Translational Innovator Program

Environmental Toxins:

Everyday Exposures - Toxins and Health

Request for Applications (RFA)

Application Due: October 23, 2020 at 5:00 pm EDT

I. Key Dates

RFA Announcement: September 14, 2020
Full Application Due: October 23, 2020
Application Review Completed: late November, 2020
Community Engagement Studios by Select Investigators: January 6-8 2021
Amended proposal submission: February 8, 2021
Proposal Presentations by Select Investigators: early March 2021
Funding Decisions Announced: late March 2021
Anticipated Funding Start Date: April or May 2021

II. Award Amount

Applicants may request awards of up to $50,000, direct costs only, for a period of one year. The actual amount allocated will depend uppon proposal details at the time of the award.

III. Funder Statement

Harvard Catalyst is an NIH/NCATS (National Center for Advancing Translational Sciences) funded, pan-University organization committed to harnessing the human, technological, and fiscal resources of Harvard and its academic healthcare centers to reduce the burden of human illness. Harvard Catalyst Translational Innovator Pilot Grants are similarly directed to improving human health in its broadest terms.

IV. Overview & Goals

This pilot grant opportunity will focus on the effects of environmental toxins on human health. Environmental toxins are frequently, but not exclusively, derived from human activity and may be present in the air, water, land, food, or manufactured products in concentrations affecting human health. For example, a recent SCIENCE review, “Exposome & Health” (367:392-6 (2020)”, captures the diversity and range of exposures to a
variety of stimuli, including synthetic chemicals, dietary constituents and increasingly recognized environmental provocations including noise and temperature, as well as their corresponding biological responses. The impact of local air quality, as assessed by concentrations of particulates, has recently been defined as a very significant contributor to increased mortality from COVID-19. We strive to fund innovative translational research proposals that address unmet human health needs that are outside of currently funded research work or that extend such work into novel applications.

Pilot Grant Proposals may focus on a variety of environmental toxin concepts, including, but not limited to, the following:

- Diagnostic technologies;
- Biomarkers for disease detection, disease progression, or clinical response;
- Preventative or therapeutic treatment modalities;
- Metabolism;
- Educational methodologies;
- Associated disease causation;
- Health disparities;
- Toxin remediation;
- Public policy and;
- Environmental or architectural design

Areas of inquiry should focus on translational research and human health. Proposals requiring the use of non-human samples/models will only be considered if there is a clear and direct link to subsequent investigation of some aspect of human health. Proposals investigating basic research questions or those solely limited to pre-clinical applications will not be considered.

Investigators from any field are encouraged to apply.

V. Eligibility
This is an open call for proposals. Any principal investigator with an innovative idea related to the purpose of this RFA is welcome to apply.

Principal Investigator (PI) Eligibility
Any faculty member who holds a Harvard University appointment as assistant professor, associate professor, or professor, irrespective of degree or institutional affiliation, is eligible to serve as the PI. Investigators who hold appointments such as lecturer, instructor, or research scientist/associate are eligible to apply as PI if approved by and with the support of their department chair. Investigators at these ranks must provide a letter from their department/division chief as appropriate, verifying their appointment title, status at Harvard, and departmental/divisional support of their application.

Co-Investigator (Co-I) Eligibility
A Co-I is a substantial contributor who helps conceive of the experimental idea, contributes to the intellectual development of the project, and/or designs the study or part thereof (e.g., scientific or technical details), and will be involved in the study throughout the funding year. Co-Is can be from any institution; however, if you are working with a Co-I from a non-Harvard affiliated institution, please provide justification for how their external expertise adds to the project.

Although trainees (e.g., students, clinical trainees, postdoctoral fellows, and clinical fellows), visiting and adjunct faculty, and those with pending faculty appointments at the time of submission cannot serve as the PI on an application, they may serve as Co-Is if they make a substantial contribution to the project.
A Co-I is not required, nor is there a limit to the number of Co-Is that may be listed on an application. While researchers may submit only one application as PI, they may be listed as a Co-I on multiple applications.

This RFA encourages applications from junior or mid-level investigators. For junior investigators, appropriate supervision and mentoring must be provided.

For questions regarding eligibility, see Section IX – Contact Information.

