Claude D Pepper Older Americans Independence Centers (OAIC)
Coordinating Center Program
Research Program Funding Announcement (RFA)
With a focus on collaborative, multi-center, health system implementation of
a successful prior OAIC single site clinical trial

BACKGROUND AND PURPOSE

The purpose of this RFA is to build capacity within the Pepper OAIC program for implementation of evidence established at an OAIC for routine use within OAIC-affiliated health systems. Successful applicants will focus on an intervention that has been proven to preserve or promote functional independence in older adults at least one OAIC site. This RFA is also meant to support cross-center collaborations within the OAIC network by funding the development and initial evaluation of pragmatic implementation of the intervention to a site beyond where the it was originally established. The desired outcomes, in addition to building collaborations across OAIC sites, are meant to generate and disseminate the preliminary data necessary to propose to conduct a future full-scale Stage IV hybrid implementation-effectiveness trial (based on the NIH Stage Model) funded through other grant mechanisms (National Institutes of Health or other sources).

In accord with the OAIC mission, proposals should address implementing interventions that impact maintenance of physical function and the prevention or reversing of physical disability in older persons. As a Coordinating Center pilot study, the application should present a strong plan for collaborative and complementary clinical and implementation research that involves 2 or more sites. Due to the nature of health system change and implementation requiring existing relational trust at the health system leadership level, junior faculty applicants (instructor or assistant professor) must be paired with higher academic rank faculty (professor or associate professor) and also a health system leader who can sponsor change and implementation. While all team members in an application do not need to be part of either institutions' OAIC, the senior leaders of the application must be from their Pepper Center. Only OAIC affiliated institutions may apply.

GUIDANCE FOR PILOT GRANT PROGRAM

The intent of this specific pilot grant program is to ready projects for a proposal to rigorously test pragmatic implementation in a funded trial. All aspects of the proposal should be viewed through this lens. The pilot study should be leveraged to develop and demonstrate the feasibility of a full-scale pragmatic implementation design with focus on:

1) Revising or adapting the implementation strategies to be contextually appropriate beyond the health care setting for which they were initially developed.
2) Demonstrating the feasibility of intervention implementation by testing the strategies for implementing the intervention in at least two OAIC health care systems/sites.
3) Demonstrating the feasibility and validity of subject identification and outcome assessment in these health care systems using pragmatic methods where possible.

The sites/participants do not need to be randomized. If a control group is included, the pilot study is not expected to be "powered" to show a significant effect between arms. The pilot study should be designed for strategy adaptation, participant identification, intervention implementation fidelity, and clinical and implementation outcome ascertainment in a pragmatic fashion. Regardless of design, the OAIC CC leadership requires a reasonably robust sample of people with poor or at-risk for decline in physical function be included in the pilot study.

COMPETITIVE TWO STEP APPLICATION PROCESS

Step 1: Letter of Intent (LOI) to Apply for Full Proposal

Please submit the LOI via email to the OAIC Coordinating Center at peppercenter@wakehealth.edu by March 15, 2024. For scientific consultation prior to submission, please email Abby Archer to schedule (aarcher@wakehealth.edu).

The LOI application includes the following 4 main elements:

1) Cover Page: Title, OAIC Sites, and Team Members
   (Team: Diverse Investigator Group Including Early Career and Senior Faculty, Health System Collaborator, Methodologic Expertise and Other Partners Preparing for Next Phase of Implementation)

2) Pilot Study description not exceeding 3-pages (single spaced, 11 Arial font, 0.5" margins) including:
   Page 1:
   ☐ Background and Rationale for the Evidence Based Intervention and Alignment with OAIC Theme and Priorities
   ☐ Intervention Description, Evidence Base and Supporting Citations
   ☐ Specific Aims Outlining Strategies to be Developed and Tested, and Implementation and Clinical Outcomes to be Evaluated
   Pages 2-3:
   ☐ Overview of Implementation Pilot Study Design and Implementation Frameworks Used
   ☐ Setting(s) (Types and Names of Health Care Systems - Explicit Use of Multiple OAIC-related Health Systems)
   ☐ Participants, Their Identification, Enrollment and Inclusion of Individuals Experiencing Health Disparities
   ☐ Intervention and Implementation Strategies
   ☐ Defined Implementation and Clinical Outcomes and Data Collection Approach

3) Bibliography and References Cited: maximum of 20; not included in the 3-page limit above

4) Letter of support from Pepper Center Directors (for participating sites): include brief description of proposed allocation of funds. Anticipated total direct costs (maximum of $100,000 – *maximum of 8% indirects is required*). A subaward for the second site is anticipated. Whenever feasible, purchase of services and consulting agreements are strongly preferred to multiple subawards.

LOIs will be evaluated on the following:

- Scientific merit and likelihood of long-term impact.
- No more than minimal risk to human subjects in accordance with Federal regulation 45 CFR §46.102(j).
- High potential to progress to a larger, definitive implementation effectiveness trial within or beyond the OAIC network or expansion to full scale at the participating sites.
- Have a feasible approach to participant identification and enrollment using existing electronic health care system data sources or infrastructures (e.g., electronic health records).
- Have at least one single, primary clinical outcome that can be collected pragmatically (i.e., from electronic health records, billing claims, or widely used electronic surveys such as Consumer Assessment of Healthcare Providers and Systems (CAHPS)). The main purpose of delineating a primary clinical outcome is to demonstrate the feasibility of collecting it pragmatically.
- The pilot study is NOT expected to be powered to demonstrate an effect.
- Have implementation endpoints evaluating fidelity (i.e., enactment, delivery, receipt), feasibility (e.g., reach/participant enrollment, collecting key measures from electronic health records), acceptability of strategies, or additional metrics (e.g., > 80% adherence, reach, etc.).
- Have high alignment with OAIC and health system, provider, patient and/or caregiver priorities.

