

OCRICC Guidance Document for Investigators & Research Teams

OPERATIONAL FEASIBILITY DETERMINATION & TOOL

INVESTIGATORS & RESEARCH TEAMS: PLEASE READ CAREFULLY

The Office of Clinical Research and Innovative Care Compliance (OCRICC) is responsible for providing administrative approval to conduct research in all of the Froedtert Health Affiliates. The purpose of this document is to provide research teams with guidance on how to approach operational feasibility when the research requires services, resources, or support from a Froedtert Health affiliate or will be conducted in a Froedtert Health affiliate location. This activity is separate and distinct from MCW's determination and whether an MCW department can support the research.

Following the guidance below will help research teams provide the information needed for operational feasibility assessment, helping to reduce delays and enhance the overall approval process.

You do not need to get Froedtert Health administrative approval if your project will not use any Froedtert Health resources and all research activities will be conducted in MCW space.

General:

- All research that requires a Froedtert Health resource is required to get Froedtert Health administrative approval from OCRICC. This approval includes validation of operational feasibility from the institution's perspective.
- The documents needed to start the operational feasibility review are:
 - Protocol
 - Informed Consent Form in its final negotiated state, i.e. the ICF version that will be submitted to the IRB.
 - Schedule of events identifying items/services as Research (R) versus Standard of Care (SOC)
 - Also acceptable:
 - Comparable documentation of R vs SOC (excel spreadsheet or other table)
 - Detailed statement of what is R vs SOC (word document or other)
 - GuideStar Medicare Coverage Analysis (MCA) (applies to CCCTO only)
 - FDA Approval Letter (un-redacted; IND, IND exempt, Post-market approval or Device/IDE trials only) **or** FDA/IRB letter of IND exemption
 - Centers for Medicare and Medicaid (CMS) Device Approval Letter (Device/IDE trials only)
 - Specification Manuals/Guidelines, if protocol mentions (i.e. imaging manual, instructions for use, etc.)
 - Sponsor-Provided Staff Training Materials (when applicable)
 - [Completed Operational Feasibility Tool](#)

It is the responsibility of the research staff to make sure that OCRICC always has the most up-to-date documents from the sponsor.

- An intake review is performed on all OCRICC applications and if documentation is missing, the project will be placed on-hold and returned to research team with instruction.
- A project Operational Feasibility Meeting with OCRICC, the Research team, and Froedtert Health clinical leaders will be scheduled if required by OCRICC or requested by Froedtert Health Clinical leaders.

Froedtert Health Operational Feasibility:

Operational feasibility determination includes assessing internal processes required to support the research as the protocol and sponsor expect it to be carried out. This includes evaluation of resources, use of any

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Froedtert Health owned space, Froedtert Health staff training needs, and alignment of trial design with our routine clinical practice. **It is the responsibility of the research team to be knowledgeable about the clinical trial and requirements so they can answer questions and speak to the detail of how they think the study will be carried out at Froedtert Health.**

Research teams should consider the following elements prior to contacting OCRICC:

- **Know your protocol:** The research team **must** have discussions with the Principal Investigator and have knowledge about what is required by the protocol and whether it is like what we do clinically every day.
- Research activities must align as closely to the normal clinical pathways as possible.
- Researchers need to understand Froedtert Health resources versus MCW resources and outline their operational plan.