

Policy and Guidelines for the Pulmonary Hypertension Association’s Innovation Research Award

I. Research Award Description

The purpose of the Pulmonary Hypertension Association’s Innovation Research Award is to support highly meritorious, innovative research that could have a great impact towards accelerating the field of pulmonary hypertension research.

Research projects for the PHA Innovation Research Award may introduce a new scientific or medical paradigm, challenge a current paradigm, or look at an existing problem from a new perspective. The research project should be a novel area of research that would not be able to be explored without PHA funding.

Any areas of innovative pulmonary hypertension (PH) research will be accepted. Areas of focus include but are not limited to:

- Novel in vitro or in vivo models of PH
- Unique approaches for leveraging PH biorepositories or clinical databases or registries
- Novel clinical trial endpoints or outcomes to support PH clinical trials
- New pathways or mechanisms of action for PH

PHA is committed to promote diversity, equity, and inclusion in PH research. Research proposals that will increase inclusivity and broaden our understanding of PH and address health disparity in underrepresented PH patient populations are encouraged.

Underrepresented populations include but are not limited to Black, Latino, Asian, Native American, LGBTQ+, lower socio-economic groups, and under-served geographical regions (i.e., rural). As applicable, proposals should reflect diversity, equity, and inclusion of the PH patient population within the study design.

II. Funding Amount

Awards may be approved for up to a two (2) year period up to \$60,000/year (\$120,000 total) may be requested. Indirect costs are not allowable.

III. Eligibility

- Candidates may be U.S. citizens, permanent residents, or non-residents working at a U.S.-based institution. Applicants who are not U.S. citizens but are currently based in the U.S. must provide evidence of employment at a qualified U.S. institution.
- Applicants must have a post-baccalaureate Ph.D. degree or equivalent, or a doctoral-level clinical degree such as MD, DO, PharmD or Ph.D. in public health or other clinical health sciences and have complete all fellowship or post-doctoral training.
- Simultaneous submission of grants with scientific overlap is allowed, but if multiple applications are funded, then the applicant must notify the Pulmonary Hypertension

Association within one month of formal notification of award. The Research Committee of PHA's Scientific Leadership Council will assess the degree of overlap. In the case of significant scientific overlap, the applicant will have to choose between the PHA Innovation Research Award and the other grant. Budgetary overlap is not allowed. A Principal Investigator (PI) may hold only one PHA Award at a time.

- Diverse research teams are encouraged to bring together and capitalize on innovative ideas from different perspectives, experiences, and backgrounds.

IV. Review and Award

- All applications are evaluated by PHA's Scientific Leadership Council (SLC) Research Committee whose recommendations are reviewed by the PHA's Board of Trustees. Funding of awards is based on the priority score awarded to each application and the recommendations of the SLC Research Committee.
- Funding decisions are based on:
 - **Innovativeness:** Is the proposed research original and innovative? Does the research have the potential to lead to critical discoveries or major advancements that will accelerate PH research? Does the proposal introduce a new scientific or medical paradigm, challenge a current paradigm, or look at an existing problem from a new perspective? Does the research use or develop novel approaches, methodologies, tools, or technologies?
 - **Impact:** Does the research have the potential to have a sustained and impactful influence on PH science or clinical care? Does the proposal address a critical problem towards advancing PH research? Is the research aligned with PHA's mission to improve the lives of all affected by PH?
 - **Scientific and technical merit:** Are the study design and methods adequately developed, well-reasoned, and appropriate to the aims of the research? Does the applicant sufficiently acknowledge and address any potential barriers or challenges in the proposal? Is the proposed research feasible? Is there sufficient preliminary data to support the proposed research?
 - **Investigator(s):** Does the applicant's training, expertise, and accomplishments support successful completion of the research? If applicable, does the investigative team bring complementary, qualified, and integrated expertise to the proposal?
 - **Environment:** Will the institutional environment provide the laboratory resources and equipment and collaborative arrangements to support success of the proposed research?
- Primary causes for assigning low priority scores to applications during review include:
 - Failure to demonstrate that the proposed research is novel, innovative, and impactful for accelerating PH research
 - Inadequate statement of hypothesis, experimental design or methods
 - Failure of the applicant to demonstrate awareness of and plans for coping with key problems and pitfalls associated with the proposed research
 - Insufficient information or documentation

- Failure of the applicant to document the necessary skills or training to accomplish the goals of the proposal
- Failure of the applicant to meet all of the eligibility criteria
- An application will be awarded on the basis of individual and institutional merit. The award will not be transferable to another individual or institutions unless previously approved by the Pulmonary Hypertension Association.

