



Medical College of Wisconsin Cancer Center Investigator-Initiated Trial Steering Committee Charter

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Reporting Relationships:

- **Reports To:** Medical College of Wisconsin Cancer Center (MCWCC) Clinical Research Executive Committee and MCWCC.
- **Oversees:** MCWCC investigator-initiated trial (IIT) concept and protocol development.

Meeting Frequency: The committee meets once a month, on the first Friday of the month, between 10:00 AM and 11:00 AM. *Ad hoc* meetings may be scheduled as needed if a specific issue must be expeditiously addressed.

IIT Steering Committee Purpose and Composition: The MCWCC IIT Steering Committee provides support and mentorship to principal investigators (PIs) hoping to develop a concept into a complete clinical trial protocol for submission to the MCWCC Scientific Review Committee (SRC). A meeting quorum requires a review of the submitted concept(s), grant(s), and/or protocol(s) *by at least* 50% of the members on the committee roster. Committee members can review submitted documents remotely, which will count towards this quorum, but with the expectation that their written review is sent back to the committee before the relevant meeting.

The key functions of the IIT Steering Committee include, but are not limited to:

- Provide constructive feedback to PIs that improve the clinical and scientific rigor of the proposed study.
- Assist in defining vision, initial project scope, and identify stakeholders.
- Provide logistical assistance to MCW investigators, including project framework, timelines, milestones, budgets, and risk-benefit assessments.
- Supports the development of a concept and clinical trial protocol that meets Disease-Oriented Team (DOT) and SRC approval.

The composition of the IIT Steering Committee reflects both the clinical and scientific breadth of the IIT concepts that the committee expects to encounter and the administrative experience required to facilitate the development of a complete and well-written trial synopsis and protocol. The IIT Steering Committee is led by a Chair and Co-Chair, who both possess the authority to appoint individuals to the committee. Individuals that agree to become a member of the IIT Steering Committee are expected to retain their appointment for a two-year, renewable term.

IIT Steering Committee Meeting Process – Concept Development: If a PI(s) expresses interest in meeting with the IIT Steering Committee to gather feedback on their concept design, the Medical Writer will work with the PI(s) to schedule a meeting date. This date should be shared with the IIT Steering Committee members *at least one month* before the meeting and start the following process outlined below:

- The PI(s) will be asked to submit their concept to the IIT Steering Committee *at least two weeks* before the scheduled meeting through an online Qualtrics submission form. The submission form can be accessed using the provided link, which is made available on the MCWCC website: https://mcwisc.co1.qualtrics.com/jfe/form/SV_9HK60N6otrIT5Fs
- The submitted concept and, if available, supporting materials provided by the PI(s) will be added to the next available meeting agenda and disseminated to all committee members *at least two weeks* before the scheduled meeting date.
- The PI(s) and relevant study personnel will be invited as guests to the IIT Steering Committee meeting, where they will be allowed to present their concept for approximately 30 minutes.
- Time will be allotted for committee members to provide feedback to the PI(s).
- After the meeting, a follow-up letter from the Co-Chairs will be sent to the PI(s) with feedback and action items.

IIT Steering Committee Meeting Process – SRC Referral: If the SRC refers an IIT protocol to the IIT Steering Committee for additional development, the Medical Writer will work with the PI(s) responsible for the IIT protocol to schedule a meeting date. This date will then be shared with the IIT Steering Committee members *at least one month* prior to the meeting and start the following process outlined below:

- Upon referral, the SRC will share their response letter and the version of the IIT protocol with the IIT Steering Committee.
- The PI(s) and the IIT Steering Committee members will be given at least two weeks to review the SRC comments before the meeting date.
- The PI(s) and relevant study personnel will be invited as guests to the IIT Steering Committee meeting, where they will work with the IIT Steering Committee members to address the critiques noted in the SRC response letter and recommend ways to improve the study's clinical and scientific rigor.
- After the meeting, a follow-up letter from the Co-Chairs will be sent to the PI(s) with feedback and action items.
- Using the feedback provided by the SRC and the IIT Steering Committee, the Medical Writer will be assigned to work with the PI(s) to edit and refine the IIT protocol for SRC resubmission.
- The Co-Chairs will notify the SRC chair that the PI(s) met with the IIT Steering Committee to discuss the referred IIT protocol, making the protocol eligible for SRC resubmission.

Mentorship Sub-Committee and Program: The mentorship sub-committee provides personalized guidance to investigators at an early stage in their clinical research career or with limited research experience. The sub-committee is expected to work *as early as possible* with the PI, preferably during the concept development phase and prior to its approval by the DOT. After

a PI has been deemed a fit for this program, a mentorship sub-committee is to be formed that include the following individuals:

- A current member of the IIT Steering Committee
- Medical Writer
- Biostatistician
- A content-specific expert that aligns with the PI's research interests

The PI is to be assigned to the mentorship sub-committee for the duration of the concept development process, with the overarching objective that the raw concept be developed into a synopsis that 1) possesses an objective and statistically sound study design that appropriately tests a measurable hypothesis, 2) ensures the protection and safety of all study subjects/patients, and 3) is feasible to execute. After the concept and synopsis have been fully developed, the PI is expected to present their study to the IIT Steering Committee for additional feedback and to the appropriate DOT for approval to begin the protocol development process.