



BLAVATNIK BIOMEDICAL ACCELERATOR AT HARVARD UNIVERSITY

= REQUEST FOR PROPOSALS =

Release date: October 8, 2014

Pre-proposal submission deadline: November 26, 2014

Full proposal submission deadline: March 27, 2015

Funding start date: July 1, 2015

Background and Purpose: The **Blavatnik Biomedical Accelerator at Harvard University** supports Harvard faculty in the performance and commercialization of applied life sciences research. A significant obstacle to the development of early-stage university discoveries is the lack of funding for the proof-of-concept and validation studies needed to demonstrate commercial potential. To overcome this barrier, the Accelerator provides funding and business development support to help faculty validate their nascent technologies and identify potential industry partners to advance these technologies to the marketplace.

The Accelerator seeks to support innovative, investigator-initiated research aimed at extending preliminary observations, with proof-of-concept and the generation of robust intellectual property positions as key objectives. The Accelerator is designed to accommodate projects of varying magnitude, as appropriate. Its primary goal is to advance technologies to the point where additional funding from industry and/or technology transfer is achieved.

To date, the Accelerator has provided \$11 million in direct research support to 55 projects from across Harvard University and targeting most major disease areas, including oncology, metabolic disease, diabetes, immuno-inflammatory disease, infectious diseases, and neurodegeneration. Supported projects have included therapeutics, diagnostics/biomarkers, instruments, and other biomedical technologies. Approximately half of all completed projects have been partnered with industry, through licenses to pharmaceutical, biotech, and startup firms (some launched from the Accelerator-supported technology) or via major industry-sponsored research agreements. These alliances have also led to more than \$20 million in additional industry-sponsored research funding. The Accelerator is structured as a sustainable, “evergreen” program, with revenue from successfully launched technologies cycled back to support ongoing and future Accelerator projects.

The Accelerator and the progress of its funded projects are managed by the Office of Technology Development (OTD) under the auspices of the Office of the Provost, in consultation with an independent advisory committee comprising leaders from the Boston life science community.

I. Application Timeline

Wednesday, October 8, 2014:	RFP release
Friday, October 31, 2014	Deadline for Notice of Intent (e-mail)
Wednesday, November 26, 2014:	Deadline for pre-proposals (5 pm ET)
Friday, February 13, 2015:	Announcement of projects selected for full proposals
Friday, March 27, 2015:	Deadline for full proposals (5 pm ET)
June 2015:	Announcement of FY2016 awards
Wednesday, July 1, 2015:	FY2016 funding start date

II. Program Eligibility

Applicant: Anyone with rights as a principal investigator (PI), whose employer is Harvard University and who has an obligation to assign intellectual property (IP) rights to Harvard, is eligible to apply.

Activities Eligible for Funding: The focus of the proposal must be applied research in the Life Sciences. Examples of studies eligible for funding include but are not limited to:

- Structure-based design, synthesis, and testing of small molecule modulators of high-value targets
- High-throughput screens and confirmatory studies to identify modulators of high-value targets
- Medicinal chemistry optimization of lead compounds (e.g., to define structure-activity relationships, increase potency or target selectivity, and improve pharmaceutical properties including solubility and metabolic stability for *in vivo* testing)
- Development of therapeutic or diagnostic monoclonal antibodies or other biologics
- Testing of lead molecules, monoclonal antibodies, or other biologics in cell-based and/or animal models of disease to confirm their clinical or diagnostic relevance
- Preclinical development of validated lead molecules or biologics (e.g., ADME/T, PK/PD, formulation, or safety studies)
- Development and validation of clinical biomarkers and/or relevant diagnostic methods
- Development and validation of novel vaccine technologies

III. Award Types and Funding Levels

Accelerator awards will be made in two categories: Pilot Grants and Development Grants. Within the established budgetary parameters, projects will be funded at the level deemed necessary to achieve the proposed research objectives. It is anticipated that 5-7 Pilot Grants and 3-5 Development Grants will be awarded for FY2016.

