

**The Edward N. & Della L. Thome Memorial Foundation
Awards Program in Alzheimer's Disease Drug Discovery Research
Bank of America, N.A. Trustee**

Invited Full Proposal Guidelines

Grant Cycle 2019

Invited Full Proposal Deadline:
Monday, September 9, 2019
12:00 Noon, U.S. ET

AWARD PERIOD

February 1, 2020 – January 31, 2022

AWARD AMOUNT

Up to six \$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.

RESEARCH FOCUS

The goal of the 2019 Awards Program in Alzheimer's Disease Drug Discovery Research is to support innovative drug discovery research that will lead to improved therapies for individuals suffering from Alzheimer's disease.

Researchers dedicated to the validation and testing of target compounds and therapeutic agents including biologics and small molecules, are encouraged to apply. **Consideration will be given to research focused on pathogenic mechanisms including inflammatory response, synaptic toxicity, neuronal toxicity, and endosomal/lysosomal trafficking defects.**

Basic research or new target discovery, genetic studies, biomarker research, neuro-imaging and clinical studies are currently outside the scope of this Program.

PROGRAM BACKGROUND

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.

As steward of the Thome Memorial Foundation, Bank of America, N.A., works with The Medical Foundation (TMF) to decide on the most qualified candidates. The Medical Foundation at Health Resources in Action (HRiA), a nonprofit organization in Boston, MA that advances public health and medical research.

ELIGIBILITY REQUIREMENTS

All applicants must meet the following eligibility requirements:

- Receive an invitation to submit a Full Proposal.
- Hold a faculty appointment at a non-profit, academic, medical, or research institution in the United States.
- Applicants may not have funding support for a similar project.
- Applicants may only submit one application as a PI.
- Applicants do not need to be nominated by their institutions.
- 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.

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 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

APPLICATION PROCESS AND NOTIFICATION SCHEDULE

The Alzheimer's Disease Drug Discovery Research Program is a two-stage proposal process. Only invited applicants may submit Full Proposals. Funding begins February 1.

TERMS OF THE AWARD

Please review the Terms of the Award (pgs. 3-6) for information regarding use of the grant funds, indirect costs, reporting schedules and other Grantee and Institutional requirements.

Frequently Asked Questions are available for download: hria.org/tmf/ThomeAD

Terms of the Award

Overview: Awards are made to non-profit academic, medical or research institutions throughout the United States on behalf of the Award Recipients. Funds are provided by the Edward N. & Della L. Thome Memorial Foundation, Bank of America, N.A., Trustee. The Award Recipient Institution is responsible for the administrative and financial management of the project, including any subcontracts, and maintaining adequate supporting records and receipts of expenditures.

The Edward N. & Della L. Thome Memorial Foundation, Bank of America, N.A., Trustee, Awards Program in Alzheimer's Disease Drug Discovery Research is administered by The Medical Foundation at Health Resources in Action (HRiA). HRiA is a nonprofit organization in Boston that advances public health and medical research.

Award Amount and Funding Period: Two-Year Awards totaling \$500,000 (\$250,000 per year) will be awarded for the funding period of February 1, 2020 – January 31, 2022. Award Recipients may postpone the start date for up to three months without a formal request. Longer delays must be approved by The Medical Foundation. A delayed start date will not reduce the total Award Period (i.e., a project start date of March 1, 2020 will revise the project end date to February 28, 2022).

Institutional Assurances: The Award Recipient must adhere to all federal, state, and local regulations regarding the use of human subjects or biologic samples, including informed consent when appropriate, animals, radioactive or hazardous materials, and recombinant DNA in this research project. It is the Institution's responsibility to ensure that all approvals have been secured prior to releasing the Award funds. The signatures of the Authorized Institutional Representative on the Full Proposal Application Face Sheet and the Institutional Officer on the Institutional Officer Acceptance Agreement confirm this oversight.

Liability: Bank of America, N.A., Trustee, and The Medical Foundation do not assume any liability or responsibility for activities supported by this Award including, without limitation, incidents or accidents involving any project personnel or study subjects (whether on travel, in the laboratory or classroom, or elsewhere).

