SOUTH DAKOTA STATE UNIVERSITY

Haarberg 3D Research Center

Pilot Grant RFP- 2023

1.0. Purpose

In 2021, South Dakota State University has received funding from the Board of Regents to establish the Center for Drug, Disease and Delivery (3D). Earlier this year, the center received an estate gift from the Haarberg's family and the 3D center was named after the benefactor. The primary objective of the Haarberg 3D research center is to develop an integrated drug, disease, and delivery (3D) framework and build academic-industry-clinical partnerships for advancing commercialization of technologies related to human and animal health. The goals of the 3D center are:

- Development and translation of new treatments for cancer and other diseases in humans and animals.
- Development of new IP/technologies for human and animal health.
- Foster entrepreneurship and strengthen the biomedical/pharmaceutical workforce in the state.

To this end, the 3D center invites applications for pilot grant applications from biomedical researchers in the state. The purpose of this grant funding mechanism is to support research in the state regental institutions to develop new biomedical technologies/approaches through interdisciplinary research collaboration with academic, industry and/or clinical partners. The funding for the pilot research grant is limited to **$100,000**. Funding can be requested for up to one year. The number of grants awarded will depend on the number of meritorious applications received and the available budget. The applications are due by **Nov 30, 2022**.

2.0. Objectives and Focus Areas

Consistent with the objectives of the 3D center, the goals of this grant funding mechanism are to:

- Promote interdisciplinary research collaborations
- Build partnerships with industry and/or clinical researchers
- Advance research commercialization and entrepreneurship
- Leverage 3D center resources/expertise to advance research projects

Funding can be requested to support projects that fit one or more of the following categories:

- Proof-of-concept studies.
- Prototype development.
- Regulatory preclinical studies to support research commercialization.
- Generate preliminary data to compete for a larger grant.
- Market analysis and customer identification.

- Develop industry and/or clinical collaborations.
- Other activities that support the goals of the 3D center.

The proposed research should fit within one or more of the 3Ds (Drug, Disease and Delivery) for human or animal health applications.

Drug: Develop new chemical or biological agents or repurpose existing drugs through chemical or biological approaches including structural analogs, salts, active metabolites, etc. for human or veterinary applications.

Disease: Identify new disease pathways/targets for biomarker/drug development and/or repurpose existing drugs/biologics for new indications through computational modeling, bioinformatics, pre-clinical and clinical validation etc. for human or veterinary applications.

Delivery: Develop formulations or delivery systems for new drugs/biologics or repurpose existing drugs/biologics using new delivery technologies or alternate routes of drug administration to improve efficacy and reduce side effects.

Priority will be given to applications that meet one or more of the following criteria.

- Inter-institutional and inter-disciplinary collaborations (academic, clinical and industry collaborations).
- Projects that fit within one or more of the research cores in the 3D center
    - Drug design and development
    - Drug Repurposing
    - In-vitro models for Drug testing
    - Cancer immunology and immunotherapy
    - Vaccine development
    - Drug delivery systems
- Research areas that are of interest to the local animal health companies including non-invasive delivery systems, vaccines, chemotherapeutic agents, immunotherapeutic agents, antibiotics, pain medications and anti-inflammatory agents.
- Principal Investigators who have not received significant funding (>$50,000) from the 3D center.

3.0. Eligibility & Guidelines

- Eligibility as a lead institution is open to any South Dakota Regental institution collaborating with academic, industry and/or clinical partners interested in advancing research commercialization and economic development within South Dakota.
- The lead Principal Investigator should be a researcher at one of the regental institutions in the state.
- Co-PIs from non-regental institutions, industry or clinical partners are allowed, but the contact PI should be from one of the regental institutions in the state.
- Only one application per Principal Investigator is allowed. However, the investigator can serve as a co-investigator or co-PI in other grant applications.
- Projects should fit with the goals of the 3D center (drug, disease and/or delivery) for human and/or animal health applications.
- Projects that build on existing IP or have the potential to generate new IP.
- Projects that can readily obtain new preliminary data or complement the existing preliminary data to compete for external funding.
- Projects that build on existing collaborations or develop new collaborations with academic, industry and/or clinical research institutions.
- The lead/contact PI is responsible for overall in-charge of the project, securing institutional approval and complying with the institutional policies related to ethical conduct of research, human/animal research, publications, and IP.

4.0. Exclusions & Restrictions

- F&A cost is not allowed.
- Purchase of major equipment (>$5000) is not allowed.
- The total budget cannot exceed $100,000.
- Ongoing funded projects are not eligible for this program.
- Clinical trials or human studies are not allowed.
- Patent costs are not allowed.

Required Proposal Format (should be submitted electronically as a single pdf file)

1. **Cover Sheet (Limit to 1 page):** Use the template in the attached application form.

If applicable, the PI should include the name of the academic/industry/clinical collaborators. The contact PI's signature is required for submitting the application. **Applications that do not have the lead/contact PI's signature will be returned without review.** Electronic signature is acceptable. It is the responsibility of the PI to rout the application and comply with the institutional policies.

2. Project Description (Limit to 2 pages): Organize the Project description in the specified order using the instructions provided below. Start each section with the appropriate section

heading. Preliminary data is not required but allowed. Cite relevant published work and list the references in section 4.

A. Specific Aims

State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel technology, solve a specific problem, address a market need, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field/market/clinical practice.

B. Significance

Explain the importance of the problem or critical barrier to progress in the field/market/clinical practice that the proposed project addresses. Explain how the proposed project will improve scientific knowledge, technical capability, and /or address an unmet need in one or more broad fields.

