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.).
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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

- **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 MCWCC. (1-page 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

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- 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 pr (b)2 (li Tj/TT.95 0 T3 (p)-2.nn/MCID 37 a1 Tf-0.001 Tc3 (nt)-2 (t)-2 (s7 37 BDCC /LBody /MCID 3