Request for Applications

Letter of Intent Due February 1, 2010

Full Application Due March 1, 2010

Harvard Catalyst Pilot Grants

I. Overview of the Harvard Catalyst and Rationale for Pilot Grants

Harvard Catalyst is a pan-University collaborative effort 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 is committed to bringing faculty, post-doctoral fellows, clinical trainees, and graduate students from multiple institutions and across disciplines together to collaborate to improve the diagnosis, treatment, and prevention of human illness. There is great enthusiasm among basic scientists – including biologists, engineers, chemists, and physicists – for new collaborative efforts to decipher the mechanisms of human disease, develop new diagnostics, and develop new strategies and agents to treat or prevent human illness. The barriers they face include a lack of understanding of diseases, inability to identify the most important scientific questions, and lack of access to clinical collaborators. Likewise, clinical investigators and population scientists are eager to bring their most pressing clinical questions to the laboratory but often do not know how to find scientific partners who would be interested and willing to collaborate. They frequently face obstacles that will require collaboration with colleagues who are experts in business, law, ethics, and government. Critical questions might impact a single patient, a cohort of patients with a specific diagnosis, or a population of patients or individuals at risk either locally or across the world. Success is not a specific output but rather a change in the structure and culture of our community: when investigators from many institutions and disciplines come together to collaborate on developing a new diagnostic or a novel approach to treatment or prevention, that is a success.

Pilot Grants are one approach to catalyze our goals. Seed funds in the form of Pilot Grants will be granted to foster high-impact, innovative, and collaborative research. Please read this RFA carefully as it contains important information about eligibility and review criteria. If you have any questions, or if you would like assistance identifying additional collaborators or resources to enrich your research proposal, please contact the Harvard Catalyst Research Navigators at 617-432-7810. We also encourage you to utilize the Harvard Catalyst consultation programs available under the Resources tab on our homepage (http://catalyst.harvard.edu/home.html).
II. Key Elements of the Harvard Catalyst Pilot Grant Program

Harvard Catalyst Pilot Grants are directed to improving human health in its broadest terms. Eligibility is very broad and the process is open to any individual who has a faculty appointment at Harvard University. The main impetus behind the grants is to support pilot studies that will lead to sustainable, innovative and collaborative projects that will impact human health. In addition, this mechanism favors junior faculty, with the goal of promoting the next generation of clinical and translational investigators. Pilot Grants will award $50,000 per application for one year.

Harvard Catalyst Pilot Grants should:

• address an important clinical and/or translational research question in an area that impacts human health.

• include collaborative research conducted by a team of investigators with appointments in different departments or institutions.

• propose research that is new to the group of researchers and that requires pilot funds to generate preliminary data that will enable the investigators to obtain further funding to continue the project. Please note that Harvard Catalyst Pilot Grants do not support ongoing projects.

Information about previously funded proposals can be found on the Harvard Catalyst website:

http://catalyst.harvard.edu/pilotfunding/index.html

III. Program Eligibility

A. Investigators

i. Principal Investigators:

Any faculty member who holds a Harvard University faculty appointment regardless of type of degree or institutional appointment is eligible to be the Principal Investigator.

• Individuals may serve as the Principal Investigator of only one proposal.

• Professors, Associate Professors, Assistant Professors, Instructors, Lecturers, and HMS-appointed Research Associates are eligible to apply. If your appointment is not listed here, or if you have questions about whether you are eligible to apply, please contact us at 617-432-7810.

• Undergraduates, graduate students, clinical trainees, post-doctoral and clinical fellows, visiting and adjunct faculty, and individuals with pending faculty appointments at the time of letter of intent submission cannot serve as the Principal Investigator of an application, but may serve as a Co-Investigator, provided they meet the criteria listed below.
• Since one of the goals of the Harvard Catalyst Pilot Grant Program is to help train the next generation of clinical/translational investigators, we encourage junior investigators (i.e. prior to promotion to Associate Professor) to submit grants. However, since experience and expertise will be criteria for funding, we encourage junior faculty to recruit pertinent senior Co-Investigator(s).

• Proposals listing solely senior researchers will be accepted only if the collaboration is new and the research proposed is in a new field.

ii. Co-Investigators:

Harvard Catalyst Pilot Grants require collaborative research that crosses departments or institutions. Researchers must make a substantial contribution to the project in order to be listed as Co-Investigators. Substantial contributors:

• helped conceive of the experimental idea, or contributed to the intellectual development of the concept.

• designed the study or part thereof (scientific or technical details).

Co-Investigators may hold any degree or institutional appointment, and may be members of any institution or industry, although justification will be required for Co-Investigators that are not within the Harvard Catalyst community.

