Translational Innovator Program - Two Pilot Funding Opportunities

Sight & Science: Vision Research from Diverse Fields

Request for Applications (RFA)

Application Due: January 10, 2020 at 5:00 pm EDT

I. Key Dates
RFA Announcement: November 14, 2019
Full Application Due: January 10, 2020 at 5:00 pm EDT
Proposal Presentations by Select Investigators: Midwinter, 2020
Funding Decisions Announced: Late winter, 2020
Anticipated Funding Start Date: Spring, 2020

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 upon 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
Harvard Catalyst is pleased to announce two separate and complementary pilot grant programs to increase our understanding of vision for the benefit of individuals at risk for or experiencing visual compromise. Pilot Program 1 – Harvard Catalyst Opportunity is broad in scope and covers all fields of research related to vision. Pilot Program 2 – an External Funding Opportunity is narrower in scope and covers four specific areas of ophthalmological investigation.

Pilot Program 1 - Harvard Catalyst Opportunity (Multiple Awards Anticipated): Vision-related translational science ranges from investigations of the way in which humans synthesize spatial and descriptive information about our external environment to how these mechanical and signal transduction processes give rise to sight and attempts to improve visual performance under limiting conditions. By its nature, the realm of vision science spans a variety of disparate fields such as physics, neuroscience, physiology, psychology, computer science, engineering, architecture, communication, education and medicine.
Pilot grant proposals should describe innovative projects that, if successful, reveal a path for continued translational research aimed at improving vision health or related capabilities, e.g., clinical proof of concept or small-scale clinical studies.

Proposals may focus on a variety of vision-related concepts, including, but not limited to, the following:

- Diagnostic or prognostic technologies;
- Biomarkers for disease detection, disease progression, or clinical response;
- Therapeutics or treatment modalities;
- Enhanced visual capabilities for health (e.g. night vision) or disease settings;
- Educational methodologies, e.g., for visually impaired individuals;
- Facilitative technologies for the visually impaired;
- Diagnosis, prognosis, or management of retinopathies;
- Health disparities related to visual illness or treatment;
- Vision related components or contributions to neurological disorders (e.g. migraine, epilepsy);
- Vision related Public Policy; and
- Environmental or architectural design fostering visual health or improving use for those with visual impairments.

Areas of inquiry should focus on translational research and human healthcare. 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 vision. Proposals investigating basic research questions or those solely limited to pre-clinical applications will not be considered.

Investigators from any field of vision science are encouraged to apply.

**Pilot Program 2 - External Funding Opportunity (Multiple Awards Anticipated):** The objective of this program is to sponsor innovative projects that will advance treatment solutions limited to the following areas of immediate medical need: (1) light modulation and its impact on neurological disorders such as migraines; (2) progression of myopia in a pediatric population; (3) phacoemulsification and cataract lens extraction; and (4) post-surgical refractive intraocular lens (IOL) enhancement.

Proposals should describe innovative and translational research projects that, if successful, could provide new insights into improving eye health and vision outcomes. Research should be directed toward any of the following areas:

- **The Neuroscience of Light - Moving beyond vision correction through contact lenses.** Can we improve patient health and quality of life by manipulating the intensity and/or select wavelengths of light to help manage medical disorders such as migraines? Opportunities for improving color perception may also be considered.
- **Myopia Control - The prevalence of myopia has soared in recent decades with rates >80% amongst children in China, Singapore and Taiwan whilst also increasing rapidly in western countries.** Amongst the critical areas to tackle include elucidating disease mechanisms & biomarkers, diagnosing/predicting children who may be slow versus rapid progressors and developing novel preventative & treatment modalities to slow or halt myopic progression.
- **Cataract Removal - On an annual basis, over 20 million cataract surgeries are performed globally.** Goal: to identify rapid, low energy cataract break-up and extraction technologies effective across all cataract types (nuclear, cortical, and posterior subcapsular) with reduced intra-operative and post-operative complications.
- **Post-Surgical Refractive IOL Enhancement –** While outcomes from cataract surgery are generally considered good, approximately 35-50% of surgeries do not fall within 0.5D of the intended refractive
target following IOL implantation - resulting in patients requiring additional vision correction (spectacles, contact lenses etc.). Therefore, there is a need for technologies where the optical/refractive properties of the IOL can be modified in a minimally invasive or non-surgical manner to optimize the patients’ visual outcomes.

Please note:
1. Investigators considering a proposal in any of the four areas described in Pilot Program 2 - External Funding Opportunity must contact Harvard Catalyst at reactor@catalyst.harvard.edu to learn more about the objectives of this opportunity.

2. All proposals submitted for the Pilot Program 2 - External Funding Opportunity will also be considered for funding by Pilot Program 1 - Harvard Catalyst Opportunity.

V. Eligibility
This is an open call for proposals. Any principal investigator with an innovative idea in vision science 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 though 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, 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 January 10, 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).

• Abstract: Include an abstract in lay language (250 words maximum).

• 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 Abstract** (250 words maximum). Clearly state your aim or question addressed in this proposal and its importance to the field of vision. State how this grant will support achieving this aim.

2. **Overview and Background** (1 page). State the 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 or cell models used, the status of the assay or model readiness, the means of evaluating the data or conclusions, the resource requirements, and the timing for the various research steps and overall project completion.

4. **Future Plans** (½ 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. **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 January 10, 2020, with all required documents, will undergo administrative review. Those deemed complete and responsive to this RFA will be forwarded for review to a Scientific Review Committee, comprised of Harvard faculty and potentially the CTSA External Reviewer Exchange Consortium (CEREC*), who may consider questions such as, but not limited to, the following:

- Is the proposal translational and innovative?
- Does the proposed project address an important clinical or societal need related to vision?
- 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 vision healthcare?

IX. CEREC
Harvard Catalyst is a member of CEREC, a consortium of NCATS supported institutions whose goal is to improve the scientific review process. Similar to the NIH peer review process, Harvard Catalyst and CEREC are committed to protecting the integrity of peer review. All reviewers must agree to maintain proposal confidentiality before participating in the review process. Before submitting an application, investigators will be asked to acknowledge that proposals may undergo external scientific peer review by faculty members of CEREC.

After scientific review, applications deemed most responsive and with high impact potential will be selected for presentation to the Translational Innovator Management Team. PIs and other team members will be invited to provide a 15-minute presentation about their proposal. Awards will be announced after all invited teams have made their presentations.

All applicants will be notified of the results of the scientific review by late winter, 2020. Reviewer comments or feedback will not be provided to applicants. Applicants selected for funding will also benefit from project management expertise provided by the Translational Innovator Program.

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.