The Edward N. & Della L. Thome Memorial Foundation Awards Program in Alzheimer's Disease Drug Discovery Research

Initial Proposal Application Guidelines

Grant Cycle 2024

Initial Proposal Deadline: Thursday, July 13, 2023 12:00 Noon, U.S. ET

The Thome Foundation Awards Program in Alzheimer's Disease Drug Discovery Research is a two-stage proposal process. Applicants will submit an Initial Proposal as the first step. The Initial Proposal consists of an Online Application, Application Forms, two-page Research Proposal (excluding initial questions and references), Project Milestones and Research Plan Table, Applicant Biosketch, and Co-Investigator Biosketch(es) (if applicable). Initial Proposals will be reviewed by a Scientific Review Committee.

Invited Full Proposal Deadline:

TBD: November 2023

Applicants invited to submit full proposals will be emailed detailed application instructions. In brief, the Full Proposal Application includes the Online Application, Application Forms, Project and Non-Technical Summaries, ten-page Research Proposal, Project Milestones and Research Plan Table, Applicant Biosketch, Co-Investigator Biosketch(es) (if applicable), Budget and Justification Forms, Department or Division Head Letter, and Letter(s) of Collaboration (if applicable).

Award Period

March 1, 2024 - February 28, 2026

Size of the Award

Up to five \$500,000 two-year grants (\$250,000 per year) will be made to independent investigators working in academic, medical or research institutions within the United States. Awards do not cover indirect costs.

Program Overview and Statement of Purpose

The Edward N. & Della L. Thome Memorial Foundation was created in 2002 to advance the health of older adults through the support of direct service projects and medical research on diseases and disorders affecting older adults. In keeping with the Foundation's mission, the goal of the Awards Program is to support innovative drug discovery research that will lead to improved therapies for individuals suffering from Alzheimer's disease.

In 2022, the Thome Memorial Foundation, Bank of America, N.A. granted Health Resources in Action (HRiA) funding to oversee the continuation of its programs in Age-Related Macular Degeneration and Alzheimer's Disease Research. HRiA works with a Scientific Review Committee to select the proposals that best align with the mission of the Foundation and the goals of the program. HRiA is a non-profit organization in Boston that advances public health and medical research.

Research Focus

Successful research proposals should fall along the preclinical research spectrum such that they can be "carried out using cell or animal models of disease; samples of human or animal tissues; or computer-assisted simulations of drug, device or diagnostic interactions within living systems". These projects are intended to

¹ Preclinical Research Definition: https://ncats.nih.gov/translation/spectrum

move basic science insights towards solutions, techniques, and tools that can be transferred to clinical practice in the near term. Funding areas include, but are not limited to:

- Validation and testing of target compounds and therapeutic agents (e.g., DNA or RNA oligonucleotides, and virally driven therapies)
- Strategies that target pathogenic mechanisms (inflammatory response, synaptic toxicity, and oligodendrocyte or endosomal/lysosomal dysfunction).

Basic research, research that is not directly linked to a clinically relevant biomarker or clinical endpoint, or research studies that align with the NIH definition of a clinical trial² are currently outside the scope of this Program.

Eligibility Criteria

- The administrative lead applicant must hold a faculty appointment at a non-profit academic, medical, or research institution in the United States.
- PIs must be independent investigators with demonstrated institutional support and specialized space and facilities needed to conduct the proposed research.
- Applicants and key personnel may not have funding for a similar project.
- Individuals who are current Thome Foundation Awards Program in Age-Related Macular Degeneration or Alzheimer's Disease Research awardees at the time of Initial Proposal deadline are not eligible to apply for the 2024 grant cycle.
- Each PI may only submit one application.
- Institutional nomination is NOT required.
- United States citizenship is not required; visa documentation is not required.

Eligibility is not limited to those investigators currently working in Alzheimer's Disease research. In addition, investigators from other fields are encouraged to apply with drug discovery and development research proposals directly relevant to Alzheimer's Disease.

Key Personnel, Definitions

- Principal Investigator (PI): One principal investigator (Applicant) must be identified as the lead or administrative PI of the award, who will be responsible for all grant reporting and fiscal management. The lead or administrative PI will be the main contact for budget and reporting management.
- Collaborators: Collaborators may share Award funding.

Concurrent, Pending and Post-Award Funding

Please note that if a Thome Memorial Foundation award is made, neither the Institution nor the awardee may accept funding that results in an overlap of funding for the Thome Memorial Foundation project. If the work proposed in the Thome Memorial Foundation proposal is funded by another source before the Thome awards are announced, the applicant must notify HRiA at ThomeAwards@hria.org and withdraw the application immediately.

The sponsoring institution must accept responsibility for the scientific, administrative, and financial management of the overall project including any subcontracts involved in the project.

² NIH's Definition of a Clinical Trial: https://grants.nih.gov/policy/clinical-trials/definition.htm

Diverse and Inclusive Research

To promote and enable diversity in biomedical research, the Thome Memorial Foundation is committed to awarding researchers of all backgrounds, including racial/ethnic groups that are underrepresented in science. The National Science Foundation and the National Institutes of Health have established that individuals from the following groups are underrepresented in science: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaskan Natives, Native Hawaiians, and other Pacific Islanders. Applicants that identify as a member of these groups are encouraged to apply. In addition, applicants are encouraged to speak to their commitment to diversity, equity, and inclusion within the invited Full Stage proposal. Please see the University of California, Irvine site for helpful guidance: https://ap.uci.edu/faculty/guidance/ieactivities/.

Consistent with current NIH policies³, funded clinical research must include women and minority groups as well as a rationale that speaks to composition of the study population. Any exclusions within the study population need to be described and scientifically justified.

Review Criteria

The Scientific Review Committee uses the following criteria to evaluate proposals:

- Hypothesis and Research Aims that are clearly stated and supported by relevant literature and preliminary data (if applicable).
- Objectives that are of strong premise, and technically feasible.
- Rigorous research methodology, data collection, and data analyses.
- Qualifications of the applicant and prior experience in conducting innovative research.
- Potential of the research project contributing to the effective treatment of Alzheimer's Disease.
- Preference will be given to originality of ideas, regardless of faculty seniority.

Proposal Writing Tips

Applicants are strongly encouraged to prioritize good grantsmanship in writing their applications to maximize their chances of being invited to submit a full application. *The writing of the proposal will not be directly assessed*; however, it is recognized that clarity of the writing enhances the ability of the reviewers to reflect upon how the proposal aligns with the review criteria.

The Review Committee is composed of a multi-disciplinary group of professionals such as biotech executives and academic researchers, with expertise in AD and pharmaceutical development, and have the ability to assess a wide range of proposal topics.

Characteristics of a well-written proposal are reflective of the following practices:

- Funding via non-governmental agencies should be tailored. Make sure the proposal is reflective of the program goals and review criteria.
- Tell the story and <u>sell</u> the proposed work; make sure the background outlines why the proposed questions are important to answer, and the proposed approach is promising.
- The language should be understandable to a general scientific audience. When jargon must be used, it is clearly explained, and complex technical points are put in context.
- Any other personnel included in the project should be clearly justified.
- Don't fall victim to proposing to complete too much work. Reflect on the timeline of the work to ensure it can be feasibly completed.
- Provide enough time to obtain feedback and allow for proofreading prior to submission.

³ NIH Grants and Funding: Inclusion of Women and Minorities as Participants in Research Involving Human Subjects: https://grants.nih.gov/policy/inclusion/women-and-minorities.htm

Applicants are encouraged to seek feedback on their proposals within their institutions and externally. Examples of successful proposals can be found in the grant-writing tip sheets for NIH research grants. Institutions and colleagues may also be willing to provide examples of well-written and successful grant applications.

Suggested resources:

Secrets to Writing a Winning Grant: https://www.nature.com/articles/d41586-019-03914-5 NIH grant writing tips:

https://www.nlm.nih.gov/ep/Tutorial.html

https://www.nimh.nih.gov/funding/grant-writing-and-application-process/grant-writing-tips.shtml https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/write-your-application.htm#Important%20Writing%20Tips

Terms of the Award

Please download the Terms of the Award from www.tmfgrants.org/ThomeAD for information on use of the grant funds, indirect costs, payment schedule, reporting schedule, and other Awardee and Institutional requirements.

