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Office of Research and Innovation
Office of Research Administration and Compliance

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To Whom It May Concern:

SUBJECT: Administrative Fees for Industry-Sponsored Clinical Trials

The Office of Research Administration and Compliance issues Compliance Notices to inform faculty and staff at Virginia Commonwealth University of expectations related to various requirements in the conduct of research and clinical trials. Compliance Notice 17-006.1, issued on June 23, 2017 and effective July 1, 2017, 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.

The primary objectives for establishing this service center are to:

- Establish consistent base line 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 15-014, “Full Cost Recovery Guidelines for Clinical Research Studies 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 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.

The chart on page two 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.

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

Administrative Start-up Fees	Fee*
IRB compliance (local IRB)	2,080
Regulatory preparation and filing	1,850
Cost analysis and budget	4,475
Data management	1,700
Study team; protocol review and implementation	TBD
Hospital/clinical services; protocol review and implementation	TBD
Base Total Start-up Costs (Exclusive of Study Team and Ancillary start-up fees; TBD)	**10,105**
Oncology studies: Protocol Review and Monitoring Committee	5,025
Oncology studies: Study team start-up	11,650
Base Total Start-up Costs ONCOLOGY (Exclusive of Ancillary start-up fees; TBD)	**26,780**

Amendment Fees (per event/amendment)	Fee*
Regulatory: Efforts to process protocol amendments or informed consent changes	775
Budget/Contract: Efforts to process budget and/or contract changes, including coverage analysis	950
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)	**1,725**

Annual Ongoing Management Services	Fee*
Annual Administrative Maintenance Fee: Regulatory maintenance, protocol administration; data management upkeep	2,625
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)	**2,625**

Close-out Services	Fee*
Financial and administrative close-out	2,400
Sponsor required record retention and storage	TBD
****Base Total Close-out Fees (Exclusive of record retention/storage; TBD)**	**2,400**

*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,