



Q-FASTR/I-Hub: Dean's Innovation Awards in Therapeutics

<< REQUEST FOR PROPOSALS >>

Release date: Monday, November 5, 2018

Pre-proposal due: Tuesday, December 18, 2018

Full proposal due: Friday, March 15, 2019

Funding start date: Monday, July 1, 2019

Background and Purpose: Q-FASTR, a component of the new Innovation Hub (I-Hub) within the Harvard Medical School Therapeutics Initiative, is joining forces with the Dean's Innovation Grants Program to fund exciting projects with translational potential. 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). The Dean's Innovation Grants Program aims to substantially enhance existing projects in HMS Quad laboratories and existing or new collaborations between HMS faculty members. Together, Q-FASTR/I-Hub and the Dean's Innovation Grants Program will provide 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/I-Hub 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 been funded by three initial gifts to Harvard Medical School totaling \$5 million. Four million dollars are available for any area of interest, and approximately \$1 million is pledged specifically to support collaborative research related to Alzheimer's disease and Parkinson's disease. The first cycle of Q-FASTR funding was launched in 2016 with 6 awards, the second cycle in 2017 with 4 awards, and

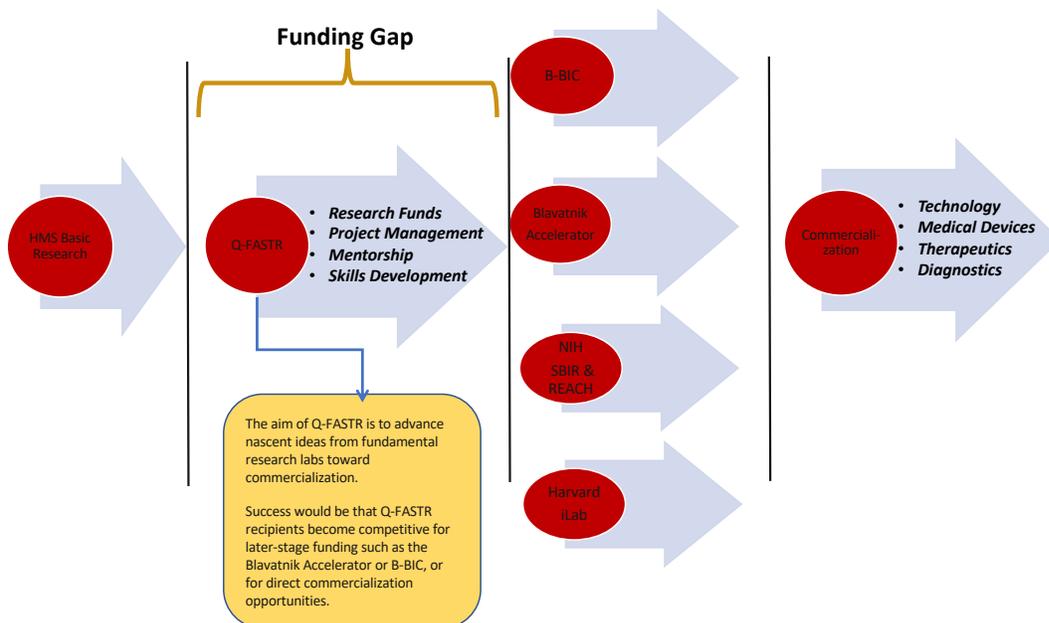
the third cycle in 2018 with 10 awards. Funds will be provided for this RFA from both Q-FASTR/I-Hub and the Dean’s Innovation Grants Program. *We anticipate that up to 10–12 new awards will be made as a result of this RFA, at least one of which will relate specifically to Alzheimer’s disease and/or Parkinson’s disease.*

This RFA will be overseen by the Q-FASTR/I-Hub 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 Office of the Dean for Basic Science and Graduate Education at HMS with active support from the University’s Office of Technology Development (OTD). Applicants and awardees receive project management and skills development support to advance and expedite proposals and projects.

I. Application Timeline

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| Monday, November 5, 2018 | RFP release |
| Tuesday, December 18, 2018 | Deadline for submission of pre-proposals (5 pm ET) |
| Monday, January 28, 2019 | Announcement of projects selected for full proposals |
| Friday, March 15, 2019 | Deadline for submission of full proposals (5 pm ET) |
| Friday, April 12, 2019 | Announcement of new awards for 2019 |
| Monday, July 1, 2019 | Funding start date for new awards |

Q-FASTR: Addressing the Funding Gap



II. Program Eligibility

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

Principal investigators (PIs) must be HMS Quad faculty as described above. Collaborations are permitted with both HMS Quad investigators and non-HMS Quad investigators. **Interdepartmental and/or inter-institutional collaborations are required for applications for funding from the gift that is pledged specifically to support collaborative research related to Alzheimer’s disease and Parkinson’s disease.**

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 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.

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 up to 10–12 new awards will be made in 2019.*

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

Pilot/POC Awards: Pilot awards will be funded at a level of \$50,000 (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.

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.

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: Tuesday, December 18, 2018 at 5 PM ET)

The format for pre-proposals is shown in Appendix A. Only one pre-proposal per applicant will be considered. Pre-proposals will undergo a confidential review process by the Q-FASTR/I-Hub 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/I-Hub Executive Steering Committee, a subset of applicants will be invited to submit a full proposal.

