Virginia Commonwealth University
Office of the Vice President for
Research and Innovation

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August 26, 2024

To Whom It May Concern:

SUBJECT: Administrative Fees for Industry-Sponsored Clinical Trials

The Office of the Vice President for Research and Innovation issues Compliance Notices to inform those internal and external to Virginia Commonwealth University of expectations related to various requirements in the conduct of research and clinical trials. Compliance Notice 17-006 describes our Clinical Trial Administration Service Center and Fees. All faculty and study staff are expected to incorporate the established fees into their study budgets as of September 1, 2024.

The primary objectives for this service center are to:

- Provide consistent baseline rates to increase efficiency in negotiation with sponsors.
- Establish an internal cost recovery mechanism to ensure costs recovered under the standardized fees are distributed to the appropriate groups performing the activity.
- Ensure compliance with requirements outlined in VCU Compliance Notice 15-004, “Full Cost Recovery Guidelines for Clinical Research Initiated and Sponsored by Industry.”

It is imperative that VCU cover the costs of opening and managing industry-sponsored clinical trials. Individuals performing these tasks include personnel from the Office of the Vice President for Research and Innovation (OVPRI), School of Medicine (SOM), Massey Cancer Center Clinical Trials Office (CTO), C. Kenneth and Dianne Wright Center for Clinical and Translational Research (Wright Center), individuals within our hospital/clinical areas supporting clinical research, as well as members of the study team. Where multiple personnel are involved, effort is captured and fees allocated accordingly.

Table 1 represents activities and processes necessary for completion in order to ensure clinical trials are activated in accordance with ICH GCP guidance and FDA regulations, as well as to ensure efficient start-up and ongoing management at our site. The appendix provides justification for the charges outlined in table 1.

We trust that our industry sponsors will appreciate our efforts to include reasonable, consistent costs in our clinical trial budget negotiations.

Table 1: Industry Fees

Administrative Start-up Fees	**Fee***
IRB compliance (local IRB)	2,275
Regulatory preparation and filing	2,150
Cost analysis and budget	5,200

Regulatory software and management	695
Data management	1,950
Study team; protocol review and implementation	TBD
OVPRI Division of Sponsored Programs industry contract review	2,600
Hospital/clinical services; protocol review and implementation	TBD
Base Total Start-up Costs (Exclusive of Study Team and Ancillary start-up fees; TBD)	**14,870**
Oncology studies: Protocol Review and Monitoring Committee	5,825
Oncology studies: Study team start-up	13,475
Base Total Start-up Costs ONCOLOGY (Exclusive of Ancillary start-up fees)	**34,170**

Amendment Fees (per event/amendment)	**Fee***
Regulatory: Efforts to process protocol amendments or informed consent changes	900
Budget/Contract: Efforts to process budget and/or contract changes, including coverage analysis	1,125
Study Team Coordinator: Amendment review and implementation, e.g., update forms, re-consent subjects	TBD
Base Total Amendment Fees (Exclusive of Study Team amendment fees; TBD)	**2,025**

Annual Ongoing Management Services	**Fee***
Annual Administrative Maintenance Fee: Regulatory maintenance, protocol administration; data management upkeep	3,025
Study Team Coordinator: Ongoing coordination and study management, e.g. monitoring visits, audits	TBD
Base Total Annual Ongoing Fees (Exclusive of Study Team annual ongoing fees [beyond regulatory maintenance]; TBD)	**3,025**

Close-out Services	**Fee***
Financial and administrative close-out	2,800
Sponsor required record retention and storage for paper study documents	TBD
****Base Total Close-out Fees (Exclusive of record retention/storage)**	**2,800**

*Fees are inclusive of Institutional overhead @ 30%.
The above fees represent base amounts for activating and maintaining clinical trials at our site. If there are extraordinary sponsor or protocol requirements that increase the scope of work required to open a study, additional fees may be assessed.

Sincerely,

DocuSigned by:
Michael Newsome
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Michael Newsome
Senior Associate Vice President for Research
Director Finance and Administration - Office of Research and Innovation

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Appendix: Justification for fees

