Medical College of Wisconsin Cancer Center

Feasibility Review Charter

Version Date: 03.20.2023

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 our catchment area. Disease-Oriented Teams (DOTs) perform the initial reviews of potential trials, focusing on their clinical value, whereas the Scientific Review Committee (SRC) verifies that new studies are scientifically sound. While DOT review touches on trial feasibility, the MCWCC utilizes separate committees for more in depth feasibility review. Adult trials are reviewed by the Feasibility Review Committee (FRC), which complements DOT and SRC review by ensuring that new studies are rigorously vetted for patient population availability, competition with trials already in the portfolio, and operational resource utilization (personnel, financial, material). The FRC is charged with identifying any issue that may impact the success of a trial, making the DOT aware of the issue, and helping to resolve the issue if possible. Pediatric trials are reviewed by the Pediatric DOT, which has a similar feasibility review function. Both committees are described more fully below.

1. SCOPE AND FUNCTION

Scope
All new clinical trials or studies involving human subjects being considered for activation at MCWCC and management by the adult Cancer Center Clinical Trials Office (CCCTO) or the pediatric MACC Fund Center Clinical Trials Office (MFCCTO) are required to undergo feasibility review before proceeding to SRC.

Function
The primary responsibility of the feasibility committees is to review new studies approved by the disease teams. DOTs perform the initial review of each study. Given their multidisciplinary, disease-specific expertise, DOTs are best positioned to evaluate a study's clinical value to their respective patient populations. The DOTs are also most familiar with how a new study would complement their existing and pending trial portfolios. Feasibility review serves as a check on DOT decisions, as well as an evaluation of the resources needed to safely and successfully implement a given trial. This review occurs before SRC to identify problematic studies early in the activation process.

2. MEMBERSHIP

The adult and pediatric feasibility committees are made up of faculty and CTO staff.

FRC Voting Members
The FRC is chaired by the MCWCC Associate Director of Clinical Research and co-chaired by the Associate Director of Translational Research, who performs the duties of the chair in their absence. Other faculty members include the CTO Medical Director and Assistant Medical Director, as well as Chairs/Vice Chairs from at least two DOTs. Staff voting members include the MCWCC Associate Director of Administration, Director of Finance & Business Operations, CCCTO Business Manager, and the CCCTO Assistant Directors of Clinical Research Operations and Clinical Research Compliance.

Pediatric DOT Voting Members
The Pediatric DOT is chaired by a senior faculty member as described in the MCWCC DOT Charter. Other voting members include faculty representatives from each of the five pediatric

programs (Bone Marrow Transplant/Cell Therapy, Leukemia/Lymphoma, Solid Tumors, CNS Malignancy, Non-Therapeutics), the MCWCC Associate Director of Pediatrics and Survivorship, the MFCCTO Medical Director, and the two MFCCTO managers.

3. FRC REVIEW PROCESS

Study Submission to FRC
A study may be submitted to FRC only after (1) the DOT has approved, (2) the sponsor has selected MCW has 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).

When ready, the research manager submits the protocol, New Trial Submission Form and adult prioritization scoresheet to the FRC for review.

DOTs should carefully consider studies with prioritization scores <5 before sending them forward to FRC. Low-scoring studies will need additional justification for activation, and PIs will be invited to the FRC meeting to defend the study.

FRC Meeting
The FRC meets twice per month. Quorum is defined by the presence of at least 50% of the voting members, at least two of whom must be faculty. CTO research managers are invited to present their DOT's studies, conveying a short summary of the study, the projected accrual and timeline, and an assessment of study complexity/logistical concerns. The FRC 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 DOT's plan for prioritizing accrual
- Staffing/operational/logistical issues
- Funding source/budget gaps
- Protocol prioritization scoring

The committee may perform expedited reviews via email for high priority or low complexity studies (e.g., NCTN trials).

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** – FRC has a concern with a study and needs further information or resolution of a point.
- **Disapproved** – FRC determines that a study has a significant issue and should be abandoned.

Decisions are carried by a majority vote. A member with a conflict of interest on a study (e.g., principal investigator or co-PI) must abstain from voting.

Communication of decisions
After the meeting, the FRC coordinator notifies the PI and DOT chair of the decision. The final prioritization score is sent, as are any comments the FRC wishes to convey to the DOT. For

studies that were tabled, the FRC sends a query to the PI and DOT 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 FRC's concerns.

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

Operational Feasibility Review
MCWCC also formed the Operational Feasibility Committee (OFC) to better anticipate logistical difficulties with implementing adult clinical trials. This committee reviews new studies being considered for activation at Froedtert; however, it is only advisory rather than decision-making. OFC reviews occur in parallel with FRC and SRC. The committee is composed of CCCTO staff and Froedtert Hospital investigational pharmacy and nursing staff. OFC discusses all logistical aspects of each study, including where each assessment/procedure will take place, what equipment will be used, need for specialty physician or lab involvement, extended or after-hours support (e.g., for PKs), etc. If OFC identifies a serious obstacle to operationalizing a study, then it alerts the DOT, FRC, and SRC to potentially abandon the study or pause activation until a solution is found.

4. PEDIATRIC DOT FEASIBILITY REVIEW PROCESS

Pediatric studies undergo a separate but similar feasibility review. The unique nature of the pediatric enterprise (small patient population, fewer physicians, integrated care systems) requires consolidation of effort to a single pediatric DOT. There are five programs within pediatrics (Leukemia/Lymphoma, Solid Tumors, CNS malignancy, Transplant/Cell therapy, and Non-Therapeutics/Survivorship/Supportive Care), which function similarly to adult DOTs, determining the scientific questions of relevance and considering/prioritizing appropriate studies for activation. Some protocols may be reviewed across programs, especially those related to cancer survivorship or psychosocial impacts of cancer.

Studies selected for activation by these programs are then put forward for review to the Pediatric DOT, which serves both as the official pediatric DOT and as the venue for feasibility review. The Pediatric DOT is the final decision point for approving (or disapproving) a pediatric study to move forward in the activation process to SRC for review.

Study Submission to the Pediatric DOT
A study may be submitted to the Pediatric DOT only after (1) one of the five pediatric programs has approved, (2) the sponsor has selected Children's Wisconsin 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).

When ready, the Investigator submits the protocol, New Trial Submission Form and pediatric prioritization scoresheet to the Pediatric DOT for review.

Pediatric DOT Meeting
The committee meets twice per month. Quorum is defined by the presence of at least 50% of the voting members, at least two of whom must be faculty. The MFCCTO managers present the new studies, conveying a short summary of the study, the projected accrual and timeline, and an assessment of study complexity/logistical concerns. Committee members ask questions and

discuss the following aspects:

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

The committee may perform expedited reviews via email for high priority or low complexity studies (e.g., NCTN trials).

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** – The committee has a concern with a study and needs further information or resolution of a point.
- **Disapproved** – The committee determines that a study has a significant issue and should be abandoned.

Decisions are carried by a majority vote. A member with a conflict of interest on a study (e.g., principal investigator or co-PI) must abstain from voting.

Communication of decisions
After the meeting, the MFCCTO manager or other voting member notifies the PI of the decision. The final prioritization score is sent, as are any comments the committee wishes to convey to the investigator. For studies that were tabled, the appropriate DOT voting member requests a meeting with the PI to address concerns. If the PI wishes to advocate for a study, they are encouraged to attend an upcoming meeting to discuss the committee's concerns.

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

6. OVERSIGHT OF FEASIBILITY 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.