

Duke MEDx – Kaganov Research Initiative in Pulmonary Medicine and Engineering
REQUEST FOR 2018-2019 APPLICATIONS
Application Deadline: 11:59 p.m. ET, October 17, 2018

MEDx is the administrative home of the Kaganov Research Initiative in Pulmonary Medicine and Engineering. This Initiative, supported by a generous gift from Dr. Alan and Mrs. Carol Kaganov, is to build robust collaborations between engineers and physicians to conduct research that focuses directly on or has relevance to lung function and diseases, especially pulmonary fibrosis.

I. Purpose

Successful proposals will receive funding up to \$150,000 (direct costs only) to support novel biomedical, clinical or translational research that achieves the goals of the Kaganov Research Initiative. While we anticipate that the maximum award will be \$150,000, proposal seeking smaller amounts are also welcome. In all cases, the scope of the proposed research must be matched to an appropriately sized and well-justified budget.

Broadly, the Kaganov Research Initiative in Pulmonary Medicine and Engineering focuses **on research on lung function or diseases of the lung, especially pulmonary fibrosis**, with the following priorities:

- To improve our understanding of disease mechanisms,
- enhance diagnosis,
- create more effective treatments, and to
- ultimately find pathways to cure idiopathic pulmonary fibrosis and other lung diseases.

Proposals should describe multidisciplinary scientific research on lung diseases or lung function, and particularly idiopathic pulmonary fibrosis. Research on relevant basic biomedical questions, development of enhanced understanding of disease mechanism, the development of therapies, diagnostics or devices, clinical research/trials (excluding Phase 2 or beyond), epidemiological, and/or community-based studies is within scope. Population health improvement projects should demonstrate significant stakeholder involvement to advance applicability of the results to broader practice patterns, clinical guidelines, and other applications.

A Kaganov Initiative grant application need not have extensive background material or preliminary information. Accordingly, reviewers will be encouraged to focus their evaluations on the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge or understanding of, or the treatment of, lung disease, particularly idiopathic pulmonary fibrosis. Appropriate justification for the proposed work can be provided through literature citations, data from other sources or, when available, from investigator-generated data. Preliminary data are not required but may be included. All applications must demonstrate a clear path to subsequent financial support through grant funding, new company formation, licensing, not-for-profit partnering, or other channels.

II. Key Dates

- Application Submission Deadline: **October 17, 2018**
- Final Selection: November 5, 2018
- Project Planning Run-In Period (if needed): November/December, 2018
- Funding Period: January 1, 2019 - December 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 must represent a collaboration between a faculty member with an appointment in the Pratt School of Engineering and a faculty member with an appointment in the School of Medicine. Applications are encouraged from new teams of investigators and existing collaborators proposing a new research topic.
- The co-PIs cannot have **primary** appointments **in the same School** and priority will be given to applications that include one or both PIs with a primary appointment in Medicine or Pratt.
- Because of the focus of this funding opportunity, the applicants are encouraged to have physicians or scientists with lung disease expertise as part of the collaborative team.
- 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.
- Teams whose proposal to a previous Kaganov Pilot Project RFP 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 \$150,000 (direct costs only) with an expected start date of January 1, 2019 and ending on December 31, 2019. No-cost extensions (carryovers) will not be permitted. Particularly promising projects may be invited to apply for a renewal in the subsequent year.

V. Proposal Preparation

1. Email indication of intent to apply to [Donna Crenshaw](#). We suggest indicating interest and consulting with MEDx Leadership or with a member of the Kaganov Initiative Steering Committee.
2. MEDx recommends involving a biostatistician/bioinformatician early in the application development process and including biostatistical or bioinformatics support in the budget where necessary to ensure success. For investigators without access to a biostatistician, biostatistical support may be obtained through the [Duke CTSI Biostatistics Core](#). The core provides an initial, brief consultation upon request at no cost. For teams requiring bioinformatics or genomic analysis support, contact the [Genomic Analysis and Bioinformatics Core Facility](#), which also provides an initial consultation service at no cost.

