



Pre-Clinical Concept Award Request for Applications

Purpose and Overview

Clinical trials help develop new ways to prevent and treat cancer, providing participating patients with access to the most advanced treatments. The MCW Cancer Center (CC) provides support for development of pre-clinical concepts based on laboratory discoveries made at the CC. CC leadership anticipates distributing awards of up to \$50,000 for one year.

Priority Areas of Funding for the Current Funding Cycle

Cancer relevant research from all areas of science are invited to apply to this RFA. However, collaborations between basic/translational science and population science researchers who propose to study topics related to understanding or addressing cancer disparities will be given priority. Proposals that utilize MCW CC Shared Resources are encouraged.

Eligibility and Evaluation Criteria

Eligibility

- Proposed research must be cancer relevant.
- MCW Tenure track faculty members are eligible to apply.
- Research can take place, and expenditures incurred, at MCW, Versiti BRI, Children's Research Institute or the Zablocki VAMC.
- Applicants are encouraged to seek project advice and support from the appropriate Associate Director and/or Program Leader.
- Demonstration of feasibility of applicant's investigational intervention including (if applicable):
 - Source and availability of a clinical grade product (collaborations with pharmaceutical companies should provide approved LOI, concept invitation, *etc.*);
 - Anticipated path to IND (including citations from previous INDs for the same material, source from food products, *etc.*); and
 - Purity info (previously published or determined by study investigators).

Evaluation

Each application will be assigned to internal and external reviewers who have substantial expertise in clinical cancer research and in reviewing grants. Proposals will also be reviewed by the CC Biostatistics Shared Resource (BSSR). Proposals involving animal studies require consultation with CC biostatisticians at least 30 days prior to the submission deadline ([click here for biostatistician consult request](#)).

Review criteria include

- Standard NIH criteria (significance, innovation, approach and investigative team);
- Likelihood that preliminary results will lead to a successful LOI, externally funded protocol, or extramural grant funding;
- Projects involving transdisciplinary, team-based coordination and collaboration will be prioritized;
- Projects that promise to enhance collaborations between cancer outcomes disparities researchers and basic / translational scientists will be prioritized;
- Participation in CC programs (*e.g.*, attend program meetings, participate in grant review panels, participate in recurring seminars or research symposia);

- A well-thought-out Future Funding Plan (see instructions) describing how the funds will provide study data that is critical to the future development of an investigator initiated clinical trial;
- When appropriate, description of how the proposed research may ultimately produce IP (intellectual property, like patents).

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.
- **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) Insert an additional document describing key changes that have been made in response to the reviewer comments. (1-page limit)
- **Specific Aims:** State concisely the hypothesis to be tested and the specific aim(s) to be achieved during the one-year project period. (1-page limit)
- **Research Strategy:**
 - a. Background-Significance-Innovation (1-page limit)
 - b. Approach (3-page limit)
- **Future Funding Plans:** State the corporations, agencies, mechanisms and timing of planned future grant applications that will utilize the preliminary data produced under this award. Describe how data from this application will be used to support extramural proposals. (200-word limit).
- **Budget:** Use [budget](#) template found on the Cancer Center webpage followed by a Budget Justification. Budget cap is \$50,000 direct costs. There are no indirect costs allowed. No faculty salaries, student tuition and fees, or equipment should be included. Faculty effort related to this award must be listed. Salary or stipend support for laboratory personnel, RAs, post-doctoral fellows, study coordinators, *etc.* may be included. Every budgeted item must be classified into a category (*e.g.*, personnel, supplies, patient care costs). Travel expenses will only be allowed when necessary to carry out the proposed project. Any no-cost extensions will require review of the final report and prior approval by CC Leadership. If timely progress is not made throughout 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. 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 Pre-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 this form.
- **Letters of Support:** Letters of support from the appropriate individuals, which may include your CC Program Leader, collaborator(s), and/or mentor (if pertinent).

- **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 are uploaded into eBridge.
- **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 human and animal studies protocol approvals. Nicole will initiate and then work with approved PI's department administration to complete eBridge submission. Please contact Nicole with any questions.

Program Expectations

- Publication or presentation of results in a national forum.
- Intent and progress toward developing an investigator initiated clinical trial: Awardees are required to submit a timeline showing when a cancer-relevant investigator initiated trial (IIT) will be submitted to the IRB for review.
- A report is required upon project completion, including an outline of project results and discussion or comments on planned future clinical trials.
- Acceptance of LOI and extramural support for a clinical trial.
- Awardees will be required to serve on pilot study sections for three years.