

## **NEXT STEPs Pilot Study RFA:**

### **Key Dates**

- Publication Date of FOA: by February 10, 2025
- Informational webinar:
  - February 24, 2025 @ 2-3pm ET / 1-2pm CT / 12-1pm MT / 11-12pm PT
  - March 18, 2025 @ 2-3pm ET / 1-2pm CT / 12-1pm MT / 11-12pm PT
- Proposal Application Due Date: April 8, 2025 @ 8pm ET
- Estimated Award Date: June 1, 2025

### **Issued by**

NEXT STEPs is funded by the National Institute on Aging [*Grant U24AG087939*].

### **Purpose**

The NEXT STEPs program was established in 2024 with funding by a cooperative agreement from the National Institute on Aging (NIA) [*Grant U24AG087939*]. The goal of NEXT STEPs is to support high-quality research by advising on research design, disseminating best practices, and sharing findings with those who can use them to improve the lives of nursing home residents, their families, and staff.

The intent of funding NEXT STEPs pilot projects is to support investigators in their effort to obtain preliminary data necessary to successfully garner funding for and to conduct explanatory clinical trials in nursing homes. In addition to receiving funding, awardees will have access to relevant curriculum content and receive input from experts to help them hone their research skills and ensure successful project completion.

Examples of clinical trials that could be considered:

- Using data from the LTDC, to study the impact of an intervention to promote vaccination on vaccination rates and hospitalizations due to influenza.
- Test an intervention to train nursing home providers on the use of point of care ultrasound to improve outcomes during heart failure exacerbations.
- Test an arts and music therapy intervention to reduce agitation among nursing home residents with dementia.

To be responsive, pilot projects must be preparatory for a full-scale explanatory clinical trial defined by the NIH stage model

(<https://www.nia.nih.gov/research/dbsr/nih-stage-model-behavioral-intervention-development>).

### **Scope:**

This Funding Opportunity Announcement (FOA) encourages pilot research grant applications focused on: 1) generating pilot data for planned clinical trials; and 2) supporting investigator development for conducting research in nursing homes.

Applicants are encouraged to use data from the [Long-Term Care Data Cooperative \(LTCDC\)](#) Use of [LTCDC data](#) is encouraged but not required. *Please email us at [nhtrials@iu.edu](mailto:nhtrials@iu.edu) if you are considering using the LTCDC for this project proposal. Do not wait to reach out to schedule a meeting!*

The LTC Data Cooperative encourages two types of research:

- o Observational comparative effectiveness studies, which compare outcomes for residents who were or were not exposed to a particular treatment (drug, test, or care regimen) or who were exposed to different treatments intended to address the same clinical condition
- o Clinical research studies that test and evaluate interventions in post-acute and long-term care facilities, such as pragmatic trials.

**The NEXT STEPs Pilot Review Committee, NIA program officers, and NEXT STEPs leadership will prioritize projects that:**

- Focus on nursing home explanatory clinical trials;
- Are feasible to accomplish in 12 months;
- Generate pilot data that would support future extramurally funded clinical trials involving nursing homes;
- Use LTCDC data and/or add new nursing homes contributing data to the LTCDC;
- Demonstrate alignment with nursing home operators, staff, resident and/or family priorities; and
- Demonstrate a clear partnership with one or more nursing homes

**Funding Information**

- Each individual award budget is limited to \$75,000 [Total costs].
- Duration one year (12 months).
- Investigators selected for this award will be expected to present their findings at a national NEXT STEPs meeting and should budget travel accordingly.
- We anticipate funding a maximum of 3 awards in the first cycle, with additional cycles available.

**Eligibility**

Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to submit an application. Anyone eligible for an NIA award is eligible for a NEXT STEPs pilot award.

