



## 2024 INNOVATOR AWARD RFA & Submission Guidelines

The **Innovator Award** provides seed funding for **innovative** research which has the potential to transform the field of hydrocephalus. This award will support research projects aligned with the Hydrocephalus Community Research Priorities ([published here](#), and [summarized here](#)). The complete list of priorities can also be found in Appendix A. These priorities cover a wide range of topics under the following categories:

### **Developing novel non-invasive and/or one-time therapies**

The hydrocephalus community wants new therapies to be developed to prevent, treat, manage, and reduce the damage caused by hydrocephalus with a focus on non-invasive and one-time treatments.

### **Reducing the burden of current treatments**

The hydrocephalus community wants current treatments to be less invasive, have lower failure rates, and be easier to monitor. This includes the development of ways to accurately and easily monitor shunt function, improvements in current treatments (lower failure rates and new methods to unblock shunts), and better ways to determine the correct treatment protocol for each person.

\*Shunt-related research applications are encouraged

### **Improving the screening and diagnosis of hydrocephalus**

The hydrocephalus community wants to improve outcomes for people not yet diagnosed. This includes improving our understanding of why hydrocephalus develops, improving early screening and diagnosis, and improving our understanding of who needs to be treated to decrease the burden of the condition on future generations.

### **Improving quality of life**

The hydrocephalus community wants to improve long-term outcomes and quality of life for those living with hydrocephalus. This includes reducing headaches and migraines and decreasing the burden of psychological, cognitive, and physical challenges caused by hydrocephalus.

### **Improving access to care**

The hydrocephalus community wants better access to knowledgeable doctors and coordinated care teams including during the transition from pediatric to adult care.

In the Letter of Intent (LOI), investigators must indicate which priority statement(s) (Appendix A) are addressed by the project. Investigators studying hydrocephalus are invited to submit a [Letter of Intent \(LOI\) by March 28, 2024](#). Employment of cross-disciplinary teams is encouraged.

### **Award Details:**

*This award supports:*

- projects that can be completed within 12 months
- projects that can be completed at one of two funding levels, \$25,000 or \$50,000.

*This award does not support:*

- incremental progress of an established research program or project.
- projects in association with commercial development partners (i.e., participation of for-profit corporation(s)).

### **Eligibility Criteria:**

*To be eligible, applicants must:*

- have a publication record containing research articles that are innovative and high impact.

- have demonstrated the ability to independently supervise staff and research.
- have completed one or more of the following degrees: MD, PhD, DSc, DO, Pharm.D, or equivalent.
- hold an assistant professorship, associate professorship, professorship, or any equivalent academic or non-academic position.
- be based at an accredited non-profit research or academic institution worldwide.
- be a member of the HA Network for Discovery Science (<http://hands.hydroassoc.org/>)

**Final award decisions** will depend on the number, scope and quality of the applications received, and alignment with the Community Research Priorities published by the Hydrocephalus Association. It is anticipated that two to six Innovator Awards will be funded during this grant cycle. This award provides no institutional overhead. All applications must be submitted in English.

**All applicants must submit an LOI. LOIs must be submitted to [research-loi@hydroassoc.org](mailto:research-loi@hydroassoc.org) before 5:00 PM (Eastern) on March 28, 2024.**

**LOI invitations to submit full proposals will be sent out in April**

### 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 the Community Research Priorities addressed by project
- 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).
- Biographical sketches are required for the Applicant, Co-Investigator (if applicable), and Key Personnel. Do not exceed five (5) pages for each biosketch (Biosketch).
- Describe why this research is innovative. List any active or pending grant support that has or may appear to have a significant scientific or budgetary overlap with the research proposed in this application. Do not exceed one (1) page (Innovation).
- The Research Plan for the proposed project that contains a summary, specific aims and hypotheses, background and significance, research design and methods, next steps, and literature cited. Do not exceed six (6) pages. Note: Literature Cited does not count against the 6-page limit (Research Plan).
- Describe the Institutional Facilities and any Consultations/Collaborations if applicable. Do not exceed two (2) pages (Facilities and Collaborations).
- Applications from all candidates 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 June 12, 2024.**

**Grant finalists will be contacted in September 2024.**

**For additional information, please contact [Samantha@hydroassoc.org](mailto:Samantha@hydroassoc.org) or [research@hydroassoc.org](mailto:research@hydroassoc.org)**



## Submission Information

**Letter of Intent Deadline: March 28, 2024**

**Full Application Deadline: June 12, 2024**

Potential applicants must submit a letter of intent **by March 28 by 5:00 pm ET** describing the nature of the proposed project and its relationship to hydrocephalus, identifying their institution, identifying the Community Research Priorities addressed by project, and identifying three (3) potential reviewers. Completed LOIs should be emailed to [research-loi@hydroassoc.org](mailto:research-loi@hydroassoc.org). Completed full applications, including institutional commitment, must be submitted as a single PDF document **on June 12, 2024 by 5:00 pm ET**. Completed applications should be emailed to [research@hydroassoc.org](mailto:research@hydroassoc.org). Applicants will be notified September 2024.

**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:

- **Innovation.** Reviewers will score how innovative the research is and the extent the research represents more than an incremental advance upon published data or more than the next logical step in a research projects
- **Research Strategy and Feasibility.** Reviewers will score how well the scientific rationale, hypothesis, experimental design, methods and analyses support the research question and the completion of the aims as well as the feasibility of the project in the one year time frame.
- **Impact.** Reviewers will score the extent the research impacts a critical problem or important scientific question, will generate preliminary data that can be used as the foundation for future research projects, and has the potential to impact, either short- or long-term, the field of study and/or patient care.
- **Investigator and Environment.** Reviewers will score how well the investigator(s) and environment are suited for and will contribute to the success of the research.

Based upon the assessment of applications by the Scientific Review Committee, the National Director of Research 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

- **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 the full application as a single PDF Document to the Director of Research Programs ([research@hydroassoc.org](mailto: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). 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 combined dollar amount 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, or budget justification 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.
- C. 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 ongoing and completed research projects for the past three years (Federal and 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. Innovation

This section is the opportunity to describe why the proposed research is innovative and a non-incremental step or a departure from your current research program or projects. If you currently hold a grant that overlaps or may be perceived to overlap with the project proposed here, please explain. The Innovation Page is limited to one (1) page including citations.

- A. Innovation.** State why this work is innovative and non-incremental. Innovative research may introduce a new paradigm, look at existing problems from new perspectives, or exhibit other highly creative qualities. Research that represents an incremental advancement on previously published work is not considered innovative.

The following list, although not all-inclusive, provides examples of research that is **not** innovative:

- Exploring a previously tested hypothesis in a different cell line or in a new population
- Using a published series of invitro assays to further characterize a model system
- Incorporating known biomarkers into in vivo or clinical models of the disease or condition
- Investigating the next logical step or continuation of a previous research project
- Proposing work that is an incremental advancement of published data

- B. Other support.** If applicable, please list any active or pending grant support that has or may appear to have a significant scientific or budgetary overlap with the research proposed in this application. Please provide details or state that there is no overlap.

Scientific overlap occurs when (1) substantially the same research is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific research objective and the research design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source.

Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source.

## 5. 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. Do NOT exceed 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.

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/treatment of hydrocephalus.

- 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.

Preliminary data is not required but is allowed. The presentation of substantial preliminary data suggests that the proposed research project would be more appropriately submitted to a different award mechanism. The outcome of research supported by this award should be the generation of robust preliminary data that can be used as a foundation for future research projects.

Provide details on the statistical analyses that will be used, 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. Impact.** If the aim(s) of the application is achieved, state how scientific knowledge will be advanced and how this work will inform your future research projects. 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).

## 6. 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 individuals outside the applicant's institution, 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.

