



BLAVATNIK BIOMEDICAL
ACCELERATOR
AT HARVARD UNIVERSITY

REQUEST FOR PROPOSALS Full Description

Release Date: August 3, 2020

Pre-Proposal deadlines:
September 11, 2020, for funding in January 2021;
January 8, 2021, for funding in July 2021

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 helps faculty validate and further develop their nascent technologies and identify potential industry partners to advance these technologies to the marketplace. In addition to funding, the Blavatnik Accelerator supports projects by providing access to specialized technical and other consultants with extensive industry experience in product development, as well as to a network of nearly 100 contract research organizations (CROs) from across the globe that can be engaged for projects as needed.

The Blavatnik Accelerator seeks to support innovative, investigator-initiated research aimed at developing preliminary observations into robust intellectual property positions. The Accelerator is designed to accommodate projects of varying magnitude, as appropriate, and its primary goal is to advance technologies to the point where additional funding from industry and/or technology transfer is achieved. There are two application cycles per year; one cycle accepts Pilot Grant applications only, while the other accepts Pilot and Development Grant applications.

Now in its 14th year, the Blavatnik Biomedical Accelerator has provided more than **\$22 million in direct research support to 122 projects** from across Harvard University 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. **Nearly half of all completed Accelerator projects have been partnered with industry**, whether through licensing transactions with existing pharmaceutical and biotech companies, through the formation of new startups, or through the establishment of new research collaborations. The **17 new startups** that have launched to commercialize Accelerator-funded innovations have collectively raised over **\$1.2 billion in equity financing**.

In all, the Blavatnik Biomedical Accelerator's partnered technologies and collaborative research projects have **generated more than \$82 million in licensing revenue and research funding**, supporting continued discovery and innovation at Harvard.

The Accelerator and 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 Timelines

	Fall 2020 cycle	Spring 2021 cycle
Application type	Pilot applications	Development and Pilot applications
Pre-proposal due date	September 11, 2020	January 8, 2021
Announcement of finalists	October 2020	February 2021
Full proposal due date	November 13, 2020	April 2, 2021
Announcement of awards	December 2020	June 2021
Funding start date	January 1, 2021	July 1, 2021

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. Only one pre-proposal per applicant will be accepted per cycle.

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:

- Optimization of small molecule modulators of novel therapeutic targets
- Development and validation of cell therapies and gene therapies
- Development of therapeutic or diagnostic antibodies or other biologics
- Testing of lead molecules or 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
- Development and validation of drug delivery 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.

Pilot Grants: Pilot Grant awards will be funded at a maximum of \$100k for a period of up to 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. Examples of such activities include:

- Confirmation that candidate therapeutic compounds or biologics demonstrate target-specific biological activity
- 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
- *In vitro* development and validation of a therapeutic delivery platform

Development Grants: Development Grants will be funded at a maximum of \$300k for a period of up to 24 months. Development Grants are expected to generate partnerable technology within the proposed timeframe. Examples of activities under a Development Grant include:

- Optimization, efficacy testing, and preclinical evaluation of lead therapeutic molecules or biologics
- Demonstration that a candidate vaccine elicits protection against 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
- *In vivo* validation of a therapeutic delivery platform

IV. Proposal Review and Selection Process

1. Pre-proposals

OTD staff will work with applicants to develop a pre-proposal according to the format in Appendix A. Only one pre-proposal per applicant will be accepted per cycle. Based on recommendations from the Accelerator Advisory Committee and OTD, a subset of applicants will be invited to submit a full proposal.

2. Full proposals

Full proposals must be prepared according to the format in Appendix B. OTD will assist applicants with the development of full proposals, particularly 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. The Advisory Committee will make all award decisions in consultation with OTD.

3. Evaluation criteria

The goal of Accelerator funding is to advance technologies to the point where technology transfer is achieved or additional funding is secured from industry. 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 are considered during the review process:

- Potential impact and significance for human health and public benefit
- Significant market need and opportunity
- Competitive advantage over technologies that are currently available or in development
- Likelihood of generating high-value intellectual property assets
- Significant de-risking or value inflection point, without which the technology is not partnerable
- Demonstrated interest from potential industry partners
- Innovation and technical/execution risk
- Appropriateness of the research objectives and proposed technical milestones

Note: Pre-proposals and Proposals may be shared with a limited number of Harvard's industry partners, under confidentiality, to solicit feedback regarding research plans, support the Accelerator's assessment of the technical and commercial viability of proposed projects, and begin engaging partners with the goal of increasing the likelihood of eventual commercialization.

V. Budget and Funding Period

Pilot Grants will be funded for up to 12 months of effort, and Development Grants will be funded for up to 24 months of effort. Funding will be awarded in tranches according to milestones agreed upon by the applicant and the Accelerator. Accelerator funding **will not be subject to Harvard indirect expense charges.**

Awardees must inform the Accelerator immediately if any internal or external funding is obtained to support any of the same specific aims included in the awardee's Accelerator project. Any overlapping funds provided by the Accelerator may be reallocated to other activities, provided that those activities are directly related to the funded project and approved in writing by the Accelerator.

Funding may only be used for research approved by the Accelerator and may not be used for any other purpose. Budget items may not include equipment, computers, travel, PI salary, or salary for collaborators at other institutions. The research project may be structured such that 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 award, a project team will be assembled to manage the project's particular needs and progress throughout the funding period. In addition to the PI, team members may include Accelerator/OTD staff, research personnel, or external consultants with specific technical expertise (e.g., medicinal chemistry, PK/PD, and 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 June 11, 2019, 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 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. It may be desirable to revise the research plan or budget during the funding period, in response to arising scientific or commercial developments, but any significant changes to the plan or budget must be approved by the Accelerator.

