel as indicated
- Completing physician order templates, laboratory order forms, etc.

- 2. Clinical Trials Office Fee & Quarterly Department Maintenance.** Clinical Trials Office Fee charged to all studies, irrespective of sponsor to allow adequate regulatory oversight and compliance with GCP, Human Subject Protection, and University requirements. Some of the CTO activities conducted at our site that are included in the fee for this and all trials:

2.1. Internal Feasibility Assessment

- Addressing pre-trial questionnaires
- Providing required documents to sponsor (site information sheet, GCP, etc.)
- Assessing eligible study population resources
- Preparing for Sponsor visit (site selection)
- Completing Sponsor visit (site selection)

2.2. Providing streamlined and consistent contracting and budgeting processes to decrease startup and amendment timelines

2.3. Providing quality assurance and improvement to the proposed clinical research project

- Protocol review to:

2.3.1. Streamline any potential IRB conflicts,

2.3.2. Address protocol issues that would potentially be misinterpreted by the Principal Investigator (leading to study decline)

2.4. Data queries to determine feasibility of recruitment efforts and the adequate population specific to the protocol

2.5. Determining the extent and duration of regulatory requirements relating to the population being studied, especially crucial due to working with special population participants

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- 2.6. Providing recruitment planning and retention assistance
- 2.7. Continuing quality assurance and improvement to the proposed clinical research project throughout life of trial
- 2.8. Ensure protocol adherence by:
 - 2.8.1. Reviewing informed consent process in real time
 - 2.8.2. Identifying areas of local risk (i.e., protocol training, staffing, study procedures, etc.)
 - 2.8.3. Training on protocol amendments
 - 2.8.4. Revising documentation to maintain consistency with protocol amendments
- 2.9. Managing audit prep of subject charts and regulatory documents when notified of submission of NDA, FDA, or sponsor audits
- 2.10. Providing additional quality control on case-by-case basis to ensure data integrity and subject safety. Examples that necessitate internal quality control could include:
 - 2.10.1. Sponsor monitor turnover
 - 2.10.2. High enrollment (high risk for audit)
 - 2.10.3. Complexity of trial (phase I, study endpoints)

3. IRB Preparation and Review

- 3.1. Regulatory Preparation
- 3.2. Regulatory document collection, copying and submission (mailing)
- 3.3. Create and maintain the Investigator Site File
- 3.4. Maintain correspondence with the Sponsor and all institutional departments regarding the status of the study
- 3.5. Prepare ICFs per IRB specifications
- 3.6. Prepare IRB submission
- 3.7. Track submission progress and facilitate revision resolution, if applicable
- 3.8. See <https://irb.utah.edu/fees.php> for local IRB Fee Schedule

4. CMS Coverage Analysis. Fee associated with ensuring clinical trial billing compliance. Activities include but are not limited to:

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- 4.1. Performing comprehensive and independent review of all documents related to clinical trial research study funding, including the research study budget, protocol, contract, informed consent, and other supporting core documents
- 4.2. Completing coverage analysis by reviewing and documenting CMS guidelines and policies for national and local coverage determinations

5. Sponsor monitoring

- 5.1. Scheduling and coordinating with research staff; Principal investigator, Sub-investigators, Study coordinators, Lab personnel, and Investigational pharmacy
- 5.2. Preparing necessary documents for visit
 - 5.2.1. Uploading documents to shared platform
 - 5.2.2. Redacting and emailing/mailing documents
- 5.3. Meeting between sponsor and research staff; Principal investigator, Sub-investigators, Study coordinators, Lab personnel, and Investigational pharmacy
- 5.4. Over the shoulder electronic medical record review (study coordinator must be present – in person or remote)
- 5.5. Monitor change (additional effort for research staff to acquaint new monitor with facilities and site procedures)
- 5.6. See UUSOP-10 Monitoring Visits for Externally Sponsored Clinical Trials

6. Pre-screening/Recruitment. Fee will be assessed based upon the specifics of the protocol and will include, but is not limited to the following (as applicable):

- 6.1. Implementing recruitment strategies in accordance with IRB requirements and approvals
- 6.2. Screening and determining subject eligibility based on inclusion/exclusion criteria and document each potential participant's eligibility or exclusion by:
 - 6.2.1. Running internal queries
 - 6.2.2. Performing extensive medical chart review
 - 6.2.3. Communicating with treating physicians and additional clinical staff
 - 6.2.4. Screening clinic schedule for eligible participants daily
 - 6.2.5. Completing screening Log and ongoing submission to sponsor

7. Outside Agency Audit (not for cause)

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- 7.1. Preparing for and hosting outside agency (sponsor, FDA, other external party) for site audit
- 7.2. Providing required documentation
- 7.3. See UUSOP-02 FDA Inspections

8. Research Facility Fee

- 8.1. Utilizing dedicated research space to complete protocol required visits

9. Foreign Language Translation & Interpretation

- 9.1. Onsite interpretation services
- 9.2. Coordinating and scheduling with interpreter
- 9.3. Translating study documents – i.e., Informed Consent Form, Assent, Parental Permission Forms, etc.

