

## STANDARD AWARD IN ALZHEIMER'S DISEASE RESEARCH

#### A PROGRAM OF BRIGHTFOCUS FOUNDATION

#### LETTER OF INTENT GUIDELINES

Due by 5:00 PM EST (Washington, D.C.)

Friday, August 25, 2023

#### **Award Overview**

Standard Awards are open to tenure- and non-tenure track investigators of any career stage who are appropriately trained to lead an independent research study and are permitted by their organizations to manage grants and supervise key personnel.

Award Amount: \$100,000 per year (total value \$300,000)

Duration: up to 3 years

All applications must be submitted online through the application portal.

Please note that all deadlines are 5:00 PM East Coast Time (Washington, DC) on the day of the deadline.

**Deadlines are posted at** http://www.brightfocus.org/grants/deadlines

If you have any questions regarding the program, please contact the BrightFocus scientific affairs department at <a href="mailto:researchgrants@brightfocus.org">researchgrants@brightfocus.org</a>. If you have any difficulties with the application portal, please contact proposalCENTRAL at pcsupport@altum.com or during normal business hour (8:30am - 5:00pm Eastern Time, Monday through Friday) by phone (toll-free): 800 875 2562 (Toll-free U.S. and Canada) or +1 703 964 5840 (Direct Dial International).

The BrightFocus Foundation is a 501(c)(3) nonprofit charitable organization that seeks to save mind and sight by funding innovative research worldwide and by promoting better health through education.

## **GUIDELINES IN BRIEF**

## **PROGRAM DESCRIPTION**

The goal of the BrightFocus Foundation research grants program is to advance innovative research promoting advances in the etiology, prevention, and treatments of Alzheimer's disease, macular degeneration, and glaucoma. Our mission is to help people live free from diseases of mind and sight. The Foundation is interested in supporting high risk studies that illuminate areas for which there currently is little understanding, helping to bring to light crucial knowledge about these three devastating diseases.

This is accomplished by relatively small grants for investigator-initiated research that are designed to allow scientists the opportunity to develop the preliminary data necessary to be considered competitive for larger government or corporate types of sponsorship. The focus of the program is on projects that, although associated with high risks, will offer high yields in terms of growth of the field. More incremental proposals, or proposals that might be easily funded through existing resources, are discouraged. While prior awardees are welcome to submit new proposals following the conclusion of the previously sponsored project, the new proposals should not be extensions of the prior project.

## **NOTES ON ELIGIBILITY**

Standard Awards are open to tenure and non-tenure track investigators at any career stage who are appropriately trained to lead an independent research study and are permitted by their organizations to manage grants and supervise key personnel. An individual may only hold ONE active grant in the Standard Award program at a time.

## Specific eligibility criteria include:

- Candidates must hold an MD, PhD, DVM, DO, OD or equivalent degree
- Applicant must serve as the Principal Investigator on the project and have dedicated laboratory space. The
  applicant should use the indicated space in Section [4] of the application to clarify any position that is not
  immediately recognizable as an independent research position
- While some of the grant can be used to support salary for the PI, the percent requested should be limited to the lesser of 35% of the total grant request, or 35% of the individual's salary. Co-Principal Investigator (Co-PI) salaries are capped at the lesser of 25% of the total grant request, or 25% of the individual's salary.
- Applicants may currently be working in a non-profit, governmental, academic research institution, or at a for-profit including start-up and biotech institution

All grant funding is subject to the availability of funds.

# **TERMS AND CONDITIONS**

For detailed information about the Terms and Conditions and Patent and Intellectual Property Policy and Contract that will apply if an application is successful, visit the BrightFocus website (http://www.brightfocus.org/grants/terms-conditions-grant-awards for the Terms and Conditions, and

http://www.brightfocus.org/grants/terms-conditions/patent-intellectual-property-policy for the Patent and Intellectual Property Policy.

#### **REVIEW OF APPLICATIONS**

BrightFocus uses a peer-review system to evaluate all applications. Submissions are evaluated and given a priority score by a Scientific Review Committee comprised of established scientists in fields related to the proposed research. The recommendations of the Scientific Review Committee are subject to final approval by the Board of Directors of BrightFocus. To ensure that BrightFocus is funding meritorious research proposals that have a high potential for success, the Board of Directors bases its funding decisions on the results of a formal, rigorous peer-review process.

Due to the high number of applications, the review process is separated into a letter of intent (LOI) stage and full proposal stage. After the Scientific Review Committee reviews and scores the LOIs, those above the determined ranking cut-off are invited to submit Full Proposals.