Scientific Misconduct. The appropriate federal, state, and local guidelines with regard to scientific misconduct must be in place and enforced at all institutions where the Award Recipient is affiliated. In the unlikely event that an Award Recipient is involved in an investigation of scientific or financial misconduct, he or she will be subject to the procedures in place at the Institution. The Institution must notify The Medical Foundation of both the investigation and the procedures that the Institution will follow.

According to the NIH/U.S. Department of Health and Human Services, research misconduct is defined as the "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." A finding of scientific and/or financial misconduct must be reported to The Medical Foundation and may affect the Award Recipient's continued eligibility for support under this Program.

Use of the Award Funds: The laws of the United States place certain restrictions on the manner in which funds awarded to organizations by charitable trusts and foundations may be expended. The award from

the Edward N. & Della L. Thome Memorial Foundation, including any interest earned thereon, may be used to support the Award Recipient's salary and fringe benefits; salaries and fringe benefits of personnel essential to the project; publication of scientific data; travel to scientific meetings; laboratory and data processing supplies; and other direct expenses such as equipment essential to the project. Salaries must be in proportion to the percent effort on the research project. However, percent effort may exceed the percent of total salary support requested from the Thome Awards Program.

Funds may not be used for new construction, the renovation of existing facilities, general operating costs, fundraising projects or endowments. Funds may not be used for any political activity or for any other purpose prohibited by the Internal Revenue Service Code.

Indirect Costs (Institutional Overhead): The Award monies may not be used to cover any Indirect Costs at either the Award Recipient Institution or any contracting institution. The monies which have been awarded, including any interest earned therein, may only be used for the purposes stated in this agreement. Funds may not be expended for any other purpose without the prior written approval of Bank of America, N.A., Trustee.

Re-budgeting: Expenditures are expected to be within reasonable range of the Budget that was submitted with the grant application. All requests for re-budgeting or reallocation of grant funds *over \$20,000* must be conveyed by email to The Medical Foundation Program Officer. The request must include the current and revised allocation of funds along with specific detail and justification for the reallocation.

Financial Responsibilities of Award Recipient Institution: The Award Recipient Institution will keep systematic records of all expenditures relating to this Award. Vouchers consisting of bills, invoices, cancelled checks, receipts, etc. will be retained by the Institution for three (3) years after the close of the Award period and will be available for inspection by representatives of Bank of America, N.A. Trustee, of the Edward N. & Della L. Thome Memorial Foundation during normal business hours and upon reasonable notice throughout this period. Bank of America, N.A. Trustee, may, at its own expense, examine, audit, or have audited the records of the Institution insofar as they relate to activities supported by this Award.

Carryover of Funds: Funds, up to \$50,000, remaining at the end of Year 1 of the Award period may be carried over to Year 2 and incorporated into that year's budget.

No-Cost Extension: A no-cost extension for up to nine months may be granted upon receipt and approval of the completed Research Progress and Financial Reports. The Progress Report will contain a section for justifying the extension, the unexpended balance, and a timeline for expenditure of the remaining funds. A Final Scientific report is due at the completion of the extension period. Any portion of the Award not expended at the conclusion of the extended project period must be made payable to Bank of America, N.A., Trustee, and returned to The Medical Foundation within sixty (60) days.

Transfer or Termination of Award: Awards are made to the Institution on behalf of the Award Recipient. If the Award Recipient moves to another nonprofit research institution during the Award period, transfer of funds to continue the project at the Award Recipient's new institution must be approved by The Medical Foundation. The Award Recipient must email the Program Officer and include a letter from the proposed Department Chair confirming the availability of resources to continue the project as well as a Fiscal Report

stating the remaining fund balance. If the transfer is approved, the Award Recipient and new Institution will be responsible for notifying The Medical Foundation of the new payee information and coordinating the fund transfer.

If the Award Recipient is not continuing his/her research in another nonprofit research setting, the Award will be cancelled and unused funds must be returned within sixty (60) days. Transfer of the Edward N. & Della L. Thome Memorial Foundation Award to another P.I. is not permitted. Disposition of any equipment purchased by the Award Recipient with Award funds will be evaluated on a case by case basis.

If the project is terminated for any reason, any unused funds must be made payable to Bank of America, N.A. Trustee, and returned to The Medical Foundation within sixty (60) days.