VI. Allowable and Unallowable Costs
- Requests may not exceed $50,000 (direct costs only). Funding allocations will be determined at the time of award and in conjunction with Harvard Catalyst.
- Faculty salary support: Applicants may request faculty salary support for up to 5% effort and in compliance with the NIH salary cap. In unusual circumstances, exceptions to this 5% limit may be granted by Harvard Catalyst if justified. While there is a 5% cap on the amount of salary supported under this pilot award, there is no minimum or maximum for effort committed to the proposed projects, beyond any minimums or maximums which may be imposed by the effort policies of your school/institution. Committed effort in excess of that supported through this award and any salary costs that exceed the NIH salary cap must be cost-shared.
- Other personnel support: Salary and fringe benefits are allowed for other participatory personnel such as research fellows, research assistants, clinical coordinators, research nurses, etc. However, salary support for ancillary personnel, such as mentors, administrative, or grant management staff is not allowed.
- Non-personnel research expenses: All expenses must be directly related to the proposed research and part of the approved budget. Some examples of allowable expenses are supplies, equipment (under limited circumstances; must be specifically requested and justified in the proposal), travel to research meetings if within existing institutional travel guidelines, study subject stipends, study subject transportation costs, and statistical and computational services including personnel and computer time.
- Unallowable costs: General office supplies and equipment, computers and laptops (unless specifically requested and justified), membership dues and fees, subscription costs, mailing costs, rent, and other costs generally identified as facilities and administrative (F&A) are not allowed.
- F&A costs: F&A costs, also known as indirect costs, are not permitted.
- Subcontracts: Pass-through subcontracts for research performed at other sites are not permitted. A separate budget page must be submitted from all sites that are to receive grant funds. Subsequently, Harvard Catalyst will directly award funds to all sites.

VII. Application Submission Information
Please use this application form to submit your proposal.

Note: This form cannot be saved. Please gather the required submission documents (Part 1 and Part 2) ahead of time to prevent data loss. The documents are uploaded when you are ready to submit the entire application.

Paper copies of the application or any other accompanying documentation will not be accepted. All application materials must be submitted via the online process no later than 5:00 pm EDT on October 23, 2020. There will be no exceptions.

The Application
Part 1 – Supporting Documentation (uploaded as one PDF)

Please use this naming convention: PIFirstName_PILastName_Admin_Docs
For each institution that will receive funds, the following forms must be completed:

- PHS 398 Face Page, to be signed by institutional official. One Face Page per site requesting funds. Please remember that each site requesting funds will receive a separate award agreement to provide the funding; pass-through subawards are not allowed.
- PHS 398 Form Page 4: Detailed budget for one year. Refer to Section VI for allowable and unallowable costs. If more than one site will share the budget, the combined total should not exceed $50,000 (direct costs only) and each site is required to submit a separate budget page.
- Narrative Budget Justification from each site requesting funds.
- Statement of Work: A brief statement describing the work to be performed at each institution.
- NIH-style biosketch for the PI, Co-Is and significant collaborators. An eRA Commons ID is requested for all Co-Is.
- Letter from the PI’s department chair/chief verifying appointment title if investigator’s appointment is other than assistant professor, associate professor, or professor (see Section V – Principal Investigator Eligibility).

Project Summary: Include a summary in lay language (250 words maximum). This summary is required as a way of conveying the essence of your proposal briefly and clearly. It should be written in a way that non-academic specialists can understand, free of complex scientific jargon. Lay summaries will be shared with community stakeholders during the review process and help reviewers understand the accessibility and potential impact of the proposal.

Harvard Catalyst is supported by the National Institutes of Health National Center for Advancing Translational Sciences (NIH/NCATS) via the Clinical and Translational Science Award (CTSA) Program. As such, Harvard Catalyst is required to submit documentation based on IRB or IACUC approval (if applicable) for each applicable pilot project that has been recommended for funding. NCATS requires IRB and IACUC approval and all related documentation at least 90 days before the project start date. To accommodate this timeline, we strongly encourage IRB/IACUC submission as soon as possible.

Part 2 – Research Proposal

Please use this naming convention: PIFirstName_PILastName_Scientific

- Scientific Proposal (to be uploaded as a separate PDF): This is limited to 5 pages, not including references. Use Arial, black font color, and a font size of 11 point only. Applications (covering items 1-5 below) should be single-spaced, with 0.5 inch margins. All figures and tables must be included in the body of the application and count towards page limits. Appendix material will not be accepted.

1. **Project Title and Scientific Abstract** (250 words maximum). Clearly state your aim or question addressed in this proposal and its importance to the field of environmental toxins and human health. State how this grant will support achieving this aim.

2. **Overview and Background** (1 page). State the research question or hypothesis to be tested. This overview should summarize why the project is important and innovative, the limitation of current knowledge, and how this problem will be addressed. Briefly state existing work in the field and how the proposed research will advance knowledge beyond the current condition. The overview must clearly state the aims of the proposal and the feasibility of completion within the one-year grant period. Include sufficient background information to provide context for grant reviewers.

