



BOSTON BIOMEDICAL INNOVATION CENTER

Policies and Guidelines for Pilot and DRIVE Funding Programs

The Boston Biomedical Innovation Center provides funding to accelerate the development of device, diagnostics, and therapeutic solutions to heart, lung, blood, and sleep disorders. Applications must address unmet clinical needs to improve healthcare outcomes and aim to generate viable technologies for commercial development. Projects that are in the earlier stages of pre-commercial development will be considered as applications to the Pilot funding program. Awards through the DRIVE program are provided as investments in early-stage technologies that have the potential for commercial translation within two years. Awards include resources provided through business development expertise and entrepreneurial mentorship.

Areas of Interest:

B-BIC will select early stage technologies that address unmet medical needs or offer great scientific opportunities with either immediate commercial potential or otherwise present compelling reasons for continued development. B-BIC is currently focused on innovative devices, diagnostics, and therapeutics related to heart, lung, blood, and sleep disorders. Program priority areas include, but are not limited to, the following:

- **Cardiovascular Diseases:** heart failure, atherothrombosis, myocardial infarction, hypertension, atrial fibrillation along with other atrial and ventricular arrhythmias, sudden cardiac death, adult and pediatric congenital heart disease, cardiovascular complications of diabetes and obesity, acquired valve disease, cardiomyopathies, and peripheral vascular diseases.
- **Lung Diseases and Sleep Disorders:** asthma, bronchopulmonary dysplasia, chronic obstructive pulmonary disease, cystic fibrosis, respiratory neurobiology, sleep-disordered breathing, critical care and acute lung injury, developmental biology and pediatric pulmonary diseases, immunologic and fibrotic pulmonary disease, rare lung disorders, pulmonary vascular disease, and pulmonary complications of AIDS and tuberculosis.
- **Blood Diseases and Resources:** sickle cell disease (SCD), the thalassemias, Fanconi anemia, Diamond-Blackfan anemia and other bone marrow failure syndromes, iron metabolism, fetal hemoglobin production, white blood cell disorders, myeloproliferative and myelodysplastic syndromes, hematopoietic stem cell transplantation and novel cell-based therapies, transfusion medicine (red blood cells, platelets, and plasma) and blood banking including technologies to store and process blood, thrombosis and hemostatic disorders including but not limited to idiopathic thrombocytopenic purpura (ITP), thrombotic thrombocytopenic purpura (TTP), hemophilia, and coagulation factor deficiencies and disorders.

Eligibility:

Faculty from the B-BIC member institutions are eligible to apply. Applicants are encouraged to contact their institutional site manager before submitting an application.

For-profit entities are eligible to apply as collaborators with Principal Investigators at member institutions.

The proposed work must support the advancement of technology that is owned by a B-BIC member institution.

Funding Considerations:

Applications to the Pilot program may request up to \$50,000 direct costs plus full Federal overhead.

Applications to the DRIVE program may request up to \$200,000 direct costs plus full Federal overhead.

Indirect costs are provided at the applicant institution's Federally-negotiated rate up to 77% MTDC for awards supported with Federal dollars.

The current NIH salary cap must be applied to personnel costs.

B-BIC supports the advancement of technology towards commercial development. Funds are not awarded for the purchase of equipment, travel, or publication costs except under unusual circumstances.

DRIVE awards will be released in accordance with milestone and tranche plans included with the application.

Institutional Support:

Awards to investigators at Boston Children's Hospital, Boston University, Boston Medical Center, Draper Laboratories, Massachusetts Institute of Technology, Northeastern University, and the Forsyth Institute include an institutional support requirement, per the agreements reached with these institutions as affiliate members of B-BIC. The institutional support requirement is equal to half of the direct costs of the project and must be transferred to B-BIC. A commitment to support the project will be needed prior to award; the commitment is *not* needed at the time of proposal submission.

Deadlines:

Pre-proposals may be submitted anytime throughout the year. There is no set deadline for pre-proposal submissions.

A subset of applicants who submit pre-proposals will be invited to develop full proposals.

Format:

All pre-proposals and full proposals must be submitted using the on-line application system.

All required supporting documents, including the B-BIC budget form, compliance form, NIH biosketches, and institutional authorization should be included in one .pdf file and uploaded into the on-line application system.

All text material must be in a readable font (at least Arial 10 point), and margins must be at least 0.5 inches.

Questions regarding your application may be sent to Lesley Watts, B-BIC Administrative Director, at

(617) 954-9731 / info@b-bic.org.

