PennState College of Medicine | PennState College of Engineering | PennState Health Milton S. Hershey Medical Center

REQUEST FOR APPLICATIONS

2024 Grace Woodward Grants

For Collaborative Research in Engineering and Medicine

Release Date: September 29, 2023

PSU InfoReady Competition Page:
https://psu.infoready4.com/#freeformCompetitionDetail/1914725

***Register Intent to Submit an Application by:* 12 Noon (EST), March 12, 2024**

***Application Receipt Date:* 12 Noon (EST), April 1, 2024**

A. Overview

The Dean of the College of Engineering and the Dean of the College of Medicine announce the availability of the Grace Woodward Grants for Collaborative Research in Engineering and Medicine. These grants are supported by generous endowments to the Colleges of Engineering and Medicine from the estate of Grace Woodward. The Grace Woodward Collaborative Research in Engineering and Medicine grants are intended to support projects that create or capitalize upon opportunities for new applications of engineering to problems in the life sciences and medicine. The program is designed to encourage genuine collaborations between engineers and clinicians or biomedical scientists. For 2024, proposals in alignment with either the College of Medicine or College of Engineering strategic plans and in the topic area of biodevices are particularly encouraged.

B. Eligibility Criteria

1. All proposals **must include two Co-Principal Investigators (Co-PIs)** that are substantially invested in the project and who work together to draft and revise the proposal. Requirements:
   - One of the two Co-PIs must have a **primary academic appointment in the College of Medicine as an Assistant Professor, Associate Professor or Professor.** In addition to the basic science faculty, all physicians employed by Penn State Health Milton S. Hershey Medical Center have a primary academic appointment in the College of Medicine and thus are eligible to apply.
   - One of the two Co-PIs must have a **primary academic appointment and tenure home in the College of Engineering at the University Park Campus.** College of Engineering faculty members from other Penn State campuses will also be eligible to serve as a Co-PI of an application to this program if the resources to support their participation are provided by their local campus unit.
   - Additional investigators from these and other campuses/colleges are eligible to participate as Co-Investigators (Co-Is).
2. Investigators who are currently serving as a PI/Co-PI of an ***active*** Grace Woodward Grant **OR** Center for Biodevices Seed Grant **are not eligible** to submit an application in response to this RFA.

3. **An investigator may only serve as a PI/Co-PI on one Grace Woodward Grant *OR* Center for Biodevices Seed Grant application for 2024.**

C. Program Guidelines

1. Proposals representing a new area of collaboration between the Co-PIs that has not previously received support from this or other competitive grant programs are encouraged.
2. New proposals as well as revised versions of previously unfunded proposals to this program will be considered.
3. Applicants together may request **up to $80,000 total direct costs** ($40k College of Medicine/$40k College of Engineering) to be spent over a period of **up to 2 years** to fund either:
   a. **Fundamental Research** that aims to generate preliminary data for co-authored publications in a new line of research leading to external grant submissions.
   b. **Applied Research** that aims to demonstrate feasibility or develop a prototype of a new medical device, instrument or other diagnostic or therapeutic modality that will become attractive for commercial development.
      - Projects focused on Applied Research should include: 1) a **Development Plan** describing the scope of work with supporting technical detail and clear milestones to advance the technology toward commercialization, and 2) a **Commercialization Plan** that provides the overall strategy to commercialize the technology both during and after the funding period.
      - While applicants are not expected to have a detailed business plan at this stage, the proposal should demonstrate an understanding of issues that relate to commercial relevancy (see Appendix 1). A summary of how the proposed Development Plan helps to address key commercial questions should be included.
      - Investigators wishing more information on this type of application should contact Erika Swift, Associate Director, Center for Medical Innovation (eus59@psu.edu).
      - Awardees will interact with representatives from Penn State's Center for Medical Innovation (https://research.med.psu.edu/departments/medical-innovation/) in order to assist with potential technology commercialization.
4. Although no minimum percent effort is required for the Co-PIs, the effort that Co-PIs and others plan to devote to the project **must be specified in the budget justification**. Each Co-PI may charge the grant for a maximum of 10% effort. Should a Co-PI's full salary exceed the NIH cap, the anticipated percent effort should be indicated and budgeted to reflect the current NIH cap.
5. Funds **may** be requested for student stipends and tuition, research staff, postdoctoral fellows, small equipment, materials/supplies, and expenses related to the involvement of human subjects.
6. Funds **may not** be requested for publication expenses or travel to conferences; however, travel expenses necessary for the conduct of the research project are allowable.
7. **Each application must include separate budgets for the portions of the project that will be conducted in the College of Engineering and in the College of Medicine. Co-PIs are encouraged to develop proposals requesting approximately equal funding to support the activities in each college.** Skewing of the budget toward one College requires a statement in the budget justification addressing the need for a skewed distribution and the nature of the involvement of the PI from the other college.
8. **Co-PIs of Grace Woodward Grants must agree to:** 1) present a progress report for their project at the Center for Biodevices Outcomes Day in September 2024; 2) submit a final written progress report within 60 days of completing the project; 3) report periodically on the impact of this award on subsequent sponsored research activities, upon request; and 4) serve as a member of the joint College of Medicine/College of Engineering Collaborative Research Review Committee in future years, upon request.

