Comprehensive Cancer Center
Neuro-Oncology Program PUSH Pilot
Request for Applications for Pilot Awards

Purpose

The Neuro-Oncology (NRO) Program is soliciting applications for "PUSH" pilot projects. The pilot award will be used to fund research relevant to the scientific aims of the Program:

1) Determine the role of cancer stem-like cells in tumor initiation and progression through studying signaling pathways and interaction with other cell types in the tumor microenvironment. Areas of particular focus are malignant gliomas, including glioblastoma, and breast and lung cancer brain metastases. The aim reflects a focus on mechanisms regulating participation of these cells in cancer initiation and progression, and those that are potential targets for therapeutics.

2) Develop novel therapeutic approaches for these difficult-to-treat cancers based on a) anti-cancer biophysical forces, b) bio- and immunotherapeutics, c) disrupting signaling between cancer cells and other cells in the tumor microenvironment, and d) drug delivery specifically to cells of the tumor microenvironment. This reflects broad interest in identifying new therapeutic strategies including those that lead to improved delivery of drugs to the CNS to better manage both primary and metastatic brain tumors.

3) Conduct innovative clinical interventions which will affect the course of the disease and/or preserve the well-being of patients. The aim leverages the rich history of early phase clinical brain tumor research at Wake through long-standing participation in the Adult Brain Tumor Consortium (ABTC), other national brain tumor collaborations, as well as investigator-initiated trials.

The goal of the "PUSH" pilot grant is to catalyze new and innovative ideas that allow investigators to pursue a line of research with likelihood for extramural funding. We continue to be interested in projects that highlight the "value-added" aspects of the Comprehensive Cancer Center (CCC), such as those focused on novel use of technology platforms, translational research, inclusion of investigators from more than one of the four CCC scientific research Programs, new investigator pairings, disparities research focused on the catchment area, and use of Cancer Center Shared Resources. We specifically encourage applications that increase inter-, and intra-programmatic collaborations, particularly those that can lead to multi-PI extramural grant applications (R01s, P01s and SPOREs), as well as inter-institutional (with other institutions) collaborations. Special consideration will also be given to projects that address directly higher incidence and mortality of brain tumors in the CCC catchment area. This pilot project opportunity is available to all interested Neuro-Oncology Program investigators, and any non-Cancer Center faculty members who wish to collaborate with a NRO investigator as the PI/Co-PI.

Eligibility

These awards are open to all Neuro-Oncology Program investigators, and any non-Cancer Center faculty members who wish to collaborate with a (insert program name) investigator as the PI/Co-PI.

Key Dates

Date	Detail
12/16/20, 11:59 pm	Full Application Deadline
2/15/21	Selection of Awardees
3/1/21	Project Start Date
3/1/22	Latest Project End Date

Funding

The CCC will fund up to $100,000 in direct costs per project, with funds to be dispersed in increments pending successful progress and attainment of milestones. See section on Budget Guidelines for more details on allowable and non-allowable budget items.

Application Procedure

Full Application Deadline: 12/16/20, 11:59 pm

The application can be submitted through the ePilot electronic submission system, by the deadline noted above. Application instructions are summarized below.

Format Specifications
- Arial font and no smaller than 11 point
- Margins at least 0.5 inches (sides, top and bottom)
- Single-spaced lines
- Consecutively numbered pages

Submission/Applicant Information
- Project Title
- Submitting Investigator, Co-Investigator(s), and other Key Personnel information

Abstract (250 words max)

Research Plan (6 pages max)
- *Specific Aims*
- *Significance* – Explain how the project addresses an important problem, how it will improve scientific knowledge, technical capability and/or clinical practice.
- *Investigator(s)* – Describe how each member of the team will contribute to the project. Include their expertise and experience that will be utilized on this project.
- *Innovation* – Explain how this project uses novel concepts, approaches or methodologies, instrumentation or interventions.
- *Approach* – Describe the overall strategy for this project, including potential problems, alternative strategies and benchmarks for success.
- *Projected Timeline*

References (no page limit)

Information Regarding Human Subjects
Address the following if the project **involves human subjects**.
- Provide a one-page document addressing the Protection of Human Subjects, if applicable.
- IRB Approval Status (please note: IRB approval is not required for full application submission, however **a delay in IRB approval does not alter the project end date**) Pre submission discussion with the Wake Forest IRB is strongly suggested.

Information Regarding Live Vertebrates if applicable.
- IACUC Approval Status (please note: IACUC approval is not required for full application submission, however **a delay in IACUC approval does not alter the project end date**)

Budget and Justification (budget template plus 1-page justification)
- Complete the budget template form provided along with a brief justification for the funds requested for this RFA. Please include explanation of other resources that may be leveraged to support the project.
- Sub-awards to other institutions to carry out work on a project are not allowed.

NIH-style biographical sketch for all Key Personnel (new style)

Budget Guidelines

The budget period is for 12 months, ending no later than 3/1/22. Up to $100,000 in direct costs may be requested.

Grant funds may be budgeted for:
- Research support personnel (including undergraduate and graduate students)
- Travel necessary to perform the research
- Small equipment, research supplies and core lab costs, or
- Other purposes deemed necessary for the successful execution of the proposed project

Grant funds may **not** be budgeted for:
- Office supplies or communication costs, including printing
- Meals or travel, including to conferences, except as required to collect data

- Professional education or training
- Computers or audiovisual equipment, unless fully justified as a need for the research
- Manuscript preparation and submission, or
- Indirect costs

Awarded funds must be used to conduct the work proposed. All direct charges to this award must adhere to federal regulations and requirements regarding the use of CCC funds. The CCC leadership reserves the right to revoke funding in the event it is determined that funds were not spent in accordance with the approved protocol. The general criteria for determining allowable direct costs on federally sponsored projects is set forth in 2 CFR Part 200: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (The Uniform Guidance).

Review Criteria and Process
Proposals will be evaluated by the leadership of the NRO and additional content experts as deemed necessary. Funding decisions will be made based on the reviews of an evaluation of the projects' connection with the goals of the CCC. Final award approval will be at the recommendation of CCC Leadership. Any IACUC and/or IRB protocols must be approved prior to funding of the approved pilot.

Reviewers will score applications from 1 to 9 based on:
1. Significance of the problem to be addressed;
2. Innovation in the proposed solutions;
3. Strength and breadth of the investigative team;
4. Methodological rigor and feasibility with clear milestones;
5. Likelihood the innovation will be broadly applicable and have impact on translational research, and;
6. A reporting plan regardless of whether the study yields positive or negative results;
7. Other elements to be considered in the review include: the likelihood that the investment will lead to external funding or a licensable innovation, early-career faculty involvement, race/gender inclusiveness of the research team and inclusion of women, minorities, older adults and children as potential participants.

Program Expectations
Should any significant issues arise, the study team will be required to work with the CCC Director to define an intervention strategy for the study to be successfully completed (or in rare cases, terminated).

Specific Deliverables Include (not a complete list):
- Key preliminary data needed for a revised extramural grant application.
- Proof of concept data to establish a novel scientific hypothesis or approach
- A completed application to an extramural RFA.
- A publication establishing a new collaboration.

Other Guidelines
1. Prior to receiving funds, research involving human subjects must have appropriate approvals from the IRB. Either an IRB approval letter or an IRB response to a "Determination Whether Research or Similar Activities Require IRB Approval" must be submitted to the CCC prior to funds being released. Human subjects must be reviewed in accordance with the institution's general assurances and HIPAA. All key personnel must have certification of training in the protection of human subjects prior to the start of the grant period.
2. It is expected the PI will report outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations and patents.
3. Any awardee who leaves his or her position should contact the CCC Director to discuss future plans for the project.

Grant Administration
The Principal Investigator is responsible for the administration of grant funds. Projects will be for a 12-month period of time.

Contacts

Questions about your research proposal should be directed to Dr. Waldemar Debinski, debinski@wakehealth.edu or Dr. Glenn Lesser, glesser@wakehealth.edu

Questions about your research project or the ePilot electronic submission system should be directed to Brittney Jackson, britjack@wakehealth.edu.