Center for Vaccines at the Extremes of Aging Request for Applications for Pilot Awards

Purpose

The Center for Vaccines at the Extremes of Aging (CVEA) is seeking proposals for projects that address any aspect of vaccines to protect infants/elderly/immunocompromised or the immune system in these individuals. It is expected that these pilot funds will catalyze unfunded projects to allow investigators to successfully compete for extramural funding. Applications that seek funding for the development of multi-investigator projects are desired but not required. In addition to being/becoming an active CVEA member, if not already, and presenting results at a CVEA meeting, pilot recipients will be expected to submit a one-page final progress report at the end of the funding period detailing research progress and plans for extramural funding.

Up to 3 projects will be funded. Successful pilots will receive up to \$40,000 to be spent within a 12-month project period. Letters of Intent (LOIs) are due April 25, 2025 (see below).

Successful proposals may include:

- Applications with or leverage funding from Centers
- Applications from junior faculty
- Utilization of the Center core facilities
- Applications with multi-Pls, cross-departmental and new collaborations

Eligibility

These awards are open to investigators with faculty rank across Advocate Health. If you have questions about your eligibility for this award, please contact Katelyn Still (kastill@wakehealth.edu).

Key Dates

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Date	Detail		
04/25/2025, 11:59 pm EST	Letter of Intent (LOI) Deadline		
05/23/2025	Investigators Invited for Full Application		
07/01/2025, 11:59 pm EST	Full Application Deadline		
08/13/2025	Selection of Awardees		
10/01/2025	Project Start Date		
09/30/2026	Project End Date		

Funding

The Center for Vaccines at the Extremes of Aging will fund up to \$40,000 in direct costs per project. See section on Budget Guidelines for more details on allowable and non-allowable budget items.

Application Procedure

1. Letter of Intent Deadline: 04/25/2025, 11:59 pm EST

Letters of Intent (LOI) (1 page max) require the following:

- A brief abstract, including specific aims.
- A clear statement of how the project will address any aspect of vaccines to protect infants/elderly/immunocompromised or the immune system in these individuals. Study methods and feasibility of projects should also be included.
- A list of study team members for the proposed project. All team members should have agreed to participate in the project.

The LOI should be submitted through the ePilot electronic submission system by the deadline noted above.

Review Criteria and Process for Letters of Intent

- 1. Administrative review will assure that project is responsive to RFA and that LOI adheres to submission quidelines.
- 2. LOI review by CVEA steering committee will assess the study's potential impact and whether study's feasibility/methods are likely to achieve actionable results.
- 3. An invitation to apply for a full application, or notification if you are not selected, will be communicated via e-mail by 05/23/2025.

2. Full Application Deadline: 07/01/2025, 11:59 pm EST

Investigators invited to apply will receive an e-mail by 05/23/2025 with a link to submit a full application by 07/01/2025. **Applications received after 07/01/2025 will not be reviewed.** 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 (250 words max)

Research Plan (4 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 (examples can be found in Appendix I)
- Identify if application is under submission or submitted for other Center awards

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 <u>not required</u> for full application submission, however a delay in IRB approval does not alter the project end date)

Information Regarding Live Vertebrates

 IACUC Approval Status (please note: IACUC approval is <u>not required</u> 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 <u>budget template form</u> 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:

- A Summary Statement from the previous grant submission justifying the need for additional experiments.
- 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 ending no later than 09/30/2026. Up to \$40,000 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 CVEA funds. The Center for Vaccines at the Extremes of Aging 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).

Multiple Submissions

The PI must identify whether the application is submitted to CTSI or other Wake Forest School of Medicine Centers for consideration of funding.

Review Criteria and Process

CVEA proposals are competitive and peer reviewed. Proposals will be evaluated by CVEA Pilot Fund Committee members based on NIH review criteria and scoring. Final award approval will be at the recommendation of CVEA Pilot Fund Committee.

Funding decisions will be made based on the reviews of an evaluation of the projects' connection with the goals of the Center for Vaccines at the Extremes of Aging. 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

If any significant issues arise, the study team will be required to work with the Center for Vaccines at the Extremes of Aging 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

- 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 Center for Vaccines at the Extremes of Aging 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 Center for Vaccines at the Extremes of Aging prior to funds being released.
- 3. CVEA staff will work closely with funded teams throughout the grant period to monitor progress and, when necessary, provide assistance. A final progress report will be required. 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 the Center for Vaccines at the Extremes of Aging at Wake Forest School of Medicine." Publications must also be registered in PubMed Central.
- 5. Any awardee who leaves his or her position should contact the Center for Vaccines at the Extremes of Aging 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 project should be directed to Martha A. Alexander-Miller, PhD at martha.alexander-miller@wakehealth.edu and Katherine A. Poehling, MD, MPH at kpoehlin@wakehealth.edu.

Questions about the ePilot electronic submission system should be directed to Katelyn Still at kastill@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
- ...

Example 2:

Timeline and Milestones				
Quarters		2	3	4
Activity/Aim/Milestone 1	Х	Χ	Χ	
Activity/Aim/Milestone 2	Χ	Χ		
Activity/Aim/Milestone 3		Х	Χ	Χ