



## << REQUEST FOR PROPOSALS >>

**Release date: Tuesday, December 12, 2023**

**Pre-proposal due: Wednesday, February 7, 2024**

**Full proposal due: Tuesday, April 30, 2024**

**Funding start date: Monday, July 1, 2024**

**Updated: December 15, 2023**

**Background and Purpose:** Q-FASTR, the Quadrangle Fund for Advancing and Seeding Translational Research at Harvard Medical School, identifies, supports, and expedites early-stage research with eventual commercialization potential. A significant obstacle to the development of early-stage discoveries is the lack of funding for risky and novel research and for the basic or translational studies needed to demonstrate the innovation's potential or proof-of-concept (POC). Q-FASTR provides funding and other support to help HMS Quad faculty identify promising, nascent **therapeutics projects** within their labs and develop them to a stage where they are attractive to other funding sources such as public or private agencies, other institutional sources, or potentially industry.

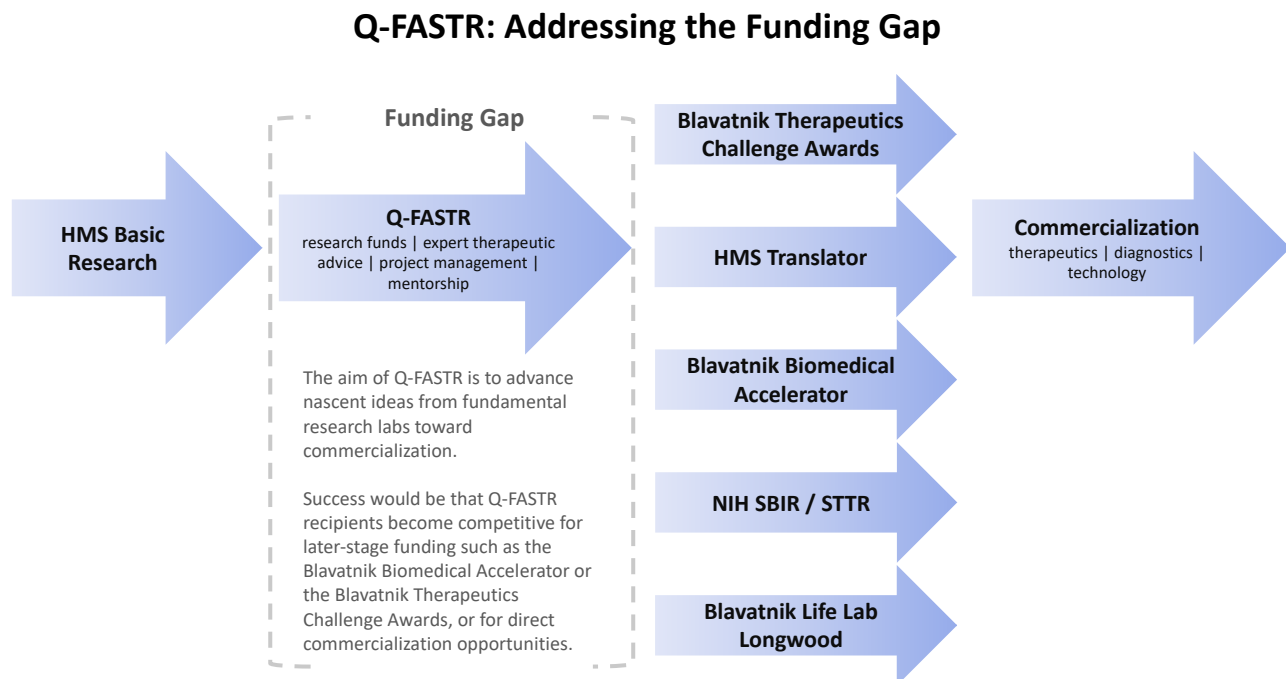
The chart on page 2 shows the relative positioning of Q-FASTR projects in the basic to translational research funding pipeline. Q-FASTR is intended to bridge the funding gap identified on the chart.

