

2019 INNOVATOR AWARDS

Innovator Award Research Focus:

Goal: To provide seed funding for high-quality, innovative research which potentially changes

our understanding of hydrocephalus or improves treatments and outcomes.

Project Focus: Identifying new mechanisms responsible for the development of the various types of hydrocephalus;

Identifying or testing new therapeutic targets; and

Preclinical or clinical testing of new drug therapies and other treatments.

Emphasis will be placed on innovation and potential impact of the project on hydrocephalus research and clinical outcomes. Investigators studying **any etiology** of hydrocephalus are invited to submit a <u>letter of intent (LOI)</u>. There are no restrictions on the age of onset or stage of hydrocephalus that can be studied.

This award will support research in the following areas:

- hydrocephalus pathogenesis and secondary injury mechanisms;
 (e.g. cellular, molecular, signaling, developmental, and genetic mechanisms)
- drug target identification and testing;
- preclinical drug development and testing;
- preclinical medical device testing;
- clinical treatment innovation, including new medical device testing*
- *All applicants intending to include human subjects must indicate this in the LOI and will be contacted to determine if the project falls within the scope of this RFA.

This award will not support:

- incremental progress of an established research program or project;
- minor modifications to current treatment approaches;
- development of new animal, *in vivo*, or *in vitro* models; (See NIH PA-18-623 for funding opportunities in this area)
- imaging studies (intervention studies using imaging as an outcome measure are allowed);
- development or testing of intracranial pressure monitors;
- development or modification of tools to advance hydrocephalus research;
 (See NIH PA-18-623 for funding opportunities in this area)
- business plan development

Award Details:

This award provides short term seed funding (up to 12 months).

- The project must be designed to be completed within the 12 month timeline.
- Proposals must be submitted for actual costs at one of two funding levels, \$25,000 or \$50,000.

- Total funding for this award mechanism is expected to be \$200,000.
- Preliminary data is not required.
- The award provides no institutional overhead.

The final award decisions will depend on the quality of the applications received and the research priorities determined by the Hydrocephalus Association. Special consideration may be given to projects that increase diversification of HA's research portfolio and focus on underrepresented areas of hydrocephalus research. Evaluation of cognitive and behavioral outcomes as well as research on adult forms of hydrocephalus are encouraged. The Hydrocephalus Association will accept applications from researchers based at accredited non-profit research and academic institutions throughout the world. The award provides no institutional overhead. All applications must be submitted in English. In upcoming years, the Hydrocephalus Association anticipates, but cannot guarantee, a follow-on RFA for multiyear support.

Eligibility Criteria:

To be eligible, candidates must have:

- a publication record containing research articles that are innovative and high impact;
- demonstrated the ability to independently supervise staff and research;
- completed one or more of the following degrees: MD, PhD, DSc, DO, Pharm.D, or equivalent;
- a research associate, assistant professorship, associate professorship, professorship, or any equivalent academic or non-academic position.

Candidates must be a member of the HA Network for Discovery Science. To create an account, please visit: http://hands.hydroassoc.org/.

All applicants must submit an LOI. LOIs must be submitted to research-loi@hydroassoc.org before 5:00 PM (Eastern) on May 29, 2019. LOI decisions and invitations to submit full proposals will be made in mid-June.

Application Details:

The Letter of Intent (LOI) components include:

Click here for the LOI

- A one-page summary of the project*
- Identification of the supporting institution
- Identification of three potential reviewers

The Full Application components include:

Click here for the Full Application

- Contact details and other relevant administrative information (Face Page)
- Proposal Budget (Budget)

^{*}All applicants that intend to include human subjects will be contacted to determine if the project falls within the scope of the RFA.

- Biographical sketches are required for the Applicant, Co-Investigator (if applicable), and Key Personnel. Biographical Sketches should not exceed five (5) pages (BioSketch)
- A Research Plan for the proposed project, of not more than six (6) pages, that contains a summary, specific aims and hypotheses, background and significance, research design and methods, next steps, and literature cited. Note: Literature Cited does not count against the 6 page limit. (Research Plan)
- A description of the Institutional Facilities and any Consultations/Collaborations if applicable (Facilities and Collaborations)
- Applications from <u>all candidates</u> should also include a letter from the appropriate administrative
 institutional official confirming the institution's commitment to the responsible conduct of research,
 the candidate's eligibility and good standing, and that, if selected, the candidate would be able to
 accept the award.

All applicants must provide assurance of compliance with local research regulatory bodies and with local laws in advance of the start of research activities. Additionally, for applications using human embryonic stem cells or human tissue, the candidate must obtain appropriate Embryonic Stem Cell Research Oversight Committee (ESCRO) and human subjects research approvals in advance of the start of research activities.

