OCRICC Guidance Document for Investigators & Research Teams

OPERATIONAL FEASIBILITY TOOL

INVESTIGATORS & RESEARCH TEAMS: PLEASE READ CAREFULLY

The purpose of the below tool is to provide research teams an instrument that helps them describe the execution of the protocol in our institutions. **Research teams are required to complete this tool and submit to OCRICC with all other documentation at the time of Froedtert Health approval request.** The tool will be sent to Froedtert Health clinical leaders as part of their review. The tool will also be used to facilitate collaborative discussion at the Operational Feasibility Meeting, if one is required by OCRICC or requested by Froedtert Health leaders/research staff. You may be asked to revise a section if sufficient detail is not provided.

OnCore Protocol No. (or alternate study short title if OnCore unavailable):	
IRB#:	
Primary Study Contact:	
PI:	
Study Description, Brief Summary, and/or Study Purpose:	

Topic	Examples/Questions	Research Team's Response
1. Froedtert Health Locations Link to F&MCW Network Location Map on intranet Froedtert Memorial Lutheran Hospital (FMLH) Sargeant Health Center Acute Surgery Center (ASC) at Sargeant Health Center Orthopedic Sports and Spine Center (located at the 87th street WAC) Froedtert Menomonee Falls Hospital (FMFH) Froedtert Hospital Cancer Center at Menomonee Falls Hospital Froedtert West Bend Hospital (FWBH) Froedtert Hospital Cancer Center at West Bend Hospital West Bend Health Center (separate from FWBH, located a few miles up the road) Pleasant Valley Health Center (located directly next to FWBH) Drexel Town Square Health Center (DTSHC) Moorland Reserve Health Center (MRHC) Tosa Health Center McKinley Health Center Jackson Health Center Jackson Rehabilitation and Sports Med Center Kewaskum Health Center Hartford Health Center Town Hall Health Center Germantown Health Center North Hills Health Center Mequon Health Center Good Hope Health Center Greendale Health Center Greenfield Highlands Health Center Lincoln Avenue Health Center Calhoun Health Center Westbrook Health Center Springdale Health Center Brookfield Heart and Vascular Center	**A. Identify what research-related activities will happen where.** Be specific, especially if enrolling from multiple Froedtert Health entities (FMLH/FMF/FWB/CP). Explain what activities will occur at each location by answering the following: a. Which FH Entity (see list in column to the left); b. Which department(s) at that location will be involved; c. Which research-related services will occur in each location - this should align with the activities listed in the protocol / schedule of events. B. **Involvement of Non-Froedtert locations (MCW/CW/Marquette/etc.):** Identify which research-related activities on the Schedule of Events will be managed in non-FH space with non-FH resource (if any) C. **Use of Froedtert space for research-only visit(s):** Hospital based clinical care spaces cannot be leased for research, they must be designated for patient care at all times. If you need to use FH space for research-only visits, opportunities may exist to utilize a consult room or waiting room. This would need to be vetted and approved by the clinical department leaders through the OCRICC process.	

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2. Subject Population	A. Will study subjects include outpatients, inpatients, or both? a. If inpatient involvement, will the study require a planned inpatient admission? B. What is the diagnoses and/or diagnosis code(s) of the patient population being studied? C. Will study subjects include FH and/or MCW staff? D. Will study subjects include healthy volunteers?	
3. Enrollment Goal, Recruitment Plan & Consenting We are looking for a clear picture of how study staff will approach the patient, for example: In-person or virtual? Outpatient or Inpatient? Before a clinic visit? Before a procedure? Be specific.	A. How many subjects will the project enroll? a. If enrolling from more than one entity, identify how many for each location B. Explain how/where potential participants will be approached & consented. a. If patient population is not already known to the PI as part of their provider role, please describe how potential subjects will be targeted & approached.	
4. Protocol Arms and Sub-Studies	A. Are there protocol arms that will not be opened at our site? If yes, which arm(s)? B. Are there sub-studies listed in the protocol? If yes, will these be done at our site?	
5. Froedtert Health Staff Involvement	A. Are you asking FH staff to do any study-specific activities outside of what they do routinely every day? For example: identifying potential patients (screening), completion of research data collection, completion of research-only surveys / questionnaires, extra vitals, extra blood draws or frequent/timed blood draws not alongside routine care, etc. B. Will Froedtert Health staff be considered "engaged in research activities" and need to be CITI trained? If you are unsure, contact the MCW IRB office to find out. C. Will FH staff need sponsor-required training? If yes, answer the following: a. Who will need to be trained? b. How many staff? c. How much time does training require? d. Who is conducting that training?	

