





REQUEST FOR APPLICATIONS

Grace Woodward Grants

For Collaborative Research in Engineering and Medicine (2-10-2021)

Register Intent to Submit an Application by: Noon, March 12, 2021 Application Receipt Date: Noon, March 26, 2021

A. <u>Background:</u> The Dean of the College of Engineering and the Senior Vice President for Health Affairs and Dean, 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 2021, proposals in the areas of artificial intelligence and/or biodevices are particularly encouraged.

B. Eligibility Criteria:

- 1. All proposals must include two substantially invested Co-PIs who work together to draft and revise the proposal.
- 2. One of the two Co-Principal Investigators (Co-PIs) of an application to this program 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.
- 3. One of the two Co-Principal Investigators (Co-PIs) of an application to this program 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.
- 4. Additional investigators from these and other campuses/colleges are eligible to participate as coinvestigators.
- 5. 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.
- 6. Investigators who are **currently** serving as a PI or 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.

7. An investigator may serve as a PI or Co-PI on <u>one</u> Grace Woodward Grant <u>or</u> Center for Biodevices Seed Grant application.

C. <u>Program Guidelines:</u>

- 1. New proposals as well as revised versions of previously unfunded proposals to this program will be considered. Applicants may request up to \$50,000 direct costs to be spent over a period of up to 2 years for:
 - a. Fundamental Research (to generate preliminary data for co-author publications and external grant submissions)
 - Applied Research (demonstrate feasibility or develop a prototype of a new medical device, diagnostic, instrument or other diagnostic or therapeutic modality that will become attractive for commercial development)

Partners submitting applications in either of these two categories may include either clinical science or basic science faculty members at the College of Medicine.

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, at eswift@pennstatehealth.psu.edu.

- 2. Although no minimum percent effort is required for the Co-Principal Investigators, the effort that they and others plan to devote to the project must be specified in the application. Each Co-PI may charge the grant for a maximum of 10% effort. Should a PI's full salary exceed the NIH cap, the anticipated percent effort should be indicated and budgeted to reflect the current NIH cap.
- 3. Funds may also be requested for student stipends and tuition, research staff, postdoctoral fellows, small equipment, materials/supplies, and expenses related to the involvement of human subjects.
- 4. 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.
- 5. Each application must include <u>separate</u> 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 <u>equal</u> 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.
- 6. Co-Principal Investigators of Grace Woodward Grants must also agree to: 1) present a progress report for their project at the Center for Biodevices Outcomes Day in September, 2021; 2) submit a final written progress report within 60 days of completing the project; and 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.** <u>Identification of Collaborators:</u> 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 (<u>mxf36@psu.edu</u>) or Dr. Sarah Bronson at the College of Medicine (<u>skb8@psu.edu</u>) for information and assistance.
- E. <u>Register Intent to Submit:</u> Investigators planning to submit an application in response to this RFA should register their intent via email <u>researchdevelopment@pennstatehealth.psu.edu</u> on or before **Friday, March 12, 2021.** Registration should include (1) the names, departments and colleges of the Co-PIs; (2) a descriptive title of the application; and (3) a summary of the objective, specific aims and health-relatedness of the project. **Please include "Grace Woodward Collaborative" in the subject line.**
- **F. Review Process:** Applications will undergo a review for scientific and technical merit by a joint College of Medicine/College of Engineering Collaborative Research Review Committee that will consider the responsiveness of the proposal to this RFA and evaluate the scientific and technical merit of the proposal using the NIH review criteria and scoring metric. In this regard, the Committee will evaluate the significance, investigators, innovation, approach and environment and any additional criteria that are relevant to each proposal including 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 identify changes in study design and methodology that would strengthen each proposal and these recommendations will be returned to the applicant with the reviewer's critique at the conclusion of the review process. The Review Committee will make its recommendations through the Director, Research Development 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 who will make all final decisions regarding awards.
- **G.** <u>Awards:</u> Contingent upon the receipt of meritorious applications, two awards will be announced on or about June 1, 2021 in response to this RFA. The anticipated start date for these awards is September 1, 2021. 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.
- **H.** <u>Additional Information:</u> Any questions regarding this RFA may be referred to Research Development (Email researchdevelopment@pennstatehealth.psu.edu).

