Office of Clinical Research & Innovative Care Compliance (OCRICC)
OCRICC 101 – FOR FH CLINICAL LEADERS

BACKGROUND

Froedtert Health (FH) started the OCRICC Program in January 2008. The program objective is to provide a centralized service to research teams so they have one place to go for FH pricing, coverage information, operational feasibility, compliance support, and questions related to conducting research at any FH Affiliated Entity (i.e., Froedtert Hospital, Froedtert Menomonee Falls Hospital (FMF), Froedtert West Bend Hospital (FWBH) and/or any F&MCW Community Physicians clinic/program).

DEFINITIONS

FH Resources used for the purpose of research include, but are not limited to:

- Clinical imaging services (including site verification/qualification of equipment and/or phantom studies)
- Surgical/Interventional/Procedural area services
- Outpatient/Inpatient services - including use of space only (i.e. FH clinics, FH ancillary support areas, inpatient admissions, at any FH affiliated entity)
- Laboratory/Phlebotomy services (inpatient and/or outpatient, except for services provided by Wisconsin Diagnostic Laboratory External Client)
- Pharmacy services
- Drugs and/or devices
- Clinical equipment
- Staff time
- Specimens – fresh or archive, including discard tissue from any FH procedural or Surgical Services area
- Patient Health Information (PHI)
- Forms Completion - information specific to any FH supported service/source (i.e., Legal Health Record (EMR) questionnaires/surveys, Grant Application Letters of Support, DoD Certificates of Compliance, etc.)

OCRICC RESPONSIBILITIES

Operational:

- Review compliance risks for research/innovative care activities conducted in any FH facility and/or using any FH resource, including HIPAA Privacy compliance for research
- Identify the key FH Clinical Business Leaders whose resources may be impacted by the research/innovative care
- Facilitate review and commitment of FH stakeholders, including feasibility/planning meetings if needed

Financial:

- Financial feasibility & plan development
  - Medicare Coverage Analysis (MCA) versus Study Invoicing Grid (SIG)
  - Pricing of FH resources identified as research paid for budget planning
- Research billing compliance according to the agreed upon financial plan
  - Claims management of FH services billable to patient/insurance
  - Invoicing of FH services identified as research paid, not billable to insurance

Administrative:

- Provide formal written FH Administrative Approval for individual projects, outlining agreed upon operational & financial plan
- FH centralized contact for research related questions & issues
- Provide education (scheduled and as requested) to MCW Researchers and their teams

Important Note: *OCRICC **does not** facilitate pricing or operational feasibility for MCW professional services.*

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OCRICC REVIEW AND APPROVAL PROCESS

- Researchers complete the FH OCRICC Application process in order to log the project and have it assigned for operational/financial feasibility review.
- OCRICC completes an initial review, asks questions and/or requests additional information as needed, in order to have a complete understanding of the operational/financial plan and impact to FH.
- OCRICC contacts the impacted FH Clinical Business Leader(s) via email, providing project-specific information and documents, requesting leader review to determine operational feasibility and commitments. This is done for each individual project.
- Once the project has been reviewed, operational planning has been addressed, and an agreed upon financial plan is in place, OCRICC authors FH Administrative Approval. FH Clinical Business Leader(s) impacted by the project are copied on FH Administrative Approval communications.
- The FH Administrative Approval letter provides project-specific instructions as well as general post-approval requirements for carrying out the project at FH.
- Researchers must have FH Administrative Approval prior to beginning any research activities in any FH facility and/or using any FH resource.

WHAT WE NEED FROM THE FH CLINICAL LEADER

- Redirect researchers and/or study staff to FH OCRICC when approached about supporting research and/or innovative care. This is critical to ensure FH adheres to applicable regulatory/compliance factors.
- Evaluate the research request when OCRICC contacts you to determine the impact to your clinical service line:
    - Is the project requiring support that is the same or different from your everyday clinical business? If not, can accommodations be made? What resources or instructions are necessary to do so?
    - Do you have the staffing and resources necessary to support? If not, can accommodations be made? What resources or instructions are necessary to do so?
- Respond to review requests in a timely manner or identify your anticipated timeline for review if more time is needed.
- Attend OCRICC facilitated operational planning meetings when scheduled.
- Provide any necessary instruction that the research team will need to be able to conduct their activities in your department and/or with your resources. Such instructions or requirements can always be included in the project's FH Administrative Approval Letter when identified.

For Questions:
Contact us at: OCRICC@froedtert.com

Or visit our OCRICC webpage at: http://www.froedtert.com/research/ocricc