Full applications are due before 5:00 PM (Eastern) on August 14, 2019. Grant finalists will be contacted in October 2019. For additional information, please contact Jenna Koschnitzky, PhD at research@hydroassoc.org or 240.483.4540.

Submission Information

Letter of Intent Deadline: May 29, 2019

Application Deadline: August 14, 2019

Potential applicants must submit a letter of intent on May 29, 2019 by 5:00 pm ET describing the nature of the proposed project and its relationship to hydrocephalus, identifying their institution, and identify three (3) potential reviewers. Completed LOIs should be emailed to research-loi@hydroassoc.org. Completed applications, including institutional commitment, must be submitted as a single PDF document on August 14, 2019 by 5:00 pm ET. Completed applications should be emailed to research@hydroassoc.org.

Late applications will not be accepted and the deadline will not be waived.

Letter of Intent Form Deadline: May 29, 2019, 5:00 pm EDT Application Submission Deadline: August 14, 2019, 5:00 pm EDT

Review: September 2019 Awardee(s) selected: October 2019

If, after reviewing these application instructions, assistance is needed in preparing the application, contact the HA National Director of Research Programs:

Phone: 240.483.4540

Email: research@hydroassoc.org

A Scientific Review Committee of research scientists from both within and outside of the hydrocephalus research area will review the Innovator Award applications. Each application will initially be assessed and scored by a primary and secondary reviewer(s) based upon the following criteria:

- Qualifications of the Applicant and Institution
- Use of Innovative Ideas, Techniques, Technology
- Likelihood that the Proposed Project will Advance Hydrocephalus Treatment/Cure
- Scientific Merit of the Research Proposal
- Ability to complete proposal in one (1) year timeframe

Based upon the assessment of applications by the Scientific Review Committee, the National Director of Research Programs and Research Committee will make a recommendation to the CEO for approval. The number of awards will depend on the quality of the applications received, available funds, and the research priorities determined by the Hydrocephalus Association in light of the hydrocephalus research landscape.

Format Specifications for all application components

Click here to view and download the application components

- Use provided templates. Do not alter header, footer, or margins.
- Type applications in black ink using a standard, readable font such as Arial, Helvetica, Palatino, Garamond or Times New Roman with a font size of 11 points or larger. Symbol fonts may be used to insert Greek letters or special characters. Smaller type size is acceptable in figures, graphs, charts, tables, figures, legends and footnotes, but these must be in black ink and readily legible.
- Use standard 8 ½ x 11 paper with at least half inch margins on all sides, a single column format, single-sided, single-spaced with consecutively numbered pages.
- Submit as a single PDF Document to the Director of Research Programs (research@hydroassoc.org)

1. Face Page

The Face Page includes the main identifying information for the application including applicant's name and contact information, institution name and address and title of application. Please use the Word document provided. If it is necessary to recreate the form, please adhere to the original format and wording. Please include a scan of the completed face page as part of the single PDF file. The Face Page is limited to one (1) page.

2. Budget

Please complete the **Budget** section for the total duration of support requested (maximum of 12 months). Please include personnel costs, subcontract costs, and estimate material costs according to general categories (i.e. animal costs, supplies, equipment etc.).

Budget:

- Personnel Designate the percentage of the applicant's time devoted to research on this
 project. If the salary is supplemented by support from other agencies, the percent of salary
 requested must be equal to or less than the percent of time allotted to this project. Indicate
 dollar amounts separately for salary and benefits. If support is requested for a technician,
 identify the amount of time the technician will devote to the study.
- Subcontracts Identify the dollar amount of any subcontracts.
- Materials Please estimate material costs according to general categories (i.e. animal costs,

- supplies, equipment, etc.). A detailed budget is not necessary.
- Indirect Costs Indirect costs are not covered by this grant and cannot be included.

Applicants can apply at either a \$25,000 or \$50,000 level. Applications for funding that exceeds \$50,000 will not be considered. The Hydrocephalus Association reserves the right to request a budget justification after application submission.

3. Biographical Sketch

Complete a biographical sketch for the Applicant, Co-Investigator (if applicable), and Key Personnel. Use the format provided. Clearly identify innovative and high impact research. Highlight prior publications relevant to the present application. Biographical Sketches should not exceed five (5) pages. NIH Biographical Sketches are acceptable.