Pilot Grants: Pilot Grant awards will be funded at a maximum of \$100k for a period of 12 months. Pilot Grants are intended to support proof-of-concept activities that (if successful) would establish a basis for a subsequent Development Grant proposal. For example:

- Performance of a high-throughput screen for candidate therapeutic compounds or antibodies, and confirmation of specific biological activity in identified hits
- Demonstration that a candidate vaccine antigen or technology elicits a functional immune response in a suitable animal model
- Demonstration that a candidate biomarker detection method is appropriately sensitive and specific under ideal lab conditions.

Development Grants: Development Grants will be funded at \$200k-300k total for a period of 12-24 months. A formal project review will be conducted at the end of the first year, and approval of second-year funding will be contingent on the achievement of first-year milestones. Development Grants are intended to support efforts that may reasonably be expected to result in partnerable technology within the proposed timeframe. For example:

- Medicinal chemistry optimization and preclinical studies of lead therapeutic molecules
- Determination of a candidate vaccine's ability to elicit protection against pathogen challenge, formulation/stability studies
- Validation of a biomarker and an appropriately sensitive and specific detection method using clinical samples, correlation of biomarker status with clinical outcomes.

IV. Proposal Review and Selection Process

1. Pre-proposals (submission deadline: November 26, 2014 at 5 PM ET)

Applicants should notify blavatnik_accelerator@harvard.edu as soon as possible and no later than October 31, 2014, of intent to submit a pre-proposal. OTD staff will work closely with applicants to develop a pre-proposal according to the format in Appendix A. Only one pre-proposal per applicant will be accepted, and pre-proposals should be no more than 2 pages in length. Publications/manuscripts and CVs/biosketches do not count toward the page limit. Based on recommendations from the Accelerator Advisory Committee, a subset of applicants will be invited to submit a full proposal.

2. Full proposals (submission deadline: March 27, 2015 at 5 PM ET)

Full proposals must be prepared in accordance with the outline in Appendix B. OTD staff will work closely with PIs to assist in the development of full proposals, in particular with respect to determining a technology's commercial potential and establishing sound technical milestones to enhance that commercial potential. Full proposals will be reviewed by the Accelerator Advisory Committee and a small group of external technical advisors and experts. The Advisory Committee (in consultation with OTD) will make all award decisions. It is anticipated that 5-7 Pilot Grants and 3-5 Development Grants will be awarded in the FY2016 cycle.

3. Evaluation criteria

The goal of Accelerator funding is to advance technologies to the point where additional funding from industry and/or technology transfer is achieved. Thus, proposals will be evaluated on overall potential for technology transfer, including scientific/technical merit, need, and commercial potential of the technology. The following evaluation criteria will be taken into consideration during the review process:

Scientific and Technical Merit

- Innovation and novelty
- Feasibility and risk
- Clarity of the research objectives and proposed technical milestones
- Potential impact and significance for human health and public benefit

Potential for Technology Transfer

- Likelihood of enabling a strong patent position or enhancing an existing patent position
- Significant market need and opportunity
- A relatively clear and short path to a commercially viable technology
- Competitive advantage over currently available technologies
- Significant de-risking or value inflection point without which the technology would not be partnerable

V. Budget and Funding Period

Pilot Grants will be funded for up to 12 months of effort. No-cost extensions may be granted, subject to demonstrated progress and approval by the Accelerator.

Development Grants will be funded for 12-24 months of effort. A formal project review will be conducted at the end of the first year, and approval of second-year funding will be contingent on the achievement of first-year milestones. No-cost extensions may be granted, subject to demonstrated progress and approval by the Accelerator.

For both Pilot and Development Grants:

During the funding period, if funding support for the same work is secured from industry, any remaining (unused) funds provided by the Accelerator will be returned to the Accelerator.

Accelerator funding will not be subject to Harvard indirect expense charges. Funding may only be used for research directly related to, and budgeted under the project, and may not be used for any other purpose. Budget items may not include PI salary, capital equipment, or travel. The research project may be structured such that some, or even a large portion of the approved, budgeted activities are outsourced to one or more approved contract research organizations (CROs). Accelerator staff will assist the PI in identifying qualified CROs and developing work plans, and OTD will negotiate work-for-hire agreements on behalf of the PI.

VII. During the Award

For each Accelerator project, a project team will be assembled to match the project's particular needs and monitor progress throughout the funding period. In addition to the PI, team members may include Accelerator/OTD staff, research personnel, and external consultants with specific technical expertise (e.g., medicinal chemistry, PK/PD, product development and commercialization).