INSTRUCTIONS FOR APPLICANTS

Grace Woodward Grants

For Collaborative Research in Engineering and Medicine
Applicants must use the following format

STEP 1 – Prepare the Grace Woodward Grant as a single PDF with the filename *PILastname.pdf*. The final PDF should include all of the information listed below in the order indicated:

- 1. Cover Page: Complete the attached cover page.
- 2. Table of Contents: Include page numbers starting with the cover page and 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. Introduction:** For **revised applications only,** to address previous reviewer comments (1 page).
- **5. Program Goals:** Identify the goal of the program as either (1) establishment of a new line of research that will likely lead to extramural funding, or (2) 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: The Research Plan** should not exceed **5 pages single-spaced** including figures and tables, using 11 pt. font and should be organized as follows:
 - **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; and
 - 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 of the application 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. COE faculty should work directly with the Engineering Research Office. Indicate any cost-share from local departments, research centers, or university consortia. No indirect costs are to be recovered from these funds. The budget period should be 9/1/2021 through either 8/31/2022 or 8/31/2023. There will be no need to initiate an IAF.

- **11.** Budget Justification: Provide a <u>separate</u> 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 Biosketches for both Co-Principal Investigators and all Collaborating Investigators. (Use short NSF or the current NIH format. For template and examples go to https://grants.nih.gov/grants/forms/biosketch.htm.
- **13. List Other Support:** Include all active and pending support for both Co-Principal Investigators. <u>Indicate clearly whether each project listed does or does not overlap with this application</u> and explain the nature of any overlap.
- **14. Future Plans:** 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 feasibility/prototype projects, describe the most probable licensee, plan for commercialization, and summary of 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 projects only:

- a. **Development Plan:** (2 pages) Describe the scope of work with supporting technical details, including any compliance considerations, and clear milestones.
- b. **Commercialization Plan**: (1 page) Provide a brief business plan describing the overall strategy to commercialize the technology both during and after the funding period.

STEP 2 – Submit the application before Noon, March 26, 2021 at https://psu.infoready4.com/#competitionDetail/1833836.

Please refer any questions regarding these instructions to researchdevelopment@pennstatehealth.psu.edu.

Appendix 1: Thoughts to Consider 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?

<u>Please direct any questions or interest in receiving assistance with your commercialization plan to Penn State's</u> <u>Center for Medical Innovation.</u> <u>Contact: Erika Swift at eus59@psu.edu or 717-531-3029.</u>







Title of Application:

(Should not exceed 81 characters) Please indicate the following: New Application Revised Application Please choose one: Fundamental Research Applied Research College of Medicine Co-PI Information: Name and Degree: Phone: Phone: Phone: Title and Degree: Phone: Phon

List all other investigators or collaborators including name, degree and department:

Funding Requested in this application (Direct Costs): ______Please provide the following information:

Are animals or animal-derived tissues being used in this study? \Box Yes \Box No
If yes, has the protocol been approved by the IACUC? \Box Yes \Box No
If yes, provide approval date:
IACUC Protocol#:
Are human subjects, human-specimens or human data part of this study? □Yes □No
If yes, has the protocol been approved by the IRB? \Box Yes \Box No \Box Determined to be Exempt
If yes, provide approval date:
IRB Protocol#:
Are Recombinant DNA Techniques/Biohazards used in this study? □Yes □No
If yes, has the protocol been approved by the Biological Safety and Recombinant DNA Committee?
□Yes □No
If yes, provide approval date:
rDNA Protocol#:
Are core facilities being used in this study? □Yes □No
If yes, provide details: