OVPRI Compliance Notice

No. 17-006.3
Last Approval Date: June 26, 2024

NOTICE: Clinical Trial Administration Service Center and Fees

Since July 1, 2017, VCU has assessed applicable administrative fees to all services provided to industry-initiated and industry-sponsored clinical trials.

The primary objectives for establishing this service center are to:

1) Provide consistent baseline rates to increase efficiency in negotiation with sponsors;
2) Establish an internal cost recovery mechanism to ensure costs recovered under the standardized fees are distributed to the appropriate groups performing the activity; and,
3) Ensure compliance with requirements outlined in OVPRI compliance notice 15-004, "Full Cost Recovery Guidelines for Clinical Research Initiated and Sponsored by Industry."

Description of Services Covered by This Notice:

I. Study Activation/Start-up Services, including:

a. **Regulatory** – Preparation of an initial Institutional Review Board (IRB) submission, preparation of the site's regulatory submission to the study sponsor, and preparation for and attendance at the site start-up meeting
b. **Coverage Analysis/Congruency** – Protocol review; preparation and approval of coverage analysis and billing plan documentation; congruency review of protocol, informed consent documents, contractual and budget documents
c. **Contract Review** – Review by the OVPRI Division of Sponsored Programs for contractual language to assure institutional and regulatory compliance
d. **Budget Development & Negotiation** – Preparation of ancillary service requests, budget development, budget negotiation, and preparation of Research Administration Management System-Sponsored Programs Online Tracking (RAMS-SPOT) submission
e. **Data Management** – System licensing costs plus the development of study protocol records and study protocol and financial calendars in VCU's clinical research management system of record, OnCore
f. **Regulatory Software and Management** – System licensing costs for VCU's electronic study binder system, Veeva, which houses all study documents, facilitates remote monitoring and archives electronic study records. Integration is in place between OnCore and Veeva SiteVault to facilitate study and participant creation and study status changes.
g. **Protocol Review & Monitoring Committee (Oncology only)** – Administrative support and management for all oncology related clinical research that must be reviewed by the Protocol Review and Monitoring Committee for scientific merit and competition prior to activation and at least annually thereafter

II. **Sponsor-driven Amendments, including:**
   a. **Regulatory**
      i. Preparation of IRB amendment due to protocol and/or informed consent document changes
      ii. Compliance review – evaluate the impact of study changes on coverage analysis/billing plan, budget, and contract
      iii. Update study calendar record in OnCore according to protocol and/or informed consent document changes
   b. **Budget & Contract**
      i. Revisions to coverage analysis, billing plan, and RAMS-SPOT submission
      ii. Revisions to budget and contract – budget development & re-negotiation
      iii. Congruency review – billing plan, budget, contract approvals
      iv. Updates to financial study calendar according to budget/contract changes

III. **Other Administrative Fees**
   a. Ongoing study maintenance – annual costs associated with ongoing regulatory requirements
   b. Ongoing protocol administration – annual costs associated with ongoing central administrative management; monitoring, reporting, and training costs
   c. Ongoing data management – annual per-protocol license costs associated with VCU clinical research management system
   d. Financial closeout – the one-time cost associated with the financial review conducted to verify study's financial closeout has been completed in an accurate and timely fashion.
   e. Administrative closeout – the one-time cost associated with the central administrative review conducted to verify study closeout sponsor requirements are met
   f. Archival of paper study documents – A fee associated with the archival of paper documents will be added if there is an anticipated need to archive paper documents associated with the study

Exception to Established Fees

In most cases, the full-service fee is assessed to the study when services of central offices are used for tasks identified. In limited circumstances where study complexities may warrant a downward adjustment to established fees, the fee may be modified as approved by the fiscally responsible units impacted. This is done by evaluating study complexity, evaluating detailed time/effort estimates used to develop fees, and adjusting fees as appropriate. Records of the quantity and type of downward fee adjustments are maintained and used in subsequent years when analyzing and updating established rates.

When a study is abandoned before a contract is executed, internal fees to be assessed to the study (or fiscally responsible unit) are evaluated and determined on a pro-rated basis based on activation activities that were performed up to the point the study was abandoned. Every attempt is made to recover funds from sponsors to cover such costs. Funds received from sponsors are distributed equitably amongst service providers performing start-up activities. The fiscally responsible units managing the study are expected to cover any costs not covered by sponsor payments unless the study is abandoned due to system or process delays beyond the control of the fiscally responsible unit. These situations are reviewed on a case-by-case basis.

Financial Service Center Management
The service center is administered by the Office of the Vice President for Research and Innovation (OVPRI), the Wright Center for Clinical and Translational Research (Wright Center) with both School of Medicine (SOM) and Massey Cancer Center (MCC) entering their information. A detailed order of events follows:

- Explanation of administrative fees to be assessed on a per study basis is finalized, then uploaded to OnCore during the final stages of study activation.
- Study activity/status is tracked in OnCore.
- Monthly OnCore Activity Report is generated identifying service center items to be billed. The report includes a link to a detailed Explanation of Fees document.
- Units (OVPRI, Wright Center, SOM, and MCC) enter applicable study charges in RAMS-Facilities Ordering Reporting Core Enterprise (FORCE) and upload supporting documentation.
- FORCE billing processed on a scheduled basis (e.g., 10th of each month)
- Banner journal voucher (JV) generated – department/index fiscal administrator approves charges to study index [JV approval]
- Sponsored index charged for expense; funds credited to appropriate service center index.
- Units manage staff time and other expenses (OnCore and Veeva licenses) applied to service center indexes according to workload/study activity that has occurred.
- OVPRI, Wright Center, SOM, MCC reconcile revenue/expenses monthly and adjust staff/cost allocations as necessary. Fiscally-responsible units maintain expense records for service center recovery indexes.
- Financial reports are analyzed annually by OVPRI, the Wright Center, SOM, and MCC. Updates may be proposed to fees/fee structure as needed to ensure appropriate cost accounting.

Fee Schedule
Fees will be reviewed and revised during the triennial review of this compliance notice or sooner if market increases dictate. The Administrative Fees for Industry-Sponsored Clinical Trials letter is posted on the Clinical Research Resources webpage and included at the end of this compliance notice. Study teams are also provided a study-specific summary of internal fees to be assessed prior to study budget finalization.

Contact
Questions regarding this compliance notice can be sent to rescomply@vcu.edu.

Issued By
VCU Office of the Vice President for Research and Innovation –
Michael A. Newsome
Senior Associate Vice President for Finance and Operations

Review/Revision History
06/23/2017: Creation as 17.006.1
08/28/2020: Reviewed and applied clarifying edits (17.006.2)
06/26/2024: Triennial review completed – added involvement of OVPRI and additional fees including for regulatory software and management, contract review, and archival of paper study documents (17-006.3)

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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.