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6. Environment	A. Does the study require special radiation precautions (e.g. lead-lined rooms, aprons, shields, etc.)? If yes, explain what is required. B. Does the study require special handling of patient bodily fluids/waste and/or items that have come in contact with the patient? If yes, explain what accommodations are required. C. Does the study protocol require the subject to stay within the vicinity of the hospital for a period of time? If yes, explain the plan to accommodate.	
7. Study Activities Timeline	A. Will study activities need to take place at a specific time of day and/or on a particular day of the week to ensure staff availability or continuity of care? a. If yes, what timeframe & resources are needed to support these study requirements? B. Will any parts of the study take place after hours, on weekends, or holidays? D. If yes, what is the research team plan to support off-hours needs? What timeframe & resources are needed?	
8. Investigational Products – Drug/Biologic or Device (if any)	**<u>If Drug/Biologic:</u>** A. Will IDS or Cell Processing Lab (CPL) be supporting drug storage and accountability? **<u>If Device:</u>** B. Is the device an implant (intended to be left in the body) or a supply (not to be left in the body)? If there are any additional supplies provided for the device use, are these packaged with the device or provided separately? If provided separately, are they packaged as a sterile supply or a non-sterile supply? C. Are there any special device purchase and/or storage requirements? ***Note:*** Research staff are responsible for managing the receipt & storage of research devices unless FH will be billing as a Category B IDE. Exceptions for urgent/emergent situations must be vetted through the OCRICC process.	

9. Drug Administration	A. Does the project have any ***unusual*** drug administration details? If yes, please describe what is required. Examples: • Lengthy infusion timing (Infusion ≥ 6 hours; ≥ 3 infusions; total time of patient care ≥ 10 hours) • Special administration techniques not typically performed by FH staff and/or in the location • Special equipment not currently used at FH (pumps, tubing, etc.) • Blinded administration requiring special accommodations • Strictly prohibited concomitant medications • Coordination with procedural depts. for infusion (Nuclear Medicine, OR, Cath Lab, Interventional Radiology, etc.) B. Will Froedtert Health or the Sponsor provide any protocol required supportive meds (if applicable)? C. Will Froedtert Health or the Sponsor provide any protocol required meds for the treatment of adverse events (if applicable)?	
10. Imaging ***Note:*** Please make sure you request the imaging manual/guidelines from the sponsor if applicable and provide to OCRICC. If no imaging manual is provided and no specified guidelines are indicated, the Radiology Departments will use standard of care imaging techniques	A. Does this protocol require imaging at Froedtert Health? If yes, indicate the following: a. What type of imaging modality or modalities? (e.g. CT, MRI, US, PET scan, X-ray, TTE, etc.) b. If applicable, will imaging be with or without contrast? ***Note:*** **If MRI is needed and the sponsor is requesting that NO image interpretation be performed**, route to MCW Center for Imaging Research (CIR) for MRI. B. Does this protocol require phantom imaging, test imaging, and/or scanner credentialing on FH imaging equipment? If yes, explain what is needed.	

11. Research-Only Blood Collections **REMINDER: There is a difference between use of the FH Clinical Lab Pathway & use of the WDL External Client Pathway.** Example scenarios: **Ex. 1 – Central lab:** Collection of blood for research-only while participant is in FH IP/OP space, whether alongside FH routine care lab collection or as a standalone collection, with no FH clinical local lab processing & resulting • Vetting with FH clinical/phlebotomy leadership must be facilitated through the OCRICC process. • When needed, standalone venipuncture pricing/invoicing is provided through OCRICC. • Use of Research Lab Order (LAB147) is supported in IP and OP non-cancer units – see tip sheet here. • Research-only processing and/or shipping support is coordinated via separate workflows with WDL External Client. **Ex. 2 – Local lab:** Research-only, sponsor paid labs with FH clinical local lab processing & resulting • Pricing and invoicing is provided through FH OCRICC. • Research team/MD orders lab in EPIC, lab is resulted in EPIC, OCRICC invoices study. • OCRICC process facilitates any additional planning needed with impacted FH clinical leadership. **Ex 3 – External Client:** Research-only labs where either the results cannot be entered into the medical record **OR** the collection does not involve FH patients **OR** there is a need for only processing, packaging, and/or shipping support. **These scenarios must be contracted with WDL External Client.**	A. Does the study involve research-only blood to be collected and sent to an external lab? **If no:** Move onto section 12. **If yes:** Will the collections be done in the inpatient or outpatient setting? **If outpatient, answer the following:** B. Will collection time points align with routine care outpatient blood draws and be drawn by FH phlebotomy lab staff? a. **If yes,** logistics facilitated through the OCRICC process b. **If no,** will collection occur in MCW/non-FH space with MCW/non-FH resources? c. **If no,** will WDL external client be contracted to support outpatient collection needs? **If inpatient, answer the following:** C. Will collection time points align with routine care blood draws, to be drawn by FH staff (nursing or phlebotomy depending on location)? a. **If yes,** logistics facilitated through the OCRICC process. ***Note:*** If working with WDL external client for only processing and/or shipping needs, research staff are responsible for transporting blood from inpatient unit to WDL b. **If no,** explain the protocol requirements (i.e. draw frequency & timing) and the proposed plan	