10. Document Archival and Storage

- 10.1. Storing of study documents to comply with HIPAA regulations
- 10.2. Compiling and organizing study documents at study closeout to prepare for archival
- 10.3. Purchase of archival boxes
- 10.4. Length of storage is per contract or protocol, whichever is longer
- 10.5. In the event the contract or protocol does not clearly state the required length of storage, site will invoice sponsor 15 years' worth of annual fees at closeout
- 10.6. See UUSOP-06 Study Records Management

11. Site Closeout. Fee encompasses all study close out activities, which include but are not limited to:

- 11.1. Conducting study close out visit with sponsor
- 11.2. Communicating with sponsor and additional research staff regarding close out activities
- 11.3. Completing and reporting final queries
- 11.4. Coordinating closeout with investigational pharmacy, laboratory, etc.
- 11.5. Performing financial audit of all study related payments
- 11.6. Preparing and submitting administrative forms necessary to close out account

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- 12. CTMS Fees:** This covers the software license fee for access to the University of Utah's Clinical Trial Management System (CTMS), *OnCore*, which supports the following activities over the lifetime of the study:
- 12.1. Reconciliation of financial management, invoicing, and compliance monitoring
 - 12.2. Tracking and payment of clinical research study billing
 - 12.3. Participant tracking and payment (compensation/reimbursement)
 - 12.4. Creation and maintenance of e-binders for regulatory documents
 - 12.5. Reporting of clinical trial management and financial milestones
- 13. IDS Pharmacy.** Fees will be assessed based upon the specifics of the protocol and will include, but is not limited to the following (as applicable):
- 13.1. Setup
 - 13.1.1. Reviewing protocol
 - 13.1.2. Preparing forms
 - 13.1.3. Meeting with PI and study team
 - 13.1.4. Developing dispensing guidelines and IDDF
 - 13.1.5. Inservicing pharmacy staff
 - 13.2. IDS Pharmacy Drug Destruction
 - 13.2.1. Ensuring destruction and/or return handling
 - 13.2.2. Fee is charged at study initiation
 - 13.3. IDS Pharmacy Protocol Amendment
 - 13.3.1. Redesigning Epic scheduling/ordering system & adding additional arms
 - 13.3.2. Completing additional inventory
 - 13.3.3. Updating study binders
 - 13.4. Maintenance
 - 13.4.1. Ordering & receiving investigational product
 - 13.4.2. Completing monthly inventory
 - 13.4.3. Documenting record maintenance

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13.4.4. Fee begins after SIV occurs

13.5. IDS Pharmacy Special Monitoring

13.5.1. Creating manual logs

13.5.2. Documenting monthly temperatures

13.5.3. Additional monitoring of study drug

13.6. IDS Pharmacy Additional Paperwork

13.6.1. Manually completing and/or signing protocol required form/worksheet

13.7. IDS Pharmacy Closeout

13.8. Quote provided by IDS Pharmacy

14. Laboratory Setup

14.1. Determine scope of service and requisite space for specimen acquisition, processing, and storage

14.2. Staff training on the study protocol and lab manual

14.3. Inventory and store adequate supplies and ensure receipt of necessary items

14.4. Collecting lab normal ranges

14.5. Collecting Equipment temperature logs monthly (i.e., freezer/ refrigerator)

15. Specimen processing management fee

15.1. Receiving and storing sponsor provided laboratory kits and supplies

15.2. Tracking and maintaining sponsor provided laboratory kits and supplies

15.3. Disposing of expired sponsor provided laboratory kits and supplies

15.4. Rates vary depending upon the following:

15.4.1. Number of central labs

15.4.2. Total kits

15.4.3. Kits per time point

15.4.4. Specimen schedules

15.4.5. Timed collections

15.4.6. Timed ECGs

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15.4.7. After hours and weekend collections

16. Radiology Setup & Maintenance

16.1. Quote provided Radiology and Imaging Sciences

17. Radiological Drug Research Committee and Human Use Subcommittee

17.1. Providing regulatory support to prepare the Protocol Radiation Use Sheet (PRUS). Review is mandatory for all studies requiring imaging that uses radiation, radiation therapy, and any kind of radioactive agent.

