

The Blavatnik Therapeutics Challenge Awards

<< REQUEST FOR PROPOSALS >>

Release date: November 12, 2019

Pre-proposal due: December 20, 2019

Full proposal due: March 16, 2020

Funding start date: June 1, 2020

Background and Purpose: The Blavatnik Family Foundation (BFF) has given Harvard Medical School (HMS) the largest gift in its history, with the aims of accelerating therapeutic discovery and spurring scientific advances. The \$200 million commitment will help propel the School's mission of transforming health through curiosity-driven research that stimulates the development of new therapies and the creation of new tools to diagnose, prevent and treat disease. Part of this gift, the Blavatnik Therapeutics Challenge Awards, is intended to accelerate the development of therapeutics within HMS and its affiliated hospitals, with the goal of achieving licensable intellectual property and creating new companies within a two-year timeframe.

This RFP will be overseen by an Executive Steering Committee that is chaired by BFF and HMS senior leadership and comprised of experts from industry, business and the HMS faculty. The program will be managed by the Office of the Dean for Research Operations and Global Programs at HMS, with active support from the technology development and technology licensing offices at Harvard University and the HMS-affiliated institutions. The grant will help investigators overcome obstacles to commercial translation by funding promising technologies and positioning them to attract venture and industry partners. Awards will include significant financial resources in addition to business development, commercialization and project management expertise.

I. Application Timeline

November 12, 2019	RFP release
December 20, 2019	Deadline for submission of pre-proposals (5 p.m. ET)
February 3, 2020	Announcement of projects selected for full proposals
March 16, 2020	Deadline for submission of full proposals (5 p.m. ET)
May 1, 2020	Announcement of new awards for 2020
June 1, 2020	Funding start date for new awards

II. Program Eligibility

Applicants Eligible for Funding: All faculty at the rank of assistant professor, associate professor and full professor at HMS and its affiliated hospitals are eligible to apply for funding as the lead PI.

Collaborations are encouraged to create the appropriate team for translating the early-stage discovery to licensable intellectual property within the two-year award period.

Awards will be granted directly from the Blavatnik Family Foundation to the PI's institution.

See also Section VII.2. for requirements related to inventions and intellectual property.

Activities Eligible for Funding: The focus of the proposal should be late-stage therapeutics research that has the potential to lead to commercialization within two years. The committee has a broad view of therapeutics and will consider projects involving, among others, protein therapeutics, small molecules, gene therapy, AAV-vector based therapies, oligonucleotide-based therapeutics and cell therapies. For small-molecule therapeutics, the project should aim to deliver compounds that are commercializable within two years. The target should be known, and/or there should be some method or assay to determine its effect. For biologics or cell-based therapies, the biologic or cell population should be identified and some reasonable method of development, sourcing, manufacture, or proliferation should be proposed. Mechanism of action should have been determined to a sufficient extent that there is a reasonable understanding of the product to be developed or tested in the project.

Proposals to develop new licensable entities will be prioritized over proposals to repurpose existing therapeutics. Proposals to develop diagnostics or medical devices will not be considered.

III. Award Type and Funding Levels

Awards are intended to support late-stage therapeutics research that (if successful) would establish a basis for forming a new company or licensing a new therapeutic to pharma/biotech. Within established budgetary parameters (see below), projects will be funded at the level deemed necessary to achieve the proposed research objectives. *It is anticipated that up to five new awards will be made every year for the next four years.*

Funding Level for the Blavatnik Therapeutics Challenge Awards: Projects will be funded at a level of up to \$1,000,000 (total costs) over a period of up to two (2) years.

Awards will be milestone-driven, and continued funding will be contingent on progress made toward the achievement of sequential milestones.

IV. Proposal Submission, Review, and Selection Process

1. Pre-proposals (submission deadline: December 20, 2019 at 5 p.m. ET)

The template for pre-proposals is shown in the Appendix. Only one pre-proposal per applicant (lead PI) will be considered. Pre-proposals will undergo a confidential review process by the Executive Steering Committee with consultation, as needed, from expert reviewers selected from the HMS community or external entities. Based on recommendations from the Executive Steering Committee, a subset of applicants will be invited to submit a full proposal.

