Medical College of Wisconsin Cancer Center

Feasibility Committee Charter

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The Medical College of Wisconsin Cancer Center (MCWCC) is committed to maintaining a high-quality portfolio of clinical trials that meet the specific needs of its catchment area. Integrated Disease-Oriented Teams (iDOTs) perform the initial reviews of potential trials, focusing on their clinical and scientific value, whereas the Scientific Review Committee (SRC) verifies that new studies are scientifically sound. With iDOT input, trials are reviewed by two Feasibility Committees (FCs), one for pediatric and one for adult trials, before submission to the SRC. These reviews, which use a common template, complement the iDOT reviews by ensuring that new studies are rigorously vetted for patient availability and operational resource utilization (personnel, financial, material).

1.0 Scope and Function

1.1 Scope

All new clinical trials or studies involving human subjects being considered for activation at MCWCC and management by the Clinical Trials Office (CTO) are required to undergo feasibility review before proceeding to SRC.

1.2 Function

iDOTs perform the initial review of each study. Given their multidisciplinary, disease-specific expertise, iDOTs are best positioned to evaluate a study's clinical value to their respective patient populations. The iDOTs are also most familiar with how a new study would complement their existing and pending trial portfolios. FC review serves as a check on iDOT decisions and evaluates availability of the resources needed to safely and successfully implement a given trial. Because those resources are largely hospital-specific, separate FCs evaluate pediatric trials conducted at Children's Wisconsin and adult trials conducted at Froedtert Hospital.

2.0 Membership

The adult and pediatric FCs are made up of faculty and CTO and other administrative staff.

Adult FC Voting Members
The pediatric FC is chaired by the MCWCC Associate Director of Clinical Research. Other voting members include the CTO Medical Director and Assistant Medical Director, Chairs/Vice Chairs from at least two iDOTs, the MCWCC Associate Director of Administration, Director of Finance & Business Operations, CTO Business Manager, CTO Administrative Director, and the CTO Assistant Directors of Clinical Research Operations and Clinical Research Compliance.

Pediatric FC Voting Members
The pediatric FC is chaired by a senior Pediatrics faculty member. Other voting members include the CTO Assistant Medical Director for Pediatrics, the Pediatric Hematology/Oncology Section Chief, the Pediatric iDOT Chair, the Pediatric Bone Marrow Transplant Program Chair, the Pediatric Hematology/Oncology Division Administrator, two CTO managers. The CTO Administrative Director or an Assistant Administrative Director also participate.

3.0 FC Review Process

3.1 Study Submission to FC

A study may be submitted to the FC only after (1) the iDOT has approved it, (2) the sponsor has selected MCW as a participating site (if applicable), and (3) the sponsor has provided all the study documents necessary for internal review/activation (e.g., full protocol, investigator brochures, budget/contract templates, manuals).

The protocol, New Trial Submission Form and prioritization scoresheet (Appendix) are submitted to the FC for

review. The iDOT's current protocol flow diagram (illustrating the new trial's position in the portfolio and any competing trials) is also made accessible for FC review. Studies with prioritization scores <5 may need additional justification for activation, and PIs may be invited to the FC meeting to defend the study.

3.2 FC Meetings

The adult FC meets twice per month, and the pediatric FC meets once per month. Quorum is defined by the presence of at least 50%+1 of the voting members, at least two of whom must be faculty. CTO research managers present the studies, conveying a short summary of the study, the projected accrual and timeline, and an assessment of study complexity/logistical concerns. The FC also reviews the strategic relevance of trials to the overall MCWCC vision, facilitating prioritization as appropriate. Committee members ask questions and discuss the following aspects:

- Local accrual goal
- Competing trials and iDOT's plan for prioritizing accrual
- Staffing/operational/logistical issues
- Funding source/budget gaps
- Protocol prioritization scoring

The committee may perform expedited reviews (rather than waiting for the next full committee meeting) for high priority or low complexity studies (e.g., NCTN trials). For expedited reviews, the review materials are circulated via email to voting members. The outcome is finalized once a quorum of reviewers has responded.

3.3 Outcomes and Communication

After discussion, the committee assigns each study one of the following outcomes:

- **Approved** – Study is approved to proceed forward in the activation process.
- **Tabled pending clarification** – FC has a concern with a study and needs further information or resolution of a point.
- **Disapproved** – FC determines that a study has a significant issue and should be abandoned.

Decisions are carried by a majority consensus. A member with a conflict of interest on a study (e.g., principal investigator or co-PI) must abstain from participating in scoring and final outcome determination.

Communication of decisions
After the meeting, the FC coordinator notifies the PI and iDOT chair of the decision. The final prioritization score is sent, as are any comments the FC wishes to convey to the iDOT. For studies that were tabled, the FC sends a query to the PI and iDOT Chair noting its concern and requesting a response. If the PI wishes to advocate for a study, they are encouraged to attend an upcoming meeting to discuss the FC's concerns.

For studies approved to move forward in the activation process, the prioritization scoresheet with FC decision is also included in the review materials submitted to the SRC.

4.0 Oversight of Feasibility Committee Activities

Both the adult and pediatric committees are subject to review by the MCWCC Clinical Research Executive Committee (CREC) to ensure processes are consistent with Cancer Center clinical research strategic priorities.

Appendix

MCWCC Clinical Trial Prioritization Scoresheet
For Interventional Trials

Sponsor and Protocol No.:	**Date:**
PI:	**iDOT:**
Full Protocol Title:	
Mechanism of action of each experimental drug given (if applicable):	

Evaluation Factor	Categories	Points	Earned
Sponsor/Funding Source	NIH-funded IIT/NCTN trial with MCW national PI	6	
	IIT funded by a grant (non-NIH), industry, or institutional source	5	
	NCTN or BMT CTN trial	3	
	External cancer center, non-NCTN consortium	2	
	Industry trial	1	
Annual Accrual Potential	Adult: ≥11; Pediatric: ≥5	4	
	Adult: 5-10; Pediatric: 2-4	2	
Academic Value	First/Last authorship	3	
	Second, second-to-last authorship	2	
	Middle authorship	1	
Clinical/Scientific Impact	Likely to be a breakthrough drug/treatment modality	4	
	Phase I first in class/FIH having potential impact across multiple tumor types/preclinical data support/unique pediatric access to a therapeutic	3	
	Phase I-III trial with possible practice changing implications	2	
	Phase I-III trial with few practice changing implications	1	
	Post-marketing study	0	
Competing Trials	No competing trials (same eligibility/similar mechanism) open or pending	1	
Local PI is junior investigator (<5 yrs out from fellowship)	Yes	1	
MCW Lab Correlates (Hypothesis-driven)	Yes	3	
Uniquely Addresses Populations in Catchment Area	Yes	3	
Alignment with MCWCC Strategic Goals (scored by Feasibility Committee)		0-6	
		Total:	

Clinical/strategic importance of this study to the iDOT: