



Research Award in Cerebrospinal Fluid (CSF) Production, Flow, and Regulation Therapeutics and Diagnostics

Request for Applications

Policies and Guidelines

Executive Summary: The purpose of this Request for Applications (RFA) issued by the Hydrocephalus Association in partnership with The Rudi Schulte Research Institute (RSRI) is to support one or more high quality, innovative, and timely research projects by established investigators which will advance our understanding of cerebrospinal fluid (CSF) dynamics in the etiology, diagnoses, and treatment of hydrocephalus.

Our partner in this RFA is The Rudi Schulte Research Institute. Rudi Schulte was one of the two founders of a shunt manufacturing company called PS Medical, later acquired by Medtronic. Through his ground-breaking work, the hydrocephalus shunt was developed. Later, in order to further advance research in the treatment of hydrocephalus, Mr. Schulte generously created and endowed The Rudi Schulte Research Institute. Today, RSRI conducts studies to improve treatments for hydrocephalus and other neurological disorders.

- Applications will be accepted from experienced investigators with established research programs in basic, translational, or clinical research relevant to the dynamics of cerebrospinal fluid in hydrocephalus. Candidates for this award:
 - Must have a health-professional doctoral degree or its equivalent. Such degrees include but are not limited to the M.D., PhD, ScD, Pharm.D.
 - Must have an established record of independent, peer-reviewed research grant funding at the time of application and record of publications.
 - Must be U.S. citizens, non-citizen nationals, or legal permanent residents of the U.S. and Canada.
 - Should typically be in the mid-career stage at the Associate Professor level or higher or functioning at that rank in an academic setting or equivalent non-academic setting.
- A total of \$200,000 in each of the three years beginning in late 2013 is available to be awarded. This funding amount can provide support for between one and three research awards of one to three years in length. All funds must be used to support the original awardee.

- The number of awards made will depend on the scope and quality of the applications received, available funds, and the research priorities determined by the Hydrocephalus Association in light of the hydrocephalus research landscape.
- Eligible organizations include institutions in North America; public or private institutions such as universities, colleges, hospital and laboratories; and for-profit and non-profit organizations.
- The RFA is not intended to support the development of medical devices, instrumentation or other commercial applications.
- Budget guidelines and restrictions include:
 - Salary support request should be commensurate with level of education and experience and reflective of the percentage of the applicant's time to be spent on this project.
 - Supplementation of salary from other sources is allowable.
 - Purchase of large equipment (>\$2,000) is not allowed.
 - Indirect costs must be included within the total grant award and may not exceed 10% of the total budget.

Submission Information

Letter of Intent Deadline: January 4, 2013

Application Deadline: March 1, 2013

Potential applicants must submit a letter of intent by January 4, 2013 describing the nature of the proposed project and its relationship to hydrocephalus, and identifying their institution. Completed applications, including letters of recommendation and institutional commitment, must be submitted in a single PDF document by March 1, 2013. Applicants will receive instructions on uploading applications, including letters of recommendation and the signed Face Page, to the HA secure server in response to their letters of intent.

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

Letter of Intent Form Deadline: January 4, 2013

Application Submission Deadline: March 1, 2013

Review: April 2013

Awardee(s) selected: May 2013

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

Phone: 301-202-3811, Email: research@hydroassoc.org

Review and Reward

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

- Qualifications of the Applicant
- Likelihood that the Proposed Project will Advance Hydrocephalus Diagnosis and Treatment/Cure
- Scientific Merit of the Research Proposal

Based upon the assessment of applications by the Scientific and Medical Review Committee, the Research Committee of the Board of Directors will make a recommendation to the full Board of Directors 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.

Instructions for completing Specific Application Components

Format Specifications for all application components

- 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.
- Limit the Research Plan section of the application, including literature cited, to ten (10) pages.

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 Excel form 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.

Abstracts

Please provide two abstracts describing the nature of this work and its importance to hydrocephalus: one Lay Abstract to inform the non-scientific members of the Hydrocephalus Association and the lay public and one Scientific Abstract to inform the scientific community. Please limit each abstract to no more than 250 words.

Budget Summary, Detailed Budget and Budget Justification

Please complete the Budget Summary form as well as a Detailed Budget and Budget Justification for all years of support requested (maximum of two years). Please include the full cost of the proposed research project, how this award money will be used toward those costs, and how any additional money needed to complete the research will be obtained.