VIII. Other Requirements: Terms and Conditions of the Award

1. Time and Effort: All personnel on funded projects must commit time and effort appropriate to their roles on the project.

2. Inventions and Intellectual Property: There is no requirement for any background or pre-existing inventions, nor any prior intellectual property. However, if there is any background intellectual property, it must have been assigned exclusively to Harvard. Any new inventions that are conceived or reduced to practice in the course of performing an Accelerator-supported research project must be disclosed to the Office of Technology Development and, thereafter, assigned exclusively to Harvard. The PI **must** report any and all inventions to OTD no fewer than 30 days in advance of a public disclosure to allow OTD staff to determine if such public disclosure contains new, potentially patentable subject matter.

Intellectual property conceived, reduced to practice or otherwise made, improved or further developed with Accelerator support and assigned to Harvard will be managed in accordance with Harvard's "Statement of Policy in Regard to Intellectual Property" (the "IP Policy"), as most recently amended on December 12, 2013, and any Net Royalties received on account of the licensing or other distribution of such intellectual property will be done *per* Section V.C. of that Policy.

3. Research Plan and Milestones: Each Accelerator award is made for a research plan with proposed objective technical milestones that are accepted by the Accelerator. The achievement of such milestones will serve as key decision points for the assessment of progress and the determination of continued funding. A project may be terminated if agreed-upon technical milestones are not met. Any significant mid-course revisions to the research plan must be approved by the Accelerator.

4. Funding Status: In the event that a proposed project secures funding support from industry during the interval between the date the proposal is submitted to the Accelerator and the time funding decisions are made, it will no longer be eligible for Accelerator funding. If a project is awarded Accelerator funding, but funding support for the same project is secured from industry during the Accelerator funding period, the remaining (unused) funds provided by the Accelerator will be returned to the Accelerator.

5. Research Compliance: Accelerator grants are an internal funding mechanism and will therefore not be set up in GMAS or require OSP/SPA approval. The PI and department are responsible for meeting all compliance requirements associated with the award.

6. Publications: "The Blavatnik Biomedical Accelerator at Harvard University" must be cited in all publications that describe work supported by the Accelerator. Reprints of all publications containing this acknowledgment should be provided to the Accelerator. As noted above, the PI **must** report any and all inventions to OTD no fewer than 30 days in advance of a public disclosure to allow OTD staff to determine if such public disclosure contains new, potentially patentable subject matter.

7. Reporting Requirements: Progress reports are due on November 1, March 1, and July 1 during the funding period. A final report is due within 30 days of the end of the funding period. Each report should specifically address research results relative to each specific aim and a statement of any inventions made in the course of the performance of the funded project. Periodic financial reports will be run to verify the appropriateness of project expenses.

Appendix A: Pre-proposals

Pre-proposal submission deadline: November 26, 2014 at 5:00 PM ET

Applicants should notify blavatnik_accelerator@harvard.edu as soon as possible and no later than October 31, 2014, of intent to submit a pre-proposal. Applicants should work closely with OTD staff to develop a pre-proposal. Only one pre-proposal per applicant will be accepted. Sections 1 and 2 together should not exceed 2 pages; the cover page and Section 3 do not count toward the page limit.

Cover Page (not included in page limit)

(i) PI name and department

(ii) Project title

(iii) Total budget request

(iv) Non-confidential executive summary (150 words maximum): please note that this non-confidential summary will be shared with industry partners to obtain preliminary comments. If an applicant has concerns about sharing information with industry, OTD will work with the applicant to address those concerns.

Section 1: Background and Significance

(i) Need and Significance: describe the biomedical need for the technology, its novelty, and the envisioned potential applications. Compare the proposed applications to the current state of the art and competing technologies.

(ii) Briefly describe recent research directly relevant to the proposal, including that of others in the field and, in particular, your own work.

Section 2: Research Plan

(i) Specific Aims: For each aim, provide a specific statement regarding its value for commercialization activities, and an estimate of the time required for completion.

(ii) Describe the criteria that will be used to determine if the specific aims have been achieved.

(iii) Total budget requested: provide estimated costs by category (salary, supplies, services and fees, etc.).

