



# 2025 Clin-STAR Aging Research Development and Training Awards Informational Slides

## CLIN-STAR AWARD

- Emphasis on research career development and training.
- Awards will be made to early-career clinician-scientists who work collaboratively with established (senior) investigator/mentor(s).
- A mentor with aging research expertise is required. This mentor can be at the same institution or another institution. Additional mentors are allowed.
- Clin-STAR can assist with mentor matches if needed. Search the Clin-STAR Database for researchers!
- Up to four our grants will be awarded in 2025 (up to \$50,000 in direct cost/up to 8% for indirect cost).



## Award will support a range of activities.

Examples include:

- **Pre-planning** of a clinical trial or a clinical research study (not collecting human subject data)
- Clinically-relevant secondary data analysis
- Setting up mentorship and clinical research infrastructure
- Travel funds to meet with mentor(s) outside of own institution
- Training (e.g., content expertise, clinical trial planning, publication and analytic workshops).

**Note: Non-exempt human subject research cannot be supported through this mechanism.**



## ELIGIBILITY FOR APPLICANT/PI

- Completed terminal research degree or end of post-graduate clinical training, whichever is later, within the past 10 years
- Conduct research at a U.S. based academic site
- U.S. citizen or permanent resident
- Has not had previous substantial research funding, nor current substantial funding (>\$100,000 in direct costs in single year).



## SELECTION CRITERIA

- Relevance of the proposed project for future clinical research of older adults.
- Feasibility of the proposed activities.
- Strength of mentor plan and clear evidence of their role and engagement in the project.
- Evidence of commitment to scholarship.
- Applications are especially encouraged from women and underrepresented groups as defined by NIH, and from institutions that do not have significant aging research resources.



## **LETTER OF INTENT DESCRIPTION OF RESEARCH AND TRAINING PLAN**

- Include a summary, significance, goals, and approach.
- Provide details on proposed activities, including the role of your mentor(s) and how they will help you develop your career in aging research.





## Timeline

<b>Letters of Intent due:</b>	May 1, 2025
<b>Notice for full applications:</b>	Late May 2025
<b>Full application deadline:</b>	July 14, 2025
<b>Award announcement:</b>	Late August 2025
<b>Projected start date:</b>	October 1, 2025
<b>Clin-STAR Meeting:</b>	Nov 18-20, 2025

## Q&A



### **NIH ESI definition:**

Completed terminal research degree or end of post-graduate clinical training whichever is later, within the past 10 yr and who has not previously competed successfully as a PD/PI for a substantial NIH independent research award (\$100,000+)

### **Who can apply for Clin-STAR Aging Research Development and Training Awards?**

Only Early-Stage Investigators with an academic appointment are eligible to apply for the Clin-STAR awards, including investigators with an MD and/or a range of other clinical, doctoral-level degrees (e.g., an individual with a PhD in Occupational Therapy would be eligible). Post-doctoral candidates are not eligible for this Clin-STAR award at this time.

### **Are junior faculty with PhD eligible or do you need an MD degree?**

MD is not necessary; applicants are eligible if clinically trained at the doctoral level

### **How do you define a mentor with aging expertise?**

Associate Professor or higher with aging research experience (grants, publications), affiliated with an aging center (eg, GRECC, Pepper)

Questions:  
[andrea@afar.org](mailto:andrea@afar.org)



**Do you need to practice primarily in an academic setting with university infrastructure to apply for an award if you can identify an established (senior) investigator to be a mentor? Or can your clinical research stem from a private/non-academic practice.**

Investigators must conduct the research at a U.S. based academic institution. The primary established investigator must also be at US academic institutions, but secondary established investigators (not required) may be from a non-US academic institution.

**Are non-US citizens eligible?**

Investigators must be a US citizen or permanent resident.

**Does one have to have a surgical or medical subspecialty to be eligible? How can aging researchers with family/internal medicine and geriatrics training, best make use of their background?**

No, you don't need to be from a surgical or medical subspecialty to be eligible for this award.

Questions:  
[andrea@afar.org](mailto:andrea@afar.org)

### **Do you have interest in animal/experimental research?**

The focus of the Clin-STAR grants are for development of clinical aging research projects. Animal/experimental research may be considered if it has direct relevance to human aging and can show the potential to lead to clinically-relevant strategies that address human aging.

### **Is the award available for ADRD/brain health or is the focus of Clin-STAR on non-cognitive manifestations of aging?**

Yes, ADRD/brain health projects are appropriate for the Clin-STAR award.

### **Who is considered an "established (senior) investigator"?**

An "established investigator" is anyone who is beyond early-stage investigator as defined by the NIH.

### **Does the "established investigator" need to be a clinician?**

The established investigator can be a non-clinical investigator (e.g., a biostatistician), but the junior investigator must be a clinician-scientist for the Clin-STAR award.



Questions:  
[andrea@afar.org](mailto:andrea@afar.org)



**Can one be eligible if background is basic sciences though most of work is clinically oriented?**

Background in basic science is fine but have a clinically relevant health profession degree

**What types of research are allowed, e.g., clinically relevant, basic science with human application?**

*Research focused on older adults with a focus on future clinical benefits*

**Are there specific research areas the award is looking to fund?**

Clinically relevant aging research

**Is there a dedicated % FTE required for the duration of the award?**

At least 20% suggested

Questions:  
[andrea@afar.org](mailto:andrea@afar.org)

**Will Clin-STAR ‘match’ me with an established investigator if I request one?**

The Clin-STAR Database will be a resource to help make mentee-mentor matches. Clin-STAR staff can also help applicants identify an established investigator upon request; reach out with a few sentences on your (1) clinical and research background (2) research interests, and (3) expertise you would like your mentor to provide.

**Can I include a budget for the "established investigator" in my Clin-STAR award application?**

Yes.

**I am a current GEMSSTAR awardee or am currently applying for a GEMSSTAR, will that preclude me from applying for the Clin-STAR award?**

Current GEMSSTAR awardees are not eligible. Those applying for a GEMSSTAR award cannot concurrently hold both GEMSSTAR and Clin-STAR awards.

**Can somebody who had a GEMSSTAR previously, but no K award yet still apply for the award?**

Yes.



Questions:  
[andrea@afar.org](mailto:andrea@afar.org)

# How do you define non-exempt human studies research, i.e., what is included/excluded?



## NIH Exempt Human Subjects Research 8 Exemptions

**1 Meets the definition of human subjects research.**  
Exempt studies involve human subjects research: research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generated

**2 Meets the criteria of one of the following exemptions:**



**Exemption 1:** conducted in an educational setting using normal educational practices\*  
\*Cannot include any other procedures, such as collection of clinical data or biospecimens

**Exemption 2:** uses educational tests, surveys, interviews, or observations of public behavior\*  
\*Limited IRB review may be required.

**Exemption 3:** benign behavioral interventions in adults\*  
\*Limited IRB review may be required.

**Exemption 4:** involves the collection/study of data or specimens if publicly available, or recorded such that subjects cannot be identified\*  
\*May be identifiable in limited cases. See §46.104(d)(4)(iii) and (iv)

**Exemption 5:** research or demonstration projects designed to study, evaluate, improve, or examine an NIH public benefit or service program\*  
\*Applies to projects that NIH itself administers

**Exemption 6:** taste and food quality evaluations

**Exemption 7:** storage of identifiable information or biospecimens for secondary research use. *Broad consent* and *limited IRB review* are required

**Exemption 8:** secondary research use of identifiable information or biospecimens. *Broad consent* and *limited IRB review* are required

For more information see the [NIH OER Human Subjects Research website](#). Send questions/comments to [OER-HS@nih.gov](mailto:OER-HS@nih.gov).

