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**.

Priority Areas of Funding for the Current Funding Cycle

Researchers proposing relevant projects from all areas of science are invited to apply to this RFA. **Priority will be given to multi-disciplinary collaborations between clinical scientists, basic or translational scientists, and population science researchers who propose to study topics related to understanding or addressing cancer disparities**. Applications that propose correlative studies, especially those that utilize MCWCC Shared Resources, are 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
    - Anticipated regulatory path to test investigational product in human research subjects (IDE/IND including citations from previous INDs for the same material, source from food products, *etc*.).
- Proposals focused solely on correlative studies are eligible if the following conditions are met:
    - Clinical scope of the correlative studies are justified in the LOI and application. Examples of appropriate studies include, but are not limited to, assessing molecular response to treatment, utilizing imaging as a predictor of outcomes, and novel evaluation of minimal residual disease.
    - Budget reflect support for correlative studies only and must leverage a funded clinical trial (a letter of support demonstrating proof of funding must be submitted with the application)

Evaluation Criteria

Each application will be assigned to internal and external reviewers who have substantial expertise in clinical. cancer research and in reviewing grants, including the MCWCC Biostatistics Shared Resource (BSSR) as applicable. Proposals involving clinical trials or complex clinical projects require consultation with a MCWCC biostatistician at least 30 days prior to the submission deadline which can be requested through iLab.

Multi-disciplinary collaborations between investigators in the clinical sciences, basic sciences and population sciences are encouraged. Trials that address outcomes and interface with cancer prevention and control studies are also highly encouraged.

Review criteria include

- Standard NIH criteria (significance, innovation, approach and investigative team);
- Inclusion in the Approach of sound statistical plan formulated in consultation with a BSSR statistician;
- Innovative plan to increase accrual of underrepresented groups to clinical trials.
- Likelihood that preliminary results will lead to an externally funded protocol, a LOI from pharma or NCTN, and/or extramural grant funding;
- Projects involving transdisciplinary, team-based coordination and collaboration will be prioritized;
- The extent to which PI and key personnel participate in MCWCC programs or activities (*e.g.,* participate in program meetings, grant review panels, recurring seminars, symposia, clinical trial advisory committees such as SRC, IIT Steering Committee, *etc.*);
- Inclusion of a clear description of how the studies will provide data that is critical to the future development of an investigator initiated extramurally funded clinical trial (IIT) or extramurally funded project; and
- When appropriate, description of how the proposed research may ultimately produce IP (intellectual property, like patents).

Budget

Up to $150,000 for two years.
A detailed budget is not required at time of application. Refer to the application instruction below. Do NOT engage CTO Business Operations personnel in the application process for this pilot RFA: They will be engaged later to produce a detailed budget for successful applications.

Workflow for Pilot Application Process

1. PI contacts the appropriate CTO manager to get on the Disease Oriented Team (DOT) schedule to present concept for input and comments.
2. PI incorporates the DOT and mentor feedback into concept.
3. PI consults with the BSSR statistician on trial design and statistical considerations.
4. **PI presents concept to the IIT Steering Committee for high level feedback. Note: This step is mandatory before applying to this RFA.**
5. PI revises concept proposal and obtains DOT leader approval (New Trial Submission Form).
6. PI submits an LOI to the MCWCC indicating their intent to apply for the award.
7. If invited, PI submits an application to this Clinical Trial Concept pilot award RFA for competitive review.

Application Instructions

Please see the MCW Cancer Center website for additional information and forms.

Application Format: Use standard 11-point font, single space, and half-inch margins throughout the application. Consecutively number all pages.

- **Cover Page:** To initiate, please visit the Faculty Collaboration Database website to sign in so that certain fields can be auto-populated. Include project title, investigators and affiliations. 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:** List only references pertinent to the proposed research. References do not count against the page limit.
- **NIH-format Biosketches:** Biosketches for all faculty team investigators must be included. Personal statements must include the specific role of the team member. Include information on any faculty investigator clinical trials. In addition to the standard NIH-format biosketch sections, include a section on Current and Pending Research Support. Provide the expected notification date for each pending application and describe any overlap or relationship between each pending application and this application.
- **Form D: Return on Investment.** Previous Cancer Center Pilot Grant recipients must complete.
- **Letters of Support:** Letters of support from the appropriate individuals/organizations, such as MCW Centers or Institutes, which may include your MCWCC Program Leader, Disease Oriented Team Leader, collaborator(s), pharma partner, sources of funding, and/or mentor (if pertinent).
- **Mentoring Plan:** Junior faculty please include a mentoring plan with your application (1-page limit).
- **New Trial Submission Form:** Initial concepts must be approved through the Disease Oriented Team (DOT) prior to submission (see Workflow section above). Form must be obtained from the appropriate Clinical Trials Office (CTO) disease team manager.
- **Clinical Trial Summary Table:** Applications proposing a clinical trial should include a table (*e.g.*, protocol summary table) that concisely describes, at a minimum, the following fields: study population, study objectives, study endpoints, main eligibility criteria, study design, intervention, number of subjects, estimated time to complete accrual, and estimated time to study completion.

Timeline

RFA release: 01/15/2024. An LOI indicating your intent to submit and briefly describing your proposal and team members (250-word limit) is due on or before 02/15/2024. If invited, full applications are **due by 11:59pm on 04/15/2024**. Please email one PDF file of the application to MCWCCResearchPrograms@mcw.edu. Notifications of award will be made after peer review and Director's Council approval, near the beginning of June 2024. 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 within **six months** 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.