Wake Forest Alzheimer's Disease Core Center (ADCC)

Request for Applications for ADCC Pilot Award

Purpose

The newly funded Wake Forest ADCC is seeking applications for a first round of pilot projects. The goal of these projects is to stimulate new and innovative research relevant to Alzheimer's disease (AD).

The primary focus of this award is the development of projects focused on AD that will utilize ADCC resources and *lead to publications and extramural research applications* –or- *produce resources* useful to the ADCC community. Applications that are aligned with the goals of the ADCC will be looked upon favorably. The scientific theme of the Wake Forest ADCC is focused on the general hypothesis that metabolic and vascular diseases promote transitions from normal aging to mild cognitive impairment (MCI), AD, and other disorders such as vascular cognitive impairment (VCI).

Funds totaling $40,000 are available to fund 2-4 pilots, and must be spent within a **one year project period.**

Successful proposals will:

- Be focused on Alzheimer's disease or related disorders
- Utilize existing data from one of the following:
  - Wake Forest ADCC resources (*e.g.*, data and/or blood and CSF specimens from the Wake ADCC or from our affiliated brain bank at the University of Washington). An extensive list of available resources is available at www.WakeHealth.edu/Alzheimers
  - The National Alzheimer Coordinating Center (https://www.alz.washington.edu/)
  - The Alzheimer's Disease Genetics Consortium (http://www.adgenetics.org/)
- Provide a rationale for the project's thematic relevance to the Wake ADCC and its potential for generalizability (*i.e.*, how can the results of this project be used to improve our knowledge of AD).
- Lay out a reasonable project plan that is feasible to complete in the one year project period as there will be no opportunity to request carry-over
- Projects producing resources or methodologies useful for the ADCC will also be considered

Eligibility

Applicants are encouraged to include at least one investigator from the Wake Forest ADCC. Applicants can be postdoctoral fellows (with appropriate senior collaborators) or junior faculty, provided they will be at Wake Forest for the duration of the funding period. Mid-level and senior faculty members are also encouraged to apply provided that they do not have substantial prior experience in AD research.

Key Dates

Date	Detail
10/10/16	Letter of Intent (LOI) Deadline
10/14/16	Investigators Invited for Full Application
11/14/16, 11:59 pm	Full Application Deadline
01/30/17	Selection of Awardees
Early 2017	Project Start Date
Early 2018	Project End Date

Funding

The Wake Forest ADCC will fund up to $20,000 in direct costs per project. See section on Budget Guidelines for more details on allowable and non-allowable budget items ADCC funds cannot be carried over from one budget period to the next, requests for no-cost extensions will not be approved.

If awarded, additional funding may be available through the Clinician Supplement. Please review the Clinician Supplement RFA for more information.

Application Procedure

Letter of Intent Deadline: 10/10/16

Letters of Intent (LOI) should be no more than one page and include a brief abstract including specific aims and study team members for the proposed project. Applicants are encouraged to consult with ADCC pilot committee members regarding expectations. The LOI should be submitted through the ePilot electronic submission system, *preferably by the deadline noted above, however if applicants need more time, they should contact the ADCC*. An invitation to apply for a full application or notification if you are not selected will be communicated by 10/14/16.

Full Application Deadline: 11/14/16, 11:59 pm

Investigators invited to apply will receive an email with a link to submit a full application. Application instructions are included in the ePilot system and 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 (1 page max)
- Background and significance, translational importance, experimental design and methods, dissemination and implementation plan (3 pages max)
- Study milestones and anticipated outcomes with timeline (1 page max) (examples can be found in Appendix I)
- Contribution and summary of qualifications of each contributing investigator (1 page max)

References (no page limit)

Information Regarding Human Subjects

Address the following if the project **involves human subjects**.

- IRB Approval Status (please note: IRB approval is not required for full application submission)
- Clinical Trial Classification
- Protection of Human Subjects (1 page max)
  - Needs to clearly describe risk, protections, benefits and importance of the knowledge to be gained by the revised or new activities as discussed in Part II of NIH competing application instructions
- Inclusion Plans for Women, Minorities, and Children, if applicable
- Targeted Enrollment Table, if applicable (using NIH Targeted Enrollment Table)
- Data and Safety Monitoring Plan (DSMP) and Board (DSMB), if applicable
  - If you need assistance determining the level of safety monitoring your study will need, please contact the CTSI DSMB Administrator, Issis Kelly Pumarol at ikellypu@wakehealth.edu.