Section 3: Supporting Information (not included in page limit)

(i) Describe the current intellectual property position of the proposed technology, indicating whether the technology is based on already reported inventions, and whether the IP for such inventions is held solely by Harvard, jointly with other institutions or has been licensed to a partner.

(ii) Curriculum vitae (2-page maximum each) for the Principal Investigator, collaborators, and any other key project participants.

(iii) Identify all prior, current, and pending sources of support to the PI's lab related to the proposed research project.

(iv) Relevant publications/manuscripts (maximum of 3).

Pre-proposal submission: Pre-proposals must be received by 5:00 PM ET on **November 26, 2014** as a single Microsoft Word (.doc or .docx) file. Proposals should be submitted via e-mail to: blavatnik_accelerator@harvard.edu. The subject line should include the words "FY2016 Accelerator Pre-proposal" and the PI's last name.

Appendix B: Full proposals

Full proposal submission deadline: March 27, 2015 at 5:00 PM ET

PIs are expected to work closely with OTD staff in the development of full proposals, particularly with respect to the commercial development analysis and establishing technical milestones to enhance the technology's commercial potential. For Pilot Grant proposals, Sections 1 and 2 together should not exceed 5 pages. For Development Grant proposals, Sections 1 and 2 together should not exceed 10 pages. The cover page and Sections 3, 4, and 5 are not counted toward the page limits.

Cover Page (not included in page limit)

(i) PI name and department

(ii) Project title

(iii) Total budget request

Section 1: Executive Summary (suggested 250 word maximum)

(i) Describe the biomedical need or opportunity and the significance of the proposed technology.

(ii) State the major research objectives of the project and how they will advance the technology and enhance its patentability or commercial potential.

Section 2: Background, Significance, and Research Plan

(i) Brief introduction to the area of investigation. Summarize significant recent research related to this proposal, including your own work and others in the field.

(ii) Specific research objectives and the experiments planned to achieve each. Describe how the proposed research will enhance the invention's patentability, commercial potential, and/or importance.

(iii) Key technical milestones, including a description of anticipated results and go/no-go decision points where possible.

(iv) Estimated cost and time required for each objective, including a work performance schedule or Gantt chart.

(v) Reference list (not included in page limit).

Section 3: Commercial Development Analysis (not included in page limit)

Based on past experience, it is anticipated that OTD staff will have primary responsibility for preparing the commercial development analysis for the proposed technology, working in close consultation with the PI. Specific arrangements will be made for this when applicants are invited to submit full proposals.

(i) Intellectual property: describe any inventions that have already been made related to the proposed research, and provide a statement about the current IP status of the invention. Also describe how the proposed research will enhance existing IP.

(ii) Market potential: estimate the size and composition of the potential market, including comparisons to current technologies (if any). Describe the competitive landscape, including current development efforts, and what position the proposed technology occupies within this landscape.

(iii) Commercialization strategy: describe potential commercialization strategies that could be pursued for the technology if the research aims are achieved. Include specific input from potential partners (e.g., companies, investors).

Section 4: Detailed budget (not included in page limit)

A detailed budget should be provided for the entire proposed funding period (up to 24 months for Developmental Grants). The budget should provide estimated costs by category:

(i) Salary (please state percent effort)

(ii) Supplies

(iii) Services and fees

(iv) Other (please specify)

Section 5: Supporting Information (not included in page limit)

(i) Curriculum vitae (2-page maximum each) for the Principal Investigator, collaborators, and any other key project participants.

(ii) Identify all prior, current, and pending sources of support to the PI's lab related to the proposed research project.

(iii) Support letters: a support letter must be included if any research objective will require substantial involvement of collaborators (e.g., use of any core facility, collaboration with investigators who are not directly funded by the Accelerator for the proposed work). Support letters are not required from contract research organizations, but CRO quotes may be submitted as budget justification.

(iv) Relevant publications/manuscripts (maximum of 3).

Full proposal submission: Proposals must be received by 5:00 PM ET on **March 27, 2015** as a single Microsoft Word (.doc or .docx) file. Proposals should be submitted via e-mail to: blavatnik_accelerator@harvard.edu. The subject line should include the words "FY2016 Accelerator Full Proposal" and the PI's last name.