Unused Funds and Reversion: Should any of the following events occur, The Medical Foundation, on behalf of Bank of America, N.A., Trustee, may demand repayment of all unexpended portions of the Award; moreover, all unpaid installments may be cancelled. The Award Recipient Institution is also required to give written notice if there is a change in the Institution's status as noted below:

- A determination, preliminary or otherwise, is made by the United States Internal Revenue Service that the Award does not constitute a qualifying distribution.
- The Award Recipient Institution fails to perform any of its duties, in the judgment of Bank of America, N.A., Trustee of the Edward N. & Della L. Thome Memorial Foundation, The Medical Foundation, or its Scientific Review Committee, required by the Terms of this Award. In such cases, The Medical Foundation shall provide no less than thirty (30) days termination notice in writing to the Institution, upon which the Institution shall have an additional thirty (30) days following receipt of such notice within which to cure any deemed failures.
- The Award Recipient Institution ceases to be exempt from income taxes under the Internal Revenue Service Code or becomes a private foundation.
- There is a material change in the purpose, character, or method of operation of the Award Recipient Institution such as to jeopardize its tax status.

Family and Medical Leave: The Award Recipient may continue to expend any Award funds allocated to salary during medical or parental leave consistent with the Institutional level of paid leave for such purposes. Medical leave may be taken for a serious health condition of the employee or to care for the employee's spouse, child, or parent who has a serious health condition. Family leave may be taken by either parent for the adoption or the birth of a child.

Reporting Requirements: Acceptance of an award from the Thome Foundation includes a commitment to provide both Progress, Financial, and Final Research Reports. Continued funding is contingent upon the timely submission of a Progress and Financial Report, regardless of the start date of the Award. All Report Templates will be emailed to Awardees approximately one month prior to their due date. Progress Reports are due in December. Final Scientific and Financial Reports are due sixty (60) days following conclusion of the Award Period. Bank of America, N.A. Trustee and The Medical Foundation reserve the right to withhold award payments in cases where the Award Recipient is non-compliant with these Reporting Requirements.

Patents, Copyright and Intellectual Property: Award Recipients should follow their institutions' patent, copyright, and intellectual property policies regarding discoveries that result from research conducted under this Award. Bank of America, N.A., Trustee of the Edward N. & Della L. Thome Memorial

Foundation and The Medical Foundation will not retain rights to any intellectual property including patents, copyrights, trademarks, or other proprietary rights that result from the research.

Confidentiality and Third Party Release: Application materials as well as Scientific Progress and Final Reports are considered confidential. The Medical Foundation engages third parties who have the necessary expertise to review the submitted materials and evaluate each project. Although The Medical Foundation endeavors to protect the confidentiality of the reports by requiring reviewers to sign confidentiality agreements, confidentiality cannot be guaranteed. Bank of America, N.A., Trustee and The Medical Foundation are not responsible for any consequences resulting from the disclosure of the content of these materials to such third parties.

The Medical Foundation and the Edward N. & Della L. Thome Memorial Foundation Awards Program reserve the right to public acknowledgement of Award information (recipient name, institution, project title, Award amount, research project summary). This information will be made available through the website of The Medical Foundation at HRiA (hria.org/tmf/ThomeAD) and may be posted on other affiliated organization websites, included in publicly accessible databases of privately funded awards, or published in print form or other media.

Scientific Poster Sessions and Events: The Edward N. & Della L. Thome Memorial Foundation may hold a scientific meeting or symposium in Boston. Award Recipients will be expected to attend the meeting and present their research in a prepared talk or scientific poster. When this event is scheduled, Award Recipients are required to retain a portion of their Award, up to \$2,000, to cover any travel related expenses. There will be a minimum of six months notice prior to the date of any meeting. Award Recipients will not be reimbursed for charges associated with attending this meeting.

Change in Award Recipient Status: It is also the responsibility of the Award Recipient as well as the Award Recipient Institution to notify The Medical Foundation of any change in employment status of the Award Recipient **at least 30 days prior to such change.**

Additional Support: Awards from the Edward N. & Della L. Thome Memorial Foundation are made for a period of two years. In making this Award, Bank of America, N.A., Trustee assumes no obligation to provide additional support to the Award Recipient.

