

November 26, 2019

Froedtert Health

Office of Clinical Research and Innovative Care Compliance (OCRICC) Start-Up Fee Justification

MEMO re: OCRICC Start-Up Fee Justification

Froedtert Health is a Milwaukee, Wisconsin-based integrated health care system providing a variety of services including hospitals and health centers, home care, laboratory, and other health services. Froedtert Health is a partner with the Medical College of Wisconsin and together our mission is to advance the health of the communities we serve through exceptional care enhanced by innovation and discovery.

In order to make sure we meet regulatory requirements and provide a good experience for our patients and investigators involved in clinical research, effective July 1, 2018, Froedtert Health charges a one-time start-up fee of \$1,500 for all studies where the funding source is an industry sponsor. This fee includes the costs for operational planning, conduct Medicare Coverage Analysis (MCA), Informatics set-up, and Research Patient Billing Compliance Administration. The specific tasks we are responsible for are:

- Operational feasibility and planning to work out all the details of how the study will be conducted and carried out at our facilities.
- Qualified Clinical Trial (QCT) determination and review.
- Medicare Coverage Analysis to determine what services are billable to third-party payers as standard of care.
- Creation and updates of study-specific calendars with full list of visit schedule, procedures, billing designations, charge codes.
- Informatics system set up to allow for tracking subjects enrolled in a clinical trial, status of clinical trial, billing code setup, etc. through our Electronic Health Record (EHR).
- Tracking and reviewing amendments, consents, serious adverse events, and deviations to determine if there is action required by our hospitals or health centers.
- Research patient billing compliance administration to accurately record and track research activity for each study-related visit.

Signed,



Nancy Schallert, CHC

Executive Director, Corporate Compliance & Internal Audit
Froedtert Health