



## **Holden Comprehensive Cancer Center Funding Opportunity Investigator-Initiated Trials' Support Initiative (IITSI)**

### **Letters of Intent due by Noon, Friday February 16, 2024**

Email LOI as a single PDF file to [tami-thompson@uiowa.edu](mailto:tami-thompson@uiowa.edu)

The Holden Comprehensive Cancer Center (HCCC) is inviting letters of intent for this grant initiative to assist members in their efforts to advance cancer research in both therapeutic and non-therapeutic trials (e.g. dietary and behavioral interventions). The maximum amount for individual IITSI grants is a total of \$100,000 for therapeutic and \$ 50,000 for non-therapeutic trials. These funds can be utilized to support any (or all) components of an investigator-initiated study e.g. infrastructure support (regulatory, coordinator), correlative science etc. Eligible proposals will include interventional trials design to either prevent, diagnose, treat or modify any cancer-related health outcomes as their primary endpoint. Trials evaluating biomarkers or imaging techniques will also eligible as long as they meet the above criteria.

Briefly, the procedure will be as follows.

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#### **Investigator-Initiated Trials' Support Initiative (IITSI):**

Letters of intent (LOI) will be solicited. The IITSI committee will meet approximately 2 weeks after the LOI due date. The LOIs will be brief (2 pages maximum). Endorsement of the LOI by the leadership and additional members of a MOG or Program will be encouraged.

LOIs are expected to contain the following information.

- The specific aims and scientific rationale for study
- Overall study design including hypothesis, objectives, endpoints, schema, and intervention
- Research team and collaborators
- Enthusiasm for the proposal from the leadership and key members of a MOG and/or research program and how the proposal was discussed with the MOG or research program
- Feasibility of the proposal such as information on the relevant patient population, availability of drug, 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 salary.

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

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

The IITSI committee will provide feedback to investigators who submit LOIs including an explanation for why the proposal was not selected for the support. 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 in length with a clinical protocol included as an appendix - will be due within 8 weeks of initial LOI approval. (submit as a single PDF to tami-thompson@uiowa.edu).** This will allow the IITSI committee to review the full proposal. The committee uses the same criteria to review full protocols as it does 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 study is IRB approved
2. Progress report (publication and funding) will be required every six months for IITSI committee and the HCCC leadership by 15<sup>th</sup> of June and December of each calendar year until the term of the award (5 years from the initial approval). Template will be provided.
3. Unused funds at the end of term will be returned to the Cancer Center (5 years from initial approval). Awardees may request one no-cost extension for an additional year. Requests must be submitted no later than 30 days prior to end of grant period.
4. The Cancer Center must be acknowledged in all resulting publications. Template language: *"This work was supported by the Holden Comprehensive Cancer Center, P30CA086862."*