Prior committee members are published on the BrightFocus website at <u>View a list of experts who have served on</u> the committee.

The final status of proposals will be communicated to applicants by mid-April. Declinations are made by email. BrightFocus staff are not authorized to provide information on priority scores, ranking, or likelihood of funding of applications prior to official notification of applicants.

## **HUMAN/ANIMAL RESEARCH SUBJECTS**

BrightFocus requires that the Principal Investigator, Co-Principal Investigator(s), Collaborators, Consultants, Mentors, Consortium partners, or Sub-Contractors abide by the BrightFocus policy regarding human subject and vertebrate animal research.

Research projects involving human subjects and/or vertebrate animals must meet or exceed standards required for United States of America federal government funding including all rules and regulations developed by the National Institutes of Health. Particularly, **the inclusion of sex as a mechanistic (not statistical) biological variable should be addressed**. If the proposed research will involve the use of human or vertebrate animal subjects, a signed release from the appropriate committee of the Grantee Institution must be provided to BrightFocus, to demonstrate approval of the proposed research protocol(s) before Grant Award funds are released. For research conducted in the U.S., this release is satisfied by IACUC or IRB approvals.

If the project is to be funded through an award to a foreign institution or through an individual fellowship award that will support activities at a foreign institution, BrightFocus requires a statement of compliance from the Grantee Institution that the activities will be conducted in accordance with all applicable local laws and regulations in the foreign country. Such foreign protocols must meet or exceed standards required for United States of America federal government funding for research projects.

# **PUBLIC EDUCATION**

BrightFocus is a publicly supported charitable organization funded by donor contributions and has an active public education program that informs donors and other interested individuals about the research we sponsor. Information provided to the public by BrightFocus may include the technical and non-technical titles of the project, the name and institutional affiliation of the Principal Investigator and Co-Principal Investigator(s), the amount of the award, and the non-technical project descriptions provided by the applicant. This information is also included in BrightFocus' required reporting to the Internal Revenue Service on our Form 990, which will be made available to the public. Therefore, any section of the application designated by BrightFocus as non-confidential should not be used to communicate confidential information. The submission of the application shall be deemed consent of the applicant and affiliated Grantee Institution to the publication of this information, should a grant be awarded. Declined proposals will remain confidential in their entirety.

#### **BRIGHTFOCUS FOUNDATION**

# INSTRUCTIONS FOR COMPLETION OF THE APPLICATION TEMPLATE AND ONLINE SUBMISSION

All applications must be completed through our online portal. To access the application portal, click 'learn more' on the BrightFocus website at: <a href="http://brightfocus.org/research/apply/main.html">http://brightfocus.org/research/apply/main.html</a>.

#### **General Submission Guidelines**

- Submit your application using the instructions provided in the application portal
- Use font at a size no less than 11 points
- Use margins no less than 3/4" on all sides
- The color of the narrative text should be black
- Applications must be legible and written in English
- Do not use jargons or unusual abbreviations
- Maximum character and/or word/page counts for individual sections will be enforced
- Text in the descriptive legends or captions of figures, tables, or photographs must be included within maximum limit

You MUST complete ALL of the sections in your application. Applications that are incomplete or fail to adhere to formatting instructions will be DECLINED without review.

## **Section 1**

## **TITLE PAGE**

## **Project Title**

This section of the application asks for Project Title (maximum 150 characters)

## **Keywords**

Excluding keywords selected from the CADRO list, which will be selected in section 8, please indicate 6-10 comma separated keywords or phrases related to your proposal.

## **Total Amount Requested**

Enter the total costs for the entire project period. Payments will be released on a quarterly basis, evenly distributed throughout the award duration. If you request funds for one year, you may only request a maximum of half of the award value.

# Response to Prior Critiques/Changes from Prior Submission

If you have previously submitted a proposal to BrightFocus that was declined an award, provide your response to previous critiques (if applicable) including the changes incorporated to address reviewer's concerns.

## **Support from other Granting Organizations**

If the same specific aims that are used in this application have been submitted to another funding organization, list the name of the organization and specify

#### **Section 2**

# **DOWNLOAD TEMPLATES AND INSTRUCTIONS**

This section contains Research Plan Document and Biographical Sketch that are required to complete, or which might be necessary for the full submission of your application. You MUST use the "Research Plan" template provided in this section for submission.

#### **Section 3**

## ENABLE OTHER USERS TO ACCESS THIS PROPOSAL

This section is used specifically for providing access rights to other people whom you may wish to have access to your application. You may choose their access as "View" or "Edit." If you give someone "Edit" ability they can upload documents or add attachments in your absence.