18. Shared Investigator Platform Setup & Maintenance

18.1. Registering and creating profiles in system

18.2. Uploading applicable documents

18.3. Maintaining and updating profiles as needed

19. Ancillary Services Sponsor Required Protocol Training

19.1. See UUSOP-03 Protocol Training for Investigators and Study Staff

20. Sponsor specific equipment maintenance & storage:

20.1. Receiving and storing sponsor provided equipment

20.2. Tracking and maintaining sponsor provided equipment

20.3. Exchanging malfunctioning/damaged equipment

20.4. Returning sponsor provided equipment

21. Safety Event Reporting and Follow-up

21.1. Notifying sponsor of SAE as outlined in protocol (typically 24 hours)

21.2. Completing SAE report form as outlined in protocol

21.3. Following resolution/permanent outcome as outlined in protocol

21.4. Obtaining medical records from external facilities/hospitals

21.5. Redacting and emailing/ mailing source to sponsor

21.6. Other reportable events may include:

21.6.1. Adverse events of Special Interest

21.6.2. Unanticipated Problems

21.6.3. Unanticipated Device Effects

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21.6.4. Immune-mediated Events

22. Pregnancy Follow-up

22.1. Following pregnancy to term as outlined in protocol

23. IND/SUSAR External Safety Reports

23.1. Reviewing and acknowledging sponsor provided safety reports

23.1.1. Event is unforeseen in terms of nature, severity, or frequency

23.1.2. Event is related or likely related to participation in research

23.1.3. Event likely affects the safety, rights and welfare of current participants or suggest that the research places subjects or others at a greater risk of harm

23.2. Managing sponsor safety reporting portal

24. Participant Payments

24.1. Directly administering stipends and/or reimbursements to clinical trial participants

24.2. Debit cards are valid for three years after activation. At the expense of the project, expired cards should be replaced as necessary.

25. Budget Translation Fee

25.1. Translating site budget to sponsor template

25.2. Amending sponsor template to remedy errors and identify unmarked updates

26. Institutional Oversight Fee:

26.1. Preparing study to present to various committees for review and prioritization

26.2. Overseeing protocol trainings and study coordination

26.3. Reviewing adverse events and protocol deviations

26.4. Reconsenting and overseeing participant education

26.5. Engaging in sponsor correspondence, signoffs, study teleconferences, etc.

26.6. PI effort is removed from the per-patient costs since this covers all PI oversight.

26.7. See UUSOP-04 Investigator Responsibilities

27. Primary Children's Hospital Board Review

27.1. Fee associated with performing research at Primary Children's Hospital

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location (Intermountain Healthcare)

28. Center for Quantitative Cancer Imaging (CQCI):

28.1. Setup

28.1.1. Reviewing protocol and related documents including imaging manuals and CRFs to evaluate participant eligibility requirements, image acquisition specifications, image analysis requirements, response assessment criteria, and determination of routine versus research imaging requirements.

28.2. Analysis and response assessment

28.2.1. Image analysis and response assessment incurred for each participant time-point resulting for disease assessments; additional fees assessed for multiple response criteria. Response criteria includes: RECIST, WHO, IWRC, Cheson, Choi, irRC, IMWG, RANO, EORTC, PERCIST, etc.

28.3. See HCI Policy 005-19

29. CTSI Application Submission and Startup

29.1. Fee associated with review and approval of new protocol applications

29.2. Quote provided by CTSI

References

- UUSOP-02 FDA Inspections
- UUSOP-03 Protocol Training for Investigators and Study Staff
- UUSOP-04 Investigator Responsibilities (Institutional Oversight fee)
- UUSOP-06 Study Records Management
- UUSOP-10 Monitoring Visits for Externally Sponsored Clinical Trials
- UUSOP-13 Clinical Research Institutional Fee Schedule
- Budget Process for Industry Trials – UofU **Internal Only** Guidance Document: <https://qualitycompliance.research.utah.edu/budget-process-for-industry-trials/index.php>
- HCI Policy 005-19

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- Clinical Research Budget Training – University of Utah Research Education:
 - Clinical Research Budget Development and the Importance of Clinical Research Billing Compliance:
<https://utah.catalog.instructure.com/browse/research-education/research-education-red/courses/red-online-clinical-research-budget-development-and-the-importance-of-clinical-research-billing-compliance>
 - Clinical Research Budget Negotiation:
<https://utah.catalog.instructure.com/browse/research-education/research-education-red/courses/red-online-clinical-research-budget-negotiation>
 - Clinical Research Budget Oversight:
<https://utah.catalog.instructure.com/browse/research-education/research-education-red/courses/red-online-clinical-research-budget-oversight>