

# Establishing an IIT Committee to Streamline Oncology Investigator-Initiated Trials (IITs)

Molly Fortune, CCRP; Jamilah Anderson, MACPR, CCRP; Asia McDavid, MS, CCRP; Kathleen Stamper, MPH, CCRP; Kristina Humphries, MS, CCRC; Angela Campbell, MS; John Hays, MD, PhD  
The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute

## Background

Investigator-Initiated Trials (IITs) are a vital component of oncology research, providing clinicians with opportunities to explore innovative hypotheses and improve patient care. Recognizing the complexity of these trials, our Clinical Trials Office (CTO) identified the need to strengthen collaboration and ensure that all appropriate stakeholders are engaged early in the process.

## Objectives

To establish a dedicated IIT Committee aimed at creating a more efficient and standardized process for IIT development and infrastructure support. Committee goals include:

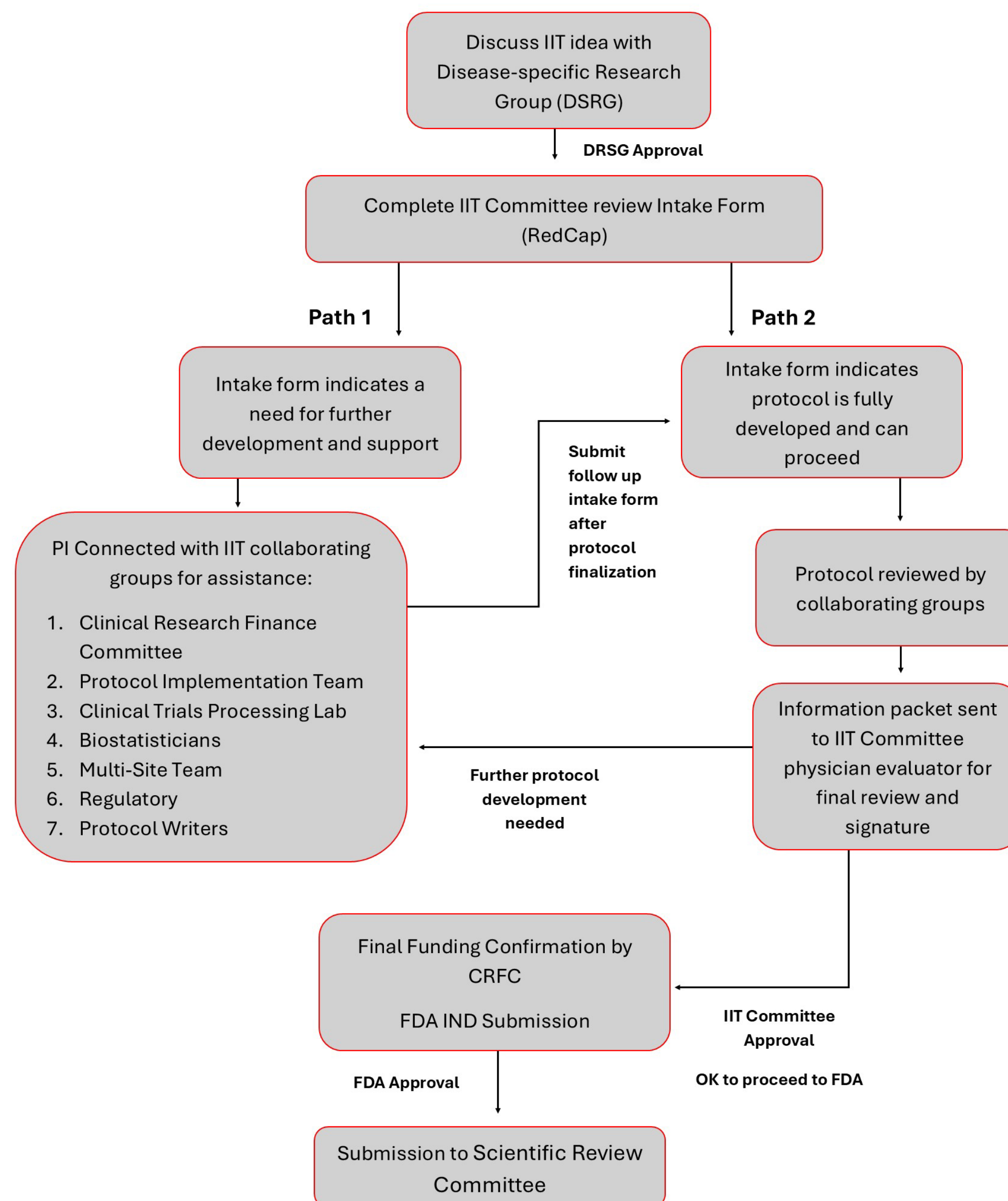
- Implement standardized templates to streamline protocol development.
- Reduce startup timelines to accelerate trial activation.
- Ensure the trial is ready for FDA and Scientific Review Committee (SRC) submission.
- Engage the Principal Investigator (PI) with the budgeting team at the earliest stages of project planning.
- Support PIs at any stage of protocol development by connecting them with essential resources, including statisticians, protocol writers, regulatory officers, multi-site coordination teams, and laboratory staff.

