

The Blavatnik Therapeutics Challenge Awards

<< REQUEST FOR PROPOSALS >>

<https://btca.hms.harvard.edu>

Release date: Tuesday, October 12, 2021

Pre-proposal due: Wednesday, December 15, 2021

Full proposal due: Tuesday, March 15, 2022

Funding start date: Monday, August 1, 2022

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 potentially 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 Translator at HMS (led by the Executive Director of Therapeutics Translation), in collaboration with the Office for Research Operations at HMS (led by the Dean for Research Operations and Global Programs), with active support from the technology development and technology licensing offices at Harvard University and the HMS-affiliated institutions. The resulting grants 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 scientific project management expertise.

I. Application Timeline

October 12, 2021	RFP release
December 15, 2021	Deadline for submission of pre-proposals (5 p.m. ET)
February 1, 2022	Announcement of projects selected for full proposals
March 15, 2022	Deadline for submission of full proposals (5 p.m. ET)
May 23, 2022	2022 BTCA awardees selected
August 1, 2022	Funding start date for new awards

II. Program Eligibility

Applicants Eligible for Funding: All faculty at the rank of assistant professor, associate professor or full professor in the Harvard Faculty of Medicine (i.e., faculty at HMS, the HMS-affiliated institutions and HSDM) 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.

The Blavatnik Family Foundation will provide the funds for the awards, which will be administered by Harvard via a Grant to the PI's institution.

Please also review Section VII for requirements related to intellectual property and investment right to confirm eligibility.

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 Executive Steering 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. A proposal for a combination therapeutic/device or therapeutic/diagnostic may be submitted, but the proposal should strongly emphasize the therapeutic aspect of the project to receive full consideration.

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 four years. This RFP announces the third year of the Blavatnik Therapeutics Challenge Awards. Details regarding the awardees in the first and second program years can be found at the BTCA website: <https://btca.hms.harvard.edu>.

Funding Level: Projects will be funded at a level of up to \$1,000,000 total costs (inclusive of direct and indirect costs) over a period of up to two (2) years.

Indirect costs may be requested at a maximum rate of 38% on a modified total direct costs basis. The modified total direct cost base shall exclude equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs, amounts in excess of the first \$25,000 of each subcontract with a subcontractor, and amounts in excess of the first \$25,000 of each contract with a contract research organization.

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 15, 2021 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.

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

2. Full proposals (submission deadline: March 15, 2022 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 Executive Director of Therapeutics Translation, Dr. Mark Namchuk, and HMS Senior Director, Translational Research, Dr. Ifat Rubin-Bejerano, 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. The Blavatnik Family Foundation will make all final funding 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, and potential to commercialize within two years.

V. Budget and Funding Period

Period of Performance: The requested period of performance may not 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 Harvard Medical School and the Blavatnik Family Foundation. A project may be terminated if agreed-upon milestones are not met.

Time and Effort: All personnel on funded projects must commit time and effort appropriate to their roles on the project. Lead PIs at HMS are expected to budget at least 5% effort and institutional base salary (not NIH-capped salary), and co-PIs at HMS are expected to budget at least 1% effort and institutional base salary on the award. Lead PIs and co-PIs at affiliate institutions should follow their institutional policies regarding time and effort commitments. Lead PIs and co-PIs who are not permitted to budget salary on applications of this type (e.g., HHMI investigators) should budget effort but not salary.

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

In some cases, the research project may be structured such that some of the activities are outsourced to 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 PI's institution will negotiate work-for-hire agreements with the CROs on behalf of the PI. Any such CRO expenses must be appropriately documented within the approved budget.

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. Funds may be re-budgeted without prior approval as long as no single direct cost budget category changes by an amount that exceeds 25% of the total costs awarded. Changes that lead to an increase or decrease in a single direct cost budget category of more than 25% total costs awarded require

prior written approval from the Executive Director of Therapeutics Translation prior to implementation.

The responsibility for management of the award is held by the PI's institution.

VI. During the Award

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

VII. Intellectual Property and Investment Right

1. **Intellectual Property:** Background IP or pre-existing inventions are required. Any background 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.
2. **Investment Right:** In the event that the grantee institution exclusively licenses its rights in any patent or patent application claiming an invention made or practiced by researchers in the performance of the BTCA project to a newly-formed start-up venture (a "New Venture"), the grantee institution will ensure that any such exclusive license will require that the BFF (or its designated affiliate) be afforded the right, but not the obligation, to invest, or commit to invest, funds in the New Venture to inure to the benefit of charity in an amount up to and equal to the amount committed by any lead investor of an investment syndicate offering cash in exchange for equity or equity-linked securities issued by the New Venture and on the same terms and conditions available to the lead investor.

VIII. Requirements: Terms and Conditions of the Award

The full terms and conditions of the award can be found in the BTCA Grant Agreement Template, which will be made available to applicants invited to submit a full proposal.

As part of the full proposal submission, the authorized organizational representative of the lead PI's institution must endorse a statement that they have reviewed the terms and conditions included within the BTCA Grant Agreement Template and agree to accept such terms and conditions in the event that the proposal is funded.

IX. Reporting Requirements

We anticipate that a scientific 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 Executive Director of Therapeutics Translation with any questions at any time during the term of the project. All projects must provide final written reports to the Executive Director of Therapeutics Translation within 90 days of the project end date. 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 15, 2021 at 5:00 p.m. ET

Submission: Pre-proposals must be received by 5:00 p.m. ET on **December 15, 2021**, as a single PDF file. Applications should be submitted via the Harvard Medical School online submission system: <https://harvardmed.tfaforms.net/f/2022btca>

Template: A copy of the pre-proposal template in Word format will be posted on the BTCA website: <https://btca.hms.harvard.edu>.

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 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 (total costs, \$1 million maximum)
- iv. Project period of performance (two years maximum)
- v. Executive summary (150 word maximum)

Pre-proposal (not to exceed 4 pages)

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?

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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 (not included in page limit)