FREQUENTLY ASKED QUESTIONS

These FAQs are broken out into those that address the program overview, proposal requirements, what to expect after proposal submission, supporting documentation that is needed, and expectations for post-award collaborations. If additional information is needed, please contact the B-BIC office at 617-954-9731 or at info@b-bic.org

PROGRAM OVERVIEW:

Who can apply for B-BIC grants?

Anyone holding a faculty appointment at a B-BIC member institution may apply for a B-BIC grant.

What are B-BIC's areas of interest?

B-BIC will select early stage technologies that address unmet medical needs or offer great scientific opportunities with either immediate commercial potential or otherwise present compelling reasons for continued development. B-BIC is currently focused on innovative devices, diagnostics, and therapeutics related to heart, lung, blood, and sleep disorders. Program priority areas include, but are not limited to, the following:

- Cardiovascular Diseases: heart failure, atherothrombosis, myocardial infarction, hypertension, atrial fibrillation along with other atrial and ventricular arrhythmias, sudden cardiac death, adult and pediatric congenital heart disease, cardiovascular complications of diabetes and obesity, acquired valve disease, cardiomyopathies, and peripheral vascular diseases.
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- Blood Diseases and Resources: sickle cell disease (SCD), the thalassemias, Fanconi anemia, Diamond-Blackfan anemia and other bone marrow failure syndromes, iron metabolism, fetal hemoglobin production, white blood cell disorders, myeloproliferative and myelodysplastic syndromes, hematopoietic stem cell transplantation and novel cell-based therapies, transfusion medicine (red blood cells, platelets, and plasma) and blood banking including technologies to store and process blood, thrombosis and hemostatic disorders including but not limited to idiopathic thrombocytopenic purpura (ITP), thrombotic thrombocytopenic purpura (TTP), hemophilia, and coagulation factor deficiencies and disorders.

What is a DRIVE grant?

A DRIVE grant is an investment in which the B-BIC will be significantly involved to help demonstrate proof of value. In addition to financial support, DRIVE projects receive active mentoring during proposal development from a team with significant entrepreneurial, product development, technology, and business development expertise. DRIVE projects also receive substantial project management support during the award.

What are the differences between DRIVE grants and Pilot grants?

DRIVE grants offer up to \$200,000 to support direct costs for milestone-driven projects that are expected to be completed within 18 – 24 months. A B-BIC project manager will be assigned to the project in addition to the award. Pilot grants offer up to \$50,000 to support direct costs for completion of work that help demonstrate proof of concept, such as prototype development or reproducibility experiments in different model systems. Pilot grants are expected to be completed within one year.

May I submit more than one application?

Applicants may submit more than one application to both the Pilot and DRIVE programs. However, each application must have a distinct set of aims and workplan.

Is there a limit to the number of applications I can submit?

B-BIC encourages and supports the entrepreneurial personality. Investigators are encouraged to re-apply with proposals for different applications of the same technology as well as new technologies. Early determination of technology failure is part of the process.

PROPOSAL REQUIREMENTS:**When are applications due?**

B-BIC accepts pre-proposals for DRIVE and Pilot grants at any time throughout the year in accordance with the priority areas noted above. Focused requests for applications also may be published during the year and timelines for them will be posted on our webpage at B-BIC.org

Where and how do I submit my pre-proposal and full proposal?

All pre-proposals and full proposals must be submitted through the online submission system at _____

What needs to be included in my pre-proposal?

Pre-proposals should not exceed two pages and must include a brief description of the

- background describing the scope and nature of the problem that the technology will address,
- unmet clinical need,
- proposed product or solution,
- intellectual property position, and a
- short summary of the project plan, including key milestones, and the final goal of the project.

Are there format requirements for pre-proposals and full proposals?

All text material must be in a readable font (at least Arial 10 point), and margins must be at least 0.5 inches.

Should I disclose any unprotected proprietary information in the submission?

Do not disclose any unprotected proprietary information. Protecting proprietary information is the responsibility of the applicant and the applicant institution. Pharma and device companies are actively involved in the center providing expertise and supporting the development of commercial outcomes.

How do I respond to the business development questions if it is too early to know. What support does B-BIC provide to applicants during proposal preparation?

B-BIC Coaches, staff members, Site Miners, and Domain Experts are available to answer questions throughout the year. A list of all B-BIC coaches and staff members can be found at b-bic.org/people.

WHAT TO EXPECT AFTER PROPOSAL SUBMISSION:**When will I be notified if my pre-proposal has been selected to submit a full proposal?**

You can expect to receive an answer within six weeks. Pre-proposals will be reviewed by at least three members of the B-BIC. Every attempt will be made to return an answer as quickly as possible, but heavy volume and reviewer availability will determine the actual turn-around time.