C. Innovation

Describe any novel concept, technology, methodologies, or interventions to be developed or used, and any advantage over existing methodologies, technologies, or interventions.

D. Approach

Describe the overall strategy, methodology, timeline, and analyses to be used to accomplish the specific aims of the project. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. If human specimens or vertebrate animals are used, it is the PI's responsibility to obtain necessary institutional approvals before starting the study.

E. Commercialization potential

Proposals must describe a compelling market opportunity to be enabled by the proposed innovation. The information should convey the scope and nature of the market opportunity. This section should briefly describe the current as well as the anticipated market landscape related to the opportunity. Also, briefly discuss the critical milestones to be met to get the product to market.

F. Potential for external Funding

Discuss how the proposal meets one or more of the program objectives. Also, address how this project will enhance the potential for external funding. Discuss the anticipated timeline for submission of the grant application, granting agency/institute and funding mechanism (i.e., SBIR/STTR grant applications, industry funding etc.). For projects that have been previously submitted for grant funding, the proposal should address the reviewers' comments of the past submission including how this funding will help address reviewers' comments.

3. Budget (use the template in the application form (Limit to 2 pages)

Complete the table in the application package and provide a detailed budget justification with respect to the proposed project (see the application form). If applicable, describe how other funds

will contribute to this project. The budget should not exceed **$100,000 (direct costs)** and should reflect the actual needs of the proposed project. The maximum budgeted project period should not exceed one year.

Allowable Costs: laboratory costs, including animal costs and related shipping and maintenance costs, tissues, cell culture, chemical and reagent costs, supplies; equipment user fees; miscellaneous supplies; external consultant costs and services. Salary support for PI, co-investigators, senior personnel, post-docs, graduate, and undergraduate students can be requested. Follow institutional guidelines for calculating the number of hours and hourly rate for graduate/undergraduate research assistants including insurance, benefits, and other associated costs.

Unallowable Costs: F&A costs, purchase of capital equipment, patent costs.

4. References Cited (1-page limit): Provide a list of references cited in the section 2. Follow scholarly practices in providing citations for source materials relied upon in preparing any section of the application

5. Biographical Sketches (include in the Appendix) (Limit: 2 pages per person)
NIH-style biographical sketches must be included for the PI and key personnel, where applicable. The biographical sketch may not exceed two pages per person; this limit includes the table at the top of the first page. Biographical sketches should be included as Appendix in the application package (use the template provided in the application form).

6. Letters of Support (**include in the Appendix**). Letters of support from academic, industry or clinical partners that indicate their commitment of expertise, equipment, time, funding, etc. must be included as appendices.

Evaluation

The center steering committee members will review the proposals. Any conflict of interest in the review will be handled appropriately by the steering committee. If needed, other external reviewers will be utilized for the review. The reviewers will be asked to score the application based on NIH review criteria. Reviewers will be asked to consider each of the six review criteria below in the determination of scientific and technical merit and score the applications (scale of 1-10) using the following NIH review criteria. The reviewers will also be asked to provide strengths and weakness for each of the review criteria. If needed, the applicants will be invited to make a brief presentation to the steering committee. The steering committee will make recommendations to the center Director.

Significance: Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?

Investigator(s): Are the PIs, collaborators, and other researchers well suited to the project based on their training, experience, and track record? If the project is collaborative, do the investigators have complementary and integrated expertise?

Innovation: Are the concepts, approaches or methodologies, technologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches, technologies, or methodologies, instrumentation, or interventions proposed?

Approach: Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?

Commercialization potential: Does the outcome of the proposed activity lead to a marketable product or process? Has the proposer evaluated the competitive advantage of this technology vs. alternate technologies that can meet the same market needs, how well is the proposed activity positioned to attract further funding from federal, industry, and other sources.

Fit with the center priorities (unscored): Does the project fit with one or more criteria for priority funding listed in section 2 of the RFP.

Overall Impact: Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s)/clinical practice/market(s) involved and the potential for external funding.

Scoring Scale

Overall Impact or Criterion Strength	Score	Descriptor
High	1	Exceptional
	2	Outstanding
	3	Excellent
Medium	4	Very Good
	5	Good
	6	Satisfactory
Low	7	Fair
	8	Marginal
	9	Poor

Responsibility of the Grant Recipient:

Acceptance of support from this fund carries an obligation to submit a grant proposal for external funding within a year of receiving the exploratory grant. In addition, the recipient is expected to acknowledge the scholarly output (e.g., a manuscript for publication, or presentation in scientific

conference/meetings, IP). The grant recipient must submit a report to the center director at the conclusion of the grant. The report (**limited to 2 pages**) should contain the following:

A. Proposed aims and objectives
B. Outcomes from the project
   -External Grant(s) application status (preparation, submitted or reviewed)
   -Patent applications submitted if any
   -Publications/Presentations
   -Industry/clinical partnerships
   -Licensing
   -Students trained

Proposal preparation and submission:

The attached application form should be used to prepare the proposal and follow the guidelines provided below:

Font: Use an Arial, Times New Roman Helvetica, Palatino Linotype, or Georgia typeface; a black font color; and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters. Figures and tables may be used but must fall within the appropriate margins).

Paper Size: Use standard paper size (8 1/2" by 11).

Margins: Use at least one-half inch margins (top, bottom, left, and right) for all pages.

Headers & Footers: Use the headers and footers provided. Insert the Principal Investigator's name (Last, First, MI) in the top left margin.

A **single pdf file** of the proposal must be submitted through email to Dr. Om Perumal, (omathanu.perumal@sdstate.edu), Center Director.

Proposals must be received by:

5:00 PM CST on Nov 30th, 2022

Earliest anticipated project start date is **Jan/Feb 2023.**