V. Submission Information

- Applicants may only submit one (1) application for the PHA Innovation Research Award
- **Application deadline: Monday, August 1, 2022 by 5:00 PM (Eastern)**
- Submit online through proposalCENTRAL: <https://proposalcentral.com/>
- General Timeline:
 - Application Deadline _____ August 1, 2022
 - Review _____ September 2022
 - Notification to Applicants _____ October 2022
- Project Awarded _____ by November 30, 2022

VI. Full Application Guidelines

Applications must be submitted online at proposalCENTRAL: <https://proposalcentral.com/>

Documents should be typed using:

- Font: Times New Roman 12 or Arial 11
- Margins: No less than a half inch on each side

Log-in at proposalCENTRAL: <https://proposalcentral.com/>

First-time applicants must register to create a username and password for proposalCENTRAL and will need to complete a profile online before applying. If you are registered and cannot remember your password, click on the **“Forgot Your Username/Password?”** link below the **“Application Login”** fields.

Award opportunities, including this Request for Applications (RFA), are listed on the opening screen, but you must be logged in first to see them.

Select the gray tab labeled **“Grant Opportunities”** found in the upper right-hand side of the page.

Locate the listing for the **“PHA Innovation Research Award”** program. Click on the **“Apply Now”** button in the column on the far right to open the application form.

Applicants may stop at any point but must click the **“Save”** button before exiting in order to save their work. When logging in to continue, click on the blue tab, **“Proposals”**, and then the **“Edit”** button.

The following sections are listed in the navigation menu to the left of the application screen. Click on each section and follow the directions:

1. **Title Page:** Enter the title of your project, indicate whether the Principal Investigator (PI) is an investigator new to PHA.
2. **Download Templates & Instructions:** Download the available templates applicable to the project, fill them out and upload them when completed. Templates available include:
 - a. Biographical Sketch(es) for Applicant and Key Personnel
 - b. Research Plans
 - c. Budget Period Detail
 - d. Budget Justification
 - e. Resources Available
 - f. Facilities Available
 - g. Other Support
3. **Enable Other User to Access this Proposal:** Complete this section online if you wish to designate access to another individual, such as an assistant who has registered on proposalCENTRAL. Enter the email address of the individual and in the “**Permissions**” column, use the pulldown menu to select the type of access you wish to give. Please note that only delegates who are granted “**Administrator**” rights can submit applications on behalf of the applicant. Click on “**Accept Changes**”.
4. **Applicant:** If a profile was completed upon registration, the fields in this section will already be populated with the information entered in your Professional Profile. If you need to make any changes, click the “**Edit Professional Profile**” button, and follow the instructions. If a profile was not completed, enter the required information, and click “**Save**”.
5. **Institution & Contacts:** If a profile was completed upon registration, the applicant’s institution will be preloaded as Lead Institution. If a profile was not completed, enter the required information and click “**Save**”. Be sure to use the full legal name of the institution.
6. **Biographical Sketch(es) of Key Personnel** (template available online)
Complete and upload an NIH Biographical Sketch for all key project personnel, beginning with the Applicant. International applicants can upload a biographical sketch that is equivalent in content to the NIH template provided. Key personnel are defined as any individual with an advanced degree that will play an instrumental role in the accomplishment of the research project.) Do not exceed five (5) pages per person.
7. **Abstracts/Relevance**
In the space provided online for abstracts, provide a statement of no more than 2,000 characters (including spaces) explaining the subject of the research proposal and how it will advance PAH research and how the research may lead to improved patient outcomes. Two different abstracts are required, as follows:

- **General Audience Abstract:** This statement will be used to inform the non-scientific public of the nature of this work. Applicants should not include any confidential or proprietary information, including intellectual property, in the lay abstract.
- **Scientific Abstract:** This statement will be used to inform the scientific community.

8. Research Plans (10-page limit)

In this section, upload the completed downloaded template in PDF format. Application with Research Plans exceeding this page limit will not be reviewed. Type the PI's name in the space available in the header of the document. The template available will track page numbers at the bottom.

Research Plan should include sufficient information to permit effective review without reference to previous applications. Information should be presented in a clear and concise manner, while being specific and informative.

