

Office of Clinical Research & Innovative Care Compliance (OCRICC)

OCRICC 101 – FOR RESEARCH STAFF/INVESTIGATORS

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 must complete the FH OCRICC Application process for [pricing](#) and/or [approval](#) requests in order to log the project and have it assigned for operational/financial feasibility review.
- OCRICC will complete an initial review and ask questions and/or request additional information as needed in order to have a complete understanding of the operational/financial plan and impact to FH.
- OCRICC will always contact the pertinent FH Clinical Business Leader(s) to determine operational feasibility for each individual project.
- OCRICC authors FH Administrative Approval once an agreed upon financial plan is in place and key operational feasibility planning has been addressed.
- Researchers must have FH Administrative Approval prior to beginning any research activities in any FH facility and/or using any FH resource.
- The FH Administrative Approval letter provides project-specific instructions as well as general post-approval requirements for carrying out the project at FH.

WHAT WE NEED FROM THE RESEARCH TEAMS/INVESTIGATOR

- When submitting your [pricing application](#) for items or services not listed on the Froedtert Health [Research Chargemaster](#), identify CPT codes for the services needing to be priced for the most efficient turnaround. We will not know what specific service you are requesting and how to price it without a CPT code, therefore, if one is not submitted with the request, additional conversations may be needed so we price the correct service.
- When submitting your [Administrative Approval Request Application](#), submit all [required documents](#), including the completed [Operational Feasibility tool](#) with sufficient, specific details of how you plan to conduct your study in FH space and/or using FH resources.
- Respond to questions from OCRICC and/or FH Clinical Business Leaders in a timely manner to keep the project moving forward.
- Attend OCRICC facilitated operational planning meetings when scheduled and come prepared to discuss your project and how you plan to execute in FH space and/or using FH resources.
- Follow all instructions provided to you in the FH OCRICC Administrative Approval, including any key instructions outlined in the comments column of your agreed upon financial plan.
- Notify OCRICC of amendments in a timely manner. For amendments that will impact the agreed upon plan for FH services (financial and/or operational), researchers must provide a summary of the changes/impact as well as applicable updated documents. Amendments that are administrative in nature (no FH operational/financial component) should be identified as such - provide a summary of the changes and indicate no impact to the agreed upon plan for Froedtert services.

Resources:

Contact us at: OCRICC@froedtert.com

OCRICC Program: <http://www.froedtert.com/research/ocricc>