Publications / Acknowledgement: The Award Recipient is expected to share research findings in a timely manner through professional meetings and/or publications. Publications or presentations resulting from research supported by this Award must acknowledge support from **The Edward N. & Della L. Thome Memorial Foundation, Bank of America, N.A., Trustee.**

Post Award Reporting: Award Recipients agree to update The Medical Foundation about any new position, affiliation, or contact information (especially an email address). The Award Recipient will respond to the Foundation's requests for information on his/her research progress following the Award Period and may be requested to provide a current C.V. or update information in an online database. The Recipient understands that this obligation survives the Award Period.

Please continue to the next page for Submission Instructions.

Instructions for Full Proposal

The application process requires completion of an Online Application and upload of a PDF document.

Invited Full Proposal Deadline:

Monday, September 9, 2019

12:00 Noon, U.S. ET

SECTION I: Online Application

NOTE: Invited applicants to the Full Proposal received an email with a link to access the online application.

Please **review and update** the following in the online form:

- Applicant Data: Institution, Contact, and Educational background information
- Research Project: Project Title, Keywords, Project Summary, Non-technical Summary

SECTION II: Attachment Instructions for PDF

Download templates for items A-C and D at hria.org/tmf/ThomeAD. All items below must be combined into ONE PDF for upload to the Online Application. Please number all pages prior to upload.

- A. Face Sheet:** The Face Sheet 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 Face Sheet should be scanned and used as page 1 of the PDF. Download the Face Sheet Template here: hria.org/tmf/ThomeAD.
- B. Table of Contents:** Follow the Table of Contents template and number all pages sequentially.
- C. Project Summary:** Copy the Project Summary from the Online Form into the Project Summary template. The 300-word summary should state the project's broad, long-term objectives and specific aims.
- D. Budget, Summary, and Justification:** Complete each tab in the Excel spreadsheet template. Total support from the Thome Foundation is \$500,000 (\$250,000 each year for the two-year award). Please note that overhead (indirect costs) may not be covered by the award.
- E. Research Proposal (maximum of ten (10) pages, excluding 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. In addition, be sure to describe how the proposal fits into the drug development pipeline.

Within the page limit, include these sections:

- 1) Background and Significance;
- 2) Specific Aims;
- 3) Preliminary data (if available);
- 4) Research Design, Experimental Methods and Analytical Plan;

- 5) Research Limitations and Contingencies;
- 6) Projected Timeline of Proposed Research Project
- 7) References Cited (*excluded from page count*)

Proposal Format:

- Arial 11 font and size must be used in the text of the research proposal section.
- Any figures, graphs, tables or pictures must be included within the 10 pages. For these visuals, the minimum is an 8 point-font size.
- Use single spacing within paragraphs, double spacing between paragraphs, and at least ½ inch margins on all four sides.
- Appendices are not permitted, however References Cited should be added to the Proposal (not included in the 10 page count)

F. Biosketch of PI/Applicant (use the current NIH biosketch, max 5 pages)

- Applicants must disclose all current (active) and pending (not closed) grants and clearly indicate any potential research or budgetary overlap with the Thome proposal. **In cases of potential overlap, a detailed explanation of project aims must be added to the biosketch, exclusive of the biosketch page limit, to address any apparent overlap or lack thereof.**
- If applicable, please also include Co-Investigator Biographical Sketch(es) to the upload. It is not necessary to include a Collaborators biosketch unless they are key personnel.

G. Department or Division Chair's Letter: This letter (forwarded to the Applicant for upload) must address the applicant's qualifications to conduct the proposed research independently as well as note the space and equipment available for the completion of the project. If the applicant is Chair of his/her department, a letter of recommendation from the Dean should be submitted.

H. Letter(s) of Collaboration (if applicable): When applicable, letters confirming the availability of resources outside the Applicant's institution or letters confirming any significant collaboration may be included (forwarded to the Applicant for upload). These are not additional letters of recommendation.

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 materials will be rejected.

Frequently Asked Questions are available for download: hria.org/tmf/ThomeAD

Contact Information:

The Medical Foundation

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