CLINICAL RESEARCH INSTITUTIONAL FEE SCHEDULE

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 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. Fees are inclusive of F&A unless otherwise stated.

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
CTMS Clinical Trial Management System
CTO: Clinical Trials Office
GCP: Good Clinical Practice
HIPAA: Health Insurance Portability and Accountability Act
IDE: Investigational Device Exemption
IDS: Investigational Drug Services
IND: Investigational New Drug
IRB: Institutional Review Board
PI: Principal Investigator
SAE: Serious Adverse Event
SIV: Site Initiation Visit
SOP: Standard Operating Procedure

1. Standard fees (applicable to all protocols):

1.1. Administrative Start-up:

- $6,750 one-time (minimal risk studies, i.e., observational, non-

CLINICAL RESEARCH INSTITUTIONAL FEE SCHEDULE

interventional, retrospective chart review)
- $10,800 one-time (all other studies)

1.2. Clinical Trials Office Fee:
- $6,750 one-time (minimal risk studies)
- $12,000 one-time (all other studies)

1.3. IRB Initial Submission and Review:
- $7,000 one-time (local)
- $4,500 (central)

1.4. IRB Amendment Fee:
- $2,725 per occurrence (local – includes prep and submission)
- $1,725 (central)

1.5. IRB Annual Review Fee:
- $2,225 annually (local – includes prep and submission)
- $1,225 annually (central)

1.6. IRB Closeout Submission:
- $2,120 one-time

1.7. CMS Coverage Analysis:
- $1,675 one-time (non-IDE trials)
- $2,184 one-time (IDE trials with sponsor submission to CMS)
- $4,095 one-time (IDE/IND trials with site submission to CMS)

1.8. CTO/Department Maintenance:
- $2,500 quarterly

1.9. Excessive Monitor Change:
- $1,425 (2nd change and each time thereafter)

1.10. Monitoring Visit:
- $918 per day

1.11. Remote Based Monitoring:
- $1,350 per event

CLINICAL RESEARCH INSTITUTIONAL FEE SCHEDULE

1.12. Pre-screening/Recruitment:
- $150 per hour

1.13. Outside Agency Audit (not for cause):
- $1,350 per day

1.14. Participant Re-consent:
- $150 per occurrence

1.15. Research Facility Fee:
- $350 per hour

1.16. Foreign Language Translation:
- $0.18 per word

1.17. Foreign Language Onsite Interpretation:
- $150 per hour

1.18. Principal Investigator Effort:
- $473 per hour

1.19. Research Nurse Effort:
- $316 per hour

1.20. Research Coordinator Effort:
- $150 per hour

1.21. Document Archival and Storage:
- $675 per year (length of storage is per contract or protocol, whichever is longer)

1.22. Site Closeout:
- $2,700 one-time

2. Additional fees (based on specifics of protocol)

2.1. CTMS Fees (i.e., OnCore):
- $5,400 one-time start-up
- $2,700 annual maintenance

2.2. IDS Pharmacy Setup:
- $4,455 one-time

CLINICAL RESEARCH INSTITUTIONAL FEE SCHEDULE

2.3. IDS Pharmacy Drug Destruction:
- $453 one-time at setup

2.4. IDS Pharmacy Protocol Amendment:
- $1,769 per occurrence

2.5. IDS Pharmacy Maintenance:
- $135 monthly (one drug)
- $61 (per additional item)

2.6. IDS Pharmacy Special Drug Handling:
- $1,013 one-time (if applicable)

2.7. IDS Treatment Plan Development:
- $419 per oncology treatment arm (if applicable)

2.8. IDS Pharmacy Special Monitoring:
- $675 one-time (if applicable)

2.9. IDS Pharmacy Additional Paperwork:
- $95 per occurrence

2.10. IDS Satellite Site Transfer fee:
- $142 per occurrence

2.11. IDS Pharmacy Closeout:
- $972 one-time

2.12. Laboratory Setup:
- $1,350 one-time

2.13. Specimen processing management fee:
- $800-$1,600 quarterly

2.14. Radiology Setup:
- $2,700 one-time

2.15. Radiology Maintenance:
- $200 quarterly

2.16. Radiological Drug Research Committee and Human Use Subcommittee:
- $2,300 one-time

CLINICAL RESEARCH INSTITUTIONAL FEE SCHEDULE

2.17. Phantom Imaging:
- $2,700 per scan

2.18. De-identification/CD/Upload of Images:
- $150 per occurrence

2.19. Shared Investigator Platform Setup
- $2,457 one-time

2.20. Shared Investigator Platform Maintenance:
- $534 quarterly

2.21. Ancillary Services Sponsor Required Protocol Training:
- $750 per occurrence

2.22. Sponsor specific equipment maintenance & storage:
- $250 quarterly

2.23. Safety Event Reporting and Follow-up:
- $621 per event

2.24. Pregnancy Follow-up:
- $150 per hour

2.25. IND External Safety Reports:
- $240 per report (after first 10 reports)

2.26. Participant Travel Reimbursement:
- Current IRS business mileage rate plus F&A

2.27. Participant Hotel Reimbursement:
- Up to $250 per night plus F&A

2.28. Participant Payments:
- $2.05 Debit Card (initial)
- $1.10 Debit Card (per transaction)
- $2.70 Direct Deposit (per transaction)
- $2.05 Debit Card (replacement)

2.29. Budget Translation Fee:
- $3,500 per protocol version

CLINICAL RESEARCH INSTITUTIONAL FEE SCHEDULE

2.30. Institutional Oversight Fee:

- $8,190 quarterly

2.31. Primary Children's Hospital Board Review:

- $2,089 one-time

2.32. Center for Quantitative Cancer Imaging:

- $1,365 one-time

2.33. CTSI Application Submission and Startup:

- $500 one-time

Materials Required

- UUSOP-13 Supplement A – Cost Structure Rationale
- Budget Process for Industry Trials – UofU **Internal Only** Guidance Document: https://qualitycompliance.research.utah.edu/budget-process-for-industry-trials/index.php
- 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

Document Approval

CLINICAL RESEARCH INSTITUTIONAL FEE SCHEDULE

1/30/2023

Erin Rothwell Ph.D. DATE
Interim Vice President for Research, University of Utah

Revision History

Version Date	Change Summary
29/Sep/2021	Original Version
31/Jan/2022	Updated to reflect F&A rate change
21/MAR/2022	Specified "OnCore" as CTMS
31/OCT/2022 25/JAN/2023	Addition of mandatory fees related to participant payment (i.e., 2.28.)

Printed or photocopied versions are considered unofficial copies unless it is the original signed document.