

**Duke School of Medicine/Pratt School of Engineering Pilot Research Grant
Request for Applications 2019-2020
Application Deadline: 11:59 PM ET, July 15, 2019**

The Marcus Center for Cellular Cures (MC3) is a joint initiative between Duke's School of Medicine (SOM) and Pratt School of Engineering. The Center seeks to develop transformative clinical therapies using cells, tissues, molecules, genes, and biomaterials to treat diseases and injuries currently lacking effective treatment. The SOM and Pratt are partnering to support inter-institutional collaborative research teams.

Purpose

This pilot program is designed to facilitate collaborative and novel translational research that applies or accelerates discovery into testing in clinical settings and/or optimizes current translational approaches. Projects must demonstrate stakeholder engagement and a high translational potential with a clear path for continued development to move into clinical practice or other applications via subsequent grant support, new company formation, licensing, not-for-profit partnering, or other channels. MC3 is interested in the following types of translational research projects:

- Projects developing new collaborative science teams with investigators from both SOM and Pratt.
- Research that generates translational discoveries using novel cellular therapies to solve unmet clinical needs.
- Research that applies or accelerates discovery into testing in clinical settings.
- Research that optimizes current biomanufacturing methods

Potential areas of concentration are listed below; however, collaborations are not limited to these specified areas.

- Harnessing mechanisms of endogenous repair
- Manufacturing and delivery of cells, tissues, and biomaterials
- Creating non-invasive *in vivo* imaging to monitor cell distribution and function

The MC3 Pilot awards are not meant as bridge funding or as supplementary funding for existing projects. Awards will promote the development of programs that advance translational science aims while also developing or nurturing collaborative scientific teams spanning both institutions. Teams are encouraged to identify areas in the application where students or trainees may be engaged as part of the research team. Pilot awards are only for joint collaborations between SOM and Pratt; investigators external to SOM or Pratt will not receive funds. Requests for no-cost extensions will not be approved.

This funding opportunity is made available thanks to the generous support of the Provost Office.

Key Dates

- Application Submission Deadline: July 15, 2019
- Selection of Awardees: August 31, 2019
- Funding Period: The budget period is for 12 months beginning September 30, 2019 and ending August 31, 2020.

Eligibility

- Proposed projects must involve a lead investigator from either the Duke SOM or Pratt with a secondary or Co-investigator from the other school. Proposals are encouraged from new teams of investigators from different disciplines. Applicants at each institution must have a full-time faculty appointment and have principal investigator status per the specific institution's written policy. ([Duke's Policy](#)). We encourage the inclusion of students and/or post-doctoral trainees in the application.
- More than one proposal may be submitted per SOM or Pratt Faculty member acting as PI, but the faculty member is eligible to receive only one award as PI from this funding mechanism during a given funding cycle.
- Interested investigators who need assistance in identifying collaborators can use Scholars@Duke or contact Duke CTSI (ctsifunding@duke.edu).

Funding

Funding for a total of three \$25,000 1- year awards is available. Funding has been provided by the Office of the Provost of Duke University.

The award is internally funded and does not need to be routed through Office of Research Administration (ORA).

Selection Process and Review Criteria

Applications will be reviewed by a joint SOM/Pratt Study Section. Review criteria will include:

- Significance of the work
- Novelty/innovation of the research idea
- Relevance of the proposed study to translational research consistent with the mission of the Marcus Center
- Applicants are a multidisciplinary team who have not previously published or been awarded grants together in this area of research OR the work represents a significant change of research direction for the collaborators
- Potential for the project to lead to future external funding, or to a commercialization opportunity, or utilization in the clinic
- Soundness of the proposed methods
- Feasibility of accomplishing the stated project goals within the one-year project period
- Level of stake holder engagement
- Trainee/student engagement plan if including trainees/students

Application Procedure

Proposal is submitted via Duke's MyResearchProposal online submission system.

To apply using MyResearchProposal:

- To apply visit <http://bit.ly/myresearchproposal>, click on "Create New User" (or log in if you already have an account). Proposals must be submitted under the Principal Investigator's name.
- A step-by-step user's guide for applying via the MyResearchProposal software is available. Please review this [document](#).
- Enter Access Code 'CTSI' then select the "SOM-Pratt Pilot Research Grant Application 2019 – 2020" funding opportunity and follow the instruction.
- For questions concerning MyResearchProposal passwords or system issues, please contact myresearchproposal@duke.edu or call 919-668-4774.