If you mark an individual as "Auto Notify" this means each time an email is sent to you through proposalCENTRAL, that person will automatically receive a copy of the email.

# Section 4 APPLICANT/PI

This section of the application asks for the Principal Investigator's information. You are required to have an ORCID ID for submission. All fields that are marked with asterisk (\*) are required fields. If you already have a professional profile within proposalCENTRAL, these fields will be automatically populated and filled in. Please review them carefully to confirm the information is correct.

Use the space for "Non-Traditional Faculty Tracks" to justify your eligibility for a Standard Award given your role/professional title.

#### **Section 5**

# **INSTITUTION AND CONTACTS**

This section contains the information of the "Lead Institution." This page defaults to the institution of the Principal Investigator. If the institution is incorrect, you may click on the "Change Institution" button and search for the correct institution.

#### **Section 6**

## **KEY PERSONNEL**

ALL personnel working, collaborating, over-seeing or coordinating on the project MUST be listed in this section. This section should also include all collaborators and consultants. You will need to insert their email address in the space provided and click "Add." Complete all required fields and click "Save" when completed. This person will now appear in the "Key Personnel" window.

**IMPORTANT:** Each Co-PI, Collaborator or Consultant identified should provide a signed Letter of Support summarizing their role in the proposed research and their compliance with all appropriate animal welfare and human subject requirements. This letter should certify that they have agreed to their role as proposed in the

version of the application received by BrightFocus. This letter should be attached to the Research Proposal Document.

# Section 7 SPECIFIC AIMS

## **Research Category**

Please select the Research Category appropriate to the proposed project. BrightFocus does not weight its funding preferentially towards or against any of the listed categories. Your choices will not influence the likelihood of funding. Responses to the fields are used to aid in the selection of appropriate reviewers for the proposal.

# Common Alzheimer's and Related Dementias Research Ontology (CADRO)

CADRO is a three-tiered classification system to organize and compare basic, translational and clinical AD/ADRD research projects across multiple funding organizations using common terminology. Please choose a primary and secondary CADRO code for your project. CADRO codes are integral to the International Alzheimer's and Related Dementias Research Portfolio (IADRP) which collates and categorizes the portfolios of major organizations for areas of shared priorities as well as areas of opportunities to inform coordination and collective efforts that seek to advance AD/ADRD research. For more information, visit: <a href="https://iadrp.nia.nih.gov/about">https://iadrp.nia.nih.gov/about</a>

## Specific Aims (2400 characters maximum)

Please number and list the proposed specific aims. State the objectives and the hypotheses to be tested and describe concisely and realistically what the specific research described in this application is intended to accomplish. Please note that this section should not include figures, tables, photographs, or other non-text information.

#### **Section 8**

## **CONFLICT OF INTEREST – SELF REPORT**

Depending on the breadth of expertise required to review the applications received in the present review cycle, a subset of the <u>listed researchers</u> may serve on the review committee that evaluates your proposal. For the present review cycle, please note that additional reviewers may be brought onto the review committee if additional expertise is required. Referring to the list provided, please indicate any Review Committee Members with whom the PI or Co-PI of this proposal has any conflict and indicate the type of conflict (co-published within preceding 3 years, co-employed or a recent trainee).

# Section 9

# **ORGANIZATION ASSURANCES**

Please indicate if the proposed research will involve the use of human or vertebrate animal subjects. A signed release from the appropriate committee of the Grantee Institution must be provided to BrightFocus, to demonstrate approval of the proposed research protocol(s) before Grant Award funds are released.

# **Human Subjects**

If activities involving human subjects are not planned at any time during the proposed project period, select "No".

If activities involving human subjects, whether or not exempt from Public Health Service (PHS) regulations, are planned at any time during the proposed project period, check the box beside "Yes." Indicate the status of Institutional Review Board (IRB) approval, insert the date of approval by the IRB of the proposed involvement of human subjects. If IRB review is delayed beyond the submission of the application, enter "pending." If the planned activities involving human subjects are exempt, insert the exemption number(s) corresponding to one or more of the eight exemption categories recognized by the PHS. The Assurance of Compliance number will appear as entered in the institution profile (for the institution you selected in the institution section of the proposal). Should the application be approved for funding, verification of the exemption or IRB approval will be required before funding begins.

All supported research, including that of collaborators, must comply with U.S. Federal, and any applicable local, regulations regarding the use of human subjects in research.

