

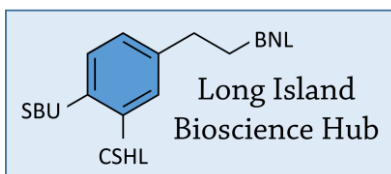
Development and Commercialization of Bio-Based Technologies

Program Overview & Proposal Guidelines

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Program Overview

The Center for Biotechnology (CFB), a New York State Center for Advanced Technology, in collaboration with Stony Brook University, Cold Spring Harbor Laboratory, and Brookhaven National Laboratory, and with critical support provided by the National Institutes of Health REACH initiative (Research Evaluation and Commercialization Hub), The Research Foundation for State University of New York, and Empire State Development, is pleased to announce the formation of the **Long Island Bioscience Hub**.

The **Long Island Bioscience Hub (LIBH)** will foster the development of therapeutics, preventatives, diagnostics, devices and research tools emerging from LIBH partner institutions that address diseases within the NIH's mission. The development of these technologies will be supported by several funding mechanisms as well as a comprehensive suite of technology commercialization services that will help faculty and fellow innovators move their academic innovations into the commercial sector via a start-up company, licensing opportunity, and/or a strategic partnership. The LIBH will focus its resources on four specific areas:

1. Expanding existing infrastructure to foster, prioritize, and commercialize innovations across partner institutions,
2. Implementing translational funding initiatives that will accelerate technology development and create a pipeline of "commercial ready" innovations (*the focus of this information packet*),
3. Recruiting a regional talent pool of experienced Bio-Entrepreneurs in Residence (BEIRs) to facilitate early-stage company formation,
4. Educating faculty, post-docs, and graduate students about entrepreneurship and commercialization in the life sciences, and establishing a formal mentor network.

Translational Research Initiatives

The LIBH will implement a three-tiered technology development initiative that will collectively contribute to a pipeline of commercially promising biomedical technologies. Faculty and post-doctoral associates, alone or in partnership with New York State companies or CFB-appointed BioEntrepreneurs-in-Residence (BEIRs), are eligible to apply. In all instances, the faculty member or post-doctoral associate must serve as the principal investigator, and the project must be executed on the academic campus. Funds are intended to develop innovations emerging from the partner institutions, and only ideas/intellectual property that has been formulated within a LIBH institution, the use of which has not yet been licensed, will be considered. A company with an existing license and/or option to intellectual property directly related to the proposed project is considered a corporate partner and the application may require match funding as defined in each funding program.

A Request for Proposals will be released October 27, 2015 with a submission due date of January 7, 2015, 11:59 PM EST. Proposals submitted after the due date will not be considered. Proposals will be evaluated by the Offices of Technology Transfer of the respective LIBH institute, CFB/LIBH staff, and select external advisors. A secondary review will be performed by a panel convened by the NIH-REACH program in Bethesda, through the National Heart, Lung, & Blood Institute. Funding announcements will be made on or about April 10, 2015.

These Technology Development programs should not be considered substitutes or surrogates for basic-science programs or bridge funding for grant short-falls. This initiative is specifically focused on the

development of bio-based technology. All funding decisions are at the discretion of LIBH principals, the External Review Board and NIH.

The three technology development programs include:

Award	Funding Amount (Direct Cost)	Page Limit	Focus	Outcomes
1. Feasibility	\$50K/12 mo	5	<i>Rapidly test new, commercially promising ideas.</i>	New IP, new applications of existing IP, POC award application, and/or follow-on funding from other sources
2. Proof-of-Concept	\$100K/12 mo	12	<i>Add value to existing intellectual property, begin to develop and execute commercialization strategies</i>	Strategic partner, SBIR/STTR, Out-licensing, New co.
3. Commercialization (invitation only)	\$200K/ 2 years	12	<i>Commercialization plan developed, execute plan</i>	New co., Strategic partner, Professional financing

Feasibility Award Program (\$50k total costs for 12 months, released in two \$25K/6 month tranches, formally reviewed every 6 months; 5 page proposal): designed to rapidly test the feasibility of new ideas in a “fail-fast-or-proceed” format, or to add value to existing intellectual property leading to new market applications of an existing technology.

