May 2025
Froedtert ThedaCare Health, Inc.
Office of Clinical Research and Innovative Care Compliance (OCRICC) Start-Up Fee Justification

MEMO: Justification of FH OCRICC Clinical Trial Startup Fee

As part of our commitment to maintaining the highest standards of research excellence, regulatory compliance, and operational efficiency, Froedtert ThedaCare Health, Inc. ("Froedtert") charges a standardized, one-time startup fee of $2,200 for industry-sponsored clinical trials conducted at our institution. The startup fee must be included in the trial budget. Our fee assessment methodology is modeled after the MCW IRB invoicing and waiver rules.

The startup fee is necessary to cover the administrative, regulatory and operational efforts required to initiate a clinical trial. These costs include, but are not limited to:

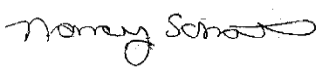
- Operational feasibility assessment and planning to work out the details of how the trial will be conducted at our facilities. This includes facilitating the commitment to the research by the involved clinical service line leaders.
- Qualified Clinical Trial (QCT) determination.
- Medicare Coverage Analysis.
- Issuing standard research pricing of hospital/technical resources.
- Creation and maintenance of trial-specific billing grids reflecting the visit schedule, procedures, charge codes, and billing designations.
- Informatics system setup through our Electronic Health Record (EHR) to allow for tracking of enrolled subjects and clinical trial status for billing compliance and invoicing activities, as well as other necessary research-related operational functionalities.
- Tracking and reviewing amendments, consents, serious adverse events, and deviations to determine if there is action required by our institution.
- Research billing compliance administration to accurately record and track research-related patient billing activities through 100% pre-billing claims review.
- Invoicing of research-paid hospital/technical services.
- Central contact for all questions related to research conduct & billing at our institution.

We are committed to ensuring transparency and will partner closely with research teams to facilitate a smooth and efficient startup process.

If you have any questions or require further clarification, please contact Research Administrative Director Roberta Navarro at roberta.navarro@froedtert.com.

We look forward to continuing our collaboration in advancing clinical research and improving patient care.

Sincerely,



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