Maine Medical Center Research Institute
2019 Standard Ancillary Fees

Below is a list of standard fees associated with conducting and maintaining a clinical trial at Maine Medical Center.

**Administrative Start-Up Fee** is intended to cover all start-up cost associated with opening a study at MMC, including regulatory preparation, study training, logistical planning, and budget development. This fee will be based on the complexity of the study and the time and effort required by the CRC, PI, Project Management, and Financial Services.

**Billing Compliance and Medicare Coverage Fee** covers the time and effort associated with development of the Medicare Coverage Analysis and the ongoing review of clinical events specified in the protocol to ensure appropriate billing of these items.

**Pharmacy Start-Up** is intended to cover costs associated with the review of the study protocol, pharmacy manual, related trainings, study drug receipt, and logistical planning.

**Annual IP Maintenance and Storage Fee** covers the costs associated with procuring, handling, storing, returning, and destruction of investigational product in accordance with relevant guidelines and regulations.

**Annual Administrative Fee** encompasses administrative and regulatory management of the clinical trial. Associated activities include preparation of annual IRB renewal, maintenance of regulatory documents, and sponsor communications.

**Amendment Implementation Fee** is intended to cover costs associated with the time and effort of the study relating to intake, processing, IRB submission, training, and operational integration of protocol amendments.

**Pre-Screening/Chart Review Fee** is a one-time fee to cover the costs of pre-screening and recruitment activities including chart review and preliminary eligibility assessment.

**Re-Consenting Fee** is intended to cover time and effort relating to re-consenting subjects, as result of amendment based consent revisions.

**IND Safety Report Fee** accounts for the time and effort of the study team associated with collection and submission of IND safety letters to the IRB.

**Serious Adverse Event Fee** encompasses time and effort of the study team to obtain and review clinical records in order to submit an SAE report in accordance with sponsor, site, and federal regulations.
Record Archiving Fee is intended to cover the costs associated with long term storage of research records.

Monitor Visit Fee compensates our study team for their efforts involved in pulling charts, requesting record access, reviewing queries, etc.

Remote Monitoring Fee (if applicable) compensates our study team for their efforts involved in pulling charts, requesting record access, reviewing queries, etc. remotely.

Monitor Change Fee covers the time and effort of the study team to familiarize new monitors with site resources, processes, and network access.

Study Close-out Fee is a one-time fee encompassing costs associated with regulatory preparation, document reconciliation, study close-out visit, and final invoicing.

Signature: [Signature]

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Approved by Krista Garrison, MPH, CCRP
Director, Clinical Trials Office