Detailed 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. Explain other sources of funding for the salary and fringe benefits.
- Equipment – List all items of minor equipment requested and the cost of each item. If funds are requested for purchase equipment that is equivalent to items listed under Facilities Available, justify the duplication. Justify any item of equipment for which the need may not be obvious. Major equipment purchases of over \$2,000 are not allowable.
- Supplies – includes items such as glassware, chemicals, animals, etc., in separate categories and give the estimated cost of each category. If animals are involved, state the number, unit purchase cost, and the unit care cost.
- Other Expenses – Itemize other expenses by major categories, such as duplication costs, publication costs, computer charges, equipment maintenance, etc.
- Indirect Costs – Indirect costs must be included within the total grant amount and may not exceed 10% of the total budget.

Applications for funding that exceed \$200,000 per year will not be considered.

Budget Justification:

- Use this page to describe the nature of costs listed in the Detailed Budget under each major category (Personnel, Equipment, Supplies, Other)

Biographical Sketches

Complete a biographical sketch for all key personnel, beginning with the Applicant, co-investigators, if any, and other key personnel. Use the format provided, or provide an NIH biosketch. If you use an NIH biosketch, please limit and identify references as requested in the HA format. HA defines “key project personnel” as anyone with an advanced degree who will play an instrumental role in the accomplishment of the training or project. Clearly identify the results of any previous hydrocephalus research highlighting prior publications relevant to the present application. Each complete Biographical Sketch should not exceed three (3) pages.

Other Current Support

Please describe all current funding that the applicant receives and whether or not it is related to the research project proposed here. There is no page limitation for other support.

Research Plan

This section is the opportunity to describe the Research Plan in sufficient detail to permit a thorough scientific review. The Research Plan for this award is limited in length to 10 pages, including the literature cited. Reviewers will look favorably on writing that is clear, concise, specific and informative.

- A. **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 or the need(s) to be fulfilled. Do not exceed one page.
- B. **Background and Significance.** Briefly describe the background of the present proposal. Critically evaluate existing knowledge and specifically identify the gaps that the project is intended to fill. Concisely state the importance and rationale of this research by relating the specific aims to longer-term objectives. This section should also show the potential importance of the proposed work to hydrocephalus treatment and cure. If the aims of the application are achieved, state how scientific knowledge and clinical practice will be advanced.
- C. **Preliminary Results.** If applicable, provide a detailed discussion of any preliminary results.
- D. **Milestones.** Define at least two progress-related milestones that you expect will be completed by the end of one year and will indicate that the research project is proceeding in a timely and effective manner. These milestones are not expected outcomes of the research, but actions that will have been completed and documented which demonstrate effective progression of the research project. If funding is requested for two years, second year funding will be contingent on completion and documentation of these milestones.
- E. **Research Design and Methods.** Provide a detailed discussion of the research design and methods to be used to accomplish the specific aims. Discuss the data expected to be obtained and the means by which data will be collected, analyzed and interpreted. If clinical studies are involved, provide details of the methods for patient selection and care. 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. Include a timeline for the project.
- F. **Responsible Conduct of Research.** Applications must include a plan for the responsible conduct of research, including the rationale, subject matter, appropriateness, format, frequency and duration of instruction.

- G. Consultant or Collaboration Arrangements. If the proposed project includes consultant arrangements and/or collaboration with other individuals outside the applicant's group, describe the working relationships and support this description by letter(s) of intent 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.
- H. 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).

INSTITUTIONAL COMMITMENTS AND REQUIREMENTS

A signed letter from the appropriate sponsoring institutional official must accompany this application to verify that 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, or indicate that the protocol is pending and will be approved before work is begun.
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, or indicate that the protocol is pending and will be approved before work is begun.
6. Adequate protection will be assured for any Biohazards involved in the research.

ADDITIONAL MATERIAL

If you feel that the following materials will be helpful to reviewers in assessing the worthiness of the application, the following may also be submitted with the application. These are not necessary to a complete application, but are allowable. Extensive appendix materials may not be reviewed, please include only the most relevant documents from the following list:

- Letters of Collaboration (if applicable).
- For research involving human subjects, a copy of the IRB application and patient
- Other materials pertinent to the grant proposal, not already described.