

REQUEST FOR PROPOSALS

Translating Basic Science into Advanced Therapies

Release Date: September 3, 2024

Background and Purpose:

The Blavatnik Biomedical Accelerator and Harvard's Office of the Vice Provost for Research (OVPR) are pleased to offer Harvard University researchers a unique funding opportunity to support projects executed at [Landmark Bio](#). **This opportunity, distinct from other Accelerator RFPs, is well suited for investigators looking to develop a therapeutic candidate or develop, prototype and/or evaluate process and analytical technologies with applicability to advanced therapies (e.g., cell therapy, gene therapy, mRNA). Investigators will benefit through interactions with Landmark Bio's team of experienced drug developers and by leveraging Landmark Bio's state-of-the-art development and manufacturing facilities.**

A significant obstacle in moving early-stage discoveries from the bench to the clinic is access to pharmaceutical development Chemistry, Manufacturing and Controls (CMC) expertise to translate lab protocols into processes suitable for execution in manufacturing facilities meeting current Good Manufacturing Practices (cGMP) requirements for human use. To bridge this gap, Harvard has partnered with MIT, five Harvard-affiliated hospitals, the Massachusetts Life Sciences Center, FUJIFILM Diosynth Biotechnologies, and Cytiva to create Landmark Bio, an innovative advanced therapies translational contract development and manufacturing organization in Watertown, Massachusetts. Landmark Bio's mission is to translate groundbreaking research into life-changing therapies, and its vision is to create a world where advanced therapies are accessible to all. Academic investigators can quickly bridge the gap from bench to patient by leveraging Landmark Bio's expert CMC translational and GMP manufacturing services, deep industry expertise, and flexible partnership models. Today's advanced therapies often incorporate diverse genomic, cellular, and delivery technologies. Landmark Bio's modular, reconfigurable manufacturing capabilities were designed from the ground up to support a diverse cell and gene therapy technology toolbox.

The Blavatnik Biomedical Accelerator is managed by Harvard's [Office of Technology Development](#) (OTD) under the auspices of the Office of the Provost and in consultation with an independent advisory committee comprising leaders from the Boston business and investment community.

I. Application Timelines

	2024 funding cycle
Pre-proposal submission deadline	October 8, 2024
Announcement of finalists	November, 2024
Full proposals due	December, 2024
Announcement of awards	January, 2025
Funding available	February, 2025

II. Program Eligibility and Funding Levels

Applicant: Anyone with a faculty appointment 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. HMS applicants must hold a faculty appointment with PI rights and must accept their award and run their project through one of the HMS Basic and Social Science departments listed [here](#).

Activities: Examples of projects eligible for funding include but are not limited to:

- Optimization, efficacy testing, and preclinical evaluation of lead advanced therapies (e.g. cell, gene, mRNA)
- Development of manufacturing processes and analytical methods for novel advanced therapies (e.g. vectors with engineered/novel capsids, novel autologous cell or gene therapies, extracellular vesicles, mRNA, LNP, etc.)
- Prototype development, evaluation and/or scale-up for cell or gene therapy manufacturing or analytical process technologies
- Translation of research protocols to manufacturing procedures suitable for GMP manufacturing
- Preparation of material to support IND enabling safety studies or early clinical trials

Funding Levels and Stipulations: **Up to \$500K in funding will be provided per project, with the goal of funding at least two projects.** A minimum of 75% of the overall budget should be used for direct support of Landmark Bio services. Indirect costs/overhead are not permitted, in keeping with the terms of the funding source. Funds will be made available in February 2025 upon receipt of a signed award letter with terms and conditions and provision of any other required documentation. Delayed receipt of documentation may delay the disbursement of funds.

Assurance of Compliance: All recipients of this award are expected to comply with all University policies governing the conduct of research, including, but not limited to, the use of animals, human subjects, hazardous materials, and export controls. Awardees will be asked to provide the name and signature of a Harvard school, department, or institutional administrator who, in addition to the principal investigator, will certify that the project complies with all relevant policies. Funds will not be made available, and invoices from non-Harvard entities will not be reimbursed without such certification. All applicants are subject to audit.

IV. Proposal Review and Selection Process

1. Pre-proposals

Any Harvard Principal Investigators who are interested in learning more about this funding opportunity should contact blavatnik_accelerator@harvard.edu. The Blavatnik Biomedical Accelerator, OTD, and OVPR will work with applicants to develop a pre-proposal according to a Word template that will be provided.

2. Full proposals

The Blavatnik Biomedical Accelerator team, OTD, and OVPR will assist finalists with the development of full proposals. Finalists will also meet with Landmark Bio scientists to develop a detailed project plan and budget. Full proposals will be reviewed by an independent advisory committee, which will make recommendations for award decisions in consultation with BBA, OTD, and OVPR.

3. Evaluation criteria

The following evaluation criteria are considered during the review process:

- Potential impact and significance for human health and public benefit
- Differentiation with respect to technologies that are currently available or in development
- Likelihood of generating a strong intellectual property position
- Innovation and technical/execution risk
- Potential for follow-on funding/additional development

V. Budget and Funding Period

Projects will be funded for a period of up to 24 months. Funding is exempt from Harvard indirect expense charges and may only be used for activities approved by the Accelerator and the independent advisory committee. Budget items may not include capital equipment, computers, travel, student tuition, PI salary, or salary for collaborators at other institutions. It is anticipated that 75% of the funded activities will be performed at Landmark Bio and that no more than 25% of the funding shall be spent on salary support for personnel or supplies within the PI's lab.

VI. During the Award

For each award, a project team will be assembled to manage the project and review its progress throughout the funding period. In addition to the PI, team members will include Accelerator and OTD staff, Landmark Bio staff, research personnel, and external consultants with specific technical expertise as needed.

VII. Terms and Conditions of the Award

1. **Time and Effort:** Personnel expenses should accurately reflect the time commitment necessary to complete the agreed-upon work. Funding is intended to support only the effort required for the project and is not intended to cover a full-time salary unless the project demands 100% of the individual's time. If the project is completed earlier than the anticipated timeline or secures external industry funding before the original end date, personnel support will end.

2. Inventions and Intellectual Property: There is no requirement for any background, pre-existing inventions, or prior intellectual property. However, if there is any background intellectual property for the project, 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 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 award is made for a research plan with objective and achievable technical milestones that are agreed upon with the Accelerator and OVPR. The achievement of these milestones will serve as key decision points when assessing progress for approval of continued funding. A project may be terminated if the agreed-upon technical milestones are not met within specified timelines. The research plan or budget may be adjusted during the funding period; however, any significant changes must receive prior written approval from the Accelerator.

4. Funding Status: Awardees must inform the Accelerator immediately if internal or external funding is obtained to support any of the specific aims that are included in the awardee's project. If the project secures significant external funding, such as industry support in the form of sponsored research funding, or if the technology is licensed to an industry partner (including a new startup company), then funding will end, and the remaining awarded amount will not be available.

5. Research Compliance: 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. Accelerator will not reimburse any interest accrued due to late payments or expenses that exceed the awarded amount.

6. Publications: Principal Investigators **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 quarterly basis. Progress reports will be required at quarterly 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 confirm that all charges adhere to the terms of the award and qualify as allowable expenses. To facilitate this, awardees must provide detailed financial reports, including transaction listings and names of any personnel whose salary and benefits are to be charged.

Additional Resources:

[Blavatnik Biomedical Accelerator](#)

[Harvard University Office of the Vice Provost for Research](#)

[Landmark Bio](#) and [here](#)