Administrative Start Up Fees
Start-up: Regulatory
○ ICF preparation: Prepare local consent form; facilitate sponsor approval of local consent form from initial IRB submission through approval, including revision(s) and resubmission(s) as necessary.
○ IRB preparation and initial submission: Finalize documents for IRB submission; address IRB comments and revise local documents for re-review where necessary; continued follow-up through approval.
○ Regulatory documents: Assemble regulatory documents and submit to sponsor, e.g., 1572, licenses, CVs, financial disclosures from all investigators, protocol signature pages, laboratory certifications and normal values, additional regulatory documents as requested; organize and set up site regulatory file.
Start-up: Cost Analysis
Coverage analysis and billing plan preparation: ○ Perform qualifying trial analysis according to NCD 310.1: Routine Costs in Clinical Trials, and document supporting information related to necessary requirements and deemed trial status ○ Analyze the investigational item/service in regards to FDA status, CMS Benefit Policy/NCO/LCD, and potential complications ○ Review protocol and informed consent document for therapeutic intent, participant cost and financial risk ○ Perform extensive NCO, LCD and literature search to support protocol defined items/services ○ Review anticipated billing classification and documentation with study team, consult with ancillary departments as necessary (e.g., IRB, Investigational Drug Services) ○ Provide study team with updates/modifications regarding informed consent language where appropriate; ○ Provide study billing grid for budgetary purposes.
Financial feasibility and congruency: Perform congruence review of study billing plan, consent form (related to therapeutic intent and costs to participant, 3rd party, and sponsor), contract and budget.
Administrative approvals: Final review and approval; finalize study billing plan for use by study team.
Start-up: Contract Review
○ Review by the Division of Sponsored Programs within the Office of the Vice President for Research and Innovation for contractual language to assure institutional and regulatory compliance.
Start-up: Site Budget
Budget development: ○ Confer with coverage analyst on complete financial assessment of trial (SOC, routine vs. research billable items); ○ Work with coverage analyst and OnCore team on study calendar build; ○ Meet with study team and coverage analyst, post meeting follow-up; ○ Obtain necessary codes for research procedures and request cost-outs ○ Prepare internal and sponsor budget for review; ○ Harmonize documents during congruency review. ○ Identify study relevant ancillary (e.g., clinical) services; request and track for cost quotes.
Budget negotiation: Ensure appropriate documentation and justification; transmit site budget to sponsor; negotiate and track through approval.
Document management: Paperless routing of project transactions; paperless record storage, internal budgeting (e.g., PI effort), communication, status tracking.
Start-up: Data Management

License fee: Use of OnCore, enterprise-wise clinical trials management system; upload and manage documents (version control); study level tracking/status; participant level tracking/status.
Calendar build: Create calendar at outset of new study; confer with coverage analyst, budget developer and study team as appropriate; enhance or review calendar as appropriate for use in participant tracking; patient finance; sponsor billing.
Start-up: Regulatory Software and Management
Use of Veeva, a 21 CFR part 11 compliant enterprise-wide system for electronic site regulatory binders; upload and manage documents for individual studies (version control); facilitate remote monitoring; archival for completed studies. Integration in place between OnCore and Veeva SiteVault to facilitate study and participant creation and study status changes.

Internal Compliance Review Fee (Local IRB Review and Routing)
IRB compliance (local IRB): Prerequisite to external IRB submissions from VCU is submission and review via RAMS-IRB (Research Administration Management System); documentation and review includes:
○ Informed consent document(s)
○ Clinical trial agreement ○ Documentation related to subject injury language ○ Cost coverage analysis ○ Conflict of interest review ○ Verification of mandatory training completion ○ Facilitation of commercial IRB submission, if applicable
Start-up: Study Team (Specific to Individual Clinical Trial)
Protocol intake: ○ Process confidentiality agreement; follow through and route for PI signature ○ Complete site feasibility assessment; ○ Coordinate site evaluation/qualification/pre-study visit; attendance at SEV; follow-through on items identified.
Protocol Review and Implementation: ○ Review protocol; raise/solve logistic issues where necessary; ○ Binder/chart set-up ○ Create source document worksheets ○ Draft orders and facilitate their review ○ Review laboratory needs; inventory lab supplies ○ Inventory and follow-up for study supplies, e.g., manuals, binders ○ Complete sponsor-required on-line training in advance of SIV, where required ○ Schedule, coordinate (with ancillary staff) and attend SIV; post-meeting follow-up ○ Attend sponsor's off-site investigator meeting (where applicable) ○ In-service ancillary staff

Annual Ongoing Management Services

Annual Ongoing Management Services: Regulatory maintenance, protocol administration; completion of sponsor documents, e.g., enrollment logs; participate in teleconferences with sponsor (routine and as needed); schedule, coordinate and facilitate in monitor visits; follow-through on items identified; data management upkeep.

Close-out Services
Financial and administrative close-out; schedule, coordinate and participate in sponsor close-out visit; prepare final documents for sponsor and IRB; reconciliation of study accounting.
Fee associated with the record retention requirements set forth by state and federal mandates. Documentation is secured and accessible for review in compliance with 21 CFR 312.62(c) and/or 21 CFR 812.140(d) as well as institutional standards. This will be calculated on an individual study basis based on anticipated volume of paper documents needing to be archived and for a designated number of years. Fee associated with archival of paper documents will be added if there is an anticipated need to archive paper documents associated with the study.

Amendment Services (per event/amendment)
Regulatory: Local IRB processing and facilitation with external IRB of record as applicable; regulatory document preparation; facilitate signatures; submission to sponsor; document version control, database updates.
Budget/Contract: Review and update coverage analysis, budget, contract; congruency review; dissemination of documents.
Study Team **(Specific to Individual Clinical Trial)**: Amendment review and implementation; revise source document worksheets where appropriate; in-service ancillaries; re-consent subjects where appropriate.