12. Research-Only Tissue Biospecimens	A. What kind of biopsy / tissue collection will be done? If there are multiple potential options due to study design, please identify up to 5 most common biopsy / tissue collection options B. Which department will the biopsy / tissue collection procedure be performed (i.e. CT, IR, US, GI lab, Operating Room, etc.)? If enrolling from multiple FH entities and there is the potential to need to collect at more than one location, list each entity and department. C. Will the research-only biopsy / tissue collection procedure be done at the same time as a routine care collection? D. Will the research-only collection require any time-sensitive or special processing, such as use of Liquid Nitrogen or Dry ice? If yes, please explain the plan. **Research-Only Specimens & use of** MCW Tissue Bank **Example scenarios:** • If research collection is alongside routine care, clinical diagnostic processing takes priority. In most cases, research staff must engage MCW Tissue Bank to coordinate collection of research tissue after clinical tissue has been obtained. Exceptions to this requirement must be vetted through the OCRICC process. • If collection is solely for research with no clinical processing, typical practices vary by procedural area. Generally, when the Operating Room is involved, research staff must engage MCW Tissue Bank to coordinate receipt & pick-up of specimen in Pathology and any collection and/or processing needs. Specimen collection plan must be vetted through the OCRICC process. Creation of study specific Pathology reports is at the discretion of MCW Tissue Bank. • If collection is solely for research with no special processing requirements and tissue will be collected and processed following normal clinical workflows, where slides/block are obtained thereafter through WDL External Client, coordination with MCW Tissue Bank is not required. **For all MCW Tissue Bank specimen and service needs, remember you must fill out the Bank's request form in iLab https://mcw.ilab.agilent.com/**	

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13. Research-Only Biospecimens – Other (i.e. sputum, stool, urine, 24hr urines, etc.)	A. What kind of specimen is needed? B. Is the sponsor providing kit(s) for collection? C. Will collection require involvement of Froedtert Health staff? a. If yes, will the collection be done at the same time as a routine care collection of the same nature? b. If yes, will the collection require special/time-sensitive processing needs?	
14. Research-Only Biospecimen Storage Requirements	A. Are there any specimen storage requirements that will involve Froedtert Health staff or space? If yes, explain what is needed and at what location(s)?	
15. Research-Only Surveys, Questionnaires, Interviews	A. If required, will this occur alongside a routine care visit in Froedtert Health space? a. If yes, where exactly and how long will it take? b. If no, where will this occur? ***Note:*** If you need to use FH space for research-only activities not adjacent to a clinical care visit, opportunities may exist to utilize a consult room or waiting room. Hospital based clinical care spaces cannot be leased for research. These spaces must be designated for patient care at all times and cannot be part-time hospital space and part-time something else.	
16. Research-Supplied Equipment ***Note:*** FH Biomedical Engineering will be required to evaluate any research supplied equipment that needs to be plugged into an FH power source and/or used on a patient participant in FH space (including FH space that is leased by MCW). OCRICC facilitates the connection with FH Biomed based on the needs of the project.	A. Is there any equipment being provided by the sponsor that will be used on participants within a Froedtert Health entity? a. If yes, will Froedtert Health clinical staff be required to operate? b. If yes, who and how many will require training and how much time will that training require?	

17. Adverse Event Management	A. Identify any potential serious adverse events that could occur. B. Does the study require potential serious adverse events to be treated according to a specific protocol? C. What type of adverse event support will be provided to the Froedtert Health clinical team by the PI & research team?	
18. PI and Research Team Support	1. Identify the availability of the PI/physician to deal with concerns and questions after hours. 2. Will study-specific tip sheets be created to support the clinical staff? ***Note:*** Most departments require huddles to be arranged to provide real-time protocol education & instruction upon subject enrollment.	