

## EARLY PHASE CLINICAL TRIALS SUPPORT

### Purpose of UCCCC RFA:

The purpose of this opportunity is to provide seed funding in support of work that will lead to the submission of an R01 application to the NCI in response to one of the following Program Announcements:

- PAR-18-560: National Cancer Institute's Investigator-initiated Early Phase Clinical Trials for Cancer Treatment and Diagnosis (R01 Clinical Trial Required) <https://grants.nih.gov/grants/guide/pa-files/par-18-560.html>
- PAR-18-559: Cancer Prevention and Control Clinical Trials Program (R01 Clinical Trial Required) <https://grants.nih.gov/grants/guide/pa-files/PAR-18-559.html>

Brief descriptions of these NCI FOAs, in particular, the types of trials funded, follows this announcement.

### Eligibility Criteria and Other Guidelines for the UCCCC Seed Funding:

- a) PI must be a UCCCC member;
- b) Study must be in preparation for submission to one of the above FOAs;
- c) Seed funding cannot be used for PI support; and
- d) Requests can be made for up to \$50K with the opportunity to renew once. If these funds will not cover the entire cost of the project, please indicate other funding sources (and amounts).

### Application:

Please submit:

- Primary and secondary objectives of the clinical trial;
- Statistical analysis plan in support of primary and secondary objectives (include projected number of patients);
- A brief (one page) description of the importance/innovativeness of the research, i.e., why it should be funded;
- How it fits the priorities of the NCI FOA, include at least one specific aim for the envisioned R01;
- Clear milestones for protocol submission, activation, accrual, and analysis as well as a timeline for submission of NCI grant;
- List of co-investigators and/or collaborators and their roles;
- Whether this project has been submitted anywhere else for funding, as if so, where and outcome;
- Budget and budget justification.

### Progress Reports:

- 6-month brief progress reports addressing progress to date and time to submission of NCI grant will be requested.

**Deadline: Monday, March 18, 2019**

**Award period: May 1, 2019 – April 31, 2020**

### Instructions for uploading your proposal:

1. Go to: <http://administration.uccrc.org/>
2. Click on "Submit Projects"
3. Enter your name and password (BSDAD)
4. Click on "Submit a new project" and follow the directions
5. **Note: please combine all pieces of the application (budget & justification, biosketch, proposal) into ONE PDF before you upload it.**

### NOTE:

- Funds cannot be allocated until protocol is IRB approved.

## NCI FOA Descriptions:

### **TREATMENT AND DIAGNOSIS**

PAR-18-560: National Cancer Institute's Investigator-initiated Early Phase Clinical Trials for Cancer Treatment and Diagnosis (R01 Clinical Trial Required) <https://grants.nih.gov/grants/guide/pa-files/par-18-560.html>

The NCI FOA will support: (see above link for further information)

- a) An early phase trial by itself, or in combination with other non-clinical trial research aims as appropriate;
- b) The conduct of investigator-initiated (IIT) oncologic intervention research at all early stages, from early mechanistic research and intervention development (e.g., stage 0 and/or I) through implementation and cost-effectiveness research;
- c) Single-site, multi-site, hypothesis-driven, pathway-related, exploratory/feasibility and pragmatic trials (as defined below) designed to improve the management of care for patients with cancer;
- d) The trial design should be appropriate for the hypothesis to be tested; and
- e) Randomized Phase II trials that can be performed within the temporal and fiscal limits of this program announcement.

The FOA will NOT support:

- a) IIT Phase III trials;
- b) Studies proposing only animal or in vitro studies;
- c) Studies proposing only observational research;
- d) Studies investigating behavioral interventions; and
- e) Infrastructure support.

### **CANCER PREVENTION AND CONTROL**

PAR-18-559: Cancer Prevention and Control Clinical Trials Program (R01 Clinical Trial Required) <https://grants.nih.gov/grants/guide/pa-files/PAR-18-559.html>

The NCI FOA will support: (see above link for further information)

- a) A Phase 0-IV clinical trial involving investigations in cancer prevention or control that should contribute to the advancement of evidence-based medicine and the practice that supports it;
- b) A clinical trial defined as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes";
- c) The following research areas: cancer prevention, cancer screening, early detection, behavioral research in cancer prevention and control (e.g., tobacco use, vaccine uptake, screening, treatment adherence, other health related factors), susceptibility to cancer and cancer-related outcomes; implementation science, healthcare delivery, cancer survivorship, supportive and palliative care and quality of life.