2. Full proposals (submission deadline: March 16, 2020 at 5 p.m. ET)

The application and budget templates for full proposals will be available to applicants invited by the Executive Steering Committee to submit full proposals. The HMS Translator Director will be available to work with PIs to assist in the development of full proposals, in particular with respect to describing the impact, establishing milestones, and determining the potential for commercialization of the proposed project. Full proposals will undergo a confidential review process by the Executive Steering Committee with consultation, as needed, from expert reviewers selected from the HMS community or external entities. Applicants will be asked to present their proposals to the Executive Steering Committee as part of the Committee's final deliberations. The Blavatnik Family Foundation will make all final award decisions.

3. Evaluation criteria

The goal of this funding mechanism is to support innovative, investigator-initiated therapeutics research aimed at obtaining the proof-of-concept, proof-of-value and validation studies required for commercial translation of the therapeutic. Thus, proposals will be evaluated on their scientific and technical impact, relevance to therapeutics and potential for technology transfer.

Applicants may contact the HMS Director of Translational Research Programs, Dr. Ifat Rubin-Bejerano (ifat_rubin-bejerano_i-hub@hms.harvard.edu), with questions about the submission, review and selection process for pre-proposals.

V. Budget and Funding Period

The duration of the award will in no case exceed two (2) years. Awards will be milestone-driven, with continued funding subject to satisfactory achievement of milestones. Ongoing and frequent project review will be conducted during the life of the award. No-cost extensions may be granted in exceptional cases, subject to demonstrated progress and approval by the Executive Steering Committee and the Blavatnik Family Foundation. A project may be terminated if agreed-upon milestones are not met.

Funding may be used only for research directly related to and budgeted under the project, and may not be used for any other purpose. Budget items may include PI salary, capital equipment and project-related travel, but not computers.

In some cases, the research project may be structured such that some of the activities are outsourced to approved contract research organizations (CROs). In such cases, HMS Translator staff will be available to assist the PI in identifying qualified CROs and developing work plans, and the technology development office at the PI's institution will negotiate work-for-hire agreements on behalf of the PI.

Re-budgeting within and between budget categories will be allowed to meet unanticipated needs and to adjust for post-award findings, changes in personnel, etc. Changes within 25% of the original budget may be made at the awardee's discretion. Changes greater than 25% must be discussed with and approved by the Translator Director prior to implementation.

The responsibility for management of the award is held by the awardee.

VI. During the Award

For each project, the research team (PI and research personnel) will be supported by the Translator Director and by external consultants with specific technical and/or commercialization expertise, as appropriate.

VII. 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. Awardees must report for discussion with the Translator Director significant changes in personnel and/or effort greater than 25% prior to implementation of such changes.
- 2. Inventions and Intellectual Property:** Background IP or pre-existing inventions are required. Any intellectual property must have been assigned, at least in part, to Harvard or an HMS-affiliated institution. If such background intellectual property is jointly owned with one or more other institutions, then an inter-institutional agreement between

Harvard or the HMS-affiliated institution and the co-owning institution(s) must be put in place prior to approval of funding.

Any new inventions that are conceived or reduced to practice in the course of conducting a Blavatnik Therapeutics Challenge Awards-supported research project must be disclosed no fewer than 30 days in advance of a public disclosure to allow sufficient time to determine whether such public disclosure contains new, potentially patentable subject matter.

Receipt of funding will carry the responsibility to negotiate with the Blavatnik Family Foundation a right of co-investment in technologies resulting from the project.

3. **Research Plan and Milestones:** Each Blavatnik Therapeutics Challenge Award is made to support a research plan with sequential milestones. Achievement of these 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 milestones are not met. Any significant mid-course revisions to the research plan must be approved by the Executive Steering Committee and the Blavatnik Family Foundation.
4. **Funding Restrictions:** In the event that a proposed project secures funding support from industry or another external or internal source during the interval between the time the proposal is submitted and the time funding decisions are made, then the Translator Director and the Blavatnik Family Foundation must be informed immediately. If a project is awarded funding, and funding support for the same project is secured from another source during the funding period, then the Translator Director and the Blavatnik Family Foundation must be informed immediately.