At least one Co-Investigator is required and there is no limit to the number of Co-Investigators that may be listed. While researchers may submit only one application as Principal Investigator, they may be listed as a Co-Investigator on multiple applications.

B. Fields of Research

• Translational experiments that propose a hypothesis that will eventually require a human experiment to validate.

• Clinical experiments or trials that involve human subjects or samples.

• Experiments on human populations. Here, the hypotheses address the multitude of approaches that have the potential to impact the health of an individual, a population, or even global health.

• Projects outside of the traditional scientific and healthcare professions. We encourage the submission of proposals that will address issues of law, ethics, policy, business, industry, and government that have the potential to impact the conduct of human experiments and/or the outcome of the health of a population.

IV. Overview of Application and Review Processes

A letter of intent (LOI), due February 1, 2010, is required to be considered for funding. The LOI consists of an on-line form for biographical and other general data, and a 250 word abstract
Applications will be screened and triaged by a preliminary review committee that will assign the proposal to the appropriate reviewer group. The only selective criteria applied at this step will be the applicability of the Principal Investigator’s faculty appointment and the presence of inter-departmental or inter-institutional collaboration.

A five page complete application (see section VII) will be due March 1, 2010. The review panels will score the applications and choose applicants for further review. Successful applicants will be invited to meet with the Pilot Grant Review Committee (see section IX). These interviews will allow the Pilot Grant Review Committee to review the proposals in depth and make the final funding decisions.

V. Timeline for the Harvard Catalyst Pilot Grants

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VI. Letter of Intent (LOI)

Due Date: Monday, February 1, 2010, 11:59am.

To be submitted online on the Harvard Catalyst website:

http://catalyst.harvard.edu/pilotfunding/index.html

Applications must be submitted electronically. Please be aware that forms cannot be saved. Also, the form will close at noon on February 1, 2010, and there will be no exceptions permitted. Please allow time before the deadline to deal with any unexpected problems submitting the application. Harvard Catalyst Staff will be available until noon to help you should you encounter problems submitting your application.

Successful submissions will receive an automated response. This email acknowledgement will contain an Application ID number that should be used in all future correspondence with Harvard Catalyst regarding your application.

Components of the LOI:

All fields marked with an (*) are required and the form cannot be submitted if any are left blank. To add information for Co-Investigators, select the ‘Add Co-Investigator’ button. At least one Co-Investigator is required.

• Name*
• eRA Commons ID*
  Please see your departmental administrator for information about obtaining an NIH eRA Commons ID. See also https://commons.era.nih.gov/.

• Degree*

• Rank*

• Institution from which investigator draws a paycheck*

• Department* and Division within institution

• Telephone number where investigator can be contacted*

• Email address*

• Optional demographic information
  We invite applicants to voluntarily self-identify their gender, race, and ethnicity. Submission of this information is voluntary and refusal to provide it will not subject you to any adverse treatment. The information obtained will be kept confidential and may only be used in accordance with the provision of applicable laws, executive orders, and regulations.

• Sponsored Program Administrator’s Contact Email Address*
  Required for Principal Investigator

• Contact Person Name and Email (if different from Principal Investigator)
  All correspondence will be sent to the Principal Investigator and it will be the Principal Investigator’s responsibility to coordinate with Co-Investigators. The Principal Investigator can indicate one additional person for Harvard Catalyst to contact with information regarding their application (for example, an administrative assistant who would deal with scheduling).

• IRB*
  Indicate whether the proposed research will require IRB approval. If IRB approval is required, indicate if you have already obtained this approval.

• IACUC*
  Indicate whether the proposed research will require IACUC approval. If IACUC approval is required, indicate if you have already obtained this approval.

• Previous collaborations with Co-Investigators*
  If the Principal Investigator has previously collaborated with any of the Co-Investigators, this should be indicated here and a brief explanation of how the previous collaboration relates to this work should be provided.

• Use of human embryonic stem cells*
  Please alert us to the use of any human embryonic stem cells in this proposal.
• Child health component*
Select 'yes' if the proposed study has a child health component, which is defined as not only studies on pediatric subjects or populations, but also maternal-fetal medicine, childhood antecedents of adult disorders, and translational studies related to diseases of children and adolescents.

• Health disparities research*
Select 'yes' if the research studies health (or health care) disparities, including differences in the incidence, prevalence, mortality, and burden of diseases and other adverse health conditions (or the care of these conditions) that exist among specific population groups in the United States (including race, gender, ethnicity, or socioeconomic factors).

• Project title*

• Category*
Indicate the category that best suits your proposal. Although a proposal may fall into multiple categories, only one can be selected. The preliminary review committee will use the designated category as a starting point to assign reviewers but a designation is NOT meant to exclude proposals that may not fit any of the listed categories. For proposals that do not fit in any of the categories listed, choose 'other'. When determining if your proposal fits the criteria of this RFA, please refer to section III and do not use these categories to determine the eligibility of your proposal.

1. Human Clinical Trials – Human experiments that investigate therapies or other interventions.

2. Human Clinical Trials with Imaging Endpoints – As above, but with endpoints that require standard medical imaging technologies.

3. Development of Imaging Technologies – Studies that focus on the development or validation of novel imaging technologies that can be applied in pre-clinical and/or clinical environments.

4. Biomarkers – Experiments designed to identify novel biological markers for diagnostic or prognostic use, or to assess pharmacological effects of a particular treatment.

5. Community Engagement – Studies that engage communities in the design and/or implementation of community-based studies.

6. Health Care Delivery/Outcomes – Studies that seek to understand or improve upon health care delivery systems.

7. Health Disparities – Studies that address differences in the incidence, prevalence, mortality, and burden of diseases and other adverse health conditions that exist among specific population groups in the United States.
8. Global Health – Studies that seek to improve healthcare or health outcomes in developing countries.

9. Epidemiology – Studies that utilize population-based methods to study patterns of disease.

10. Mechanisms of Disease – Translational studies directed at understanding a particular disease state (these do not include animal models or clinical studies).

11. Therapeutic Screens – Pre-clinical screens designed to identify novel therapeutic agents, either *de novo*, or through the modification of existing compounds.

12. Pre-Clinical Therapeutic Development – Experiments that seek to develop or optimize novel therapies, often (though not exclusively) *in vitro*. These are not human clinical experiments.

13. Devices – Studies directed at the development or improvement of devices that positively impact human health.

14. Tissue Engineering – Engineering approaches that use biological and other components to create materials that can replace lost tissues and function physiologically.

15. Illness Relevant Animal Models – Pre-clinical studies that develop or utilize animal models of human disease.

16. Human Genetics – Genome-wide association or other studies directed at understanding the genetic basis for disease.

17. Other – Surprise us! We welcome applications from diverse fields with relevance to human health, including – but not limited to – law, ethics, policy, business, social sciences, biomedical informatics, and others.

- **Abstract***
  Insert an abstract with a maximum of 250 words.

**VII. Full Application**

Due date: Monday, March 1, 2010, 11:59am.

Please note that your internal institutional application process may require additional time for review and additional documents. Thus, work with your Research Administrator during the application process.

All documents should be submitted by webform, at the following URL after February 1:

[http://catalyst.harvard.edu/pilotfunding/index.html](http://catalyst.harvard.edu/pilotfunding/index.html)
Enter your application ID and the Principal Investigator’s email address to log into the form. The form will close **at noon on March 1, 2010**, and there will be no exceptions permitted. Please allow time before the deadline to deal with any unexpected problems submitting the application. Harvard Catalyst Staff will be available until noon to help you should you encounter problems submitting your application.

A complete application consists of the following three components:

1. Biographical information you submitted in your LOI (pre-populated on the webform).
2. Administrative documents (uploaded as a single PDF via the webform).
3. Your scientific proposal (uploaded as a separate PDF via the webform).

The following administrative documents should be uploaded as a single PDF:

I. For **each institution that will receive funds**, the following forms must be completed:
   i. PHS 398 Face Page, to be signed by institutional official.
   ii. PHS 398 Form Page 4: Detailed budget for one year for maximum of $50,000. Refer to section XI for allowable costs. (If more then one site will share the budget, the combined total should not exceed $50,000.)
   iii. Narrative Budget Justification.
   iv. A brief statement of work describing the work to be performed at each institution (2-3 sentences / institution).

II. PHS 398 Biographical Sketches for the PI, co-investigators and **significant** collaborators. Make sure eRA Commons ID is supplied for all co-investigators.

The following proposal should be uploaded as a separate PDF:

Your scientific proposal is limited to five pages, not including references. Please use Arial font, size 11, single-spaced, with 0.7 inch margins. Include the following sections (suggested lengths in parentheses):

I. **Introduction** (1 page)
   Please describe the scientific background for your grant application. Critically evaluate existing knowledge; explain how your pilot proposal relates to gaps in current knowledge; and specifically discuss how your project has the potential to impact human health.

II. **Project Details** (2 1/2 pages)
   Please describe the specific aim(s) that will be completed in the funding period. For each aim, provide the experimental details, and delineate an approximate timeline for the activities related to that aim. Preliminary data is not required, but can be included if it speaks to feasibility. Please describe contributions from each member of the team in the design and execution of the proposed experiments.