- A. Hypothesis and Specific Aims:** State concisely and realistically the intent of the proposed research and the hypothesis to be tested. Describe the experimental paradigm. Do not exceed one page.
- B. Background and Significance:** Briefly describe the background leading to the present application. 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. If the aims are accomplished how will this affect the scientific field? Where will these studies lead in developing a larger research program? In addition, describe the relationship of the proposed work to your long-term career goals.
- C. Innovative Nature of the Project:** Describe how the research is novel and innovative. Include how this changes an established paradigm or brings a new concept or perspective to PH research.
- D. Preliminary Results:** If applicable, provide a detailed discussion of any pertinent preliminary results. Any key figures and legends should be of sufficient quality and size to be evaluated by the reviewer. Preliminary data may help the reviewers in assessing the likelihood of the success of the proposed project. Include in your references any publications, manuscripts accepted for publication, patents, or other printed materials that have resulted from preliminary studies.
- E. Experimental Design and Methods:** Provide a detailed discussion of the experimental design and methods to be used to accomplish the specific aims. Describe the protocols, including methods for new techniques, and explain potential advantages over existing methodologies. Include how the data will be collected, and analyzed, and describe potential problems or limitations. This section must be written so that reviewers can evaluate the scientific questions, the experimental design, and the likelihood that the experiments will produce interpretable results. Include a tentative timetable showing how you will prioritize the work. Clearly identify collaborations with other investigators at the same or other institutions.
- F. Literature Cited (no page limit):** References should be numbered in the sequence that they appear in the text at the end of the Research Plan. Each citation must include the names of

authors, title, the name of the journal or book, volume number, page number and year of publication. Recommended format: “New England Journal of Medicine” style in EndNote and “Annals of Internal Medicine” in Reference Manager.

9. Budget Justification:

The downloaded Budget Justification form will need to be completed and uploaded into proposalCENTRAL. Please note that indirect costs are not permitted.

10. Resources Available:

List the resources that you have available to you that will be needed to complete your project. Describe the resources, facilities, and equipment available at your institution that will be used for this project, such as laboratory, clinical, animal, computer, office, etc. Describe how the resources will contribute to the successful completion of your project. Provide any additional information about the environment, including any support services available that will be utilized. Please note that the limit for this section is three (3) pages.

11. Organization Assurances:

PHA requires, as applicable, that all U.S.-based awardees obtain Institutional Review Board (IRB) approvals for human subject research, Institutional Biosafety Committee (IBC) approval for recombinant or synthetic nucleic acid research, and Institutional Animal Care and Use Committee (IACUC) approval for animal research. Copies of these approvals, if available at the time the application is submitted, must be uploaded with the application as appendices. PHA will not release payments to awardee institutions until these documents are received.

12. Verification of Applicant Institution’s Tax Status (upload as PDF documents)

A copy of the applicant institution’s current W-9 and 501(c)3 letter, or other documentation verifying its federal tax status will need to be submitted for the Award to be issued.

13. Letters of Support/Reference:

Applicants are responsible for providing the name and email address of two references who can provide a letter of recommendations. Letters of recommendation are usually letters from someone not directly involved in the project but who can emphasize its importance, institutional leaders (e.g., division director, chair, dean), who can highlight the applicant’s commitment and potential success of the proposed research.

14. Invite Referees to submit Letters of Support/Reference through proposalCENTRAL:

Letters of Support/Reference must be submitted electronically ONLY. To “invite” Referees, go to the “Letters of Reference” section of the online application, and enter the email addresses of the individuals you have asked to submit letters. This will generate automated emails (with instructions) sent to each Referee through the proposalCENTRAL website.

The applicant should inform Referees to submit the letters at least one (1) week prior to the application deadline. *The letters of recommendation are due at the time of the full application deadline.*

15. Letters from Collaborators:

Letters from collaborators are optional and may be included in addition to the two (2) Letters of Support/Reference. You may include as many letters from collaborators as you would like.

Letters uploaded to proposalCENTRAL should not be password protected or otherwise encrypted. Such encryption will cause errors in assembling a single-print PDF of the application. The applicant should inform the individuals writing letters to not include password protection on their documents.

16. Appendices (upload materials as PDF documents, if applicable)

Appendices are restricted to the following three (3) categories:

- Certification of organization assurances (i.e. IRB, IACUC and IBC approvals), if applicable.
- Up to three (3) reprints of the applicant’s work relating to the general area of research in the proposal may be uploaded in PDF format.

17. Signature Page

After completing all the proposal sections, complete the signature page section on proposalCENTRAL. The Signature Page must be electronically signed by the applicant and the Authorized Institutional Official in proposalCENTRAL prior to submission. Co-investigators, if any, do not need to sign the Signature Page.

18. Validate: Upon completing the application, click on the “Validate” button on the main screen. Attend to any omissions/errors as prompted onscreen, and then click “Validate” again.

19. Submit: Click on the gray button with blue lettering labeled “submit.” PHA will not receive your application unless the “Submit” button is clicked.

Confirmation: Applicants will receive an e-mail confirmation from proposalCENTRAL directly that the Application was successfully submitted. This e-mail will be your only acknowledgement. If you do not receive this confirmation, please contact proposalCENTRAL immediately to ensure that your submission was submitted and processed.

VII. Contact Information

For technical support with the online application: proposalCENTRAL at pcsupport@altum.com or 800-875-2562 on weekdays, 8:00 a.m. to 5:00 p.m. (Eastern)

For program/content information: PHA at Research@PHAssociation.org.