

# The CCI Application Process

## Investigator Initiated Trial – Funding Competition

The Investigator Initiated Trial (IIT) funding competition is a bi-annual competition held at both the Tom Baker Cancer Centre (TBCC) and the Cross Cancer Institute (CCI). Proposed IITs are reviewed by Regional IIT Review Committees, where a review panel comprised of clinicians and clinical trial support (i.e. finance, biostatistics, and regulatory) thoroughly review and prioritize the IITs they recommend for final review at the Provincial IIT Review Committee. At the Provincial IIT Review Committee, leadership from Cancer Care Alberta and the Alberta Cancer Foundation determine which prioritized IITs will receive funding.

## The CCI IIT Application Process

The CCI IIT Regional Funding Review Committee (RFRC) holds bi-annual competitions in the Spring and Fall wherein investigators are invited to submit their local practice changing clinical trials. Funding is awarded based on the potential of each trial to improve the lives of current and future cancer patients.

A call for proposals is distributed 6-8 weeks before each deadline:

Who is eligible to apply to the CCI IIT Application Process?

The competition is open to applicants who:

- a. Hold an appointment in the Department of Oncology, OR
- b. Are affiliated with the Cross Cancer Institute (CCI), OR
- c. Have a collaborator at the CCI, who meets this criteria (a or b) and that is willing to assume the responsibilities of a Principal Investigator, as defined in ICH-GCP.

Investigator initiated trial funding is allocated to interventional clinical studies that involve patients, require patient consent, and will be run within the context of the Cross Cancer Institute Clinical Trials.

Eligible trials must:

- a) Be considered interventional (defined as: any study performed on patients with the purpose of studying or demonstrating the safety and efficacy of a therapy, to establish side effects, or to investigate absorption, distribution, metabolism or elimination, with the aim of providing clear evidence of the efficacy or safety of the intervention)
- b) Run within the context of the Cross Cancer Clinical Trials Unit to provide regulatory, project management and financial oversight

At this time, multicenter trials are not considered for funding unless investigators at other sites secure local regulatory oversight and funding. A commitment letter/confirmation is required at the time of submission.

## Spring Competition

Call for proposals sent early/mid-February. Deadline to receive proposals: April 1<sup>st</sup> (or first working day of April).



### Fall Competition

Call for proposals sent early/mid-August. Deadline to receive proposals: October 1<sup>st</sup> (or first working day of October)

*The following documents are required as part of each proposal:*

#### Study Protocol

Investigators are asked to provide a completed study protocol based on the IIT protocol template provided. This template has been designed to accommodate various clinical trials and should be edited as required for each individual study.

#### Study Budget

The IIT budget template is designed to help investigators calculate the cost of their clinical trial. This template includes many of the costs encountered during a routine trial. For specific costs please reach out to the IIT Project Manager for assistance.

As a note, chances of success may be increased if funding requests are kept to a maximum of \$125,000 (if possible).

#### Tumor Group Support

Investigators are asked to provide a letter of Tumor Group Support showing that that this trial has been reviewed by members of the associated tumor group.

Wherein applicable, investigators are asked to provide a letter of support from the Radiation Medicine Utilization Committee (RMUC) indicating that this trial is technically feasible from the Radiation Medicine perspective at the CCI.

If the clinical trial involves use of a radiopharmaceutical, investigators are asked to provide a letter of support from the Alberta Radiopharmaceutical Collaboration (ARC) – Innovation, Research and Education Subcommittee indicating that the trial is feasible from a technical and manufacturing perspective, as applicable.

#### IIT Submission Form

For updated copies of all templates or to submit completed applications, please e-mail the CCI IIT Project Management team at [ACB.CCITrial.IITProjectManager@albertahealthservices.ca](mailto:ACB.CCITrial.IITProjectManager@albertahealthservices.ca)

The Regional Funding Review Committee reviews all proposals and the Provincial IIT Review Committee follows-up with applicants as to the status of their application.