- Provides up to \$50K over one year, awarded in two \$25K/6 month tranches based upon external review and achievement of predetermined milestones. A written progress report is also required every 6 months.
- A member of the technology team is strongly encouraged to participate in the Commercialization Boot Camp before or during the funding period.
- Projects involving a NYS corporate partner
 - Proposal for licensed applications of a technology is ineligible for funding
 - Proposal for licensed technology but new, as yet unlicensed applications, is eligible for funding
 - If an option agreement is in place for unlicensed applications, a \$1:\$1 match is required
 - If no option agreement is in place for unlicensed applications, no match funding is required
 - In-kind contribution are not permitted
- Can subsequently apply, but not required, for POC program (below).

Proof of Concept (POC) Award Program (*\$100k total costs for 12 months, renewable for one year, released in two \$50k/6month tranches formally reviewed every 6 months, 12 page proposal*): provides targeted, milestone driven support for proof of concept research, development, testing, and analysis on existing intellectual property (provisional patent filed or equivalent). Provides up to \$100K/year, renewable for one additional year based upon achievement of commercially-relevant milestones, approval of External Review Board, and availability of funding.

- Provides up to \$100k over one year, awarded in two \$50K/6 month tranches based upon external review and achievement of predetermined milestones. A written progress report is also required every 6 months.
- A member of the POC technology team **must** complete the Commercialization Boot Camp before or during the funding period.
- Projects involving a NYS corporate partner
 - Proposal for licensed applications of a technology is ineligible for funding
 - Proposal for licensed technology but new, as yet unlicensed applications, is eligible for funding
 - If an option agreement is in place for unlicensed applications, a \$1:\$1 match is required
 - If no option agreement is in place for unlicensed applications, no match funding is required
 - Proposal for optioned applications of a technology is eligible for funding and \$1:\$1 match funding is required, except for BEIR
 - All match requirement will be 2:1 if the corporate partner is not a small entity
 - In-kind contribution are not permitted
- Successful POCs are eligible for the Commercialization Award program at the invitation of the LIBH principals and/or the External Review Board (below).

Commercialization Award Program (*\$200k total costs for 24 months, release in four tranche, formally reviewed every 6 months, 12 page proposal **plus** commercialization plan*): provides targeted, milestone-driven support for a subset of projects with existing intellectual property where additional investment will clearly advance the technology to a major value inflection point for commercialization. Applications are by invitation only: those considering this initiative are required to contact the LIBH staff to discuss their potential application. Guidelines are the same as those for the POC Program except:

- Up to \$200K over two years, awarded in \$50K/6 month tranches based upon external review and achievement of predetermined milestones. A written report is also required
- A full commercialization plan must accompany the application.
- Applicants are required to complete the Commercialization Boot Camp prior to receiving funding
- Projects involving a NYS corporate partner
 - Proposal for licensed applications of a technology is ineligible for funding
 - Proposal for licensed technology but new, as yet unlicensed applications, is eligible for funding
 - If an option agreement is in place for unlicensed applications, a \$2:\$1 match is required
 - If no option agreement is in place for unlicensed applications, no match funding is required
 - Proposal for optioned applications of a technology is eligible for funding and \$2:\$1 match funding is required, except for BEIR
 - In-kind contribution are not permitted

Support for Commercialization & Entrepreneurial Activities

Understanding the issues surrounding commercialization of academic innovations is critical if the goal is to impact human health. To support faculty, post-doctoral associate, and graduate student understanding of these issues, and to streamline and improve the success rate of the “translational” process, the LIBH will provide the following services:

- LIBH staff and industry advisors will be available to guide faculty innovators in all aspects of the commercialization process.
- Commercialization Boot Camp will provide a “hands on” workshop for faculty and post-docs interested in taking an active role in commercializing their innovations.
- A Mentor Network will provide teams of advisors to guide faculty, post-docs and graduate students involved in start-up ventures.
- Fundamentals of the Bioscience Industry program will provide comprehensive training to graduate students and post-docs interested in the commercialization process and expanded career paths.
- BioEntrepreneurs-in-Residence (BEIR) will develop commercialization strategies in collaboration with faculty innovators, with the objective of licensing technology for new company formation.
- Access to a network of professional service providers and investors.

