

## Background

The clinical trial start-up process presents a myriad of operational challenges that require detailed planning with hospital partners and stakeholders. Since there was a lack of clarity in the process for how and when to include these partners in operational planning, this often led to inconsistency in study feasibility and operational review and ultimately negatively impacted activation timelines. A need was identified for a dedicated clinical trial operations team to develop a well-defined process for obtaining essential documents in a timely manner and involving key stakeholders (hospital partners, sponsors, PI, etc.) earlier in the start-up process.

## Goals

- To improve feasibility review and operational planning by engaging Sponsor and hospital partners early in the start-up process
- To decrease study activation timelines

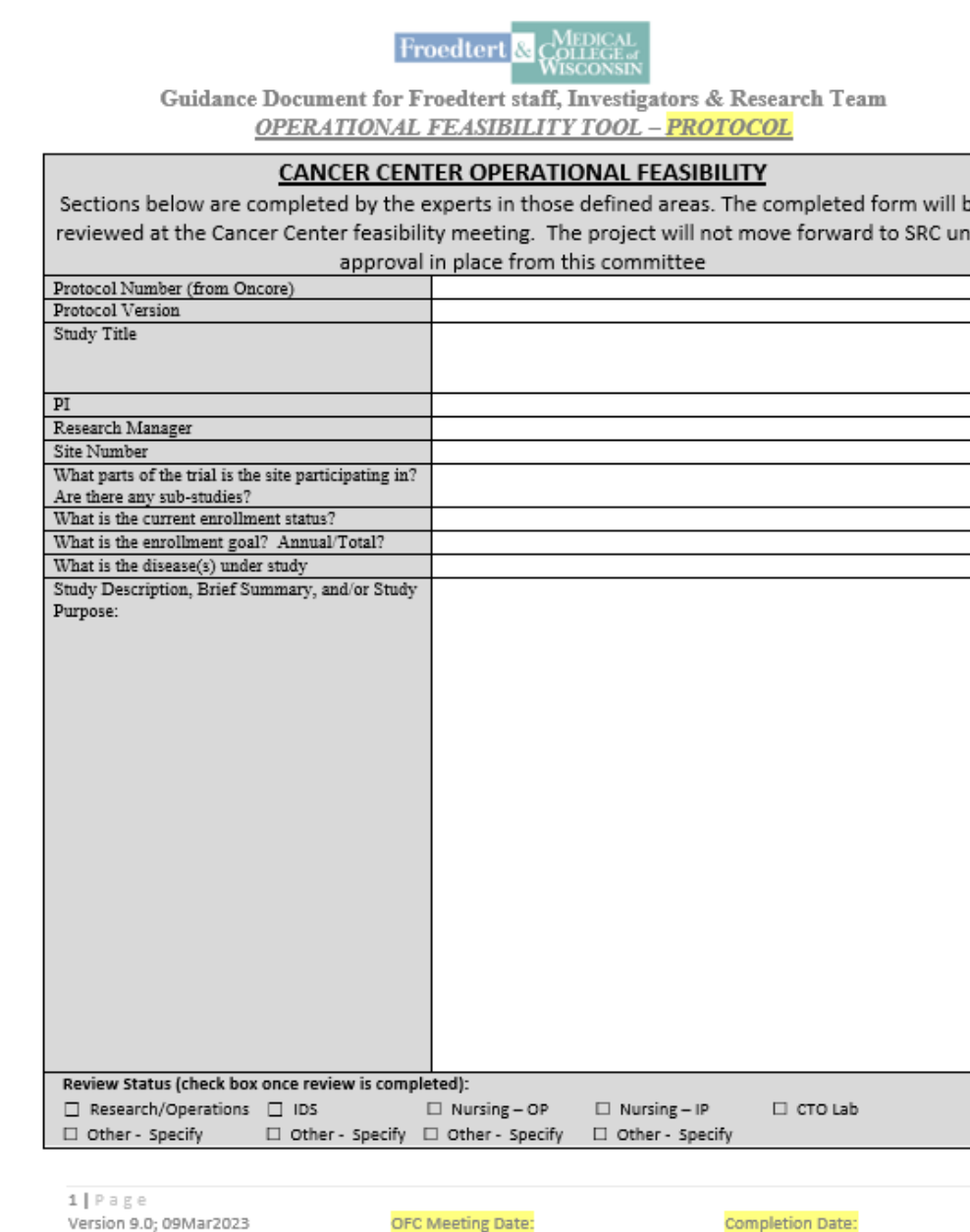
## Solution

A dedicated clinical trial operations team, including the addition of a new Program Manager, Program Coordinator, and Administrative Assistants, was created with the purpose of centralizing start-up activities. This team serves as a single point of contact for all parties involved in study start-up activities including clinical research managers, regulatory, budget/contract, pharmacy, nursing, hospital compliance, and other department leaders, as applicable. Having a dedicated team responsible for these activities allows for improved consistency, tracking of timelines, and completion of required submissions.

