

# NEUROSCIENCE CLINICAL TRIAL AND INNOVATION CENTER REQUEST FOR ACTION POTENTIAL PILOT APPLICATIONS

## PURPOSE

The Neuroscience Clinical Trial and Innovation Center promotes research programs across the continuum of Neuroscience: Discovery, Translation, Clinical Trial and Implementation. We enthusiastically support our investigators productivity as we blur boundaries and expand our mission to advance neuroscience research and improve patient care.

Pilot Applications should be related to developing innovative neuroscience research, help jump start new areas or technologies for neuroscience research as well as to foster new or current collaborative efforts. The funding can also be used to:

- Gather preliminary data to support the hypothesis for a new project,
- Prepare for taking a translational neuroscience project to the next level (e.g. ready for first-in-human testing),
- Generate preliminary data or completion of initial analysis to strengthen or be able to respond to extramural peer review critiques for an extramural grant application,
- Identify and develop novel approaches to correct barriers to health equity in the neurological disorders,
- Explore and expand the use of telehealth opportunities that can be integrated into research protocols (i.e. assessment of outcomes or delivering an intervention) and for developing new models of delivering care.
- Convene scientists and teams to “plan” a grant, supporting regular research meetings/full day working meetings, bringing in extramural expertise to develop collaborations, support staff to gather preliminary data and grant materials, project management, and consultant support.

NCTIC intends to fund up to three awards. Each award is for \$25,000 for one year.

## CRITERIA

Translational, collaborative (clinical and basic science faculty) neuroscience focus that include basic science, clinical, or population designs.

Likelihood for success for an extramural proposal; detail for a specific mechanism is encouraged. Research that can be completed within 1 year.

## ELIGIBILITY

These awards are open to all neuroscience investigators across the Atrium Health Enterprise including Atrium Health, Atrium Health Navicent, and Wake Forest Baptist Health, including Wake Forest School of Medicine. Collaborative projects across the Enterprise are encouraged. Wake Forest University faculty and all CTSI affiliated institutions with a Wake Forest co-investigator are also invited to apply. The application's PI does not have to be a member of NCTIC, but if the application is funded the PI is expected to become a member of the Center and contribute to its mission.

## KEY DATES

**April 30, 2023- Full Applications Due by 5:00 PM**

May 30, 2023- Application review completed

June 1, 2023- Project Start Date

## FUNDING

The NCTIC will fund up to \$25,000 in direct costs per project. See section on Budget Guidelines for more details on allowable and non-allowable budget items.

## APPLICATION PROCEDURE

The application is 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

## APPLICATION

Face Page:

- Submission/Applicant Information
- Project Title
- Submitting Investigator, Co-Investigator(s), and other Key Personnel information
- IRB and/or ACUC approval information (if applicable and available, *see below*)

Abstract: *What research question are you trying to answer with these funds?* (300 words)

Research Plan (up to 6 pages)

### **Specific Aims**

**Significance** – *Explain how the project addresses an important problem, how it will improve scientific knowledge, technical capability and/or clinical practice.*

**Innovation** – *Explain if this project uses novel concepts, approaches or methodologies, instrumentation or interventions.*

**Approach** – *Describe the overall strategy for this project. This should include a feasible project plan that can be completed within a year. Consideration of expected outcomes, potential pitfalls and alternative strategies should be included.*

**Projected Timeline** including next steps (e.g., submission of extramural applications)

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 justification)

Complete the budget template form provided.

Provide brief justification for the funds requested for this RFA.

- Describe how each member of the team will contribute to the project. Include their expertise and experience that will be utilized on this project.
- 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.
- Include 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**

While projects are for up to 12 months, all funds may have to be spent by Dec. 31, 2023. Up to \$25,000 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 follow NIH review criteria and scores. Applications will be scored based on:

Scientific approach, feasibility of completion

Translational focus; this includes pre-clinical to clinical, or clinical to implementation (including community-based settings);

Cross departmental investigators 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](mailto:cbushnel@wakehealth.edu)) or Carol Milligan, PhD ([milligan@wakehealth.edu](mailto:milligan@wakehealth.edu)).

Questions about your research project or the ePilot electronic submission system should be directed to Michael Skidmore, [mwskidmo@wakehealth.edu](mailto:mwskidmo@wakehealth.edu).