Q-FASTR has recently received a generous gift of \$10.5 million on top of the initial gifts of \$5 million, and is also supported by school funds. Since the start of the program in 2016, we have funded 68 awards. *We anticipate that about 10 new awards will be made as a result of this RFP.*

This RFP will be overseen by the Q-FASTR Executive Steering Committee, which is chaired by HMS senior leadership and comprised of HMS faculty and external experts from industry and business. The program will be managed by the HMS Therapeutics Initiative, with active support from the Office for Research Operations and the University's Office of Technology Development (OTD). Applicants and awardees have access to a team of scientists with pharma and biotech experience who provide scientific advice and project management to advance and expedite proposals and projects. We encourage applications from PIs with expertise in disease biology who lack experience in drug development. PIs are invited to contact the Senior Director for Translational Research, Dr. Ifat Rubin-Bejerano at [ifat\\_rubin-bejerano@hms.harvard.edu](mailto:ifat_rubin-bejerano@hms.harvard.edu) to learn how the Therapeutics Initiative can assist on drug discovery across all modalities (e.g., small molecules, proteins, nucleic acids).

## I. Application Timeline

Tuesday, December 12, 2023	RFP release
Wednesday, February 7, 2024	Deadline for submission of pre-proposals (5 pm ET)
Monday, March 25, 2024	Announcement of projects selected for full proposals
Tuesday, April 30, 2024	Deadline for submission of full proposals (5 pm ET)
Monday, June 3, 2024	Announcement of new awards for FY2024
Monday, July 1, 2024	Funding start date for new awards



## II. Program Eligibility

**Applicants Eligible for Funding:** Assistant professors, associate professors, and professors who have research programs located in the HMS Quadrangle and assign intellectual property (IP) to Harvard University (including HSCRB faculty who assign IP to Harvard University and LSP investigators whose IP is governed by joint Harvard–affiliate institutional agreements) are eligible to apply for funding as lead Principal Investigator (PI).

PIs must be HMS Quad faculty as described above. Collaborations are permitted with both HMS Quad investigators and non-HMS Quad investigators.

All awards will be managed through HMS.

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

**Activities Eligible for Funding:** The focus of the proposal should be early-stage therapeutics research that has the potential to lead to commercialization. The committee is looking for innovative ideas that could lead to significant advances in treatments or acceleration of the ability to discover them. Projects involving protein therapeutics, small molecules, gene therapies, oligonucleotide-based therapeutics, and cell therapies, as well as projects that can potentially support the development of new therapies (computational approaches, screening technologies, etc.), diagnostics, and other commercializable technologies are within scope.

### III. Award Types and Funding Levels

Awards are intended to support early-stage therapeutics research, proof-of-concept therapeutics research, and other therapeutics research activities that (if successful) would establish a basis for a subsequent proposal for funding by public or private agencies, other institutional sources, or potentially industry. 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 about 10 new awards will be made in 2024.*

Applicants may submit proposals for one of two types of awards:

**Pilot Awards:** Pilot awards will be funded at a level of up to \$100,000 (direct costs) over a period of up to one (1) year. Pilot awards will typically be used to support performance of a critical experiment or set of experiments to validate a therapeutics-related concept that may provide the basis for later-stage funding or for direct commercialization opportunities. For example, target validation studies or development and validation of an assay that would be used later for screening would both be in scope. Mechanistic inquiry aimed at identification of new targets is typically not in scope. PIs are encouraged to contact the Senior Director to help them design in-scope pilot projects.

**Development Awards:** Projects at a more advanced stage of development will be funded at a level of up to \$300,000 (direct costs) over a period of up to two (2) years. The goal of the Development Awards would be to deliver tangible results which provide a clear path to clinical or commercial development and increase confidence in the success of such development. As examples, in therapeutic development this might be done by developing chemical or biological hits with activity in validated pre-clinical models.

## **IV. Proposal Submission, Review, and Selection Process**

### **1. Pre-proposals (submission deadline: Wednesday, February 7, 2024 at 5:00 PM ET)**

The format for pre-proposals is shown in Appendix A. The Senior Director will be available to work with PIs to develop their ideas and research plans. Pre-proposals will undergo a confidential review process by the Q-FASTR Executive Steering Committee with consultation, as needed, from expert reviewers selected from the HMS community or external sources. Based on recommendations from the Q-FASTR Executive Steering Committee, a subset of applicants will be invited to submit a full proposal.

