Froedtert

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.

Study Name/Short title:	
IRB#:	
Primary Study Contact:	
PI:	
Study Description, Brief Summary, and/or Study Purpose:	

Topic	Examples/Questions	Research Team's Response
Froedtert Health Locations	If enrolling from multiple Froedtert Health entities (FMLH/FMF/FWB/CP), please specify which activities listed on the Schedule of Events will occur where.	
Enrollment Goal	How many subjects will be enrolled at each location (if enrolling from more than one entity)?	
Subject Population	What disease group or treatment population? Will subjects be inpatients? Outpatients? Froedtert Health or MCW staff? Healthy volunteers? Be specific.	
Recruitment Plan & Consenting	1. How and where is the patient being approached & consented? 2. If patient population is not already known to the Principal Investigator as part of their provider role, please describe how potential subject will be targeted/approached.	
Froedtert Health Depts. & Staff Involvement	1. Specifically, what Froedtert Health resources are being requested and which Froedtert Health department(s) will be involved? 2. Will research activities take place in a Froedtert space? If yes, specify which nursing unit, clinic, etc. 3. Are you asking Froedtert Health staff to do any study-specific activities outside of what they do routinely every day, such as identifying potential patients (screening), completion of research data collection forms,	

Topic	Examples/Questions	Research Team's Response
	completion of research-only questionnaires/surveys, extra vitals, extra blood draws or frequent/timed draws not alongside routine care, repeat ECGs, etc.? Be specific. 4. Will Froedtert Health staff need protocol-specific or sponsor-required education/training? If so, who will need to be trained? How many staff? How much time does training require? Who is conducting that training? Be specific. 5. Will study activities need to take place at a specific time of day or on a particular day of the week to ensure staff availability or continuity of care? 6. Will Froedtert Health staff be considered "engaged in research activities" and need to be CITI trained? If this is not known, please call the IRB office to find out.	
Off Hours/Weekends/Holidays	Will any parts of the study take place after hours, on weekends, or holidays? If yes, what is the plan to support these study requirements?	
Protocol Arms and Sub-Studies	Are there protocol arms that will not be opened at our institution? Are there sub-studies listed in the protocol and will these be done at our institution? Consider these when completing the rest of this tool.	
Investigational Products – Drug/Biologic or Device (if any)	**If Drug/Biologic:** 1. Will IDS or Cell Processing Lab (CPL) be supporting drug storage and accountability? Please provide the details of your plan. **If Device:** 1. Are there any device purchase, requisition, and/or storage requirements? 2. Is the device an implant? If no, please explain.	
Drug Administration	1. Does the project have unusual drug administration details (e.g. blinded administration requiring special accommodation, lengthy infusion, special administration techniques, special equipment (e.g. pumps, tubing etc.), strictly prohibited concomitant medications, coordination with other departments e.g. Nuclear Medicine, CPL,	

Topic	Examples/Questions	Research Team's Response
	Interventional Radiology, and/or other special precautions)? 2. Who will provide supportive medications and/or drugs for the treatment of adverse events, Froedtert Health or Sponsor?	
Environment	1. Does the study require special radiation precautions (e.g. lead-lined rooms, aprons, shields, etc.)? 2. Does the study require special handling of patient bodily fluids/waste and/or items that have come in contact with the patient? 3. Does the study protocol require the subject to stay within the vicinity of the hospital for a period of time?	
Imaging	Does this protocol require imaging at Froedtert Health? If yes, explain and indicate the modality or modalities. Does this protocol require Froedtert Health scanner phantom imaging, or test imaging, and/or scanner credentialing? If yes, explain. ***Note:*** Please make sure you request the imaging manual/guidelines from the sponsor if applicable and provide to OCRICC.	
Research-Only Visits	Are extra visits required that are not part of the standard of care? Where will those take place?	
Research-Only Blood Biospecimens	1. Does the study involve research-only blood specimens to be sent to a central lab? 2. Will the collection time points align with routine care blood draw and be drawn by Froedtert Health staff? 3. Will venipuncture be needed only for research? a. If yes, who will draw the blood? **Example scenarios**: • Collection of blood for research alongside routine care lab collection = no research cost; operational impact only. • Research-only labs with local processing = pricing/invoicing and operational impact. Froedtert Health OCRICC provides pricing, the research team/MD orders lab in EPIC, lab is resulted in EPIC, Froedtert Health OCRICC invoices research after service is rendered.	

