Children's Health & Discovery Initiative and MEDx
Pilot Research Grant
Request for Proposals 2018
Application deadline: June 5, 2018

The Children's Health and Discovery Initiative (CHDI) and MEDx are pleased to announce a request for proposals **to develop diagnostics, prognostics, or biomarkers for disease states that initiate early in life, or environmental sampling methods/technologies for exposures that influence childhood and/or life-long health (please see the CHDI website).**
The molecular underpinnings of diseases such as asthma, metabolic syndrome, heart disease, and neuropsychiatric diseases originate in pre- and early postnatal life. These biological processes can be exacerbated by extrinsic factors such as environmental exposures, socio-economic status, and stress, resulting in adult diseases that represent substantial health care and economic burdens. By developing tools to identify risk factors and early disease processes, or to measure environmental exposures and impact on disease progression, we can improve the health and well-being of children and society as a whole.

I. Purpose

The intent of this RFP is to support pilot studies that lead to the development of diagnostics, prognostics, or biomarkers for early life risk factors for disease or biological processes associated with diseases that initiate early in life, or methods/technologies to detect exposures that influence childhood or life-long health. One proposal will be chosen to receive funding of up to $50,000 (direct costs only). The proposed research should be appropriate to the budget and should be able to be accomplished within one year. Please note that the research team for each proposal must include two co-principal investigators – one from the School of Medicine and the second from the Pratt School of Engineering.

Proposals should describe:

- A research question or development program centered on diagnostics, prognostics, or biomarkers for risk factors or biological processes associated with diseases that initiate early in life; or methods or technologies to monitor environmental exposures that impact early life or life-long health
- Specific aims and objectives
- Research plan to achieve specific aims and objectives
- Future directions and plans for follow-on funding applications
- Budget and budget justification
- Proposal timeline
- Biosketches for all key personnel

Please note that the research team must include a faculty member with an appointment in Duke School or Medicine and a faculty member from the Pratt School of Engineering.

II. Key Dates

- Application Submission Deadline: **June 5, 2018**

- Final Selection: **July, 2018**
- Project Planning Run-In Period (if needed): **August-September, 2018**
- Funding Period: **September 1, 2018 – August 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.
- 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

IV. Funding

Each award will consist of up to $50,000 (direct costs only) with an expected start date of September 1, 2018 and ending on August 31, 2019.

V. Proposal Preparation

1. Email indication of Intent to Apply addressed to Jillian Hurst and Donna Crenshaw (Optional).
2. Consultations with members of the CHDI or MEDx leadership groups are available upon request and are highly recommended. Additionally, investigators may also meet with CHDI and MEDx leaders at the MEDx Café.

VI. Selection Process and Review Criteria

1. Application Submission: A Review Committee comprised of researchers from the CHDI and MEDx will perform a detailed review of the applications. The Review Committee will consider the following criteria when reviewing and scoring applications:
    - Overall impact
    - Significance
    - Investigators
    - Innovation
    - Approach
    - Environment
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 Coulter Foundation). It is helpful if the team can elaborate upon opportunities for future funding. All proposals

must specify how data and/or resources generated by the pilot study will contribute to submission of a grant application, including specific funding opportunities.

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

CHDI and MEDx use 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"** and follow the instructions.

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 CHDI/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, CHDI, and 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 (4-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 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 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 September 1, 2018 through August 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 students (including pro rated 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, 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. CHDI 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.

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 CHDI 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. CHDI/MEDxmay 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 CHDI/MEDx review and agreement. Projects must complete in the 12-month period; no-cost extensions are not permitted.

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

C. Post-Award Reporting

CHDI and MEDx track significant events resulting from the funding. Any significant events should be included in the final project report, and CHDI/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 communityß
- 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 Jillian Hurst or Donna Crenshaw.