3. **Project Details** (3 to 3 ½ pages). Provide specific and detailed information about your proposed
research. Describe any human-derived samples to be used, the availability of these samples, the experimental design, the means of evaluating the data or rendering conclusions, the resource requirements, and timing for the various research steps and overall project completion. Describe any assay, cell models, infrastructure or cores to be used and their availability and readiness for use, the means of evaluating the data or conclusions, the resource requirements, and the timing for the various research steps and overall project completion. For research involving human subjects, describe plans for sampling and recruiting participants.

4. **Future Plans** (1/4 page). Briefly state future aims beyond the scope of this one-year pilot grant if successful and additional resources are available. Limit future plans to an additional one-year period. Briefly outline what additional resources would be required to address these aims. Include plans on how future funding for this work might be obtained.

5. **Dissemination Plans** (1/4 page). One of the core components of Catalyst’s commitment to Community Engagement is to have our awardees think about how they could disseminate the results of their study beyond peer reviewed journals. Briefly state how study findings, would be communicated to and for the benefit of a community audience including stakeholders, relevant institutions, organizations, and individuals.

6. **References** (limit to 1 additional page).

**Part 3 – Confirmation**

Completed submissions will result in an automated email confirmation sent to the submitter and the PI of the application.

**VIII. Review Process –**

Completed applications submitted by 5:00 pm EDT on October 23, 2020, with all required documents, will undergo administrative review. All proposals that are complete and responsive to this RFA will be forwarded for double-blind scientific review by Harvard faculty with both broad and topic specific expertise. Questions that may be considered include, but are not limited to, the following:

- Is the proposal translational and innovative?
- Does the proposed project address an important clinical or societal need related to environmental toxins?
- Is the project technically feasible and achievable in the funding period?
- Do the investigators have the requisite skills and model systems to carry out the project successfully?
- Does a successful project have the potential to benefit human health?

After the scientific review, finalist applications deemed most responsive and with high impact potential will be selected for a required Community Engagement Studio (CES). Although there is no requirement for proposed projects to be performed within a particular community or with the participation of community members, Harvard Catalyst believes it is important for translational researchers to consider the perspectives of those affected by the issues they are studying. A Community Engagement Studio is a guidance session for health researchers to receive feedback from community stakeholders such as practitioners and patients. Community stakeholders serve on expert panels to provide feedback on various aspects of a research project, including the design, intervention, communication materials, recruitment strategies, community dissemination, and application of research findings to practice. These 45-minute sessions are scheduled for January 6-8, 2021 between 9:00am and 5:00pm. PIs and other team members will be invited to provide a 15-minute presentation about their proposal to a panel of community stakeholders with expertise in the areas of environmental toxins, followed by a 30-minute discussion with panelists. The CES panelists will provide feedback on the importance of the research question, study design, recruitment and data collection (if applicable), and the dissemination plan.

Proposals are expected to incorporate the CES suggestions where possible or provide clear rationales for why
suggestions cannot be incorporated. Applicants will receive written feedback from the CES within two weeks of the studio and have two weeks to make these revisions. Finally, applicants will be invited for a final 15-minute presentations to Harvard Catalyst Leadership and invited experts.

Note: Selected grant applicants will receive templated slide decks to assist their development of presentations to the CES and Harvard Catalyst’s leadership team.

Awards will only be announced after all selected teams have made both of the required presentations. All applicants will be notified of the results of their proposal review by March, 2021. Other than the comments from CES, reviewer comments or feedback will not be provided to applicants.

Funding will not commence until:
- Awardee’s institution has signed an agreement with Harvard governing the terms of the funding award.
- Awardees have completed and submitted to Harvard Catalyst materials relating to NCATS’ pre-approval of research involving human subjects. Details on this process will follow upon award notification. After receiving approval from NIH, funding can commence.
- All applicable human and animal use protocols have been approved and approval notifications emailed to reactor@catalyst.harvard.edu.
- A realistic project plan has been developed in consultation with the assigned project manager.

IX. Contact Information
Direct all inquiries regarding the suitability of a proposal, the application process, or eligibility to Harvard Catalyst at: reactor@catalyst.harvard.edu.

Direct inquiries regarding financial or grants management to Emanuel Amaral, Manager of Research and Grants Administration, Harvard Catalyst at: Emanuel_Amaral@hms.harvard.edu.