REQUEST FOR APPLICATIONS

Center for Biodevices Seed Grant Program

Released February 10, 2021

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

Overview:

Applications are sought for the Center for Biodevices (CfB) Seed Grant Program to support genuine collaborations among engineers, scientists, and clinicians. Applications should focus on biodevices to improve human and/or animal health such as implantable, surgical, wearable devices, and sensing/diagnostic devices. Seed grants will provide teams with funds to establish collaborations, generate preliminary data for external grant submissions, and co-author publications. Projects with relevant industry collaboration/partnership are particularly encouraged.

Eligibility Criteria:

1. Each application must have at least two Penn State faculty members at the rank of Assistant Professor, Associate Professor, or Professor with **primary appointments in at least two different colleges or campuses.**
2. The proposed research should be performed at one or more Penn State campuses.
3. An investigator may serve as a PI or Co-PI on **one** CfB Biodevices Seed Grant or **one** Grace Woodward Grant application.
4. Investigators who are currently serving as a PI or Co-PI of an active CfB Seed Grant or Grace Woodward Grant are **not** eligible to submit an application in response to this RFA.

Program Guidelines:

1. CfB seed grants will provide teams with funds for fundamental or applied research focused on biodevices to improve human/animal health such as implantable, surgical, wearable devices, and sensing/diagnostic devices. Relevant topics include, but are not limited to, novel materials for biomedical sensing, enabling technologies for new orthopaedic implants, advanced surgical instruments, acoustic diagnostic or therapeutic modalities, and other emerging medical device-related areas.
    a. Projects focused on **fundamental research** should describe the proposed fundamental research and how it is expected to lead to discoveries in biodevices. Seed grants will provide teams with funds to generate preliminary data for external grant submissions and co-authored publications. Applications must include a specific plan for submitting

external grant application(s), noting how preliminary data for such application will be generated by the seed grant project.

b. 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, eswift@pennstatehealth.psu.edu.

2. Projects with industry collaboration/partnership are particularly encouraged. A letter of support that describes the organization's interest in the proposed research, and the extent of the involvement and contributions of the industry partner, is expected for projects with industry participation. Examples of industry involvement include, but are not limited to, in-kind contributions for technical support, use of equipment, and donations of materials or supplies. CfB seed grant funds are to be used for PSU research only; no grant funds may be used to support any industry involvement.

3. Grants may be used to support salaries and fringe benefits for staff and fixed-term faculty, student stipends and tuition, supplies, equipment, expenses related to the use of human subjects, costs associated with collaborative publications and travel expenses directly related to the conduct of the research program. Applicants are reminded that the committed effort must be appropriate for the scope of the project and the work to be performed. However, it is anticipated that PIs who have fixed term faculty appointments would generally not request more than 5% effort. **Salary for standing faculty members may not be included in the budget**; any effort required by standing faculty members at the College of Medicine should be acknowledged as unfunded research in the letter from the department head/chair and would not be expected to exceed 2%.

4. Project budgets of up to $80,000 direct costs will be considered. **The specific aims proposed in the application must be achievable within 12 months using the funds provided.**

Instructions for Applicants:

Prepare the application as a **single PDF file** (single space, 11 pt Arial, with 1" margins) with the filename *PILastname.pdf*. The final PDF file should include all the information listed below in the order indicated:

1. **Cover page:** Please use the attached cover page template**.**
2. **Table of Contents:** Include page numbers starting with the cover page and numbering all pages consecutively.
3. **Abstract:** Summary of the research plan highlighting its impact on the understanding and/or use of biodevices. (1 page maximum)
4. **Specific Aims** (1 page maximum)
5. **Research Plan:** (6 page maximum) must include the following**:**

- **Significance:** describe the problem that the proposal will address and its significance in the field of biodevices;
- **Approach:** describe the approach that you propose to use and its innovation;
- **Impact:** describe the possible outcomes of the research and their expected impact;
- **Investigator(s):** describe why the team is qualified to implement the project;
- **Environment**: describe the unique facilities and resources available for this research;
- **Compliance:** describe aspects requiring human subjects, animal or biohazard oversight, including the status of any required approvals.

6. **Future Plans** (1 page maximum): Identify the specific externally sponsored funding opportunity(ies) that you will pursue upon the completion of the proposed project, including the funding agency, mechanism, and planned submission dates where appropriate.
7. **References** (1 page maximum)
8. **Budget and Justification:** Prepare a budget in SIMS for each college (up to $80,000 total combined direct costs) and include a detailed 1-page justification for each budget.
9. **Biosketches:** Include a current NIH or NSF biosketch (5-page format) for the Co-PIs and all other key personnel.
10. **Letters of Support:**
    a. For each Co-PI and all other key personnel at the College of Medicine who will participate in the project but cannot (per RFA guidelines) receive salary support from this award, a letter from the Department Chair/Head or Institute Director is required confirming salary support up to 2%.
    b. For projects that include industry collaboration, provide a letter of support from the industry partner describing their interest, involvement, and contributions to the proposed effort.
11. **For Applied Research projects only**:
    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.

Register Intent to Submit:

Investigators planning to submit an application in response to this RFA should register their intent via email to researchdevelopment@pennstatehealth.psu.edu on or before **Friday, March 12, 2021.** Registration should include: (1) the names, departments, and colleges of all personnel involved in the project; (2) a descriptive title of the application; and (3) a brief summary of the objectives, specific aims, and health-relatedness of the project. **Please include "CfB Seed Grant" in the subject line.**

Submission:

Submit the full application before Noon, March 26, 2021 at **https://psu.inforeadv4.com/#competitionDetail/1833797.**

Review, Selection and Award:

Applications will undergo a review for scientific and technical merit by the Center for Biodevices review committee that will consider the responsiveness of the application to this RFA and evaluate the scientific and technical merit (and commercial merit for applied research projects) 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, as well as the relevance to the mission of the Center for Biodevices, and the potential for the project to subsequently attract significant external research support. In addition, the review committee will be asked to identify changes in study design and methodology that would strengthen each application and these recommendations will be returned to the applicant with the reviewers' critiques at the conclusion of the review process. The review committee will make its recommendations to the Deans of the Colleges of Engineering and Medicine, as well as the Directors of the Huck Institutes for Life Sciences and Materials Research Institute, who will make all final decisions regarding awards.

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 will depend upon the funding source, but not before September 1, 2021. Awardees may 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.

Research compliance approvals – IRB, IACUC, Biosafety approvals 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.

Please direct any questions regarding this announcement to Dr. Mary Frecker at mxf36@psu.edu or Research Development at 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?

COVER PAGE

Center for Biodevices Seed Grant Program Application

Please choose one: ☐**Fundamental Research** ☐**Applied Research**

Project Title:

Corresponding Co-PI Information:

Name and Degree: _____

Title and Department: _____

E-mail: _____ Phone: _____

Other Co-PI Information:

Name and Degree: _____

Title and Department: _____

E-mail: _____ Phone: _____

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

Funding Requested in this application: _____

Please provide the following information:

Are **animals or animal-derived tissues** being used in this study? ☐Yes ☐No

If yes, has the protocol been approved by the IACUC? ☐Yes ☐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? ☐Yes ☐No ☐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: