

The Neuroscience Clinical Trial and Innovation Center

Request for Applications for Pilot Awards

PURPOSE

The mission of the Neuroscience Clinical Trials and Innovation Center is to promote advancement of Neuroscience Research. Our focus is to develop new collaborations among basic science and clinical investigators with the goal of providing a platform for design and development of pilot studies, multi-center trials, and models of care into real-world implementation thereby bridging the gaps between basic science and clinical interventions. Our membership embodies the enthusiasm, excellence, and productivity to blur departmental boundaries and expand our mission to advance neuroscience research and patient care.

To maintain our pipeline of innovative projects we are soliciting innovative applications to initiate or further conduct research to obtain preliminary data that will improve the likelihood of obtaining extramural funding. Applications addressing the following areas are encouraged:

- Basic science/translational approaches- essential to move from bench to bedside
- Clinical - to allow investigators to conduct an early Phase 1/2 trial.
- Telehealth- During the COVID-19 pandemic, our clinicians began to explore the use of telehealth opportunities. We believe telehealth has been under-utilized not only for patient care, but for conducting research. We encourage pilot grants that utilize telehealth that is integrated into research protocols (i.e. assessment of outcomes or delivering an intervention) and for developing new models of delivering care.
- Health equity- Applications to identify and develop novel approaches to correct barriers to health equity in the neurological disorders are encouraged.

NCTIC intends to fund three awards. Each award is for \$20,000 for one year.

CRITERIA

1. Translational, collaborative (clinical and basic science faculty) neuroscience focus that include basic science, clinical, or population designs.
2. Likelihood for success for an extramural proposal; detail for a specific mechanism is encouraged.
3. Research that can be completed within 1-2 years.

ELIGIBILITY

The application's PI does not have to be a member of the Center, but if the application is funded the PI is expected to become a member of the Center and contribute to its mission.

These awards are open to all faculty with a rank of instructor or higher from Wake Forest (Health Sciences & University). Proposals from WFU faculty must include a co-PI at the medical center with a substantial, direct role on the project.

KEY DATES

March 1, 2021- Full Applications Due by 5:00 PM

March 31, 2021- Application review completed

April 15, 2021- Project Start Date

FUNDING

The NCTIC will fund up to \$20,000 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. Requests for no-cost extensions are not encouraged, but will be reviewed on a case-by-case basis.

APPLICATION PROCEDURE

Full Application Deadline: 1/29/21, 5:00 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 (300 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

Please note: IRB approval is not required for application submission, however investigators should be prepared to submit protocol immediately upon notification of award because funds cannot be dispersed without IRB approval.

Information Regarding Live Vertebrates

Please note: IACUC approval is not required for full application submission, however investigators should be prepared to submit protocol immediately upon notification of award because funds cannot be dispersed without IACUC approval.

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) Appendix information is limited to:

If applicable, a Summary Statement from the previous grant submission justifying the need for additional experiments.

If applicable, Reviewer Comments from the previous manuscript submission justifying the need for additional experiments to secure a high visibility publication.

Budget Guidelines

The budget period is for 12 months. Up to \$20,000 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 NCTIC funds. The NCTIC 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

All applications will be reviewed by the Center's Pilot Funding Committee for scientific merit, relevance to Center missions, and ongoing research activities.

Funding decisions will be made based on the reviews of an evaluation of the projects' connection with the goals of the NCTIC. Any IACUC and/or IRB protocols must be approved prior to funding of the approved pilot.

Reviewers will score applications based on:

- Scientific approach, feasibility of completion
- Translational focus; this includes pre-clinical to clinical, or clinical to implementation;
- Applications with multi-PIs, cross departmental and new collaborations.

Other considerations:

- Applications with or leverage funding from another Center;
- Applications from junior faculty;
- Applications focused on clinical informatics

PROGRAM EXPECTATIONS

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

Specific Deliverables Include:

Disclosure of implementation/dissemination results and efforts to seek extramural funding beyond the pilot grant and subsequent notification of any funds obtained and/or related publications or significant collaborations from the project for a minimum of 4 years.

Other Guidelines

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 NCTIC 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.

Prior to receiving funds, research involving live vertebrates must have appropriate approvals from IACUC.

Either an IACUC approval letter or documentation on why activity does not require IACUC approval must be submitted to the NCTIC prior to funds being released.

It is expected the PI will report outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations and patents.

Any awardee who leaves his or her position should contact the NCTIC 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

For additional information or questions regarding the pilot application, please contact Cheryl Bushnell, MD, MHS (cbushnel@wakehealth.edu) or Carol Milligan, PhD (milligan@wakehealth.edu).

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