

**IDEA Grants: Therapeutics
Request for Applications
2021-2022 Funding Cycle**

RFA Release Date:

OVERVIEW

Innovation Development, Elevation, & Advancement (IDEA) grants are a suite of funding opportunities designed to improve the implementation, translation, and/or scaling potential of MUSC innovations.

IDEA Grants: Therapeutics request for applications (RFA) solicits research grant proposals to develop high impact potential therapeutic and/or diagnostic strategies.

Sponsored by the Office of Innovation and MUSC Foundation for Research Development, IDEA Grants: Therapeutics provide up to \$40,000 in funding to support short-term (six month) projects designed to improve the translation potential of an innovation by moving it to the next developmental milestone(s), thus increasing the likelihood of partnerships, licensing, or implementation.

Example milestones for the IDEA Grants: Therapeutics include, but are not limited to:

- Medicinal chemistry to optimize compounds
- Exploratory toxicology studies
- Validation of a pharmacological target or translational biomarker
- Efficacy studies
- Assay development
- Production

Innovations relying on development of digital or medical device technology are excluded from eligibility, as they are funded under the IDEA Grants: Technology RFA.

This RFA is open to advance **innovations protected by, or protectable by, IP that is assigned or assignable to MUSC pursuant the MUSC IP Policy**. If a patent or patent application is not currently assigned to FRD, a Record of Invention or Disclosure of Copyrightable Work must be on file with FRD at least one month in advance of the application open date.

One project is anticipated to be funded this application cycle.

KEY DATES

Application Opens:	October 1, 2021
Application Due:	November 1, 2021
Notice of Award:	December 6, 2021

PROGRAM ELIGIBILITY

Investigators

- Principle Investigators (PI) may be full-time or part-time faculty at MUSC. Students, residents, fellows and post-docs may only serve as a PI if they have a letter of support from a faculty mentor. Should the PI be a student, resident, fellow or post-doc, the six-month term of the award may not extend past any graduation or contract termination date.
- PI must be a named inventor on the Record of Invention or Disclosure of Copyrightable Work on file at FRD.
- CVs for all investigators are required

Consultants

- Please include consultant(s) names and their roles/duties in the research proposal.

Intellectual Property (IP)

- Supported innovations must be assigned or assignable to MUSC.
- Inter-institutional collaborations resulting in IP assignment to MUSC and one or more other universities are allowed.
- If a patent or patent application is not currently pending through FRD, a Record of Invention or Disclosure of Copyrightable Work must be on file with FRD at least one month in advance of the Application open date, such that the intellectual property potential can be assessed.
- Copies of any consulting agreement and/or MTA related to the innovation or materials used in a proposed study must be provided with the application.
- Innovations licensed or optioned to a startup are eligible for funding, so long as the IP is assigned or assignable to MUSC. Please note that the funds will be given to the MUSC PI as a traditional grant and not to the company.

Proposal Aims

- Fundamental discovery, such as elucidation of novel targets, is not fundable under the gap fund award mechanism. Disease pathways are not patentable substances, even if a novel target is identified, and studies focused on such are not supported. However, studies aiming to understand how a *patentable therapy* modulates a target will strengthen the IP and are eligible for funding.
- Proposals for prototyping of a medical device are encouraged. Detailed drawings of the proposed device must be included in the proposal. The proposal also must include at least one quote for the proposed functioning prototype. If awarded, the PI's role will be to determine the specifications for the prototype. The outsourcing of prototyping will be managed by FRD.
- The aims specified by the application must be distinguishable from those funded by other grants.