Full NIH graphic description:  
[https://grants.nih.gov/sites/default/files/exemption\\_infographic\\_v8\\_508\\_c\\_1-15-2020.pdf](https://grants.nih.gov/sites/default/files/exemption_infographic_v8_508_c_1-15-2020.pdf)



### Exemption 1 (X1)

- ✓ Effectiveness of on-line training as supplement to regular instructional approach.
- Effectiveness of activities to increase awareness of oral health delivered at a community science museum

- ✗ Testing a manual for parents to identify severe asthma symptoms
- Evaluation of health education that includes collection and analysis of heart rate and body measurements from students

### Exemption 2 (X2)

- ✓ Focus group of adult community members to discuss access to dental care
- Questionnaire about outdoor exercise, including collection of participants' age and zip code (limited IRB review conducted)

- ✗ Substance abuse training for individuals engaged in illegal drug use, followed by a survey about the training
- Investigator-led focus group of pre-teens to discuss bullying

### Exemption 3 (X3)

- ✓ Study among young adults evaluating preferred snack foods following a television program
- Study investigating text vs. voice message appointment reminders on self-reported annual physical appointment attendance

- ✗ Diet and physical activity intervention for people with diabetes
- Examining reactions of participants during brief exposure to painful stimuli

### Exemption 4 (X4)

- ✓ Patient data extracted from medical records without name or ID number every 6 months as follow up visits occur
- A collaborator removes an aliquot of blood from coded samples. Aliquots are re-labeled to a random, non-linked code

- ✗ De-identified blood drawn from subjects for the study by a blood bank
- Use of collaborator's coded tissue samples and the collaborator retains the code key

### Exemption 5 (X5)

- ✓ Outcomes evaluation of NIH conducted mental health service program\*
- \*NOTE: NIH anticipates use of this exemption will be rare

- ✗ Evaluation of U.S. state administered service program
- Evaluation of investigator-sponsored diabetes intervention

### Exemption 6 (X6)

- ✓ Evaluation of wholesome food preferences
- Study looking at approved levels of an agricultural chemical on taste of vegetables

- ✗ Study evaluating novel food additives
- Testing high doses of environmental contaminant on food taste

### Exemption 7 (X7)

- ✓ Creating a dataset containing identifiers from a previous study to conduct future research\*
- saving blood samples from collaborator's study for a future research question\*
- \*(Broad consent obtained and limited IRB review conducted.)

- ✗ Dataset containing identifiers from prior study stored for future research, with informed consent for study-specific research (no broad consent)

### Exemption 8 (X8)

- ✓ Using dataset from prior study containing identifiers to answer subsequent research question\*
- Using blood samples from collaborator's study for an additional research question\*
- \*(Broad consent obtained and limited IRB review conducted.)

- ✗ Using blood drawn from subjects with study specific consent for future research question

✓ = exempt    ✗ = non-exempt

Please note: these are possible examples of exempt research accepted by NIH. Final determination of exemptions should be made in accordance with 45 CFR 46.

## Clin-STAR Database: Join and create a profile!

- Search clinician-scientists in aging research across disciplines and career levels.
- Browse info on researchers, publications, and funded grants.
- Find new collaborators
- Find mentors by discipline, specialty, location, research areas; *200+ have volunteered as mentors in aging research.*
- Visualization tools/graphics display research area connections.



database.clin-star.org

A screenshot of the Clin-STAR website interface. At the top, the Clin-STAR logo and name are visible, along with a search bar and navigation links for HOME, PEOPLE, INSTITUTIONS, RESEARCH, VISUALIZATIONS, FAQ, and CLIN-STAR.ORG. The main content area displays a profile for Parag Goyal, MD, MSc, identified as a Person. It includes a profile picture, contact information (email: gog2051@med.cornell.edu), and a list of positions: Director/Co-Director, HFpEF and Cardiac Amyloidosis Program, and Associate Professor, Department of Medicine, Weill Cornell Medicine. On the right side, there is a "Publications in VIVO" chart showing 307 publications in the last 10 full years, and links to Co-author Network, Map of Science, and Co-investigator Network.