D. Identification of Collaborators

Potential applicants may obtain advice and assistance in identification of potential collaborators with engineering, scientific or clinical expertise in specific areas. Investigators may contact Dr. Mary Frecker at the College of Engineering (mxf36@psu.edu) or Dr. Yuval Silberman at the College of Medicine (yus72@psu.edu) for information and assistance.

E. Register Intent to Submit an Application (Required)

Investigators planning to submit an application in response to this RFA must register their intent via email to ResearchDevelopment@pennstatehealth.psu.edu on or before **12 Noon (EST) on Tuesday, March 12, 2024**.

Please include:

(1) the names, departments and colleges of the Co-PIs,
(2) a descriptive title of the application, and
(3) "Grace Woodward Collaborative" in the subject line.

F. Instructions for Applicants

All applications should use standard letter paper size (8 ½" x 11"), a font size of 11 points or larger with single line spacing, and provide one-half inch (0.5") margins— top, bottom, left, and right— on all pages. Applications that do not follow the required format may be returned without review. The final PDF should include all of the information listed below in the order indicated:

1. **Cover Page:** Complete the cover page template provided on the PSU InfoReady competition page (*https://psu.infoready4.com/#freeformCompetitionDetail/1914725*).
2. **Table of Contents:** Include page numbers starting with the cover page, numbering all pages consecutively.
3. **Lay Abstract:** Briefly summarize the objective, specific aims and health-relatedness of the project in terms that will be understood by a non-scientific lay audience.
4. ***For revised applications only – Introduction:** (1-page maximum) Address previous reviewer comments.
5. **Program Goals:** Identify the goals of the program as either **(1) Fundamental Research** to establish a new line of research that will likely lead to extramural funding, or **(2) Applied Research** to provide proof-of-concept or prototype development for a new medical device, instrument, or other diagnostic or therapeutic modality that will become attractive for commercial development.
6. **Research Plan:** (5 pages maximum, including figures and tables) Must include the following:
   a. **Specific Aims** – List the specific aims of this proposal and explain how their accomplishment will help achieve the program goals identified above.
   b. **Significance** – Explain how the proposal addresses an important problem or clinical barrier.
   c. **Innovation** – How does the proposal challenge or shift existing paradigms? Specifically highlight any novel concepts, approaches, methods, or instrumentation.
   d. **Approach** – Describe the proposed experimental design, preliminary studies, and anticipated results.
   e. **Environment** – Describe the research environment and resources that will contribute to this project.
7. **Investigator Contributions:** This program is designed to **encourage genuine collaborations** between engineers and clinicians or biomedical scientists, and it is anticipated that each Co-PI will make critical and meaningful contributions to the project. Use this section to clearly and fully describe the contributions that the Co-PI from COE and the Co-PI from COM will each make to this project, both individually and collaboratively. If one Co-PI will be more fully involved early and the other somewhat later, the timetable for that should be clearly described in the application. Proposals that require only token or minor contributions from one Co-PI or the other (such as obtaining tissue samples or analysis or engineering modest refinements to an existing device or process) should seek support from other more appropriate mechanisms.

8. **Human Subjects and/or Vertebrate Animals:** Describe involvement, if any.
9. **Literature Cited:** List references.
10. **Budget**: Each application must include separate SIMS budget forms for the portions of the project that will be conducted in the College of Engineering and in the College of Medicine (up to $80,000 direct costs; $40K College of Medicine/$40K College of Engineering)**.** COE faculty should work directly with the Engineering Research Office. See **Program Guidelines** for budget details.
    - Indicate any cost-share from local departments, research centers, or university consortia.
    - The budget period should be 8/1/2024 through either 7/31/2025 or 7/31/2026. There will be no need to initiate an IAF.
11. **Budget Justification:** Provide a separate justification page for the budget request from each college (1 page each). Explain and justify all proposed expenditures so that it is clear why they are essential for the success of the project. Expenditures not fully justified can be removed at any time during the review process.
12. **Biosketches:** Include a current biosketch for both Co-PIs and all Co-Is or key personnel using the short NSF (5-page) format or the current NIH format. For NIH biosketch template and examples, see https://grants.nih.gov/grants/forms/biosketch.htm.
13. **List Other Support:** Include all active and pending support for both Co-PIs. Indicate clearly whether each project listed does or does not overlap with this application and explain the nature of any overlap.
14. **Future Plans:**
    - For Fundamental Research applications – Assuming that the project is successful, describe plans to secure continued funding including the most probable sponsor, mechanism, and expected receipt date for the first application.
    - For Applied Research applications – Describe the most probable licensee, plan for commercialization, and summary of the IP portfolio.
    - **For both types of projects**, explain how you envision that collaboration between the Co-PIs and potentially other members of the team will be extended and sustained.
15. ***For Applied Research applications only** – Include:
    a. **Development Plan:** (2 pages maximum) Describe the scope of work with supporting technical details, including any compliance considerations, and clear milestones.
    b. **Commercialization Plan**: (1-page maximum) Provide a brief business plan describing the overall strategy to commercialize the technology both during and after the funding period. See Appendix 1.