Frequently Asked Questions may also be found on this site.

For a list of previous awardees, please click here: https://hria.org/wp-content/uploads/2016/02/Thome-AD-Award-Recipients-2012-2021.pdf.

Please continue to the next page for Application Instructions.

Application Instructions for Initial Proposal

Online Submission Deadline:

Thursday, July 13, 2023 12:00 PM, Eastern Time

Use this link to start a NEW application:

https://www.GrantRequest.com/SID_738?SA=SNA&FID=35063

Go to your account page to return to a SAVED application:

https://www.GrantRequest.com/SID 738?SA=AM

The following sections must be completed within the online application form:

- Institution's Tax ID Number
- Eligibility Quiz
- Applicant Data: Institution, Contact, Demographic, and Educational Background Information. Provide the PI's ORCID ID, if available.
- Key Personnel: Co-Investigator information, if applicable
- Research Project: Project Title; Key Words; Project Summary; Non-Technical Summary; Non-Technical
 Overview; Experimental System(s), Key Tools and Techniques to be Utilized; and Applicant's initials to
 certify the accuracy of submitted information.
- Research Classification*
- Research Area*
- Attachment: A PDF document must be uploaded. See further instructions below.

Attachment Instructions for PDF: The documents listed below must be combined and converted into **ONE PDF** file for upload to the Online Application. This document must be named LastName, FirstName.pdf (for example: Smith, Jane.pdf).

A. Thome AD Application Forms 2024 (<u>Use provided PDF template</u> - Application Cover Page, Table of Contents, Non-Technical Overview, and Initial Research Proposal Overview): The Cover Page must be completed and signed by the Applicant and the Authorized Institutional Representative administratively responsible for the oversight of the project. Once all signatures have been obtained, the Cover Page should be used as the first page of the uploaded document. Follow instructions on the template for the Non-Technical Overview and Initial Research Proposal Overview.

Note: Adobe Acrobat Reader is the preferred software for completing the Application Forms. If using Preview on a Mac, in order to ensure your responses are captured, please click File -> Export as PDF.

B. Initial Research Proposal (Maximum of two pages, excluding Initial Research Proposal Overview and references cited):

Outline succinctly:

- How the proposed research project may lead to significant improvements in current therapeutic strategies or create new approaches to treating Alzheimer's disease.
- How the proposal fits into the drug development pipeline.

Within the 2-page limit, include these sections:

^{*}Research Classification and Research Area are used for administrative tracking purposes only and not used in the scientific review.

- 1) Specific Aims;
- 2) Significance and Impact;
- 3) Preliminary data (if available);
- 4) Research design, experimental methods and analytical plan

Initial Proposal Format:

- Include at the top of each page the Principal Investigator's full name, degree(s) and Institution.
- Arial size 11 font must be used in the text of the research proposal section.
- Use single spacing within paragraphs, double spacing between paragraphs and one inch or larger margins on all four sides.
- Any figures, graphs, tables or pictures must be included within the two pages. For these visuals, the minimum is an 8 point-font size.
- Appendices are not permitted.

C. Project Milestones and Research Plan Table (<u>Use provided Word template</u> - maximum 1 page): Create a summary table, based on the specific aims of the project which describes the proposed milestones and benchmarks. The successful completion of these activities will form the basis of measuring achievement of the project goals. Please include specific data, methods, and benchmarks that will demonstrate achievement of the milestone. Quantitative benchmarks must include statistical methods including sample size justification. Note: 1) All personnel and collaborations should be related to the achievement of the milestones; 2) Please include a milestone that describes plans for dissemination of results.

- **D. Biographical Sketch of Principal Investigator (maximum of 5 pages)**: The most current NIH Biographical Sketch Form must be used.
- If applicable, Co-Investigator Biographical Sketch(es) should be included.

Out of fairness to applicants who adhere to the guidelines, applications that do not conform to the stated application procedures or that contain more than the specified number of pages or letters will be rejected. Applications that are not properly organized will be rejected.

HRiA is committed to making our resources accessible to everyone. If you require an accommodation or service to access our resources, please contact Program Staff.

Direct any Questions to Program Staff:

Email: ThomeAwards@hria.org