III. **Catalysis** (1 page)
   Please describe the conception of your idea, the evolution of your proposal, and the process that created your team. Highlight synergies among members of the research team.
IV. Future Plans (1/2 page)
What are your plans past the year of Harvard Catalyst funding: how do you propose to extend and fund your project? Please describe how you will build on the results of pilot project; give an overview of the future experimental plan (experimental details are not necessary) and the types of funding for which you intend to apply.

V. References (limit to 1 additional page)

Appendix material is not allowed. All figures should be included in the body of the application.

VIII. Main Review Criteria

A. Primary considerations

• Does the proposal address an important problem and, if successful, will the results have a substantial impact on human health?

• Is the proposal innovative?

• Is there an inter-departmental or inter-institutional team? Does the proposed project stimulate collaboration across institutions?

• Does the funding stimulate collaborations that otherwise might not have taken place?

• Does the project bring together investigators who have not worked together in the past?

• Is the project focused and achievable, and does it have a high potential to secure future extramural funding?

• Do the investigators have the requisite skills and experience to carry out the project successfully?

B. Secondary considerations

• Does the project support junior faculty? Is adequate supervision and mentoring provided for junior faculty and trainees who will carry out the project?

• Is the work applicable to pediatric populations, either in isolation or as part of a target population?

• Is there an opportunity to ask a question with relevance to health disparities?

IX. Interview

A critical feature of our application process is the interview, where the applicant teams will be asked to present and discuss their work. Only a subset of teams will be invited for an interview, and only a subset of those interviewed teams will be funded.
One of the primary considerations for funding during the interview will be the depth of collaboration between investigators on your proposal, since we consider your collective commitment to this project vital to its success. We therefore ask that you bring all of your listed Co-Investigators to the meeting.

In late March, we will be alerting Principal Investigators as to when they should expect their interview to be held. Then, in late April, we will inform the Principal Investigators as to whether they have been selected for an interview. At that time, we will schedule an interview for May, 2010. Details about the interview will also be made available at that time to those selected for an interview.

If your project requires IRB or IACUC approval, you will need to have submitted your protocol(s) to the relevant board(s) in advance of the interview in May. Proof of submission or approval must be provided at the time of the interview in order to be considered for funding.

X. Funding

Funding decisions will be announced on June 15, 2010, and the earliest intended award date is July 15, 2010. The maximum period of award is 12 months, counted as of the effective funding date. The maximum amount to be awarded per application is $50,000, direct costs only. Indirect costs are not allowed. Note that the funding cannot be released until all applicable human and animal subject protocols have been approved and copies sent to the Harvard Catalyst central office. Each award is non-renewable and non-transferable from one Principal Investigator to another. No-cost extensions are also prohibited.

Please be advised that upon funding, additional administrative documents may be required.

Approximately 60 to 80 pilot grants will be funded in this cycle.

XI. Allowable Costs

Faculty Salary Support: Harvard Catalyst Pilot Grants will provide salary support for up to 5% effort and in compliance to the NIH salary cap. However, please note that there is no minimum or maximum effort commitment requirement (effort above 5% will have to be cost shared by the faculty’s institution).

Other Personnel Support: Salary and fringe benefits are allowed for technical support, such as: Research Fellows, Research Assistants, Clinical Coordinators, Research Nurses, etc. However, salary support for ancillary personnel, such as Mentors, Secretaries, and Administrative Assistants, is not allowed.

Non-personnel Research Expenses: Some allowable expenses are: supplies, equipment (under limited circumstances), travel to research meetings, animal purchase cost and care, study subjects stipends, study subjects transportation costs, in- and out-patient care costs, and statistical and computational services including personnel and computer time. All expenses must be directly related to the proposed research. Unallowable costs are: 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.

Facilities and Administrative Costs: Facilities and administrative costs, also known as indirect costs, are not permitted.

Subcontracts: Pass-through subcontracts to other sites are not permitted. A separate budget page should be submitted from all sites that are to share the grant funds. Subsequently, Harvard Catalyst will directly subcontract to all sites.

XII. Agreements upon Funding

Funded investigators agree to interact with the Harvard Catalyst Research Navigators in order to define and monitor benchmarks, identify alternative resources, process the required progress reports and work on future funding.

XIII. More Information

We encourage your inquiries concerning this application process.

Inquiries falling in the scientific/research areas should be directed to the Harvard Catalyst Research Navigators at 617-432-7810, researchnavigator@catalyst.harvard.edu.

Inquiries falling in the financial or grants management areas should be directed to Lucy Kolessin, Director of Finance and Research Administration, 617-432-7804, lucy_kolessin@hms.harvard.edu.