Indirect costs required by HMS or the HMS-affiliated institution must be budgeted within the award. No additional funds to cover indirect costs will be provided.

5. **Research Compliance:** The Blavatnik Therapeutics Challenge Awards are granted directly by the Blavatnik Family Foundation to the PI's institution. The PI, department, and institution are responsible for meeting all compliance requirements associated with the award, including any IRB or animal research approvals. Such approvals must be provided to the HMS Translator Director and the Blavatnik Family Foundation prior to the release of awards.
6. **Publications:** The recipient's "Blavatnik Therapeutics Challenge Award" must be cited in all publications that describe work supported by this award. Reprints of all publications containing this acknowledgment should be provided to the Translator Director and the Blavatnik Family Foundation. As noted above, the PI must report any and all inventions no fewer than 30 days in advance of a public disclosure to allow time to determine whether such public disclosure contains new, potentially patentable subject matter.
7. **Reporting Requirements:** We anticipate that a project manager working in the HMS Translator will meet with the PI and their research team every four to six weeks, and at

all target dates for the milestones that have been specified for the project. The PI and research team should feel free to contact the Translator Director with any questions at any time during the term of the project. All projects must provide final written reports to the Translator Director. Awardees and their home institutions may be asked to provide additional information on an interim basis to assess the progress of the individual project and the effectiveness of the overall Blavatnik Therapeutics Challenge Award program. Additional information may be requested related to intellectual property and the start-up and/or licensing opportunities enabled by the Blavatnik Therapeutics Challenge Awards.

Appendix: Pre-proposal template

Pre-proposal submission deadline: December 20, 2019 at 5:00 p.m. ET

Only one pre-proposal per applicant (lead PI) will be considered.

Questions 1–7 must be completed to submit a pre-proposal. **Pre-proposals should not exceed 3–4 pages.**

All text material must be in a readable font (at least Arial 11 point), and margins must be at least 0.5 inches. The application form should not be altered.

Cover Page (not included in page limit)

- i. PI name, academic rank, department, and institution
- ii. Project title
- iii. Total budget request
- iv. Executive summary (150 word maximum)

1. Background: Describe the scope and nature of the problem the therapeutic will be designed to address and give a brief description of the solution, including the disease burden, expected users and market space in which the product would operate.

2. Unmet Need: What is the unmet need to be addressed by the therapeutic? Be sure to provide evidence to support the need from multiple stakeholder perspectives (e.g., patient, clinician, payer). Compare your solution to the current and predicted standard of care.

3. Proposed Product/Solution: Describe the proposed solution, the setting in which it will be utilized (e.g., ICU, in-patient, out-patient, primary care physician) and the primary patient population/indication for use. Characterize the expected benefit from the therapeutic and how it will enhance current or predicted standard of care or replace it. What is the evidence to support the expected benefit?

4. Preliminary Data: Provide a concise (up to 1 page) synopsis of your preliminary data, including key figures and tables where relevant.

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5. Intellectual Property: Describe the extent of interactions with your technology transfer office. Include a list of the IP filed or granted to protect your solution, including patent identification number, title, assignee, date and status. Please briefly describe the types of claims covered (e.g., method of use, composition of matter). If no patents have been filed, describe the types of IP to be generated.

ID Number (application, serial, or patent)	Title	Assignee	Date Filed	Status	Type of claims

6. Project Plan: Provide a short outline of your overall project plan including key milestones, timelines and how success will be measured. What is the final goal to be achieved at the completion of the project? Identify go/no-go decision points and potential pivot points within the plan. Explain how this project plan fits into the overall product development plan.

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7. Personnel: Provide the institutional affiliation, role, and relevant background and expertise of the individuals on the team.

Name	Institution and Dept	Role	Background/Expertise Relevant to Project

8. References

Pre-proposal submission: Pre-proposals must be received by 5:00 p.m. ET on **Dec. 20, 2019**, as a single PDF file. Applications should be submitted via the Harvard Medical School online submission system. The submission URL will be posted on the Blavatnik Therapeutics Challenge Awards website (<https://btca.hms.harvard.edu>) by Dec. 6, 2019.