2. Full proposals (submission deadline: Friday, March 15, 2019 at 5 PM ET)

The format for full proposals is shown in Appendix B. The Q-FASTR 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/I-Hub Executive Steering Committee with consultation, as needed, from expert reviewers selected from the HMS community or external sources. Applicants may be asked to present their proposals to the Executive Steering Committee prior to the Committee's final award decisions. The Executive Steering Committee will make all award decisions.

3. Evaluation criteria

The goal of this Q-FASTR/I-Hub 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. Thus, proposals will be evaluated on their scientific and technical impact, relevance to therapeutics, and potential for technology transfer. Applicants may contact Dr. Ifat Rubin-Bejerano at ifat_rubin-bejerano@hms.harvard.edu 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. 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, subject to demonstrated progress and approval by the Q-FASTR/I-Hub 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 and capital equipment but not computers or travel. All PIs are expected to budget at least 5% salary and effort on the award. Faculty who are not permitted to budget salary on applications of this type (e.g., HHMI investigators) should budget effort but not salary.

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/I-Hub 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.

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 Q-FASTR/I-Hub prior to implementation.

In accordance with usual HMS practice, the responsibility for management of the award is held by the awardee. The Office of the Dean for Basic Science and Graduate Education will regularly monitor the use of the funds.

VI. During the Award

For each Q-FASTR/I-Hub project, the research team (PI and research personnel) will be supported by the Q-FASTR 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. As noted above, all PIs are expected to budget at least 5% effort on the award. Awardees must report for discussion with the Q-FASTR 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 approval of funding by Q-FASTR/I-Hub, authorizing Harvard OTD to manage the commercialization of the jointly-owned background intellectual property on behalf of the co-owning institutions. Intellectual property resulting from Q-FASTR/I-Hub support will be managed by Harvard.

Any new inventions that are conceived or reduced to practice in the course of conducting a Q-FASTR/I-Hub-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.

Intellectual property conceived, reduced to practice, or otherwise made, improved, or further developed with Q-FASTR/I-Hub 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 December 12, 2013, and any net royalties received from licensing or other distribution of such intellectual property will be managed in accordance with Section V.C. of that Policy. The full policy may be found at: <http://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/I-Hub 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 Q-FASTR/I-Hub Executive Steering Committee.
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 Accelerator) during the interval between the time the proposal is submitted to Q-FASTR and the time funding decisions are made, then the Q-FASTR Director must be informed immediately. If a project is awarded Q-FASTR/I-Hub funding, and funding support for the same project is secured from another source during the Q-FASTR/I-Hub funding period, then the Q-FASTR Director must be informed immediately. Any overlapping funds provided by Q-FASTR/I-Hub 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/I-Hub.

In the event that some of the budgeted funds are used to support a non-HMS Quad-based collaborator, any indirect costs required by other Harvard schools or HMS-affiliated institutions must be budgeted within the award. No additional funds to cover indirect costs will be provided.

5. **Research Compliance:** Q-FASTR/I-Hub awards 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, including any IRB or animal research approvals. 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" and "the Dean's Innovation Grants Program" must be cited

in all publications that describe work supported by Q-FASTR/I-Hub. Reprints of all publications containing this acknowledgment should be provided to the Q-FASTR 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 twice 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/I-Hub to verify the appropriateness of project expenses.

Appendix A: Pre-proposals

Pre-proposal submission deadline: Tuesday, December 18, 2018 at 5:00 PM ET

Only one pre-proposal per applicant will be considered. 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. 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 on 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. Total budget requested: provide estimated costs on a PHS 398 form. Budget items may include PI salary and capital equipment but not computers or travel.
- 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 **Tuesday, December 18, 2018** as a single PDF file. Applications should be submitted via the Harvard Catalyst Apply Hub system: https://apply.catalyst.harvard.edu/offering_cycles/183/application/new. Apply Hub requires login via Harvard Medical School eCommons username and password, or via Harvard Key (<http://catalyst.harvard.edu/services/loginfaq.html>). If you have not used Apply Hub before, you will be asked to register on a "My Account" page with your name and your email address.

Appendix B: Full proposals

Announcement of pre-proposals selected for full proposals: Monday, January 28, 2019

Full proposal submission deadline: Friday, March 15, 2019 at 5:00 PM ET

Q-FASTR/I-Hub staff will be available to work with PI's 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 a PHS 398 form. The budget should provide planned costs by category:

- i. Personnel: include percent effort, role, salary, and fringe benefits. Note that salary for the PI is expected (see Section V).
- ii. Supplies: include supplies by type. Note that computers are not allowed.
- iii. 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 on 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/I-Hub 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 **Friday, March 15, 2019** as a single PDF file. Applications should be submitted via the Harvard Catalyst Apply Hub system: https://apply.catalyst.harvard.edu/offering_cycles/183/application/new. Apply Hub requires login via Harvard Medical School eCommons username and password, or via Harvard Key (<http://catalyst.harvard.edu/services/loginfaq.html>). If you have not used Apply Hub before, you will be asked to register on a "My Account" page with your name and your email address.