A lead PI may submit multiple pre-proposals, and the Q-FASTR Executive Steering Committee may invite an applicant to submit a full proposal based on one or more of these pre-proposals.

### **2. Full proposals (submission deadline: Tuesday, April 30, 2024 at 5:00 PM ET)**

The format for full proposals is shown in Appendix B. The Senior 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 Q-FASTR Executive Steering Committee with consultation, as needed, from expert reviewers selected from the HMS community or external sources. The Executive Steering Committee will make all award decisions.

The Q-FASTR Executive Steering Committee will ordinarily prioritize distribution of funds across as many lead PIs as possible, but may fund two proposals from the same lead PI if both proposals are very strong.

### **3. Evaluation criteria**

The goal of this Q-FASTR funding is to support innovative, investigator-initiated therapeutics research aimed at obtaining preliminary observations for high-impact research that may lead to potentially commercializable products. Proposals will be evaluated on their scientific and technical impact, relevance to therapeutics, and potential for technology transfer by a standing committee that includes experts in translational research from academia and industry. Applicants may contact the Senior Director with questions about the proposal submission, review, and selection process.

## **V. Budget and Funding Period**

Award duration and funding level will depend on award type (see Section III), and will in no case exceed two (2) years. Ongoing and frequent project review will be conducted during the life of the award, with evaluation of progress against the project's milestones. No-cost extensions may be granted, subject to demonstrated progress and approval by the Q-FASTR Executive Steering Committee. 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, computers, and software, but not travel. Note that capital equipment, computer, and software purchases require pre-approval from the Senior Director for Translational Research at HMS. All lead PIs are expected to budget

at least 5% of institutional base salary (not NIH-capped salary) and effort on the award for Development Awards, and at least 1% of institutional base salary (not NIH-capped salary) and effort on the award for Pilot Awards. PIs who are not permitted to budget salary on applications of this type (e.g., HHMI investigators) should budget effort but not salary. Co-PIs are expected to commit at least 1% effort on the award.

Indirect costs required by collaborating Co-PIs at other institutions must be budgeted within the award amount and are capped at a maximum rate of 20% of total direct costs allocated to such institution. No additional funds to cover indirect costs will be provided.

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, Q-FASTR staff will assist the PI in identifying qualified CROs and developing work plans.

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 category in the budget changes by an amount that exceeds 25% of the total costs awarded. Changes to the budget that lead to an increase or decrease in a single direct cost budget category of more than 25% of the total costs awarded require prior approval from Q-FASTR.

In accordance with usual HMS practice, the responsibility for management of the award is held by the awardee. The Office for Research Operations will regularly monitor the use of the funds.

## **VI. During the Award**

For each Q-FASTR project, the research team (PI and research personnel) will be supported by the Senior Director and by the Therapeutics Initiative with specific technical and/or commercialization expertise, as appropriate.

Q-FASTR highly encourages the PI and/or a designated member of their research team to attend regular meetings of the Bridges to Industry Program. This program will afford the teams the opportunity to present their research progress to other grantees and industry colleagues under confidentiality, receive feedback, and attend presentations from other Q-FASTR recipients.

## **VII. Other Requirements: Anticipated 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. As noted above, all lead PIs are expected to budget at least 5% institutional base salary (not NIH-capped salary) and effort on the award for Development Awards, and at least 1% of institutional base salary (not NIH-capped salary) and effort on the award for Pilot Awards. Co-PIs are expected to commit at least 1% effort on the award. Awardees must report for discussion with the Senior

Director significant changes in personnel and/or effort greater than 25% prior to implementation of such changes.

