Clinical Concept Award
Request for Applications

Purpose and Overview

Clinical trials help develop new ways to prevent, diagnose and treat cancer, providing participating individuals with access to the most advanced treatments. The MCW Cancer Center (CC) provides support for the development of clinical trial concepts (related to prevention, diagnosis, and treatment) based on laboratory discoveries made at MCW.

Priority Areas of Funding for the Current Funding Cycle

Researchers with relevant research from all areas of science are invited to apply to this RFA. **Priority will be given to collaborations between basic or translational science, and population science or epidemiologic researchers who propose to study topics related to understanding or addressing cancer disparities**. Inclusion of correlative studies that utilize MCW CC Shared Resources, especially those provided by the GSPMC (NGS such as genomic, transcriptomic and epigenomic sequencing and bioinformatic analysis), are encouraged.

Workflow

- PI contacts the Clinical Trials Office (CTO) (414) 805-0596 to get on the appropriate Disease Orientated Team (DOT) schedule
- PI presents concept to the appropriate DOT for input and comments.
- PI incorporates the DOT and mentor feedback into concept.
- PI presents concept to IIT Steering Committee for high level feedback.
- PI revises proposal and obtains DOT leader approval (New Trial Submission Form).
- PI submits an application to the internal Clinical Concepts RFA for competitive review.
- If approved for internal funding, PI drafts the protocol.
- Once protocol is drafted, return to IIT Steering Committee for sign-off before it goes to Scientific Review Committee (SRC) for final approval. Note: Returning to the IIT Steering Committee is optional, but highly recommended.
- Detailed budget analysis occurs after the Clinical Concepts award has been made and the protocol has been drafted, and standard process follows.

Eligibility and Evaluation Criteria

Eligibility

- Proposed research must be cancer relevant, preferably including multi-disciplinary team collaborations.
- MCW Tenure track faculty members are eligible to apply.
- Research can take place, and expenditures incurred only at MCW (*e.g.*, GSPMC, CTSI, CAPS), Children's Wisconsin, Froedtert Hospital, Versiti BRI, Children's Research Institute or the Zablocki VAMC.
- Clear demonstration of the feasibility of clinical application of applicant's 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*.).

Evaluation
Each application will be assigned to internal and external reviewers who have substantial expertise in clinical cancer research and in reviewing grants, including the CC Biostatistics Shared Resource (BSSR) as applicable. Proposals involving clinical trials and/or animal studies require consultation with a CC biostatistician at least 30 days prior to the submission deadline (click here for biostatistician consult request). 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 encouraged.

Review criteria include

- Standard NIH criteria (significance, innovation, approach and investigative team);
- Likelihood that preliminary results will lead to an externally funded protocol, a LOI from pharma, and/or extramural grant funding;
- Projects involving transdisciplinary, team-based coordination and collaboration will be prioritized;
- PI and key personnel participation in CC programs (*e.g.*, attend program meetings, participate in grant review panels, participate in recurring seminars or symposia);
- The scientific plans must describe how the funds will provide study data that is critical to the future development of an investigator initiated clinical trial (IIT); and
- When appropriate, description of how the proposed research may ultimately produce IP (intellectual property, like patents).

Budget

CC leadership anticipates distributing awards of up to $150,000 for two years.

Application Instructions- Please see the MCW Cancer Center website **here** 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 click here. This will take you to the Faculty Collaboration Database 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) Describe key changes that have been made in response to reviewer comments. (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. (3-page limit)
- **Future Funding Plans:** Awardees are required to submit a timeline showing when a cancer-relevant investigator-initiated trial (IIT) will be submitted to the IRB for review. 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. (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 trial. Budget cap is $150,000 direct costs per award. Any no-cost extensions will require review of the final report and prior approval by CC 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 CC.
- **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 (which include Current and Recent Research Support), include an additional Pending Support section that lists all pending grant applications. Describe any overlap or relationship between the pending application and this Clinical Concepts application. Give the expected notification date for each pending application.
- **Form B**: **Non-Supplanting Form.** Use separate forms for each principal and co-investigator.
- **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 CC Program Leader, Disease Oriented Team Leader, collaborator(s), pharma partner, and/or mentor (if pertinent).
- **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. Call the CTO at (414) 805-0596 for assistance.
- **Regulatory Approvals:** Awarded PIs are expected to obtain regulatory approvals [*e.g.*, IACUC, IRB] within three months of award notification. Release of funds will be contingent upon IRB/IACUC approval and all applicable human and animal subject protocols having been sent to Nicole Davis (nmdavis@mcw.edu)
- **Junior Faculty:** Please include a mentoring plan with your application. (1-page limit).

Timeline

Full applications are **due by 5:00 pm on Tuesday, December 1, 2020**. Please email one PDF file of the application to Nicole Davis (nmdavis@mcw.edu). Notifications of award will be made after peer review, mid February. The start date will be dependent on the status of any required human and animal studies protocol approvals, with the understanding that it will not take longer than three months post award notice. Please contact Nicole Davis (nmdavis@mcw.edu) with any questions.

Program Expectations

- Publication or presentation of results in a national forum
- Development of an investigator initiated clinical trial
- Acceptance of LOI and extramural support for a clinical trial
- Final report is required upon project completion, including an outline of project results and clinical trials submitted or planned.
- Awardees will be required to serve on pilot study sections for three years.