#### **Vertebrate Animals**

If activities involving vertebrate animals are not planned at any time during the proposed project period, check the box beside "No".

If activities involving vertebrate animals are planned at any time during the proposed project period, check the box beside "Yes." In the space indicated, insert the date of approval by the Institutional Animal Care and Use Committee (IACUC) of the proposed use of vertebrate animals and the Animal Welfare Assurance Number. If IACUC review is delayed beyond the submission of the application, enter "pending." Should the application be approved for funding, verification of IACUC approval will be required before funding begins.

All supported research, including that of collaborators, must comply with U.S. Federal, and any applicable local, regulations regarding the use of vertebrate animals in research.

# Section 10 REQUIRED ATTACHMENTS

## Letter of Intent (two-page maximum, 8.5" x 11" page with 3/4" margins, 11 pt Times New Roman font):

This section should elaborate on your specific aims listed in the application portal and must include a description of the objectives and hypothesis, as well as a summarized version of the experimental design and any preliminary results. This award is intended to foster exceptionally creative projects. The proposed work should not represent incremental advancements of existing lines of inquiry. Please include a statement addressing what you believe to be innovative about the proposed research, and how the project will benefit the Alzheimer's disease and related dementias field. Please include the origins of major non-commercial reagents for the study, predicted sample sizes, clinical stratifications, and power calculations, where appropriate. Tables, graphs, and photographs may be included, but are considered to contribute to the page limitations.

Please convert your Letter of Intent Research Plan to a text accessible pdf file format, save it as "lastname\_First\_LOI\_Standard\_FY24.pdf", where 'lastname' is the surname of the Principal Investigator, and upload to ProposalCentral.

Literature Cited (single page maximum, 8.5" x 11" page with 3/4" margins, 11 pt Times New Roman font): Please list all the literature cited in the proposal and upload it as a single pdf document separate from the Research Plan. Each literature citation must include the names of all significant authors, the name of the book or journal, volume number, page numbers, and year of publication. Article titles should be provided. The use of "et al." in place of listing all authors of a publication is acceptable. If a publication is public, please include its NIH PubMed Central identification number (PMID) in the text.

## **Biographical Sketches**

Prepare a National Institutes of Health (NIH) Biographical Sketch on the Principal Investigator, Co-Principal Investigator(s), Collaborators, Consultants, and the other key research staff/personnel involved in the study. List relevant training, professional experience, and publications. You may replace this section with a NIH Biosketch already in your possession. Please limit individual biosketches to 5 pages.

NOTE: All biosketches should be submitted as a single pdf document separate from the Research Plan.

# **Letters of Support**

Each Co-Principal Investigator (Co-PI), Collaborator or Consultant should provide a signed, single page Letter of Support summarizing their role in the proposed research. This letter should certify that they have agreed to their role, as proposed in the version of the application received by BrightFocus. These letters should also certify their compliance with any appropriate animal welfare or human subject regulations.

NOTE: All letters should be submitted as a single pdf document separate from the Research Plan.

#### Section 11

## PI DATA SHEET

The information in this section is used to analyze the longitudinal demographics of the Alzhiemer's Disease Research Program portfolio. While these answers are required, you always have the option not to disclose the information. The information is allows us to observe trends and ensure diversity across many metrics of our portfolio.

#### **Section 12**

#### **VALIDATE**

Please use the 'Validate' section to verify that you have entered all the required information. AFTER you have validated the document you MUST click "SUBMIT" for the application to be submitted. Validating the document DOES NOT submit the application to BrightFocus Foundation. Proceed to Section 18 for Submitting the application.

#### **Section 13**

# **SUBMIT**

#### INFORMATION FOR APPLICANTS: REVIEW POLICIES AND PROCEDURES

BrightFocus awards grants for research on the causes of, and preventions or treatments for the diseases specified by each of its disease programs (i.e., Alzheimer's disease, glaucoma, and macular degeneration). The Foundation is interested in supporting high risk studies that illuminate areas for which there currently is little understanding, helping to bring to light crucial knowledge about these three devastating diseases.

Grants are awarded on the basis of the scientific merit of the proposed research and the relevance of the research to improving our understanding of these diseases. All awards are contingent on the availability of funds.

To ensure that BrightFocus is funding meritorious research proposals that have high potentials for success, the Board of Directors bases its final funding decisions on the results of a formal, rigorous, scientific peer-review process, taking program goals and the availability of funds into consideration.