Step 2: Full Proposals by Invitation Only

Applications selected for further consideration will be invited to submit a full proposal.

Please submit the full proposal application via email to the OAIC Coordinating Center at peppercenter@wakehealth.edu by June 12, 2024 at 5:00PM ET.

In an effort to guide the development of the strongest applications, all applicants invited to submit a full proposal will have the opportunity for consultation. The applicant must submit an updated draft of the Specific Aims one week prior to the consultation meeting and incorporate any feedback from the LOI review. The consultation meeting will provide another opportunity for feedback and guidance. This meeting can occur in-person at the annual Pepper OAIC meeting in DC or virtually. The consultation team will be comprised of experts from the OAIC Implementation and Innovation work group and potentially other experts in the field.

Format of Full Proposals
Applications will follow the general format of an NIH R03/R21 with some OAIC specific additions.

1. General Audience Summary (max 500 words)

2. Specific Aims (1 page)

3. Research Plan (6 pages)
   o *Background and Significance*
   o *Preliminary Studies:* Established intervention efficacy/effectiveness at one OAIC site (results published)
   o *Research Design and Approach:* Include the following:
       • Overview of Study Design and Methods
       • Implementation Framework
       • Setting and Sites
       • Study Population
       • Randomization, Allocation and Masking (when appropriate but not expected)
       • Intervention
       • Strategies (guidance can be found here: https://impsciuw.org/implementation-science/research/implementation-strategies/)
       • Procedures for revising or adapting strategies and testing them to implement evidence-based intervention
       • Implementation outcomes defined, data sources and approach to data collection
       • Clinical outcomes defined, data sources and approach to data collection
       • Analytic plan
   o *Milestones:* Specific, measurable, and achievable by which your progress can be reviewed. Include plan and timing for subsequent proposal of a full-scale, Stage IV implementation effectiveness trial
   o *Impact:* Considerations for the impact of the proposed work on equitable access to healthcare

4. Bibliography and References Cited (not included in the page limits)

5. NIH Biosketches for the PIs and Key Personnel including the biostatistician. Note: The research team must include a qualified biostatistician as co-investigator, consultant or collaborator

6. Budget and Budget Justification. The bulk of requested support should be for technical staff salaries, training, testing and supplies; however, modest effort support for investigators can be considered, if needed.

7. Letters of Support. Applicants must submit letter(s) of support from each participating health care system/site clearly stipulating that the proposal has high alignment with: 1) Priorities of the health care system in caring for older people, and 2) Strong likelihood the intervention could be feasibly integrated and adopted into the clinical flow by frontline providers.

KEY DATES - 2024 APPLICATION PROCESS TIMELINE
- RFA Announced: February 16
- LOI Consults: Please contact Abby Archer to schedule pre-LOI submission consultation if desired
- LOI Deadline: March 15
- LOI Screening Notification and Invitations for Full Proposals: By April 10
- Scientific Consultation Opportunities: April 24-30 (At the OAIC Annual Meeting or Virtually After)
- Full Application Deadline: June 12 by 5pm ET
- Merit Review: June/July
- Awards Announced: August 1
- Earliest Project Start Date: September 15, 2024 (IRB approval required prior to start of funding)

REVIEW PROCESS AND AWARD DETAILS
Applications will be reviewed by a selection committee following a OAIC Coordinating Center adapted NIH review criteria. There is funding to support up to one pilot study up to $100,000 direct costs (direct costs should include direct costs for the awardee and direct and indirect costs for any subawards issued by the awardee). Please note that with NIA endorsement the indirect costs rate to be used for this award is 8% which is the same as early career awards throughout the OAIC program.

Because of these award requirements, it is recommended the submitting OAIC provide their institutional "Letter of Intent to Establish a Consortium Agreement" with necessary budget details included. Any applicable IRB approvals and data and safety monitoring plans as requested by the NIA, etc. will be done at the responsibility of the submitting OAIC. The Coordinating Center will require proof of these approvals prior to issuing the award. If awarded as a full pilot study, additional documentation will be necessary to start the sub-contracting process.

Once funded, the project will be facilitated and monitored by the Coordinating Center. The Coordinating Center will assist as needed in providing advice on study coordination and data management based on its prior experience in multi-center study management. A mid-year presentation on study progress by the successful awardee will be scheduled for delivery to the OAIC Coordinating Center Implementation Working Group. A brief final progress report will be required.

ADDITIONAL DETAILS
Inquiries and consultations are strongly encouraged so that we can provide specific guidance in developing relevant, responsive, successful proposals. For additional information, administrative inquiries or clarification please contact Abby Archer, OAIC Coordinating Center Project Manager at 336-713-8504, (aarcher@wakehealth.edu).

We also encourage you to consult with Pepper Center leaders at your and other institutions during preparation of your LOI and application.

Submission: All LOIs and full applications should be sent via email as a single PDF document to the OAIC Coordinating Center email (peppercenter@wakehealth.edu).

See below for assistance offered for helping identify collaborators at other Centers.

Resources to help find collaborators at other institutions for your project:
- OAIC Collaborator's database (accessible at the OAIC National website).
  Link: https://www.peppercenter.org/secure/dspCollaborators.cfm)
- Annual Directory Query engine (accessible at the OAIC National website) Link:
  https://www.peppercenter.org/public/ar/
- Research COMPASS (accessible at direct link - https://rccn.wakehealth.edu/)
- Ask your OAIC Director
- Ask your OAIC REC leader
- Contact the OAIC CC – we're here to help.

General questions should be directed to Abby Archer (peppercenter@wakehealth.edu)