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. If the proposed research is to be carried out on more than one campus/institution, please include details in the justification.
- Sub-awards to other institutions to carry out work on a project are permissible provided the majority of activity occurs within Wake Forest or one of its affiliates.

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

Budget Guidelines

The budget period is for 12 months beginning early 2017. Up to $20,000 in direct costs may be requested.

Grant funds may be budgeted for:

- Salary support for the PI or faculty collaborators (using NIH salary cap)
- 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 ADCC funds. The ADCC 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

ADCC proposals are competitive and peer reviewed. Proposals will be evaluated by selected internal and external faculty and based on NIH review criteria and scoring. Funding decisions will be made based on the reviews of an evaluation of the projects' connection with the goals of the Wake Forest ADCC. Final award approval will be at the recommendation of the NIH.

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. A reporting plan regardless of whether the study yields positive or negative results;
6. Other elements to be considered in the review include: the likelihood that the investment will lead to publication, 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

Prior to funding, awardees will be assigned to a Research Navigator to: 1) assist with study initiation; 2) convene an initial meeting with the project PI, ADCC administrative personnel, and ADCC leadership to discuss the project and how ADCC resources can be optimized to extend the planned study; and 3) provide project management and monitor progress throughout the life of the study. If any significant issues arise, the study team will be required to work with the ADCC to define an intervention strategy for the study to be successfully completed (or in rare cases, terminated).

Specific Deliverables Include:

- Participation in the study initiation meeting
- A brief update on progress to the Wake Forest ADCC Executive Committee provided at quarterly intervals.

- Upon completion of the project:
  - Close-out report with plans for implementing and disseminating innovations
  - Presentation of findings at Wake Forest ADCC Seminar Series
  - Presentation of a poster at the ADCC annual External Advisory Committee Meeting
- 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

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 ADCC 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. 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 ADCC prior to funds being released.
3. ADCC staff will work closely with funded teams throughout the grant period to monitor progress and, when necessary, provide assistance. Brief quarterly interim progress reports are required as well as a final progress report. We expect PIs to report over the lifetime of the work the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations and patents.
4. All publications that are the direct result of this funding must reference: "Research reported in this publication was supported by P30AG049638." Publications must also be registered in PubMed Central.
5. Any awardee who leaves his or her position should contact the ADCC 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 one year period of time.

Contacts

Questions about your research project or the ePilot electronic submission system should be directed to Nora Shively at nshively@wakehealth.edu.

Appendix I

Below are examples to show different methods to provide study milestones, outcomes, and timeline. However, these formats are not required.

Example 1:

- **Milestone 1 (0-1.5 months):** Milestone 1 Details **Outcome:** Outcome 1 Details
- **Milestone 2 (1.5- 4 months):** Milestone 2 Details **Outcome:** Outcome 2 Details
- **Milestone 3 (4-6 months):** Milestone 3 Details **Outcome**: Outcome 3 Details
- **Milestone 4 (6-12 months):** Milestone 4 Details **Outcome:** Outcome 4 Details
- **Milestone 5 (8-12 months):** Milestone 5 Details **Outcome:** Outcome 5 Details

Example 2:

Timeline and Milestones												
Month	1	2	3	4	5	6	7	8	9	10	11	12
Activity/Aim/Milestone 1	X	X	X	X								
Activity/Aim/Milestone 2	X	X										
Activity/Aim/Milestone 3		X	X	X								
Activity/Aim/Milestone 4					X	X	X	X	X	X		
Activity/Aim/Milestone 5					X							
Activity/Aim/Milestone 6						X	X					
Activity/Aim/Milestone 7								X		X		
Activity/Aim/Milestone 8											X	X

Example 3:

Aim	**Milestone**	**Month 1-3**	**Month 4-6**	**Month 7-9**	**Month 10-12**
1	Milestone 1	X	X		
	Milestone 2		X		

Aim 1 Anticipated Outcomes: Detail

Aim	**Milestone**	**Month 1-3**	**Month 4-6**	**Month 7-9**	**Month 10-12**
2	Milestone 1		X	X	
	Milestone 2		X		
	Milestone 3			X	

Aim 2 Anticipated Outcomes: Detail

Aim	**Milestone**	**Month 1-3**	**Month 4-6**	**Month 7-9**	**Month 10-12**
3	Milestone 1			X	
	Milestone 2			X	X

Aim 3 Anticipated Outcomes: Detail