**Eligible applicants**

Applicants must hold a faculty or research scientist position at an eligible institution (see below) by the start date of the award or be otherwise eligible to serve as a Principal Investigator as determined by their organization. Applicants who are junior faculty are encouraged to identify a mentor with research experience in nursing homes and include

this person as a mentor on the application. Interested applicants without a mentor can request to be paired with a mentor through the NEXT STEPs program. More information on who qualifies as a ESI can be found here: [Early Stage Investigator \(ESI\) Policies | Grants & Funding](#).

Applicants must be a NEXT STEPs member or have applied for membership at the time of application submission. To become a NEXT STEPs member, please complete the membership application linked on our website: <https://nextstepsnetwork.org/>.

\*Please note individuals who are currently on a training award (e.g. T32, R02, and F awards) are not eligible to apply.

Applicants must be U.S. citizens or permanent residents of the United States and project work needs to be completed in the U.S.

**Eligible Institutions:**

Any organization with a Unique Entity Identifier and processes for following federal guidelines/regulations for using research funds meet eligibility for this grant.

Applications are due on April 8, 2025, at 8pm Eastern Time.

Applications will be limited to 4-pages.

***The 4-page application must include:***

- Title of proposed activity
- Specific Aims – 1 page
- Brief background/Evidence Gap/Significance to nursing home community
- Nursing Home Partner (*if applicable/identified*)
- Study Design/Method
- Study population & setting, including planned nursing home partnership (*if applicable*)
- Plan detailing use of LTCDC resources:  
<https://www.ltcdacooperative.org/Pages/default.aspx> (*if applicable*)
- Timeline with milestones
- Required Data Sharing Plan
- Plans for future extramural funding from this work

***Additional attachments compiled in 1 PDF document (not included in 4-page limit):***

- References
- NIH Biosketches (key personnel)
- Project summary paragraph
- Inclusion enrollment report form (use the NIH form)
- Letter of support (for early career faculty applicants) from mentor. Applicants can request to be matched to a mentor if needed.

- Budget – needs to include travel to at least one national conference and travel to the NEXT STEPs annual meeting in Indianapolis. The NEXT STEPs annual meeting will be 1 ½ days. Please submit using R&R Budget Template. [https://apply07.grants.gov/apply/forms/sample/RR\\_Budget\\_3\\_0-V3.0.pdf](https://apply07.grants.gov/apply/forms/sample/RR_Budget_3_0-V3.0.pdf)
- Budget Justification
- Nursing home partner LOS (if applicable)
- IRB submission plan (approval not required at time of pilot grant application submission but awards will not be funded until IRB approvals are received)
- Brief outline of data safety plan if planning a clinical trial
- Letter from LTCDC indicating applicant discussed application with LTCDC and believes it is feasible (if using LTCDC).

By applying to this funding mechanism, you agree to follow all NIH rules and regulations.

**Review and selection process:**

Pilot applications will be evaluated on their scientific and technical merit by a NEXT STEPs review panel.

The following criteria will be considered in the reviews:

- Alignment of the proposed project to the NEXT STEPs aims;
- Use of the LTCDC;
- Importance, significance and relevance of project to stakeholders;
- Design;
- Feasibility of a 1-year timeline to completion;
- Milestones that are specific, measurable, achievable and aligned with the project; and
- Likelihood project will lead to successful future funding of a clinical trial.

The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review;
- Availability of funds. We anticipate funding a maximum of 3 awards per year;
- Relevance of the proposed project to pilot program priorities; and
- Likelihood pilot work will lead to a successful application for an explanatory clinical trial in the nursing home setting.

The NEXT STEPs team is eager to work alongside and support your focused nursing home research projects. The NEXT STEPs team has the opportunity to provide additional support to awarded pilot investigators that may include:

- 2 hours/month of a dedicated pilot advisor;
- Up to 20% of research coordinator support; and
- Up to 20% of a data scientist to support use of LTCDC.

**Please direct inquiries to:** [nhtrials@iu.edu](mailto:nhtrials@iu.edu)

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