## Methods

The first step in developing this new process was the creation of an operational feasibility committee and implementation of a review meeting to occur twice monthly. Committee members include the operations team, research managers, investigational drug pharmacy, nursing, and other departments as required. Once all essential documents are received by the research manager, the operations team is engaged to facilitate review of the protocol. Documents are saved to Florence eBinders electronic regulatory system for central access for partners, which drastically reduces the amount of emails and attachments to track. The study is added to the agenda for the next available review meeting, and committee members are notified two weeks in advance of the meeting (Figure 2) so that a thorough operational review can be completed. Review comments are added to an operational feasibility tool (Figure 1), which has been developed in partnership with key stakeholders to capture all of the operational planning details needed to ensure successful implementation of the protocol (including details for treatment plan builds, imaging capabilities, central labs, etc.). Following the review meeting, outstanding questions are compiled by the operations team and sent to the necessary stakeholders to ensure there are no remaining operational concerns at the time of final hospital compliance review and activation.

**Figure 1.** Operational Feasibility Tool (Cover Page)



Guidance Document for Froedtert staff, Investigators & Research Team  
**OPERATIONAL FEASIBILITY TOOL - PROTOCOL**

**CANCER CENTER OPERATIONAL FEASIBILITY**  
Sections below are completed by the experts in those defined areas. The completed form will be reviewed at the Cancer Center feasibility meeting. The project will not move forward to SRC until approval in place from this committee.

Protocol Number (From Oncore)  
Protocol Version  
Study Title

PI  
Research Manager  
Site Number

What parts of the trial is the site participating in?  
Are there any sub-studies?  
What is the current enrollment status?  
What is the enrollment goal? Annual Total?  
What is the disease(s) under study?  
Study Description, Brief Summary, and/or Study Purpose.

Review Status (check box once review is completed):  
 Research/Operations    ID    Nursing - OP    Nursing - IP    CTO Lab  
 Other - Specify    Other - Specify    Other - Specify

Version 9.0, 09Mar2023   OFC Meeting Date   Completion Date

**Figure 2.** Operational Feasibility Committee (OFC) Email Template

Hello all,

See attached Operational Feasibility Tool for the next Operational Feasibility Committee (OFC) Meeting on **DATE**. Please fill out your portion of the Feasibility Tool and return it to the CTO Operations email no later than **DATE**.

**Study Title:**  
**PI:**  
**Disease State:**

Supporting documents (protocol, investigator's brochures, pharmacy/lab manuals, etc.) can be found under the study binder in Florence. A list of documents to be reviewed for this study is below:

Document	Available? (Y/N/NA)	Version	Version Date	Notes
Protocol	Y	AME3	11Jan2023	
New Trial Submission Form	Y	N/A	N/A	Target Annual Accrual: 10
Adult Prioritization Score Sheet	Y	N/A	N/A	Target Total Accrual: 12
Budget/Contract	Y	N/A	N/A	Total Score: 9
Investigator Brochure(s)	Y	4	28Feb2023	Template
MSDS(s)	N/A	N/A	N/A	
Pharmacy Manual	Y	4.0	12Jan2023	
Central Lab Manual	Y	2.1.0	21Jun2022	
Additional Documents - Interactive Response Technology System (IRT) User Guide	Y	1.0	16Nov2021	
Additional Documents - Dosing Instructions and Diary QOD	Y	2.0	3May2022	
Additional Documents - Dosing Instructions and Diary QD	Y	3.0	3May2022	
Additional Documents - eCRF Completion Guidelines	Y	4.0	10Aug2022	

Please let me know if you have any questions or concerns.

Thank you,

## Outcomes

- Hospital partners are involved much earlier in the process, and in a consistent way which leads to more effective operational planning and greater confidence in trial implementation.
- Early engagement with sponsor and hospital partners ensures we have all of the required information needed for operational planning.

## Lessons Learned and Future Directions

- The implementation of an operational review meeting has been well-received by all involved, and has demonstrated value in operational planning.
- An operational feasibility tool was developed to ensure that all departments receive the information that they need to plan for any study. This tool continues to evolve and now includes specific sections for treatment plan development, inpatient treatment and assessments, expected locations of care which serves to better guide compliance and billing, and additional information specific to cell therapy studies.
- Currently, the operations team has grown to include an additional dedicated Program Coordinator, and the role of the team has expanded to include submission of studies to the hospital compliance oversight office. This is a key step in study activation, and includes submission of all study documents received prior to the operational review meeting as well as the completed operational feasibility tool. This continued engagement of the operations team and compliance office has facilitated faster review and approval of trials and we anticipate it will further reduce study activation timelines.

### Contact:

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