



Translational Project Development and Clinical Trials Awards

Deadline: Noon - Wednesday, September 23, 2009

The Holden Comprehensive Cancer Center (HCCC) seeks applications from its Cancer Center members to support **development of novel clinical cancer research projects**.

- The intent of this process is to assist investigators in the design and initiation of innovative clinical cancer studies that have a high likelihood of leading to external peer-reviewed funding, and to establish ongoing collaborations between laboratory-based programs and clinical investigators likely to result in additional research projects. Clinical research is defined as research involving human subjects, preferably in diagnostic or therapeutic cancer trials.
- Applications focused on development of clinical trials related to cancer prevention and quality of life in cancer survivors, are also encouraged.
- Studies that are strictly correlative in nature, such as involving tumor samples or genomic information, will be considered only if they are designed to lead to a clinical trial for step II of this award program.

Eligibility:

- Both junior and senior-level faculty members are eligible for these awards.
- The P.I. or a co-Investigator must be a full member of the HCCC.
- Basic, clinical and population scientists are eligible to apply.

Application Process (2 Steps - Phase 1 and Phase 2)

I. Phase 1 - Project Development

All interested applicants are to submit:

1. Cover Letter,
2. Title Cover page to list the primary investigator, his degrees, title of the research project, departmental address, phone number, and e-mail.
3. NIH abstract page,
4. Single page budget outlining costs of project and justification
5. Standard NIH biographical sketch of the Principal Investigator and Co-investigators, and,
6. Maximum of three pages of narrative summarizing the proposed research. The narrative should include;

- a. Background and preliminary data
- b. Outline of proposed research (detailed methods are NOT needed) including a very brief description of the clinical trial that will be proposed. Evidence that the patient base is adequate to achieve the needed sample size should be presented, but detailed biostatistics are not necessary
- c. Time line including steps needed before research can advance to a clinical trial (e.g. need for an IND, collaboration with pharmaceutical company, identification of additional collaborators)
- d. Opportunities for external peer-reviewed funding should studies prove to be successful.

Selected proposals will receive the following:

- Up to **\$10,000** seed funding for **Phase I** of the project
- Access to Cancer Center resources to assist in trial development
- Assistance in recruitment of an adequate clinical team to conduct the trial
- Assistance in interfacing with the University of Iowa's General Clinical Research Center as appropriate

The support from step I will be used to complete needed pre-clinical work, write a protocol, and address external and internal regulatory issues including (but not limited to) obtaining an IND from the FDA, and internal approval from the IRB and HCCC PRMC. In accepting the award, the P.I. will agree to supply the HCCC Leadership with a progress report of the research program every 6 months. Included in this report will be a description of progress towards step number 2 (clinical trial step). The HCCC will agree to work with the investigators to encourage further development of the proposal.

Note: Applicants are not required to route this Internal Application through the University of Iowa's Division of Sponsored Programs Office.

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Submit: Please send **one electronic copy** and **one hard Copy** of the application to: [Tami Thompson](#), Holden Comprehensive Cancer Center, 5970 JPP

Contact: Cancer Center Administration ([Tami Thompson](#) 319-353-8987 or [Jan Spielman](#) 319-353-8634) for related questions.

II. Phase II - Clinical Trial Step

When pre-clinical work of Phase I has been completed, the P.I. of the project will submit a report to HCCC Executive Committee that outlines this progress and includes a copy of both the clinical protocol and approval documents. If all issues have been addressed adequately, the HCCC will support conduct of the clinical trial by supplying the Investigators with the following;

- A. Access to data management and protocol management support through the HCCC clinical trials support core, and ongoing biostatistics consultation, to support the proposed clinical trial, at no charge.
- B. Up to **\$20,000** for other expenses including correlative studies (needs to be justified by the P.I.) for support of the clinical trial - **Phase II**.

Proposals will be reviewed by the Holden Comprehensive Cancer Center's Research Review Committee and Cancer Center Executive Committee, and evaluated based on the following criteria:

1. Standard NIH criteria (Significance, Innovation, Approach, Investigator).
2. Likelihood of preliminary results leading to external peer-reviewed support.
3. Availability of resources in the HCCC needed to support proposed studies including clinical trial.
4. The fit of the trial within the portfolio of clinical trials in the Cancer Center.