## Committee Development

The IIT Committee is composed of a multidisciplinary team of experts, including experienced IIT principal investigators, biostatisticians, financial analysts, regulatory specialists, laboratory personnel, a multi-center coordination team, and a protocol implementation team. Representatives from each of these collaborating groups were engaged from the initial development of the IIT Committee and contributed expertise, input, and reference materials that were compiled into a comprehensive manual. Through ongoing meetings and collaborative discussions, a standardized workflow was established to guide principal investigators planning a therapeutic oncology IIT. Investigators interested in conducting an IIT are required to submit their protocol to the IIT Committee for review prior to FDA submission, in accordance with the workflow depicted in **Figure 1**.

## Workflow

Figure 1: Investigator-Initiated Trial (IIT) Committee Workflow



## Review Process

The IIT workflow is presented in Figure 1. The process begins when the PI completes the IIT Committee intake form and answers questions to clarify protocol development needs. Based on these responses, the IIT Committee Coordinator (ICC) determines whether the PI will follow Path 1 or Path 2. If protocol development support is required, the PI enters Path 1, and the ICC connects them with committee members who can assist. If the protocol is fully developed, the PI enters Path 2, and the ICC distributes the protocol to committee members for review and confirmation of FDA readiness.

Final review is to be conducted by physician members of the IIT Committee using a standardized checklist to ensure all essential elements are present. Physician reviewers are assigned on a weekly rotating on-call schedule once the protocol is confirmed to be ready for review (Path 2). After review, the Committee will issue either a “Progress to FDA” letter, allowing the PI to proceed with FDA submission, or a “Protocol Development Feedback” letter that demonstrates a need for further refinement before submission.

The IIT Committee meets monthly to address pending trials and resolve issues that may delay protocol readiness for FDA submission, however individual protocol review happens on an ad hoc basis.

Following FDA submission and approval, the protocol will be subjected to a detailed evaluation of scientific validity and protocol quality by the SRC.

## Performance Metrics

Once fully operational and a sufficient number of trials have completed the review and start-up process, the Committee’s effectiveness will be evaluated using Time to Trial (TTT) as a key performance metric. In addition, qualitative feedback from PIs will be collected to assess whether Committee involvement supported a more streamlined and collaborative process. These findings will inform ongoing refinements to the Committee’s structure and services.

## Conclusion

By establishing an IIT Committee, we aim to transform the current IIT landscape into a more responsive and efficient system that empowers oncology researchers. Through standardized processes and robust infrastructure support, the Committee will help ensure that IIT protocols are financially viable and operationally ready—ultimately accelerating the pace of innovation in cancer research.