A full description of the review process and outcomes is available at <a href="http://www.brightfocus.org/grants/frequently-asked-questions#arp">http://www.brightfocus.org/grants/frequently-asked-questions#arp</a>

# GENERAL BRIGHTFOCUS REVIEW COMMITTEE PROCEDURES

BrightFocus recruits and maintains a Scientific Review Committee (SRC) for each of the three research programs. These committees are comprised of established investigators with the appropriate expertise to provide constructive and equitable evaluations of grant applications. These individuals serve as volunteers, but are provided with a small honorarium for the time and effort they put into the review process. Almost all serve on NIH study sections or review committees for other foundations. A roster of individuals having served on each committee in the preceding five years is available at the website noted above.

The BrightFocus Scientific Affairs Department, in consultation with the Chair/Co-Chair(s) of the Scientific Review Committee, assigns each letter of intent to at least a primary and secondary reviewer based on the expertise of the reviewers and the research area(s) of the proposal. In some cases, a tertiary reader is also assigned for the proposals. All proposals are checked against the pool of available reviewers for real or potential conflicts of interest prior to assignment of the proposal to individual reviewers.

Reviewers are required to decline assigned applications for which they do not have the appropriate expertise and must decline to review applications in which they have a real or potential conflict of interest. These applications are reassigned to other reviewers. Please note that we provide fields in the application portal for applicants to declare conflict of interest of the PI and Co-PI(s) with the list of current and/or past-serving SRC members.

Reviewers may not participate on a committee in any review cycle in which they themselves have submitted a proposal for consideration.

Reviewers are required to keep the information presented in grant applications and the deliberations of the Scientific Review Committee strictly confidential. It is the responsibility of the BrightFocus Scientific Affairs Department to communicate with applicants regarding the results of the review process and to serve as the intermediary between the Reviewers and the applicant.

## REVIEW CRITERIA AND PRIORITY SCORE RANKING

The BrightFocus Scientific Review Committee (SRC) uses the National Institutes of Health (NIH)'s 9-point scale to assess the overall impact score of each grant application, and to provide a priority score ranking recommending applications for funding to the BrightFocus Board of Directors. Ratings are in whole numbers only (no decimal ratings), where 5 is considered an average score.

Overall ImpactScore		<b>Descriptor</b>	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong, but with numerous minor weaknesses
	5	Good	Strong, but with at least one moderate weakness
	6	Satisfactory	Some strengths, but also some moderate weaknesses
Low	7	Fair	Some strengths, but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

Reviewers are instructed to take the following criteria into consideration when reviewing grants:

#### 1. Significance/Relevance to Alzheimer's disease and related dementias

Does the project address an important problem or a critical barrier to progress, and contribute significantly to current knowledge regarding the etiology, diagnosis, or treatment of Alzheimer's disease and related dementia (ADRD)? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

#### 2. Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by using novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

# 3. Approach

Does the investigator have a clear hypothesis and specific aims? Are the methods clearly explained and appropriate? Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed? Has the investigator satisfactorily addressed issues or concerns regarding appropriate care and treatment of laboratory animals? Can the research proposed be accomplished in the time period of the grant.

## 4. Investigator(s)

Are the PIs, and Co-PI(s), collaborators, and other researchers well suited to the project? If they are early-stage investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

#### **REVIEW RESULTS**

Applicants will be invited to submit a full proposal should their review score fall above the ranking threshold. The invitation should be expected in mid-October. BrightFocus staff are not authorized to provide information on priority scores, ranking, or likelihood of funding of applications prior to written notification of applicants. Please do not write or telephone BrightFocus to request such information.

# **REGARDING APPEALS**

If an applicant has evidence that a reviewer has materially misunderstood an otherwise properly and logically presented proposal, that applicant may submit a one page appeal to BrightFocus by email. Appeals of peer evaluations must be delivered to the BrightFocus Vice President of Scientific Affairs (<a href="documents-developer-devel

The appeals process is designed to address only extraordinary situations in which the review process is believed to have been compromised in such a way as to prevent unbiased or competent review of a proposal. This process IS NOT intended for routine rebuttal of specific reviewer critiques or opinions, or to overcome the consequences of poor writing or "grantsmanship." Routine rebuttal of reviewer critiques may be submitted as a revised proposal in a later review cycle.

If the appeal is found to merit further investigation, the Vice President of Scientific Affairs, in consultation with the chairs of the Board Scientific Affairs Committee and appropriate Scientific Review Committee, shall determine an appropriate action on a case by case basis. Such actions may include re-evaluation of the proposal by the original reviewers for clarification of opinions, or evaluation by new reviewers who have not previously seen or discussed the proposal.