Harvard Catalyst
Pilot Funding Opportunity

Request for Applications (RFA)
Early Clinical Data Support for Grant Submissions

Due: November 20, 2014 at 5:00pm EST

I. Key Dates
RFA Announcement: October 21, 2014
Applications Due: November 20, 2014 at 5:00pm EST
Endorsements Due: December 4, 2014 at 5:00pm EST
Funding Decisions Announced: January 2015
Anticipated Funding Start Date: Within 30 days of decision announcement

II. Award Amount
Applicants can request funds between $5,000 and $35,000 (direct costs only). Justification of the requested budget is essential and funding may be granted only for some and not all requested items.

III. Overview and Goals
Clinical investigators, especially senior fellows and junior faculty, frequently fail to obtain NIH K and R funding because their applications do not include sufficient or pertinent preliminary clinical data. Harvard Catalyst has launched a new funding initiative to address this challenge. Harvard Catalyst is interested in important clinical questions in the clinical/translational research domain and the proposed research must involve human subjects or human specimens. Harvard Catalyst funding will provide the resources needed to generate preliminary data that will be included in an application for NIH K or R funding (or equivalent federal or non-federal peer-reviewed sponsored research). It is anticipated that Harvard investigators will leverage this modest support to compete successfully for federal and non-federal sponsored funding.

Preliminary translational/clinical data may be comprised of: 1) evaluation of human specimens, 2) studies of living human subjects, or 3) more extensive analyses of existing clinical data. If not utilizing discarded specimens, an appropriate and active IRB protocol must be in place or submitted prior to the application deadline. Such preliminary data could be generated from a commercial vendor, an Institutional Core Facility, a biostatistical group, or a standard assay or procedure available at one of Harvard’s affiliated institutions. Clinical studies of living human subjects might consist, for example, of imaging studies, physiologic tests, cardiac testing, clinical data, or neurophysiologic testing.

IV. Eligibility
All Harvard investigators, irrespective of type of degree or institutional affiliation, who are applying for a peer-reviewed clinical research grant (at the K or R level) are eligible. Priority will be given to junior investigators (e.g. clinical fellows, postdoctoral fellows, instructors, and assistant professors) who need preliminary translational/clinical data for their NIH K or R application (or equivalent federal or non-federal peer reviewed sponsored research).
Investigators MUST submit their grant application to the funding agency within one year of use of Harvard Catalyst funding. Harvard Catalyst will require confirmation from the investigator’s division chief or department chair that the applicant will hold a position in his/her department through the time the grant is submitted and evaluated by the funding agency (see Section VI – Application Submission Information).

Investigators may submit only one application.

For questions regarding eligibility, see contact information below in Section VIII.

V. Funding Details
- Requests should range from $5,000 up to $35,000 direct costs only.
- All expenses must be directly related to the proposed data acquisition. Some examples of allowable expenses are supplies, study subject stipends, study subject transportation costs, core facilities costs, and statistical and computational services including personnel and computer time.
- Unallowable costs: General office supplies and equipment, computers and laptops, travel, membership dues and fees, subscription costs, mailing costs, rent, and other costs generally identified as facilities and administration (F&A) are not allowed.
- Facilities and administration (F&A) costs: F&A costs, also known as indirect costs, are not permitted.

VI. Application Submission Information
The online application form in Apply Hub requires login via Harvard Medical School eCommons username and password, or via Harvard University ID (HUID) number and PIN (http://catalyst.harvard.edu/services/loginfaq.html). If you have forgotten either of these, click on the “Forgot your PIN / Password?” on the login page. If you do not have either of these, please contact Amy Webber at grants@catalyst.harvard.edu for assistance.

If you have not used Apply Hub before, you will be asked to register on a “My Account” page with your name and your email address.

The online application itself is a three-part form. Please provide the following information.

Part 1 – The Application and Supporting Documentation
- Full name of the submitter
- Email address of the submitter
- Investigator Information
  - Full name of the investigator (edit if not the same as submitter)
  - Email address of the investigator (edit if not the same as submitter)
  - Degree(s)
  - Faculty rank/position
  - Institution
  - Department
  - Division (optional)
  - Phone number
  - Gender, ethnicity, race (all optional)

- Administrative Questions
  - Does your study require IRB approval? If yes, do you have it?
  - Does your research relate to child health?
  - Does the proposed project explicitly address disparities in health or healthcare?
Does the proposed project contribute to the development, implementation or evaluation of evidence-based policy affecting the health of communities and populations?