## **7. Institutional Commitment Letter**

Applications from all candidates 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. The letter must be on the institution's official letterhead.

## **8. Other Documentation**

In advance of research activities, grantees must submit a signed letter from the appropriate sponsoring institutional official to provide assurance of compliance with local research regulatory bodies and with local laws and 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).

## Appendix A

### Hydrocephalus Community Research Priorities

The Hydrocephalus Community Research Priorities is a list of research priorities developed by the hydrocephalus community at large through a validated process using the James Lind Alliance guidance.

#### Developing novel non-invasive and/or one-time therapies

The hydrocephalus community wants new therapies to be developed to prevent, treat, manage, and reduce the damage caused by hydrocephalus with a focus on non-invasive and one-time treatments.

- Develop new treatments that do not require brain surgery to manage hydrocephalus
- Develop new one-time treatments to manage hydrocephalus (i.e. permanent treatments that do not require additional interventions)
- Develop ways to prevent the development of hydrocephalus
- Develop therapies (e.g. stems cells, cellular regeneration) to repair brain damage for people affected by hydrocephalus

#### Reducing the burden of current treatments

The hydrocephalus community wants current treatments to be less invasive, have lower failure rates, and be easier to monitor. This includes the development of a better understanding and new ways to monitor shunt function, improvements in current treatments (lower failure rates and new methods to unblock shunts), and better ways to determine the correct treatment protocol for each person.

- Develop ways to monitor shunt function and detect shunt malfunction non-invasively and/or outside of the hospital
- Improve shunt components and surgical techniques to prevent shunt blockages and mechanical failure (e.g. broken valve, disconnected tubing, broken tubing)
- Develop methods to non-invasively or less-invasively unblock shunts
- Improve shunt designs and surgical techniques to enable less or non-invasive shunt placement and shunt revisions
- Develop a better understanding of the symptoms patients experience when their shunt is failing
- Determine which treatment strategy will be most effective for each patient by comparing clinical protocols and treatment options (e.g. shunt vs. ETV, programmable vs. non-programmable shunts)

\*Shunt-related research applications are encouraged

## Improving the screening and diagnosis of hydrocephalus

The hydrocephalus community wants to improve outcomes for people not yet diagnosed. This includes improving our understanding of why hydrocephalus develops, improving early screening and diagnosis, and improving our understanding of who needs to be treated to decrease the burden of the condition on future generations.

- Identify the causes and processes that lead to hydrocephalus (e.g. genetic influences, inflammation)
- Improve ways of diagnosing and screening for hydrocephalus to allow for earlier detection of the condition
- Develop ways to accurately determine if a patient would benefit from hydrocephalus treatment, such as shunt, prior to surgery

## Improving quality of life

The hydrocephalus community wants to improve long-term outcomes and quality of life for those living with hydrocephalus. This includes reducing headaches and migraines and decreasing the burden of psychological, cognitive, and physical challenges caused by hydrocephalus.

- Improve our understanding and develop ways to reduce the emotional and psychological challenges (e.g. stress, anxiety, and depression) of living with hydrocephalus
- Improve our understanding and develop ways to reduce headaches and migraines related to hydrocephalus and hydrocephalus treatments
- Improve our understanding and develop ways to reduce impairments in attention, learning, memory, and problem solving related to hydrocephalus
- Improve our understanding and develop ways to restore physical function and motor control (e.g. walking, balance, and urinary continence) in people with hydrocephalus

## Improving access to care

The hydrocephalus community wants better access to knowledgeable doctors and coordinated care teams including during the transition from pediatric to adult care.

- Determine how to improve patient access to doctors and hospitals that have expertise in hydrocephalus
- Determine how to improve coordinated care across medical specialties (e.g. neurosurgery, neurology, cognitive therapy, physical therapy, etc.) for people with hydrocephalus
- Determine how to improve a patient's transition from pediatric to adult medical specialists (doctors)