Duke MEDx/Translating Duke Health Pilot Research Grant
Request for Proposals 2018
Application deadline: 11:59pm ET, August 29, 2018

MEDx is pleased to announce a request for proposals for pilot projects that benefit patient health by providing important disease insights, or by developing technologies to aid in disease prevention, diagnosis or treatment. While we encourage applications that **address the major challenges highlighted by the Translating Duke Health initiative and/or current challenges in rehabilitation medicine** all applications will be considered.

I. Purpose

The intent of this RFP is to support pilot studies that lead to disease insights and the development of technologies that benefit patient health through disease prevention, diagnosis, or treatment. Applications are encouraged – but are not required to be – in areas of rehabilitation medicine or the challenges addressed by the Translating Duke Health initiative to include:

- Keeping the Heart Young
- Brain Resilience and Repair
- Ending Disease Where it Begins
- Controlling the Immune System
- Solid Tumor Brain Metastases

These proposals should be sized to require a budget of up to $50,000.

Duke MEDx pilot project grants aim to facilitate the formation of new collaborations between faculty in the Schools of Medicine and Engineering. Projects must demonstrate a new collaboration or a novel topic for an existing collaboration between regular faculty in Engineering and Medicine, and a path to subsequent support through grants, not-for-profit partnering, new company formation, licensing, or other channels. These awards are not meant to provide bridge funding or be supplementary funding for existing projects. The awards are up to $50,000 (no faculty effort may be included). The proposed research should be appropriate to the budget and must be accomplished within one year – *no cost extensions will not be granted*. Please note that the research team for each proposal must include two co-principal investigators from the School of Medicine and from the Pratt School of Engineering.

Proposals should describe:

- A cross-disciplinary scientific research question.
- Specific aims
- Research plan to achieve the specific aims
- Future directions and plans for follow-on funding
- Budget and budget justification
- Proposal timeline
- Biosketches for all key personnel

II. Key Dates

- Notify MEDx of Intent to apply: August 15, 2018

- Application Submission Deadline: **August 29, 2018**
- Final Selection: **Late September, 2018**
- Project Planning Run-In Period (if needed): **October, 2018**
- Funding Period: **November 1, 2018 – October 31, 2019**

III. Eligibility

- Proposals must be submitted by Duke regular rank faculty and comply with the Duke University Policy on PI Status in the Duke Faculty Handbook.
- Proposals are encouraged from new teams of investigators or existing collaborators proposing a new research topic.
- More than one proposal may be submitted per faculty member acting as PI, but the faculty member is only eligible to receive one award as PI during a given funding cycle.
- Research teams must include at least one investigator with an appointment in Duke School of Medicine and at least one investigator with an appointment in the Pratt School of Engineering.
- Teams whose proposal to a previous MEDx Pilot Project RFA was not selected for funding may resubmit the proposal if it meets the requirements for this announcement.

IV. Funding

Each award will consist of up to $50,000 with an expected start date of October 1, 2018 and ending on September 30, 2019. No cost extensions are not permitted. Prior to submitting your application, please contact Donna Crenshaw. Once award decisions have been made, your G&C representative will need to contact MEDx to discuss the appropriate place to administratively hold the awarded funds.

Successful applicants must provide a mid-term progress update and a final report indicating progress towards the stated objectives and achieving follow-up funding, any publications that are in progress, and other achievements. These updates will be solicited ahead of each time point. MEDx will also request an update on follow-on achievements for up to two years following completion of the award period.

V. Proposal Preparation

Consultations with members of MEDx leadership are available upon request and are highly recommended. Additionally, investigators may also meet with MEDx leaders at the MEDx Café. All prospective applicants must notify MEDx of their intent to apply. Please email Donna Crenshaw by August 15, 2018 with your intended project topic and collaborators.

VI. Selection Process and Review Criteria

1. Application Submission: A Review Committee comprised of researchers from MEDx, the School of Medicine, and the Pratt School of Engineering will perform a detailed review of the applications. The Review Committee will consider the following criteria when reviewing and scoring applications:
    - Overall impact
    - Significance
    - Innovation
    - Investigators & Collaboration
    - Approach

2. Potential for future funding: The proposed pilot work should collect preliminary data or develop tools that will lead to a competitive proposal submitted to an external funding agency or for funding from an internal source (e.g. the CTSI or Duke Coulter Foundation). It is helpful if the team can elaborate upon opportunities for future funding.
3. Project Planning Run-In Period: The projects selected for funding will undergo a run-in period of up to one month (if needed) to ensure that all requisite preliminary work, including IRB, animal use, and other institutional and NCATS approval are obtained before funding is released.

VII. Application Procedure

Duke MEDx uses the MyResearchProposal online application software to submit applications.

- 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 **'MEDX'** then select the "MEDx Pilot Projects 2018" funding opportunity and follow the instructions.
- For questions concerning MyResearchProposal passwords or system issues, please contact myresearchproposal@duke.edu.