G. Submission

All applications must be submitted as a single PDF through the PSU InfoReady competition page (*https://psu.infoready4.com/#freeformCompetitionDetail/1914725*) before **12 Noon (EST) on Monday, April 1, 2024**. Before taking steps to submit a proposal, it is recommended that applicants first review the ***PSU InfoReady Guidance for Applicants*** on page 6 of this RFA.

H. Review Process

Applications will undergo a review for scientific and technical merit by non-conflicted members of a joint College of Medicine/College of Engineering Collaborative Research Review Committee. Reviewers will use a scoring system adapted from the NIH to evaluate the following review criteria: responsiveness of the proposal to the RFA, significance, investigators, innovation, approach, environment, and the potential for the project to subsequently attract significant support for research and/or commercial development of a promising new medical device, diagnostic, instrument or other diagnostic or therapeutic modality from an external sponsor. In addition, the Collaborative Research Review Committee will be asked to comment on compliance and identify changes in study design and/or methodology that would strengthen each proposal. These recommendations will be returned to the

applicant with the reviewer's critiques at the conclusion of the review process. The Collaborative Research Review Committee will make its recommendations through the Directors of the Center for Biodevices and Research Development, College of Medicine, to the Associate Dean for Innovation, College of Engineering, and Vice Dean for Research and Graduate Studies, College of Medicine, who with the Deans of the College of Engineering and the College of Medicine will make all final decisions regarding awards.

I. Awards

Contingent upon the receipt of meritorious applications, two awards will be announced on or about June 1, 2024. The anticipated start date for this award is August 1, 2024. Research compliance approvals (IRB, IACUC, Biosafety) must be obtained before funding will be released. In addition, PIs will be expected to serve as a member of the joint College of Medicine/College of Engineering Collaborative Research Review Committee in future years, upon request.

J. Questions

Questions regarding the guidelines or eligibility for this funding opportunity, application format or the submission, review and award process should be directed to Research Development at the College of Medicine: ResearchDevelopment@pennstatehealth.psu.edu

Appendix 1: Consideration when Creating a Commercialization Plan

Describe the clinical/medical unmet need this technology addresses/solves.
What is the market size of the unmet need? How common is this problem?
What is the current standard of care? Are there existing companies that offer a solution to address the unmet need? If so, what solutions do they offer?
Compare this technology to current standard of care/market solutions. Does this technology address weaknesses of current solutions?
Has this technology been disclosed to Penn State's Office of Technology Management?
Have you worked with industry related to this technology?

Please direct any questions or interest in receiving assistance with your commercialization plan to Penn State's Center for Medical Innovation. Contact Erika Swift, Associate Director, Center for Medical Innovation (eus59@psu.edu).

PSU InfoReady Guidance for Applicants

PLEASE READ THIS BEFORE SUBMITTING A PROPOSAL

In order to submit applications through PSU InfoReady, applicants **must** first login to InfoReady using their Penn State credentials and complete the authentication process through Penn State University's Single Sign-On (SSO) *at least one time prior to submission*. InfoReady requires this one-time log in/SSO process to authenticate applicants as affiliates of Penn State. Once authenticated, applicants have the ability to submit a proposal on their own OR to designate a proxy who can submit proposals on their behalf. All users are reminded to use only PSU email accounts (e.g. jlg174@psu.edu) when using PSU InfoReady. PSU InfoReady does not recognize applicant submissions associated with other email domains.

Designating a Proxy

Proxy submitters are individuals designated by the PI to submit a proposal on their behalf. Typically, a proxy is a department research administrator that supported the applicant's submission. InfoReady provides step-by-step Instructions for Designating a Proxy. Both the proxy and applicant will receive all competition notifications.

Save as Draft

InfoReady allows users to Save as Draft and return later to complete an application. Access your draft applications through the Applications tab on the home navigation bar. Clicking 'Apply' more than once for a particular opportunity may create multiple submissions in the competition. Delete any old or duplicate drafts by clicking the trash can icon to the right of the desired application.

Editing a Submitted Application

Prior to the submission deadline, InfoReady administrators are able to return applications to applicants for edits. There is no need to start a new application. Please contact Research Development at the College of Medicine (ResearchDevelopment@pennstatehealth.psu.edu) if you need to recall a submitted application. The applicant and/or proxy submitter will receive an email notification with a link to the application, which will return to draft status in the Applications tab. The applicant will be able to make edits and re-submit. Once the submission deadline has passed, only an InfoReady administrator can make edits to a submitted application.

Questions or Concerns? If applicants or administrators encounter any technical issues with InfoReady, they are encouraged to submit a ticket for technical support by emailing InfoReady at support@inforeadycorp.com. InfoReady's support team is available from 8:00 a.m. – 7:30 p.m. (EST) and is very responsive. Research Development at the College of Medicine is also available to provide technical support. To connect with Research Development, please email ResearchDevelopment@pennstatehealth.psu.edu.