Applicants will enter general project information via the web-based form:

1. Project title, Brief Description, and Amount Requested
2. Investigator Information: Name, rank, and department
3. General Project Information: Applicants will be asked to answer general questions regarding the project (e.g. clinical need, IRB, IACUC, etc.).

Proposal sections (except the Abstract) will be uploaded as individual PDF files. The application sections are:

- A. **Scientific Abstract:** The abstract summary of the proposal for use by review committee members and Duke CTSI (500-word maximum). This section will be direct entry to the application form.
- B. **Research Plan:** The Research Plan should follow the standard NIH format: Specific Aims, Significance, Innovation, and Approach. Include where applicable clear evidence of how the proposal meets the review criteria. (5-page limit, using 1-inch margins, single line spacing and no font smaller than Arial 11, **Including** any tables or figures. References do not count toward the 5-page limit.)
- C. **Budget with Budget Justification** using PHS 398 Form Pages 4 and 5 (combined into a single PDF without a page limit). Budget Guidelines section below provides more detail on budget preparation. The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested.
- D. **Human and/or Animal Subjects Description:** Institutional Review Board (IRB) or Institutional Animal Care & Use Committee (IACUC) approval is not required prior to submission. Briefly describe any human and/or animal subject issues. If human subjects are involved, provide a description of their involvement and characteristics, specific risks to subjects who participate, and protection against those risks. Describe the sources of materials that will be obtained from human subjects as part of their study participation. Provide assurance that the project will be reviewed and approved by the Duke IRB and comply with HIPAA. If vertebrate animals are to be used, provide a description of the proposed use of the animals in the work outlined and

procedures for ensuring that discomfort, distress, pain, and injury will be limited. Projects involving animal subjects must be reviewed and approved by a Duke IACUC. (no page limit).

- E. **NIH Biosketches** for key members of the research team (as a single PDF) using this [format](#).

Budget Guidelines

Please note the following during budget preparation:

1. The budget period is for 12 months beginning September 30, 2019 and ending August 31, 2020. Up to \$25,000 in direct costs may be requested. Funding will not be available until applicable IRB and or IACUC documentation, if applicable, is provided to MC3.
2. Budget Guidelines
 - a. Grant funds may be budgeted for:
 - i. Salary support for the PI or faculty collaborators
 - ii. Research support personnel
 - iii. Student stipend, **if not** covered by other funding mechanisms. **NOTE: Teams are encouraged to identify areas in the application where students or trainees may be engaged as part of the research team.**
 - iv. Travel necessary to perform the research
 - v. Small equipment, research supplies, and core lab costs (NOTE: Project specific research supplies are allowable; however, supplies that are typically allocable across multiple projects or for lab-wide use are unallowable. See Section B below for additional information).
 - vi. Other purposes deemed necessary for the successful execution of the proposed project
 - b. Grant funds may **not** be budgeted for:
 - i. Capital equipment
 - ii. Meals or travel, including to conferences, except as required to collect data
 - iii. Computers or audiovisual equipment
 - iv. Cell Phones
 - v. Manuscript preparation and submission
 - vi. Subcontracts to other institutions
 - vii. Foreign components, as defined in the NIH Grants Policy Statement.
 - c. Awarded funds must be used to conduct the work proposed. MC3 reserves the right to revoke funding in the event it is determined that funds were not spent in accordance with the approved proposal.

Terms of the Award

- A. Approvals Required Prior to Funding Start Date
 - a. Prior to receiving funds, research involving human subjects must have appropriate approvals from the Duke IRB. If the research includes animals, the appropriate IACUC animal research forms must also be approved before the project's start date. Either an IRB approval letter or an IRB response to a "Determination Whether Research of Similar Activities Require IRB Approval" must be submitted to M prior to funds being released. Human subjects or animal research must be reviewed in accordance with the university's general assurances and HIPAA. In addition, if the research involves human

subjects, all personnel named on the budget page must have certification of training in the protection of human subjects prior to the start of the grant period.

- b. Failure to submit documents in the requested timeframe may result in cancellation of funding.
- B. Project Execution
- a. MC3 staff will work closely with funded teams throughout the grant period to monitor progress and, when necessary, provide assistance. MC3 staff will meet with each team quarterly over the year of funding. A final progress report will be due 3 months after the completion of the grant funding
 - b. All publications, posters and presentations resulting from the work performed with this funding should acknowledge the funding as a “Pilot grant from the Marcus Center for Cellular Cures”.
 - c. Any awardee who leaves his or her position during the funding period should contact MC3 to discuss future plans for the project.
- C. Post-Award Reporting
- a. MC3 expect PIs to report over the lifetime of the work the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations, and patents.