4. **Funding Status:** If 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, and other funding for any of the project aims is secured from any source during the Accelerator funding period, the Accelerator must be informed immediately. Any overlapping funds provided by the Accelerator may be reallocated to other activities, provided that those activities are directly related to the funded project and approved in writing by the Accelerator.

5. **Research Compliance:** Accelerator grants are an internal funding mechanism and therefore will 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. The Accelerator will not reimburse any interest accrued due to late payments or expenses that exceed the awarded amount.

6. **Publications:** "The Blavatnik Biomedical Accelerator at Harvard University" must be cited in all publications that describe work supported by the Accelerator. Copies 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: A project team, including the PI, will be assembled for each award and will meet on a monthly basis. Progress reports will be required at regular intervals during the funding period, and a final report is due no later than 30 days after 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.

Please find Appendix A and Appendix B on the following pages.

Appendix A: Pre-proposals

Pre-proposal submission deadlines: September 11, 2020 (January 2021 funding start) and January 8, 2021 (July 2021 funding start)

Applicants are advised to work with OTD to develop a pre-proposal. Only one pre-proposal per applicant will be accepted per cycle.

- **Cover Page**

- (i) PI name and department
- (ii) Project title
- (iii) Total budget request
- (iv) Non-confidential executive summary (150 words maximum)

- **Section 1: Background, Significance, and Research Plan**

Section 1 should not exceed 2 pages, including figures. The reference list does not count toward the page limit.

- (i) Briefly describe the unmet biomedical need and potential commercial market 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) Summarize the significant research related to this proposal, differentiating clearly between your own work and that of others in the field.
- (iii) Specific Aims: For each aim, provide a rationale and an estimate of the time required for completion, and state the criteria that will be used to determine if the specific aims have been achieved.
- (iv) Reference list.

- **Section 2: Supporting Information**

- (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 (including background IP) for such inventions is held solely by Harvard or jointly with other institutions, or if it has been licensed to a partner.
- (ii) Total budget requested: provide estimated costs for the entire proposed funding period on a PHS 398 form. Equipment, computers, travel, PI salary, and salary for collaborators at other institutions are not allowed.
- (iii) NIH biosketch for the Principal Investigator and key participants (5-page limit each).
- (iv) Identify all prior, current, and pending sources of support to the PI's lab related to the proposed research project.

(v) Supporting publications/manuscripts, provided as PDF files (maximum of 3).

Pre-proposal submission: Pre-proposals should be submitted as a single PDF file, along with a Microsoft Word (.docx) file of Section 1. Proposals should be submitted via e-mail to: blavatnik_accelerator@harvard.edu. The subject line should include the words “Accelerator Pre-proposal” and the PI’s last name.

Appendix B: Full proposals

Full proposal submission deadline: November 13, 2020 (January 2021 funding start) and April 2, 2021 (July 2021 funding start)

Applicants should work with OTD to develop full proposals, particularly with respect to the commercial development analysis and establishing technical milestones to maximize the technology's commercial potential.

• Cover Page

(i) PI name and department

(ii) Project title

(iii) Total budget request

• Section 1: Non-confidential Executive Summary (250 words 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

For Pilot Grant proposals, Section 2 should not exceed 5 pages, including figures. For Development Grant proposals, Section 2 should not exceed 10 pages, including figures. The reference list does not count toward the page limits.

(i) Brief introduction to the area of investigation. Summarize the significant research related to this proposal, differentiating clearly between your own work and that of 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.

(iv) Estimated cost and time required for each objective, including a work performance schedule or Gantt chart. See Section 5.iii regarding cost justification.

(v) Reference list.

• Section 3: Commercial Development Analysis

OTD will work with applicants to prepare a commercial development analysis for the proposed technology. Specific arrangements will be made when applicants are invited to submit full proposals. Minimally, the following items must be addressed:

(i) Intellectual property: Provide a statement on the current IP status of the invention, including a description of any inventions that have already been made (by applicant or others) related to the proposed research. 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 by applicant or others, and what position the proposed technology occupies within this landscape.

(iii) Target product profile (TPP): Describe the intended product profile for Development grants.

(iv) 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: Budget

Provide a detailed budget on PHS 398 forms (first year and entire proposed project period). For the following categories:

(i) Personnel: List all relevant personnel and their percent effort, even if salary support will not be requested from the Accelerator. Salary for the PI or collaborators at other institutions is not permitted.

(ii) Supplies: Equipment and computers are not permitted expenses.

(iii) Other: Describe any services to be used and their expected cost, and include supporting information in Section 5. Travel costs are not permitted.

• Section 5: Supporting Information

(i) NIH biosketch for the Principal Investigator and key participants (5-page limit each).

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

(iii) Support letters and budget justification: A support letter is required for any research objective involving core facilities or collaborators (e.g., investigators who will not be directly funded by the Accelerator for the proposed work). Formal cost estimates should be included as budget justification for any services to be provided by CROs.

(iv) Supporting publications/manuscripts, provided as PDF files (maximum of 3).

Full proposal submission: Proposals should be submitted as a single PDF file, along with a Microsoft Word (.docx) file of Sections 1, 2, and 3. Proposals should be submitted via e-mail to: blavatnik_accelerator@harvard.edu. The subject line should include the words "Accelerator Full Proposal" and the PI's last name.