Proposal Guidelines

Request for Proposals Released: October 27, 2015 (dates for 2016 & 2017 TBD)

Deadline for Submission: January 7th, 2016, 11:59 PM EST

Tentative Start Date: May 15, 2016

The LIBH translational research programs provide a tiered structure that allows for progressive funding as ideas move from feasibility stage through proof of concept to commercialization. Applicants should apply under the program that best aligns with the stage of development of their idea or technology. Multiple applications from one applicant are allowed, however it is advised that applicants propose their strongest technology. Individuals that have an interest in applying are strongly encouraged to meet with LIBH staff members prior to submission, and are **required** to do so prior to submission under the Commercialization Award Program. Proposal, project plan, compliance and budget forms can be downloaded from the LIBH web page at: <http://centerforbiotechnology.org/who-we-are/long-island-bioscience-hub/>

Approval from your respective LIBH Sponsored Programs Office is not required *prior* to submission, but will be required if the project is selected for funding. Further details can be found within the application form. Pls must anticipate and proactively address any potential delays due to the institutional approval process, including compliance (e.g., radioactivity, animal, human). Projects that cannot be implemented and executed according to the established award cycle may jeopardize funding.

All submissions should include the required attachments (e.g., compliance forms, project plan form) and a copy of any intellectual property documentation relevant to the proposal. No additional attachments beyond those specified in the application form will be accepted. A single PDF version of the proposal and allowable attachments should be submitted to your Office of Technology Transfer, and copied to Center for Biotechnology and your sponsored programs office by the established deadline. **The submitted document should be named as follows: last name_first name_type of application** (feasibility, POC, or commercialization). e.g., John_Smith_POC. The Technology Transfer Offices will add any additional intellectual property due diligence and forward to the Center for Biotechnology for competitive review.

Technology Transfer Contacts:

CSHL: Jennifer Hsieh jhsieh@cshl.edu

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Center for Biotechnology Contact:

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Budget Guidelines

Budgets for the Feasibility Award and Proof of Concept Award Programs should reflect one year of funding. However, funding will be allocated in six month tranches based upon progress toward milestones as detailed in the application and determined by the external review board. All funding is intended to support achievement of commercially relevant milestones at one of the LIBH partner institutions. Funding is available for salaries of students, postdoctoral fellows, technicians, staff and other non-faculty project personnel, supplies, and miscellaneous expenses. Up to 20% of the direct costs can be allocated towards the salary (including fringe benefits) of the Principal Investigator with calculated annual salary cap of \$183,300. Post-doctoral fellows who apply as a Principal Investigator must receive written permission from their host lab director and are subject to the 20% salary cap. Please note that students and Postdoctoral trainees that are supported by a 3rd party fellowship award may need prior approval from the funding organization to accept this award.

Purchase of computers or equipment is **not** permitted unless dedicated specifically and in total to the proposed project. Travel including going to conferences is also **not** supported. Use of funds to secure commercial testing and external development services as deemed necessary to add commercial value are allowed on a case-by-case basis and with prior approval by the Center for Biotechnology. Budgets should include the appropriate fringe benefit rate as established by your sponsored programs office. If your institution requires that graduate students working on the project receive tuition reimbursement, please include at the appropriate rate. The budget for these technology development programs are Total Direct Cost (TDC). Each institution will address IDC rates above and beyond the TDC, as per local agreements.

Projects conducted in partnership with NYS industry partners are required to provide a letter of support from the NYS corporate partner demonstrating commitment of match funding as outlined in the technology development programs. Only non-grant funds are considered as qualified match funding. Projects co-sponsored by industry require two budgets; one detailing the use of LIBH funding, and the other detailing use of corporate funding. Additional information appears on the budget forms and LIBH web page via: www.centerforbiotechnology.org

Proposal Evaluation

Applications must support milestone-driven technology development objectives that will create or add commercial value to innovations. Specific aims should help develop the technology toward a value inflection point that would facilitate or justify follow-on funding, out-licensing, company formation, or a strategic partnership.

