Clinical Trial Concept Award
Request for Applications

Purpose and Overview

The MCW Cancer Center recognizes that Investigator-initiated Trials (IITs) represent the apex of academic cancer research innovation, as they help develop new ways to prevent, diagnose and treat cancer and provide participating patients with access to the most advanced treatments. In line with this vision, **the scope of this pilot program is to encourage and support the development of an IIT or innovative correlative studies that capitalize on an already funded trial**.

encouraged.

Eligibility and Evaluation Criteria

Eligibility

- Proposed research must involve a study that satisfies the NIH definition of a clinical trial.
- Proposed research must be cancer-relevant.
- PI must be MCW faculty (includes VBRI investigators).
- Follow-on external funding proposals must be submitted through MCW.
- Research can take place, and expenditures incurred only at MCW, Children's Wisconsin, Froedtert Hospital, Versiti BRI, Children's Research Institute or the Zablocki VAMC.
- Proposals that are based on laboratory discoveries made, at least in part, at MCW will be prioritized.
- Proposals must show clear demonstration of the feasibility of clinical application of investigational intervention including (if applicable):
    - Source, availability and chemistry, manufacturing and controls (CMC) of the clinical grade product (collaborations with pharmaceutical companies should provide approved LOI, concept invitation, *etc*.);
    - Pre-clinical and PharmTox data if available (previously published or determined by study investigators); and
    -

the Cover Sheet will be emailed to you. Combine (concatenate) the cover page produced with the remainder of your application for submission (see below).

- **Scientific Abstract:** Provide a summary of the project. (250-word limit)**Lay Abstract:** Provide a brief summary of the proposed research project in layman's terms. If funded, this abstract may be distributed to the funding source and can be used in written correspondence with donors and interested parties. (200-word limit)
- **Response to Reviewers:** (If applicable) For previously submitted proposals, please include reviewer comments and describe key changes that have been made in response. (1-page limit)
- **Specific Aims:** State concisely the hypothesis to be tested and the specific aim(s) to be achieved during the project period. (1-page limit)
- **Research Strategy:**
  a. Background-Significance-Innovation. (1-page limit)
  b. Approach including relevant preliminary data. (3-page limit)
- **Future Impact Plans:** Awardees are required to submit a timeline for how this study will have impact in the future. This could be showing when a cancer-relevant investigator-initiated trial (IIT) will be submitted/amended to the IRB for review, how this study will impact the community, or other outcomes from the work done in this pilot. State the corporations, agencies, mechanisms and timing of planned future grant applications that will utilize the preliminary data produced under this award. State how data from this application will be used to support extramural proposals. *Extramural proposals that utilize the preliminary data produced under this award must be submitted through MCW*. (200-word limit)
- **Budget:** Detailed budget is not required at time of application, but a statistical plan and study parameters table, correlates, and cohort size should be part of the concept for input on feasibility and scope of the study. Briefly describe how funds will be allocated to support the study (*e.g.*, trial activation, trial management/conduct, correlative studies). Any no-cost extensions will require review of the final report and prior approval by MCWCC Leadership. Absent such prior approval, if timely progress is not made during the award period and funds have not been fully expended by the end of the project period, the funds will be returned to the MCWCC.
- **Literature Cited:**

of award will be made after peer review and Director's Council approval. Please contact MCWCCResearchPrograms@mcw.edu with any questions.

Post-award Requirements and Terms

If approved for funding by study section and Director's Council, PI receives an e-notification describing the following requirements:

- PI drafts the protocol or, in the case of new correlative studies proposed, amends the protocol accordingly.
- PI meets with CTO Business Operations to draft a detailed budget (including all sources of funds).
- PIs drafting a new trial protocol should:
  - Submit the protocol to the appropriate CTO Research Manager and DOT for review and approval.
  - Work with the appropriate CTO Research Manager to secure approval from the Feasibility Review Committee, which is mandatory for all IITs.
- PI submits the new or amended trial protocol to the MCWCC Scientific Review Committee (SRC) for approval.
- PI is expected to obtain regulatory approvals (*e.g.*, DSMC, FDA, IRB).

SRC approval must be obtained after e-notification for PIs to receive a Notice of Award (NOA). Release of funds will be contingent upon necessary regulatory approvals and all applicable human subject protocols having been sent to MCWCCResearchPrograms@mcw.edu. Failure to comply with the post-award terms could result in revocation of funds.

Program Expectations and Outcomes

- Comply with NOA requirements.
- Publish or present results in a national forum.
- Develop an extramurally funded IIT (submission to pharma and acceptance of LOI).
- Submit progress report one year after funding commences.
- Submit a year-one progress report and final report upon project completion, including project results and clinical trials and grant applications submitted or planned.
- Submit annual updates regarding grants, other funding, and publications leveraging results for five years.

Awardees may be required to serve on pilot study sections for three years.