



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

---

Version No.: 2.0

Version Date: 04/10/2025

---

### 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 MCWCC IIT Steering Committee (IITSC or Committee) meets virtually once a month, on the first Friday of each month, from 10:00 AM to 11:00 AM. *Ad hoc* meetings may be scheduled as needed to address specific issues expeditiously.

**IIT Steering Committee Purpose and Composition:** The IITSC provides support and mentorship to principal investigators (PIs) who aim to develop a concept into a comprehensive 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, provided that their written review is sent back to the committee before the relevant meeting.

The key functions of the IITSC 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 Integrated Disease-Oriented Team (iDOT) and SRC approval.

The composition of the IITSC reflects both the clinical and scientific breadth of the IIT concepts that the committee expects to encounter, as well as the administrative experience required to facilitate the development of a comprehensive and well-written trial synopsis and protocol. The IITSC is led by two co-chairs who both possess the authority to appoint individuals to the committee. Individuals who agree to join the IITSC are expected to maintain their appointment for a minimum of two years. The MCWCC Director is responsible for filling vacancies in the IITSC co-chair position(s).

**IIT Steering Committee Concept Development Meeting:** If a PI(s) expresses interest in meeting with the IITSC to gather feedback on their concept design, the Medical Writer will first work with the PI(s) to schedule a meeting date. This date should be communicated to the Committee members *at least one month* prior to the meeting to establish a quorum. The process of organizing and conducting the concept development meeting is outlined below:

- The PI(s) will be asked to submit their concept to the IIT Steering Committee *at least two weeks* prior to the scheduled meeting via 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](https://mcwisc.co1.qualtrics.com/jfe/form/SV_9HK60N6otrIT5Fs)
- The submitted concept, along with any 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 prior to 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 have the opportunity to present, discuss, and receive feedback on their concept over an approximately 30-minute period.

**IIT Steering Committee Mentorship Program:** The IITSC mentorship program offers personalized guidance to investigators at an early stage in their clinical research careers or those with limited research experience. The sub-committee is expected to work closely with the PI as early as possible, preferably during the concept development phase and prior to its approval by the iDOT. After a PI has been deemed a fit for this program, a mentorship committee is to be formed that includes 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 committee for the duration of the concept or protocol development process, with the overarching objective that the PI's concept be developed into a synopsis, extramural funding application, or protocol 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 or protocol has been fully developed, the PI is expected to present their study to the IIT Steering Committee for additional feedback and to the appropriate iDOT for approval to begin the protocol development process.

**IIT Steering Committee Protocol Review:** In 2025, MCWCC leadership established a policy mandating that all cancer-related IITs subject to SRC review must also undergo review by the IITSC. The first iteration of the IITSC protocol review process is outlined below.

- Any cancer-related IIT that the IITSC has not yet reviewed should be forwarded to the Medical Writer, who will initiate the IITSC protocol review process. The IITSC will work with the CTO Research Manager or PRMS Manager to identify protocols requiring the Committee's review.
- The Medical Writer will work with the IITSC Co-Chairs to identify one clinical reviewer and one biostatistics reviewer, who will be instructed to critique aspects of the protocol outlined in **Table 1**. The reviewer may be either an IITSC member or an *ad hoc* reviewer appointed

by the IITSC Co-Chairs. Reviewers are tasked with evaluating the clarity of the study plan, the quality of the statistical design, and the overall feasibility of the proposed study. Their primary goal is to assist the principal investigator (PI) in translating the concept into a practical protocol that can achieve the trial's objectives. Reviewers are expected to submit their comments back to the Medical Writer within one week.

**Table 1. IITSC Protocol Reviewers Focus**

Clinical Science Review (IITSC Clinical Reviewer)	Biostatistics Review (IITSC Biostatistics Reviewer)
<ul style="list-style-type: none"> <li>• Background and Study Rationale</li> <li>• Objectives</li> <li>• Eligibility Criteria</li> <li>• Treatment/Intervention Plan</li> <li>• Toxicity Management Plan</li> </ul>	<ul style="list-style-type: none"> <li>• Endpoint Measurements</li> <li>• Sample Size Justification</li> <li>• Analysis Population</li> <li>• Endpoint Analysis</li> <li>• Stopping Rules; Interim Analysis</li> <li>• Missing Data</li> </ul>

- The Medical Writer will compile the IITSC reviewers' comments and send them to the PI for their consideration. Those who receive extensive feedback will be asked to meet with the IITSC in person during one of their monthly meetings. In certain instances, the Committee may convene a mentorship committee (see above) to help the PI make significant improvements to their protocol.

**SRC Referrals to the IIT Steering Committee:** While deemed a last resort, the SRC may refer IIT protocols that require further development to the IITSC for review. In such events, the Medical Writer will first work with the PI(s) of the IIT protocol to schedule a meeting date. This date should be communicated to the Committee members *at least one month* prior to the meeting to establish a quorum. The process of organizing and conducting the SRC referral meeting is outlined below:

- Upon referral, the SRC will share their response letter and the version of the IIT protocol they reviewed with the IITSC.
- The PI(s) and Committee members will be given at least two weeks to review the SRC comments and protocol before the meeting date.
- The PI(s) and relevant study personnel will be invited as guests to the IITSC meeting. The 30-minute meeting will focus on addressing critiques noted in the SRC response letter and discussing protocol changes that improve the study's clinical and scientific rigor.
- After the meeting, a follow-up letter or email from the Medical Writer, on behalf of the IITSC co-chairs, will be sent to the PI(s) with feedback and action items.
- Using the feedback provided by the SRC and the IITSC, the Medical Writer will be assigned to work with the PI(s) to edit and refine their IIT protocol for resubmission to the SRC.
- The Medical Writer and IITSC Co-Chairs will notify the SRC Chair that the PI(s) met with the IITSC to discuss the referred IIT protocol, making the protocol eligible for another SRC full committee review.