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, at least in part, to Harvard and be managed by Harvard OTD. If such background intellectual property is jointly owned with one or more other institutions, then an inter-institutional agreement between Harvard and the co-owning institution(s) must be put in place by Harvard OTD prior to the initiation of the grant, authorizing Harvard OTD to manage the commercialization of the jointly-owned background intellectual property on behalf of the co-owning institutions. Harvard will have the first right, but not the obligation, to manage all intellectual property resulting from Q-FASTR support, including without limitation to prosecute, file, maintain, defend and enforce patent applications and patents that claim any technology jointly developed by Harvard and collaborator personnel through any researcher's use of Q-FASTR support, and to lead commercialization efforts and sign licensing agreements that cover such intellectual property.

Any new invention that is conceived or reduced to practice in the course of conducting a Q-FASTR-supported research project must be disclosed to the Harvard University Office of Technology Development no fewer than 30 days in advance of a public disclosure to allow OTD staff sufficient time to determine whether such public disclosure contains new, potentially patentable subject matter and, if so and if OTD determines that subject matter to have commercial value, to seek patent protection for it.

Intellectual property conceived, reduced to practice, or otherwise made, improved, or further developed with Q-FASTR 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, as defined therein, realized by Harvard from such intellectual property will be managed in accordance with Section V. of that Policy. The full policy may be found at:

<https://otd.harvard.edu/faculty-inventors/resources/policies-and-procedures/statement-of-policy-in-regard-to-intellectual-property/>.

3. **Research Plan and Milestones:** Each Q-FASTR 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. 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 Senior Director.
4. **Funding Restrictions:** In the event that a proposed project secures funding support from industry or another external (e.g., NIH) or internal source (e.g., the Blavatnik Biomedical

Accelerator) during the interval between the time the proposal is submitted to Q-FASTR and the time funding decisions are made, then the Senior Director must be informed immediately. If a project is awarded Q-FASTR funding, and funding support for the same project is secured from another source during the Q-FASTR funding period, then the Senior Director must be informed immediately. Subject to compliance with the terms of any such funding support, any overlapping funds provided by Q-FASTR may be reallocated to other activities provided that those activities are directly related to the funded project and are approved in writing by Q-FASTR.

5. **Research Compliance:** Q-FASTR awards are an internal funding mechanism and will therefore not be set up in GMAS or require OSP/ORI approval at the proposal stage. The PI and department are responsible for meeting all compliance requirements associated with the award, including any IRB or animal research approvals. Documentation of such approvals must be provided to Q-FASTR prior to the release of awards.
6. **Publications:** "The Quadrangle Fund for Advancing and Seeding Translational Research at Harvard Medical School" must be cited in all publications that describe work supported by Q-FASTR. Reprints of all publications containing this acknowledgment should be provided to the Senior Director. 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 time to determine whether such public disclosure contains new, potentially patentable subject matter.
7. **Reporting Requirements:** We anticipate that Ifat Rubin-Bejerano will meet with you (and your research team, if you wish) every four to six weeks initially, and then at the target dates for the milestones you have specified for your work. You should feel free to contact her with any questions at any time during the term of your project.

In addition to frequent meetings with Ifat, a progress report will be due once a year. Each report should specifically address research results relative to each specific aim and milestone and include a statement of any inventions made in the course of performance of the funded project. The report should also list the personnel who have been involved in the project during the reporting period. Periodic financial reports will be run by Q-FASTR to verify the appropriateness of project expenses. Lead PIs will be responsible for reviewing invoices from Co-PIs at collaborating institutions and verifying the appropriateness of project expenses prior to payment.

## Appendix A: Pre-proposals

**Pre-proposal submission deadline: Wednesday, February 7, 2024 at 5:00 PM ET**

A lead PI may submit multiple pre-proposals, and the Q-FASTR Executive Steering Committee may invite an applicant to submit a full proposal based on one or more of these pre-proposals.

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. Lead PI name and department
- ii. Project title
- iii. Total budget request
- iv. Executive summary (150 word maximum)

### Section 1: Background and Significance

- i. Need and Significance: Describe the impact and/or need for the therapeutics technology, its novelty, and the envisioned potential applications. Compare the potential applications to the current state of the art and competing technologies. Include a brief justification of the novelty of your strategy based on the current market.
- 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
- ii. Describe the criteria that will be used to determine whether the specific aims have been achieved, and describe any alternative approaches.

