

Request for Inter-NIA Center/CTSA Hub Pilot/Project Proposals

For Implementation Activities in Support of Inclusion of Older Adults in Clinical Trials

The Research Centers Collaborative Network (RCCN) is seeking to fund projects that involve NIA-sponsored research centers and Clinical and Translational Science Awards (CTSA) hubs, in support of implementation activities for the **Inclusion of Older Adults In Clinical Trials.** The RCCN is seeking to fund up to 3 projects of up to \$70,000 each, addressing this topic. Applications are due **February 15, 2022** with awards announced by **March 31, 2022**.

Background

This award program is sponsored by the NIA's Research Centers Collaborative Network (RCCN). The RCCN's goal is to bring together researchers from the 6 NIA Centers programs to foster the development of cross-center collaborations around issues important to the health and wellbeing of older adults.

The RCCN sponsors a series of workshops addressing specific problems of high salience to multiple NIA Center programs. These workshops feature the sharing of paradigms, conceptual models, and key insights from perspectives of the participating centers programs.

Workshop participants identify research priorities which then serve as the focus of workshopbased RFAs. The fifth workshop, *Inclusion of Older Adults in Clinical Trials*, organized in partnership with the **CTSA Working Group on Inclusion of Older Adults as a Model for Special Populations,** was held virtually, February 23-24, 2021. The workshop agenda, recordings, and slides can be found at <u>https://www.rccn-aging.org/inclusion-rccn-workshop</u>. The workshop identified several systemic and structural factors which together impede the inclusion of older adults. These include policies around promoting inclusion, unnecessarily restrictive inclusion/exclusion criteria, IRB's attitudes towards the frail or cognitively impaired, lack of institutional resources and support to address common barriers to older adults' research participation, and less than "age-friendly" physical environments. This RFA will support activities in the domain of implementation science, towards promoting change to address these barriers.

Proposals responsive to this RFA could include the following topics or areas, but are not limited to:

• Development of tools to assess age-friendly research environments



- Testing of strategies to empower communities to advocate for greater age-inclusivity in translational research
- Development of strategies to engage older adults in the design of clinical trials
- Pilot pragmatic trials evaluating strategies to increase age-inclusivity
- Evaluating ageism among clinical researchers, research staff and/or IRB members.
- Developing metrics of age-inclusion that would be useful in evaluating the success of policy or process changes aimed at increasing age-inclusion.
- Work to document the consequences of regulatory policies on age-inclusion.
- Assessing threats to generalizability when early phase trials are not age-representative for the population targeted for treatment.
- Identification and dissemination of best practices for age-inclusive research environments.
- Development of Guidance documents to embed implementation science measures in activities designed to increase the inclusion of older adults in clinical research.

Proposals that address topics outside of these priority areas but are relevant to the goal of increasing age-inclusion in clinical research are also welcome under this RFA.

Purpose

This mechanism provides funding for up to 3 *collaborative* grants supporting interdisciplinary research collaborations in the theme area. Each award will provide up to \$70,000 in direct costs. The proposals <u>must</u> include investigators representing an NIA Centers Program (Shock, Roybal, Older American Independence (Pepper), Resource Centers for Minority Aging Research, Centers for Demography and Economics of Aging, and Alzheimer's Disease Research Centers), and investigators from a <u>CTSA Program Hub</u>. Applications may seek support to collect or analyze data, convene experts to explore aspects of the theme area in detail, or develop multi- or interdisciplinary conceptual models to motivate further cross-center work. There must be clear evidence that all investigators will contribute importantly to the intellectual design and conduct of the project.

Applicants may propose to use the award over the course of one or two years as justified by the proposed activity. The RCCN will also include support for indirect costs at the recipient institution's NIH negotiated rate. Funding will begin **May 1, 2022**.

Eligibility

Principal investigators must be faculty who are affiliated with any of the 6 NIA Center programs or CTSA hubs as confirmed by letters from the directors of the relevant programs.



Investigators who are not (yet) faculty can be Co-Investigators on the grant. Proposals must include investigators from **at least 1 NIA Center program and 1 CTSA hub**. Proposals can be submitted by two or more investigators at the same institution or investigators at different institutions. Applications must be relevant to the Workshop topic generally, and ideally address questions and priorities addressed at the workshop as outlined above. Small clinical trials are eligible under this mechanism.

Application Guidelines

The following criteria are used to determine the merit of an application:

- Relevance of the proposed aims to the topic of the workshop;
- The significance and innovation of the proposed research or planning project and likelihood that it will develop into new on-going inter-center research collaborations;
- The feasibility of the proposed activities;
- Productivity of the investigators;
- Involvement of early career investigators;
- Participation of women and minorities.

Application Procedures

Please submit your application here: <u>https://amfedaging.wufoo.com/forms/nia-centerctsa-hub-pilotproject-application-form/</u>. Incomplete applications cannot be considered. The applications will be reviewed by the RCCN Steering Committee and independent reviewers selected by the American Federation for Aging Research. RCCN will not provide reviewer critiques to any applicants at any review level.

Timeline

- Application Deadline: February 15, 2022
- Review: February March, 2022
- Selection and announcement: by March 31, 2021
- Start Date: May 1, 2022

Questions regarding this RFA can be sent to: Elizabeth Pritchett-Montavon <u>elizabeth@afar.org</u>. Click <u>here</u> for our Frequently Asked Questions page. Please check the <u>RCCN website</u> for details.



Requests for Support **should be submitted as a single PDF document**, using 12 point font and single-spaced. The application must include the following and in this order:

- Page 1: <u>Application Cover Page</u>
- Page 2: Abstract
- Page 3 7: Narrative describing the proposed activity or activities. The narrative should include the hypotheses/rationale, specific aims, brief preliminary data (if any), an implementation plan/research strategy and proposed methods, timeline and expected outcomes and next steps.
- Page 8: References
- Page 9-10: A budget and budget justification
- NIH-style bios-sketches for the key investigators
- Additional supporting materials up to two documents, and only if directly relevant to the proposed project and not to exceed 5 pages.

Award and Reporting Requirements

Funding will be awarded via a subcontract from Wake Forest School of Medicine. Joint projects should be led by investigators from at least 1 NIA Center and 1 CTSA hub. The preference is that one of the investigators is identified as the primary (i.e., contact) investigator and the pilot project will be awarded to his/her institution. Other Multiple Investigators or Co-Investigators may be paid as a consultant through the pilot award. NIA approval of pilot projects involving human subjects or animals will occur according to the procedures used at the primary investigator's Center. All questions regarding the award should be directed to the contact listed on the notice of award.

Applicants should note that IRB certification (for human subjects) and/or Animal Use Committee approval (for animal subjects) must be provided before a grant award can be made.

Awardees are required to submit an annual progress report with a final narrative and financial reports.

About the RCCN

Managed by Wake Forest School of Medicine and the American Federation for Aging Research (AFAR), the RCCN promotes multi-disciplinary efforts in aging research across the centers through: conferences, pilot programs, early career faculty education, web-based resource



identification tools, and fundraising/proposal development. To find out more go to: <u>rccn-aging.org</u>

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