My pre-proposal was accepted and I have been invited to submit a full proposal. Where do I get a copy of the full proposal?

If you are invited to submit a full proposal to the program, you can download the proposal application form from the B-BIC.org website.

When will I be notified if my full proposal for a DRIVE grant has been selected for funding?

Successful pre-proposals will receive coaching and mentoring from a member of the Technology Assessment and Development Group (TADG). The coach will work with you closely throughout the proposal development process. Applicants also will receive help from a B-BIC project manager to prepare the final work plan, milestones, and budget, and finalize the proposal for external review. External review may take up to three months to allow for sponsor input.

When will I be notified if my full proposal has been selected for funding?

The NIH Technology Review Committee meets in March, June, September, and December. You can expect to receive an answer within three to four months. Full proposals will be reviewed by at least three members of the B-BIC and by our sponsor. Every attempt will be made to return an answer as quickly as possible, but heavy volume and reviewer availability will determine the actual turn-around time.

Who reviews the applications?

B-BIC reviewers include practicing clinical specialists and domain experts, engineers and scientists with broad experience in medical innovation, and business development and commercialization experts. Our Federal sponsor partners include the USPTO, FDA, CMS, and payor/provider organizations.

Will I receive a copy of the reviewers' comments?

Reviewer comments will be anonymized and sent to applicants.

Who retains the rights to any intellectual property generated by my proposal?

Management of intellectual property will be determined by the policies of the institution responsible for the proposal. Investigators funded by B-BIC shall seek to establish IP via disclosures and patent filings with their institution's technology transfer office, with an indication that B-BIC funding has been used to support the work. Copies of such communications should be submitted to the B-BIC program office in parallel.

When will I receive my funding?

Projects selected for funding will receive initial funds once all administrative materials have been received, should any additional materials be needed. DRIVE grant awardees will be required to submit milestone reports in order to trigger the release of additional funds.

How will I receive my funding?

Awards will be released via cost-reimbursement subcontract with the exception of projects that will be conducted at Brigham and Women's Hospital (BWH), which serves as the prime institution and fiscal agent for B-BIC. Separate funds at BWH will be established within the B-BIC chief code to support research projects conducted at the prime institution.

Once the necessary compliance and administrative approvals are received, Pilot projects will be awarded in full at the outset of the project period.

DRIVE projects will be managed by the B-BIC project managers. Funds will be released in accordance with the approved milestones.

SUPPORTING DOCUMENTATION (BUDGETS, BIOS, COMPLIANCE & AUTHORIZATIONS):**What is the "institutional sign off page?"**

The institutional signature page is the official form or letter provided by your research administration office indicating that your full proposal is approved by your institution. All full proposal submissions must include institutional authorization.

What is “Institutional Support” and when is it required?

Awards to investigators at Boston Children's Hospital, Boston University, Boston Medical Center, Draper Laboratories, Massachusetts Institute of Technology, Northeastern University, and the Forsyth Institute include an institutional support requirement, per the agreements reached with these institutions as affiliate members of B-BIC. The institutional support requirement is equal to half of the direct costs of the project and must be transferred to B-BIC. A commitment to support the project will be needed prior to award; the commitment is *not* needed at the time of proposal submission.

“Institutional Support” is used to offset the costs of coaching, project management, and the skills development center personnel who are actively engaged in the conduct of the scientific projects, their PI’s, and their team members. This support mechanism enables our member institutions to support B-BIC infrastructure while still being able to tie their support back to specific gains at their institutions.

Institutional support must be transferred to B-BIC in order to document the support provided by our member institutions in compliance with the requirements of the National Centers for Accelerated Innovation program, funded by NIH. B-BIC does not take royalties or IP ownership, because we know what it takes to get a technology to the point where accelerators enter the picture.

Awards are granted with Federal funds, including full overhead at the member institution’s Federally negotiated rate.

Are there any requirements for the budget?

Each performance site must submit a separate budget using the Center Budget Form that is modeled on the NIH 398 format. Budgets must be signed by an authorized institution official and uploaded into the web-based submission system along with the other supporting documents.

A separate budget narrative must be provided that includes personnel responsibilities and effort commitments as well as descriptions of all project costs. DRIVE grant applications must include a breakdown of the budget request in accordance with the proposed milestones and deliverables.

Are there any budget restrictions or limitations?

Personnel costs are subject to the NIH salary cap.