Supporting Documentation

- Administrative Documents (to be uploaded as a PDF)
  - Letter of Intent (a.k.a. Statement of Intent). This form is site-specific and needs to be signed by the applicant’s Institutional Official.
  - Budget: Include an itemized, detailed budget and budget justification for the experiments(s) or analyses to generate preliminary data.
  - A copy of IRB approval notification or proof of IRB submission: The IRB protocol must be either approved or at the very least submitted (with documentation of it being submitted). In case it is submitted, funds will not be released until IRB approval has been obtained, and the applicant will have two months to get approval and start the experiments for which support is requested. After the two months have passed, the award will be cancelled, but the applicant may reapply for future rounds of funding.
  - NIH Biographical Sketch for the investigator, including current sources of support.

Proposal (to be uploaded as a PDF) is limited to 2 pages not including references: Use Arial, black font color, and a font size of 11 point only. The proposal (covering items 1-3 below) should be single-spaced, with 0.5 inch margins. All figures and tables must be included in the body of the proposal and count towards page limits. Appendix material will not be accepted.

1. Overview. The overview should include a description of the type of grant, level of funding, length of funding, and anticipated date of submission.

2. Specific Aims. Include a fully developed draft of planned specific aims for the K or R (or equivalent federal or non-federal peer-reviewed) grant that you eventually plan to submit for which you need pilot data and are requesting support for.

3. Rationale. Include a statement explaining why the preliminary data for which Harvard Catalyst funding is requested are critical for the proposed grant submission. (See Section III for further information on definition of preliminary data). Include a description of the planned experiments and methodology to obtain the preliminary data.

4. References (limit to 1 additional page).

Part 2 – Endorsements

Please have the following information ready:

- Division chief/department chair’s name, email, primary institution, and department/division.

The individual you list on the endorsements page as your division chief/department chair will receive an email with a link directing him/her to a secure website where they will be prompted to confirm their divisional/departmental endorsement and support through the time your grant is submitted and evaluated.
Part 3 – Confirmation
There will be a confirmation page displaying all information entered. You will then be able to submit the application. All application materials can be reopened and resubmitted before the deadline.

Paper copies of the application or any other accompanying documentation will not be accepted. All application materials must be submitted no later than 5:00pm EST on November 20, 2014. All endorsements must be submitted by 5:00pm EST on December 4, 2014.

Successful submissions will result in an automated email response sent to the submitter of the application. This email acknowledgement will contain an application ID number that should be used in all future correspondence regarding the application. It will also include a URL that allows you to access the application within Apply Hub.

VII. Review Process and Criteria
Completed applications submitted by 5:00pm EST on November 20, 2014, with all required endorsements submitted by 5:00pm EST on December 4, 2014, will be administratively reviewed for eligibility. All eligible applications will then be scientifically reviewed solely on the basis of merit of the planned grant application, feasibility and strength of the rationale for the need of preliminary data. A review panel comprised of Harvard clinical research leaders and Harvard Catalyst leadership will complete the review. Ad hoc reviewers with content expertise will be engaged as needed. Reviewer comments or feedback will not be provided to applicants.

Reviewers will consider the following criteria:
- The importance of the clinical question in the planned grant application.
- A clear plan for utilizing funding received for research on human subjects or human specimens.
- The likelihood that the planned grant application will be successful provided the pilot data are obtained.
- Innovative approaches.
- Collection of the proposed pilot data is feasible and achievable in the funding period.
- The investigators have the requisite skills and experience to carry out the project successfully.

VIII. Contact Information
All inquiries related to the application process, eligibility, and/or scientific research areas should be directed to Amy Webber, Pilot Grants Administrator, Harvard Catalyst (617-384-8976); grants@catalyst.harvard.edu.

Inquiries related to financial or grants management areas should be directed to Lucy Kolessin, Director of Finance and Research Administration, Harvard Catalyst (617-432-7804); lucy_kolessin@hms.harvard.edu.