- **A. Personal Statement.** Briefly describe why you are well-suited for your role in the project described in this application
- **B. Positions and Honors.** List in chronological order previous positions, concluding with the present position. List any honors.
- Contribution to Science. Briefly describe up to four (4) of your most significant contributions to science related to the proposed project. Indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. Reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. Each description should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.
- **D. Research Support.** List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). Begin with the projects that are most relevant to the research proposed in the application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

4. Research Plan

This section is the opportunity to describe the Research Plan in sufficient detail to permit a thorough scientific review. The Research Plan (sections A-E) for this award is limited in length to six (6) pages, excluding the literature cited. There is no page limit for the literature cited section. Reviewers will look favorably on writing that is clear, concise, specific and informative.

- **A. Summary.** State concisely and realistically what the research described in the application is intended to accomplish during the duration of the grant. Highlight the use of innovative techniques, technology, and/or thinking in relation to hydrocephalus. Describe how your project could improve outcomes or lead to the prevention or cure for hydrocephalus. <u>Do NOT exceed</u> 150 words. The summary will be made public if the grant is awarded.
- B. Specific Aims and Hypotheses. State concisely and realistically what the research described in

the application is intended to accomplish during the period of the grant, including the hypotheses to be tested.

- C. Background and Significance. Briefly describe background information critical to understanding the present proposal. Concisely state the importance and rationale of this project including how this research is addressing a critical gap in hydrocephalus research. If the aim(s) of the application is achieved, state how scientific knowledge will be advanced and the implications for future pre-clinical and/or translational therapeutic research or the clinical management of hydrocephalus. Since you are applying to the Hydrocephalus Association for a grant, there is no need to make arguments for the significance of the condition. Please focus your application on the impact that your research will have on the state of hydrocephalus research or the clinical management of hydrocephalus. Explain why this research is innovative.
- D. Research Design and Methods. Provide a detailed discussion of the research design and methods to be used to accomplish the specific aim(s). Discuss the data expected to be obtained and the means by which data will be collected, analyzed and interpreted. Provide details on statistical analysis including power analyses. If new methods, techniques, or procedures are to be used, explain their potential advantages over existing methodologies. Discuss potential difficulties and/or limitations of the proposed procedures and alternative approaches to achieve aims. Point out any procedures, situations or materials that may be hazardous to personnel or patients and the precautions to be exercised.
- **E. Next Steps.** If this research is funded, briefly describe your next steps including submission of grant proposals to other governmental and nongovernmental agencies. Please be specific.
- **F. Literature Cited.** References should be numbered in the sequence that they appear in the text and listed at the end of the Research Plan. Each citation must include the names of authors, the name of the journal or book, volume number, page number and year of publication (titles are optional).

5. Facilities and Collaborations

All applicants must complete part (A) Facilities. If the project includes consultant arrangements and/or collaboration with other individuals outside of the applicant institution, complete part (B) Consultant or Collaboration Arrangements. The Facilities and Collaborations section is limited in length to two (2) pages.

- **A. Facilities.** Please provide an overview of the institutional facilities/equipment available for this study.
- **B.** Consultant or Collaboration Arrangements. If the proposed project includes consultant arrangements and/or collaboration with other <u>individuals outside the applicant's institution</u>, describe the working relationships and support this description by letter(s) of support signed by collaborating individual(s). If clinical material required by this grant is to be furnished by other individuals, include a statement from these individuals agreeing to their participation and precautions taken to ensure anonymity of patients.

6. Institutional Commitment Letter

Applications from <u>all candidates</u> should also include a letter from the appropriate administrative institutional official confirming the institutions commitment to the responsible conduct of research, the

candidate's eligibility and good standing, and that, if selected, the candidate would be able to accept the award.

In advance of research activities, a signed letter from the appropriate sponsoring institutional official must accompany this application to verify that the research conducted in accordance with this award has met the institutional requirements for the following:

- 1. An Institutional Review Board (IRB) has reviewed and approved the procedures for the use of human subjects, or human organs, tissues and body fluids, in the proposed research, in accordance with Department of Health and Human Services policies. Include the IRB number and a copy of the approved form with the letter.
- 2. A DATA SAFETY MONITORING PLAN (DSMP) for any proposed study that places human subjects at more than minimal risk.
- 3. A plan to include, recruit and retain subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research.
- 4. Research Involving Recombinant DNA meets the requirements contained in the document "NIH Guidelines for Research Involving Recombinant DNA Molecules" (revised April 2002).
- 5. Research Involving Animals meets the guidelines of the National Institutes of Health, U.S. Public Health Service, which require that all proposed studies be reviewed and approved by an Institutional Animal Care and Use Committee (IACUC). If applicable, please provide the federally approved Animal Welfare Research Number, and the IACUC letter of approval.
- 6. Adequate protection will be assured for any Biohazards involved in the research.
- 7. Approval for the use of human embryonic stem cells must be obtained through an appropriate Embryonic Stem Cell Research Oversight Committee (ESCRO).