BUDGET AND ALLOWABLE COSTS

- **Faculty Salary Support.** Salary and fringe benefits are not allowable budget items for faculty.
- **Effort Reporting.** For federal/institutional compliance purposes, it is PI's responsibility to make sure all the investigators efforts listed in the budget follow their institutional effort policy.
 - Please note that investigators are not required to accommodate their efforts on the project budget. However, they must follow their respective institution's effort policy should they choose to charge the effort to other funding sources.
 - In compliance with the MUSC effort policy, MUSC PIs who plan to charge investigators' efforts to other funding sources will have to provide the appropriate UDAKs during the Just-in-Time period. Please note that "other sponsored projects" or "in-kind support" cannot be used to cover the efforts.
- **Other Personnel Support.** Salary and fringe benefits are allowed for technical support, such as; Research Fellows, Research Assistants/Coordinators, Research Nurses, etc. Please confirm fringe benefit rates on your respective institution's Sponsored Awards Office website.
- **Students.** The Innovation Development Award funds cannot be used to cover student tuition, fees or health insurance costs in any way, directly or indirectly as a stipend.
- **Ancillary Personnel.** Salary support for ancillary personnel, such as Mentors, Secretaries, and Administrative Assistants, is not allowed.
- **Non-personnel Research Expenses.** Some allowable expenses are: supplies, equipment (under limited circumstances), animal purchase cost and care, study subject stipends, study subject transportation costs, in- and out-patient care costs, and statistical and computational services including personnel and computer time. All expenses must be directly related to the proposed research.
- **Unallowable costs.** General office supplies and equipment, computers and laptops (unless specifically requested and justified), membership dues and fees, traveling costs to meetings, publication and subscription costs, mailing costs and rent.
- **Facilities & Administrative (Overhead/Indirect) Costs.** Facilities and administrative costs, also known as indirect/overhead costs, are not permitted.
- **Subawards.** Please indicate potential subaward(s) to other institutions clearly on the budget. No signed documents from subaward institution(s) are needed at the time of application submission.
- **Business Manager Responsibilities.** PI's Department/Division Business Manager shall be responsible for all human resource, procurement and reconciliation activities for the funded project account(s).

AWARD DETAILS

- IDEA funding cannot be released until all required regulatory documents have been approved and copies submitted to FRD via a REDCap Survey.
- Please note that the Office of Innovation and FRD will continue to follow longitudinal progress of the technology. Progress reports are due at 3-month intervals while the project is active. Brief annual progress follow-ups are due for 5 years after project.

APPLICATION PROCESS

Application Instructions

The Application consists of five components:

- 1) Each investigator's CV
- 2) Project Summary, 1-page limit
- 3) Budget and Justification: PHS 398format
- 4) Project Proposal, 5-page limit
- 5) Letter(s) of Support

Project Summary (1-page limit)

- Please describe on a single page the need, current state of the art, description of the innovation which is the focus of the application, and the goals for the award

Budget and Justification

- Applicants must use the PHS 398 Form Page 4 (MS WORD version – converted to PDF): Detailed Budget for Initial Budget Period for the budget page and use the Continuation Format Page for the budget justification. Each budget line item must be clearly justified. **Combine your budget and justification into a single PDF file** to submit via the online application. <http://grants.nih.gov/grants/funding/phs398/phs398.html>

Project Proposal (5-page limit, combined into a single PDF file)

- **Specific Aims** - State concisely the goals of the proposed study and summarize the expected outcome(s) including the impact that the results of the proposed study will have on the development of the innovation.
- **Strategy** - Describe how the aims will advance the innovation to the next development milestone, what criteria will be used for determining a successful outcome, and the commercial significance of such criteria. Be sure to explain the roles/duties of each team member. Section must be informative enough for reviewers to understand the proposed study without any supporting documents.
- **Competitive Landscape** - Describe the current competitive landscape status of the innovation to include both direct and indirect product competitors. Investigators must note whether they are aware of any patents covering all or part of their innovation, including patents owned by another university on which the investigator is a named inventor.
- **Future Development Plan** – Provide a description of how the results of this award will be parlayed into additional funding strategies, translation, or implementation into practice.
- **Literature Cited** - Include at the end of the Project Proposal. It is not counted towards the Project Proposal page limit.

Letter(s) of Support

- If the proposed specific aims require support or service from a research core a letter of support must be provided which acknowledges the group's ability to provide said support or service within the award period.

Submission

- Applications are submitted through the REDCap Survey link available on the IDEA Grants website.
- Incomplete or late applications will not be reviewed

REVIEW

Applications will be reviewed by a panel including scientific/technical evaluators, members from an external review board, Office of Innovation leadership, and FRD.

Applications will be assessed to determine the impact that the funding will have on:

- Advancing an innovation to the next developmental milestone
- Impact potential of the innovation
- Attracting additional development funding for the innovation
- Strengthening the related IP
- Allowing a go/no-go decision to be made on future development

Additionally, work proposed in the application will be reviewed for:

- Likely completion of the aims within 6-month timeframe
- Appropriateness of the proposed budget expenditures with respect to the development plan for the innovation

EMAIL QUESTIONS TO

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