

HCCC Investigator-Initiated Trials Support Initiative (IITSI)

Letters of Intent are due by noon on Wednesday, March 5, 2025

Please submit the LOI as a single PDF file to

https://uiowa.qualtrics.com/jfe/form/SV_9ELhjhRda7WICLs

The Holden Comprehensive Cancer Center (HCCC) invites letters of intent for investigator-initiated trials to assist members in advancing clinical cancer research, both therapeutics and non-therapeutics. The maximum amount for individual IITSI grants is \$ 100,000 for therapeutic (treatment trials) and \$ 50,000 for non-therapeutic trials (e.g., prevention, screening, supportive care studies, etc.). These funds can support any (or all) components of an investigator-initiated study, e.g., infrastructural support (regulatory, coordinator, data collection), correlative science, etc. Eligible proposals will include an *interventional* trial designed to prevent, diagnose, treat, or modify cancer-related health outcomes as its primary endpoint. Trials evaluating biomarkers or imaging techniques will also be eligible if they meet the above criteria. All HCCC members (full, associate, clinical, affiliate) can apply for this funding.

Briefly, the Standard Operating Procedure will be as follows.

Investigator-Initiated Trials Support Initiative (IITSI):

The LOIs need to be brief (2 pages maximum). HCCC clinical research and program leadership, including applicable multidisciplinary oncology group (MOG) leaders, will review the LOIs. The IITSI review committee will meet for review approximately two weeks after the LOI due date.

LOIs are expected to contain the following information:

- The specific aims and scientific rationale for the study
- Overall study design, including hypothesis, objectives, endpoints, schema, and intervention.
- Research team and collaborators
- Enthusiasm for the proposal from key members of the MOG or a research program
- Feasibility of the proposal, such as information on the relevant patient population, preliminary work, availability of the drug, and status of IND or IRB applications.
- Potential sources of concurrent and future funding
- An estimated budget request from the IITSI and its justification. These funds are not meant to support an investigator's salary.

The IITSI review committee will assess the LOIs and identify select proposals for funding based on the following criteria:

- Scientific strength of the concept, including its potential clinical impact
- Appropriateness of the trial to be supported via IITSI
- Enthusiasm of the MOG or research program for the concept
- Feasibility of the study, including appropriateness of research team, cost of conducting the trial, and availability of the appropriate patient population and investigational agents
- Lack of / limited availability of an alternative source of support
- Potential for future funding or development of a larger study

The concepts for which experimental agent or drug is secured (if applicable) will be reviewed more favorably compared to trials where drug availability is still being determined. The IITSI committee will provide feedback to investigators who submitted the LOIs, including explaining why the proposal was unsupported. For LOIs selected for full proposals, the committee will advise the applicants on issues that need to be addressed in the full proposal. The full proposal and detailed budget - up to 5 pages and a clinical protocol included as an appendix - will be due within eight weeks of initial LOI approval. (Submit as a single PDF to https://uiowa.qualtrics.com/jfe/form/SV_9ELhjhRda7WICLs). This will allow the IITSI review committee to assess the full proposal. The committee uses the same criteria to review protocols as the LOIs. Additional factors considered with full proposals include:

- Appropriateness of the budget
- Availability of IITSI funds

Award Terms:

1. Funds will be released once the study is IRB-approved.
2. The IITSI committee and the HCCC leadership will require a progress report on the study, including any associated publication and funding, every six months (June and December of each calendar year) until the term of the award (5 years from the initial approval).
3. Unused funds at the end of the term will be returned to the Cancer Center (5 years from initial approval). Awardees may request one no-cost extension for an additional year. Submit requests 30 days before the end of the grant period.
4. All resulting publications must acknowledge the Holden Comprehensive Cancer Center's support: "This project is supported by Holden Comprehensive Cancer Center Philanthropic Funds."