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

- i. References: Please list references cited in Sections 1 and 2 on a separate page and keep the length of the reference list to a maximum of one page.
- ii. NIH biosketch for the lead principal investigator, collaborators, and any other key project participants.
- iii. Identify all prior, current, and pending sources of support to the Lead PI's and any Co-PI's lab(s) related to the proposed research project.
- iv. Total budget requested: Provide estimated costs on PHS 398 form Page 4 and Page 5 (if beyond one year). Budget items may include PI salary, capital equipment, and computers but not travel. Note that capital equipment and computer purchases require pre-approval from the Senior Director for Translational Research at HMS.
- v. Relevant publications/manuscripts, provided as PDF files (maximum of 3).

**Pre-proposal submission:** Pre-proposals must be received by 5:00 PM ET on **Wednesday, February 7, 2024** as a single PDF file. Applications should be submitted via the Harvard Medical School Internal Awards Submission Portal: <https://forms.hms.harvard.edu/f/2024qfastrpre>



## **Appendix B: Full proposals**

**Announcement of pre-proposals selected for full proposals: Monday, March 25, 2024**

**Full proposal submission deadline: Tuesday, April 30, 2024 at 5:00 PM ET**

Q-FASTR staff will be available to work with PIs in the development of full proposals, particularly with respect to describing the impact, establishing milestones, and determining the potential for commercialization of the project. Sections 1 and 2 together should not exceed 5 pages. The cover page and Sections 3, 4, and 5 are not counted toward the page limit.

### **Cover Page (not included in page limit)**

- i. PI name and department
- ii. Project title
- iii. Total budget request

### **Section 1: Executive Summary (250 word maximum)**

- i. Describe the impact, need/opportunity, and significance of any potential therapeutics technology.
- ii. State the major research objectives of the project and how they will advance the potential technology and enhance its impact.

### **Section 2: Background, Significance, and Research Plan**

- i. Brief introduction to the area of investigation. Describe the unmet need and clinical population for the proposed indication in your area of therapeutics investigation. Include a justification of the novelty of your strategy based on the current market, and a brief summary of how your approach is differentiated from the current landscape and standard of care.
- ii. Summarize significant recent research related to this proposal, including your own work and that of others in the field.
- iii. Specific research objectives and the experiments planned to achieve each. Describe how the proposed research will enhance the potential technology's impact and patentability/commercial potential.
- iv. Key milestones, including a description of anticipated results and go/no-go decision points and criteria where possible.
- v. Estimated cost and time required for each objective, including a work performance schedule or Gantt chart.
- vi. Reference list (not included in page limit).

### **Section 3: Intellectual Property (not included in page limit)**

Describe any inventions that have already been made related to the proposed research, and provide a statement about the current IP status of the inventions. Also, describe how the proposed research will enhance existing IP, if applicable.

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

A detailed budget and budget justification should be provided for the entire proposed funding period, using PHS 398 form Page 4 and Page 5 (if beyond one year). The budget should provide planned costs by category:

- i. Personnel: Include percent effort, role, salary, and fringe benefits. Note that salary for the lead PI and any Co-PI(s) is expected (see Section V).
- ii. Supplies: Include supplies by type. Note that computers require pre-approval.
- iii. Equipment: Capital equipment requires pre-approval.
- iv. Other: Please describe any services to be used and their expected cost, and include supporting information in section 5. Note that travel is not allowed.

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

- i. References: Please list references cited in Sections 1 and 2 on a separate page and keep the length of the reference list to a maximum of one page.
- ii. NIH biosketch 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. 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 Q-FASTR for the proposed work). Support letters are not required from contract research organizations, but CRO quotes may be submitted in the budget justification.
- v. Relevant publications/manuscripts, provided as PDF files (maximum of 3).
- vi. Supporting documentation for any services to be used as noted in section 4 above.

**Full proposal submission:** Proposals must be received by 5:00 PM ET on **Tuesday, April 30, 2024** as a single PDF file. Applications should be submitted via the Harvard Medical School Internal Awards Submission Portal: <https://forms.hms.harvard.edu/f/2024qfastrfull>