B-BIC supports the advancement of technology towards commercial development. Funds are not awarded for the purchase of equipment, travel, or publication costs except under unusual circumstances. Alterations and renovations will not be supported. DRIVE grants offer up to \$200,000 to support direct costs that are expected to be completed within 18 – 24 months. Pilot grants offer up to \$50,000 to support direct costs and are expected to be completed within one year.

What is the indirect cost rate?

B-BIC will reimburse Pilot and DRIVE recipient institutions for indirect costs in accordance with the funding source providing support for the individual project award. B-BIC is jointly funded by the National Institutes of Health, National Heart, Lung, and Blood Institute (NHLBI), its supporting partner institutions, and industry partners. Pilot and DRIVE grants will primarily be supported by Federal funds and will receive reimbursement for indirect costs in accordance with the recipient institutions’ federally negotiated indirect cost rate, MTDC, up to the rate that is received by B-BIC. B-BIC will endeavor to support grants using Federal funds to the extent possible within the overall budget but reserves the right to fund grants through non-federal funding sources in order to best manage the flow of funds into the Center and accommodate an open solicitation process.

** MTDC includes all direct costs with the exception of capital equipment, patient care costs, alterations and renovations, animal care, and sub-contract costs over \$25,000 per sub-contract aggregated over the grant project period.

Are biosketches needed?

Standard NIH Biosketches with Parts A-D for all key personnel must be combined into a single file and uploaded to the on-line submission system.

What information is needed regarding the use of human or animal subjects?

Each performance site must submit separate compliance information using the Center Compliance Form. The form must be uploaded to the on-line submission system.

Where can I find the supporting document forms?

Budget and compliance forms are available within the on-line submission system. Please contact the B-BIC office if you have any difficulty acquiring the forms. There is no standard form for institutional authorization; each institution may use their individual format.

What is the earliest possible start date?

Applicants who submit full proposals can expect to receive funding notification within three months. Awards can begin once all administrative documents have been received, should any additional materials be needed.

POST AWARD COLLABORATION:**What if I need to re-budget?**

Requests to re-budget more than 25% of the total award should be submitted to Lesley Watts, B-BIC Administrative Director, for prior approval. Re-budgeting any amount into subcontracts, patient care, or equipment, if such costs were not approved as part of the initial budget, must be submitted for prior approval to the B-BIC Administrative Director.

Will no-cost-extensions be allowed?

No-cost-extensions will be considered on a case by case basis and may be requested by completing the Request for No-cost-Extension Form that is available from the B-BIC program office. The NCE request form should be sent along with current IRB/IACUC approvals as applicable to the B-BIC Administrative Director. All reports must be up to date before a no-cost-extension request will be approved.

What if I need to change the direction or focus of my project?

Any significant change in your work plan, including a change in the use of animals or humans, must be submitted in writing by email for prior approval. Requests for change of scope should be sent to the B-BIC Administrative Director who will ensure review by the Program Directors.

How do I acknowledge B-BIC funding in publications?

Publications resulting from work supported by B-BIC should include a statement such as "Research reported in this publication was supported by the National Heart, Lung, and Blood Institute of the National Institutes of Health award number U54HL119145." Please send a copy of all publications to the B-BIC program office.

What are my reporting responsibilities if I receive a B-BIC DRIVE or Pilot award?

Pilot grant awardees will be required to submit an annual and final report. DRIVE grant awardees will be required to submit reports as milestones are achieved in order to trigger the release of additional funds. All projects must provide final written reports to the B-BIC program office.

Awardees and their home institutions may be asked to provide additional information on an annual basis to assess the effectiveness of the overall B-BIC program. Additional information may be related to intellectual property and the start-up and/or licensing opportunities enabled by the B-BIC investment.

What is expected for collaborations and how can I contribute to B-BIC sustainability?

Opportunities to share research and technology development may arise for which investigators may be invited to participate. It is anticipated that investigators are motivated to showcase and enhance their work and promote the B-BIC program.

Further, there is an expectation that investigators are motivated to see their research have an impact on patient care and the healthcare marketplace through start-up and/or licensing opportunities. B-BIC provides guidance, support, and connections with the tech transfer and entrepreneurial communities. Grantees understand that if funded by B-BIC, they will be asked to assess these opportunities with their home institutions and participate to the extent that opportunities are practicable.

ADDITIONAL HELP:**Who do I call for help if I have further questions?**

The B-BIC main office number is 617-954-9731. Email may also be sent to Lesley Watts, B-BIC Administrative Director, at lwatts@partners.org.