Proposal evaluation is also based upon the quality of the science, potential for strong intellectual property if successful, and the overall commercial potential. Proposals that do not follow the required format will not be accepted. Applications that demonstrate an understanding of the commercialization process (Intellectual property, market need, competitive analysis, regulatory pathway, value inflection points, etc)

will be more competitive, and a more detailed presentation of the commercial opportunity will be required as technologies progress through the development process.

Proposals will be evaluated by the offices of technology transfer, CFB/LIBH staff, and the LIBH External Review Board, comprised of academic scientists and commercialization experts. All external members will sign a confidentiality agreement to protect information provided in the application. A secondary review will be performed by a NIH-REACH panel convened by NIH in Bethesda. Members of both the primary and secondary review boards will remain confidential.

Award Implementation and Administration

Projects selected for funding must obtain approval at the departmental and sponsored programs level as required by their institution. PIs should have the necessary animal research or human subject applications prepared or approved as quickly as possible. Applicants are strongly encouraged to initiate compliance/regulatory issues as soon as possible, ideally at the time they are notified that their application has been recommended to proceed to NIH secondary review. Amendments to existing approvals are acceptable. In those cases where LIBH grants are approved for award, funds will be withheld until animal/human/laboratory approvals are secured. Projects involving corporate co-sponsors will require corporate sponsored research agreements, and it is recommended that they be provided with DRAFT contracts for review before submission of the application. **Lengthy delays in project start dates can jeopardize funding** if not fully anticipated. Awards will be formalized with the establishment of an account in the PI's name. Separate accounts will be established in the name of the faculty PI for the LIBH funding and the corporate funding. Funding obtained through LIBH is not transferrable to any institution beyond partner institutions.

PIs of funded projects will be required to submit a written report and make a formal presentation to the External Review Board every six months. Funding will be awarded in 6 month tranches based upon achievement of pre-determined milestones as detailed in the proposal and as approved by the External Review Board. If the project meets stated milestones as outlined in the proposal and agreed to by the ERB, and the project remains commercially viable, the balance of funding will be released. If the project does not meet the milestones, the PI will have 30 days to revise the project plan to address ERB concerns. If it is determined that continuing the project, even with revised milestones, will not add commercial value to the technology, the LIBH may choose to discontinue funding with 30 days notice.

LIBH staff support will be available to provide pre-submission and ongoing award support to PIs in terms of technology development and commercialization strategy. PIs are expected to work closely with LIBH staff and the respective technology transfer offices to move their ideas and technologies down a commercial pathway. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are encouraged to apply.

Reporting Requirements

The PI must submit a 6 month written progress report and a final written report within 30 days of completion of the project. The format for progress reports can be found on the LIBH web page. All reports should be sent electronically to the LIBH at center_for_biotechnology@stonybrook.edu, with copies to your technology transfer and grants management offices.

PIs will also be required to make a formal presentation every 6 months to the LIBH External Review Board. The review board, comprised of both academic and industry leaders, will provide feedback and actionable guidance in terms of continued commercial development. Projects that do not meet predetermined milestones may be suspended or terminated upon the recommendation of the External Review Board.

Those projects eligible and approved for an additional year of funding will be required to provide a revised work plan, specific aims, and a second-year budget.

The LIBH requires that all PIs who have received support from the LIBH continue to provide brief economic impact updates on no less than an annual basis post award for 5 years. Acceptance of funding under this program obligates the PI to comply with these reporting requirements. All publications resulting from this support should acknowledge the following sponsors as indicated below:

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Faculty members, post-doctoral associates, and BEIRs who are considering the submission of an application are strongly encouraged to contact the technology and business development staff at the LIBH prior to writing a full proposal. CFB/LIBH staff members and advisors are a resource for all faculty, post-doctoral associates and graduate students who have an interest in translational research, whether they are currently funded by the LIBH or not.