Multi-Center, Collaborative Pilot & Exploratory, Small Pilot RFA Deadlines

LOI Submission Due Date:	As early as possible, but no later than 3 weeks before deadline (Thursday August 11
Full Applications Due Date:	Thursday, September 1, 2022
Announcement of Awards:	November 1, 2022

Submission

What are the suggested elements for the Letter of Intent (LOI) of either application?
- o A Letter of Intent (LOI) is strongly encouranged in order to alert the OAIC Coordinating Center to your plans and allow the CC to provide helpful feedback. LOIs can be submitted up until 3 weeks prior to the deadline, though the earlier the better. We encourage you to consult with Pepper Center leaders at your institution and / or at the CC during preparation of your LOI and application.
- o The LOI is informal and will not be included in the review materials.
- o Exploratory, Small Application LOI: No more than 250 words
- o Multi-Center, Collaborative Application LOI: No more than 1 page and an additional page can be used for references if needed.
- o Multi-Center, Collaborative Applications: suggested LOI elements
  - · Descriptive title of proposed research
  - · Submitting Investigator: Name, institution, academic rank, e-mail address
  - · Co-Investigators: Name, institutions, roles
  - · Hypothesis, rationale, significance and aims of the study
  - · Description of study/plans
  - · How the study fulfills requirement for multicenter, collaborative projects
  - · Letter of Support from Directors of all Pepper Centers involved in the multi-site pilot (this can be very brief)

What are the required documents?
Multi-Center, Collaborative Pilot Applications:
Applications must be in NIH 398 format, and include the following components:
1. Face Page*
2. Abstract/Project Summary
3. Specific Aims (One Page)
4. Research Plan (Six-Page Limit; Does Not Include References or Human Subjects)
5. Human Subjects Section (If Applicable)
6. Biosketches for Key Personnel (New NIH format)
7. Detailed Budget Page*
8. Budget Justification

<u>Exploratory, Small Pilot Applications</u>:

o Project Summary (250 word max)
o What research question(s) are you trying to answer and what is your planned approach? (1000 word max)
o What will you do with the answer when you have it? (250 word max)
o Applications should address: 1) A clinical or translational research focus and Pepper theme; and 2) Plans to use this funding to develop a larger clinical or translational multidisciplinary project or a high impact publication
o Details about how these funds will be spent and a justification of the expenses (250 word max)
o Projected timeline for use of the funds - all funds must be spent < 12 months; shorter preferred (250 word max).
o A budget with the full details of awarded funds of $7,500 (assay kits, materials, and invoices will be paid directly by Coordinating Center)
o Reference page (if necessary) to include up to 15 references on a separate page
o Endorsement/commitment letter from Director of submitting OAIC (half page)
o A copy of IRB/IACUC approval letter will be required at the time of award (if applicable)

How do I find collaborators and or resources at other institutions that are appropriate for my project?

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

Administrative

Where did the original funding come from?
The Pepper OAIC Coordinating Center is funded by the National Institute on Aging (NIA) grant U24-AG059624. The pilot funds will be awarded through a subcontract from Wake Forest School of Medicine.

How will funds be distributed?
<u>Multi-Center, Collaborative Pilot Applications</u>: A subcontract will be issued to the primary site. It will be responsible for issuing a subcontract to the secondary site. Funds will not be distributed until IRB approval of the proposed project has been submitted to the Pepper OAIC Coordinating Center.

<u>Exploratory, Small Pilot Applications</u>: The OAIC CC will handle the funds directly and place orders for supplies and materials based on the needs provided in the budget and as requested by the project PI.

What indirect rate should be used?
<u>Multi-Center, Collaborative Applications</u>: There is funding to support up to one pilot study up to $85,000 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. These funds will be distributed to the submitting PI's OAIC and the award will be administered as a pilot study within the specific OAIC.

If awarded as a full pilot study, additional documentation will be necessary to start the sub-contracting process. 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.

Is the NIH salary cap applicable?

Yes, the NIH salary cap is applicable to the pilot grant applications. The federal salary cap must be applied to personnel whose salaries exceed the cap.

Investigator Roles

What defines an early stage investigator?

For this grant, an early stage or early career investigator will be defined as not having received a major grant from NIH, AHRQ or PCORI (R01 award or equivalent). Career development (e.g., NIH K program) awardees are considered early career investigators.

Can an early career investigator be the principal investigator of the study?

Yes, this is encouraged but not mandatory.

Can international investigators apply?

The principal investigator of the pilot study must be both a U.S. citizen and from a U.S. institution. However, other members of the project team can be non-citizens.

Scientific

Will reviewer feedback be provided?

Yes, feedback from the LOI review will be provided for all submissions. For those who are invited to submit a full application, this feedback should be incorporated into the study proposal.

All reviewer feedback from submitted proposals will also be provided after the review process is completed.

Can we obtain feedback from the Pepper OAIC Coordinating Center during study development?

Yes, soliciting feedback before submission is encouraged. Please send materials to Abby Archer (peppercenter@wakehealth.edu) with your questions.

Are there specific requirements for what data are used?

No, pilot projects data may come from variety of sources including OAIC, VA, publicly available data. Data can also be from non-US sources. However, using OAIC related data is strongly encouraged.

What are some characteristics of a potentially meritorious proposal?

1. Study is strongly relevant to the Pepper Center theme of understanding, preventing, and/or improving physical disability in older adults
2. Likelihood that the project team will produce new, ongoing collaboration between OAICs
3. Likelihood that the project will result in publishable, high impact results, and / or lead to future NIH/foundation/industry funded larger, definitive studies
4. Meaningful involvement of early career investigators
5. Leveraging of resources
6. Likelihood that the proposed study can be completed within one year.

Additional Information

How will the IRB/ACUC approvals and Data Safety monitoring plans be handled?

Any applicable IRB/ACUC approvals and data and safety monitoring plans as requested by the NIA, etc. will be done at the responsibility of the submitting OAIC and the CC will require proof of these approvals prior to issuing the award.

Where can I find additional information about the Pepper Centers?

Further information regarding the initiative can be found at the following link: www.peppercenter.org

Who should I contact with any questions?

Inquiries are encouraged and we are happy to provide guidance as you develop your LOI and full proposals. Any inquires can be made directly to Abby Archer at peppercenter@wakhealth.edu