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	Note: Research-only blood draw not aligned with routine care collection, no local processing, sent to central lab = must coordinate WDL external client and not OCRICC. Contact Dawn Monzel and Rebecca Gaspar at WDL to negotiate pricing/operations.	
Research-Only Tissue Biospecimens	1. What kind of biopsy? Where will the biopsy be done (i.e. CT, IR, US, OR)? 2. Will the research-only biopsy collection be done at the same time as a routine care biopsy or will it be solely research collection and/or require special processing? **Example scenarios:** • If alongside routine care, clinical diagnostic processing is priority, research staff must engage MCW Tissue Bank to coordinate collection of research tissue. • If solely for research, the research staff must engage MCW Tissue Bank to coordinate collection and/or processing. ***Note***: Pathology will release slides only; no block release allowed per institutional policy.	
Research-Only Biospecimens – Other (i.e. sputum, stool, urine, etc.)	1. What kind of specimen is needed? 2. Will it require involvement of Froedtert Health staff? 3. If yes, will the collection be done at the same time as a routine care collection of the same nature or will it be solely research collection and/or require special processing? Be specific.	
Research-Only Biospecimen Storage Requirements	Are there any special specimen storage requirements that will involve Froedtert Health staff or space? If yes, please explain.	
Research-Only Specimens & use of MCW Tissue Bank	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/	
Research-Only Questionnaires or Surveys	1. 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:*** Costs may apply if using a Froedtert Health exam room. Opportunities may exist to utilize a consult room, conference room, or waiting room for no charge.	

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Research-Supplied Equipment	1. 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? i. If yes, who and how many will require training and how much time will that training require?	
Adverse Event Management	1. Identify any potential serious adverse events that could occur. 2. Does the study require potential serious adverse events to be treated according to a particular protocol? 3. What type of support will be provided to the Froedtert Health clinical team by the PI & research team at the time of such events?	
PI and Research Team Support	1. Identify the availability of the PI/physician to deal with concerns and questions after hours. 2. Attach study-specific tip sheets created to support the study. ***NOTE:*** Most departments require huddles to be arranged to provide real-time study protocol education and instruction.	
Regulatory	Are there any regulatory challenges that the research team is aware of or known issues that other sites have encountered?	

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CANCER CENTER PREFEASIBILITY SECTION

(Completed by CCCTO Managers)

If any of the below are answered YES:

Pre-feasibility review by IDS and Nursing is needed to evaluate complexity & identify critical limitations/considerations for moving the trial forward.

Investigational Agent, Route and Schedule	
Study Description, Brief Summary, and/or Study Purpose:	

Topic	Examples/Questions	Research Team's Response
Froedtert Health Locations: TRU/DAY HOSPITAL	Will study activities need to occur outside of CCC TRU/DH normal operating hours of 7A-7P? **EXAMPLE:** Pause and touch base for the following: • Infusion >/= 6 hours • Total time of patient care >/=10 hours • >/=3 infusions	
Nursing Skills TRU/DAY HOSPITAL	Does protocol call for special training beyond standard nursing job expectations/daily routine/scope of practice? Pause and touch base for the following: • New ways of administration • New Skills • New types of sample collection requested (excluding blood, urine, saliva)	
Equipment TRU/DAY HOSPITAL	Is there special equipment required for study? Is FH nursing required to apply/perform/manipulate equipment? If yes, will it be supplied and trained on?	
Logistical Complexity TRU/DAY HOSPITAL	Will the protocol require same-day coordination with multiple departments **EXAMPLE:** Pause and touch base for the following: • Nuc Med study involving nursing care • Patient receiving care in more than one dept. (excluding CC clinic, lab, radiation) in a day • For BMT/Cell therapy studies- CPL involvement • IBC SOP required (also IBC agents may require 2 hours of prep time when thinking about total time in TRU)	
Logistical Complexity TRU/DAY HOSPITAL	Timed research tasks (blood draws, ECGs, vital signs, etc.) above and beyond what can be accommodated within normal staffing ratios (no	

CANCER CENTER PREFEASIBILITY SECTION (Completed by CCCTO Managers) If any of the below are answered YES: Pre-feasibility review by IDS and Nursing is needed to evaluate complexity & identify critical limitations/considerations for moving the trial forward.		
	more than 1:2; some parts of the day are 1:1 depending on study specific needs). **EXAMPLE:** Pause and touch base for the following: • VS or other tasks (ECGs, sample collection) more frequent than every 15 min (standard VS is on arrival) • Tasks required every 15 min (or more frequent) for > 2 hours • More than 2 tasks at each time point • Tasks without windows	
Hazard Category **IDS PHARMACY**	Is agent greater than a BSL 2 Risk Category? Does product involves live virus?	
Product Storage Needs **IDS PHARMACY**	Does the agent require Liquid nitrogen for storage?	
Logistical Complexity - Investigational product (IP) prep duration **IDS PHARMACY**	Does the IP prep require multiple syringes and/or significant prep tasks that will take more than 60 minutes?	
Equipment **IDS PHARMACY**	Is there special equipment required that we do not use clinically today? **Example** of standard on-site equipment/supplies: IV bags, syringes, needles, CTSD, IV BSL2 hood	
Closed System Transfer Device (CTSD) **IDS PHARMACY**	Does the sponsor prohibit the use of CTSD for preparation? If so, why?	