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

1. Project Title
2. Co-Investigators: Name, email address, department
3. Grants & Contracts contact information: name and email address (Note that MEDx will transfer funds to one fund code.)

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

1. Scientific Abstract: The abstract is a summary of the proposal for use by review committee members and Duke MEDx (4,000 characters maximum including letters, spaces, punctuation, special characters. Please include a brief introduction, the aims, and the expected outcomes). Include the project title at the top of this page.
2. Research Proposal (4-page limit, including tables and figures. Use 1-inch margins, single line spacing, and font no smaller than Arial 10. References do not count towards the 4-page limit.) The research proposal should address the following:
    a. Explanation of unmet need and/or scientific significance, and how the proposed research is responsive to the Purpose (see Section I) of this RFP
    b. Specific aims and objectives
    c. Research plan to achieve specific aims and objectives
    d. Future directions (please include likely sources for follow-on funding)
    e. References (please note that references do not count towards the 4-page limit and should be included at the end of the research proposal and assembled as a single PDF)

3. Budget with Budget Justification using PHS 398 Form Pages 4 and 5 (Page 5 is for the Budget Justification section only and you may use more pages as needed. Combine all pages into a single PDF with no page limit).
4. Proposal timeline detailing the project milestones and deliverables
5. Human and/or Animal Subjects: Institutional Review Board (IRB) or Institutional Animal Care & Use Committee (IACUC) approval **is not required prior to submission but will be required prior to funding.** Briefly describe any human and/or animal subject issues. (For example, if human subjects are involved, provide a description of their involvement and characteristics. 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. Projects involving animal subjects must be reviewed and approved by the Duke IACUC. There is no page limit to this section, but it should be as brief as possible.)
6. NIH Biosketches for key members of the research team (as a single PDF).

VIII. Budget Guidelines

Please note the following during budget preparation:

1. The budget period is November 1, 2018 through October 31, 2019. For funds housed within the School of Medicine, a G&A rate will be applied. For funds within fund codes in the Pratt School of Engineering, G&A costs will not be charged.
2. Grant funds may be budgeted for
    - salary support for students (including prorated tuition remission), post-docs and research support personnel. (Salary for research staff and students must reflect actual institutional based rates supplied to you by your grants managers or business office.)
    - travel necessary to perform the research
    - small equipment, subcontracts, research supplies and core lab costs, or
    - other purposes deemed necessary for the successful execution of the proposed project
3. Grant funds may **not** be included in the budget
    - salary support for the PI or faculty collaborators
    - foreign components, as defined in the NIH Grants Policy Statement
    - effort for post-doctoral trainees or fellows that are already on training grant equivalents
    - capital equipment
    - office supplies or communication costs, including printing
    - meals or travel, including to conferences, except as required to collect data
    - professional education or training
    - computers or audiovisual equipment
    - manuscript preparation and submission

Awarded funds must be used to conduct the work proposed. Duke MEDx reserves the right to revoke funding in the event it is determined that funds are not being spent in accordance with the approved proposal without prior notification and approval.

IX. Terms of the Award

A. Approvals Required Prior to Funding Start Date

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. Failure to pursue approval and notify MEDx of the outcome in the requested timeframe may result in cancellation of funding.

B. Project Execution

Investigators agree to submit a brief interim report (6 months after project start), a brief report at the end of the funding period, and a detailed written report 12 months after the conclusion of the funding period that includes applications for or acquisition of follow-on funding, submitted or published presentations, invention disclosures, etc. MEDx may terminate and reallocate residual funds for any team failing to submit required written reports in a timely manner. Proposed aims of funded projects may be changed, added, or deleted during the funding period, pending Investigator and MEDx review and agreement. Projects must complete in the 12-month period; no-cost extensions are discouraged.

Investigators will meet with MEDx during the 2018 project run-in period to review project plans and ensure projects are ready to start by November 1st.

C. Post-Award Reporting

Duke MEDx tracks significant events resulting from the funding. Any significant events should be included in the final project report, and MEDx will contact investigators annually to determine if any significant events have been achieved as a result of this award. Examples include:

- Abstracts/presentations, manuscripts, published guidelines
- Follow-on funding (e.g., grants from government or foundation sources, SBIR/STTR, angel and venture capital investment)
- Milestones achieved in animal models or manufacturing
- Regulatory meetings and filings (e.g., pre-submission meeting, 510K, IDE, IND, BLA, NDA)
- Initiation of clinical studies
- Improved diagnosis or treatment of disease
- Implementation in clinical practice and community
- Translation of models to other geographical areas
- Translation of models to other therapeutic areas
- Clinical outcomes in practice and communities
- Agreements with partners and strategic collaborators to translate the research
- Commercialization (e.g. new intellectual property, license, commercial partnerships, start-up company)
- Direct-to-consumer interactions (e.g. apps)

When requested, all awardees will be expected to provide updates of publications and other successes that originated from the award.

MORE INFORMATION

For additional information on this funding opportunity, please contact Donna Crenshaw, PhD MHA, or Brittany Ploss, MS BSE.