VI. 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 to the system by only one of the Principal Investigators.
- A step-by-step user’s guide for applying via the MyResearchProposal software is available - Please review the guide [here](#).
- Enter Access Code ‘**MEDX**’ then select the “**Kaganov Initiative 2018-2019**” 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 & Contract 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).
2. Research Proposal (5-page limit, including tables and figures. Use 1-inch margins, single line spacing, and font no smaller than Arial 11. References do not count towards the 5-page limit.)
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 Request for Proposals
 - b. Table of quarterly milestones to be achieved
 - c. Research plan to achieve milestones
 - i. Include stage of the project/product
 - ii. Include preliminary data if helpful (not required)
 - d. Strategy and plan for follow-on support or translation if that is the logical next step
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. References used in the Research Proposal
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). **PLEASE NOTE** the new NIH Biosketch format as of May 2015 - [click here for details](#).

VII. Budget Guidelines

Please note the following during budget preparation:

1. The budget period is January 1, 2019 through December 31, 2019. No indirect or overhead costs may be included; the awardees receive direct costs only.
2. Grant funds may be budgeted for

- salary support for the PI or faculty collaborators, students, post-docs and research support personnel (Unlike NIH grants, there are no expected minimum efforts for faculty PIs, unless directed by your primary organizational unit. Salary for faculty, research staff, and students must reflect actual institutional based rates supplied to you by your grants managers or business office.)
 - graduate student tuition or tuition remittance
 - 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
 - Projects that will build prototype devices may include purchases of large components. These are allowable expenses and for budget purposes will be listed as equipment (Explain in the budget justification that these are prototype expenses and not capital equipment).
3. Grant funds may **not** be included in the budget
- foreign components, as defined in the NIH Grants Policy Statement
 - effort for post-doctoral trainees or fellows that is 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, or
 - indirect costs (The indirect rate is 0% for all direct costs, including subcontracts. You and/or your grants manager will be responsible for working directly with your subcontractor to obtain a final budget to include with your final budget.)

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 were not spent in accordance with the approved proposal without prior notification and approval.

VIII. Application Review and Post-Award Processes

1. A Review Committee comprised of researchers from the School of Medicine and the 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 – As with NIH reviews, the impact score will reflect the reviewer’s overall evaluation, not an average of individual criterion scores. 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) or on clinical practice. Please consider alignment with the Purpose (see Section I) of this request for proposal.
 - Significance & Innovation – Does the project address an important clinical or scientific problem or a critical barrier to progress in the targeted areas (see Section I: Purpose)? Is there a strong scientific premise for the project? How innovative is the research? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that are relevant to lung diseases, particularly IPF?

- 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?
 - Feasibility – Project scope of work is appropriate for the timeframe and level of funding.
 - Investigators and Collaboration – Are the PIs, collaborators, and other researchers well suited to the project? If in the early stages of independent careers, do they have appropriate experience and training? If established, have the investigators demonstrated an ongoing record of accomplishments that have advanced their field(s)? Do the collaborators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?
2. Project Planning Run-In Period: The projects selected for funding will undergo a run-in period of up to two months (if needed) to ensure that all requisite preliminary work, including IRB, animal use, and any other institutional approvals are obtained before funding is released.

IX. Post-Award Reporting

Duke MEDx tracks significant events resulting from the funding. Any significant events should be included in the quarterly reports, and Duke 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, sponsored research, 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, patent applications, 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.

X. 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 brief written quarterly progress reports, and provide a more detailed report at 12 months that also includes applications for or acquisition of follow-on funding, submitted or published presentations, invention disclosures, etc. Duke 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 Duke MEDx review and agreement. Projects must complete in the 12-month period; no-cost extensions will not be permitted.

Investigators will meet with Duke MEDx during the November 2018 project run-in period to review project plans and ensure projects are ready to start by January 1, 2019.

MORE INFORMATION

For additional information on this funding opportunity, please contact [Donna Crenshaw](#), PhD MHA, or [Brittany Ploss](#), MSc BSE.