

Development and Commercialization of Bio-Based Technologies for Human Health and National Health Security

Program Overview & Proposal Guidelines

Request for Proposals Released: June 16, 2022

Deadline for Submission: July 18, 2022

Tentative Start Date: November 1, 2022

Technology Development RFP Contact:

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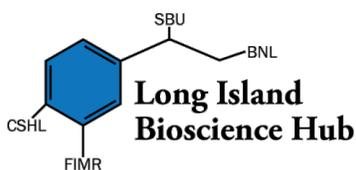
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Please note the following changes to the RFP:

1. With the 2022 deadline, approval from the Sponsored Programs Office is ***NOT*** required prior to the submission but will be required if the project is selected for HHS secondary review. Eligible applicants will be notified on or about October 1, 2022 if their application is selected to move forward.
2. As of 1/2/2022, the NIH salary cap is \$203,700.
3. Acknowledgement of support includes Stony Brook University, the Center for Biotechnology, a New York State Center for Advanced Technology, and in collaboration with the Biomedical Advanced Research and Development Authority – Division of Research, Innovation and Ventures.
4. This funding opportunity includes a pilot project that expands into ‘national health security’ and is therefore limited to Stony Brook University faculty.

Program Overview

The Center for Biotechnology (CFB), a New York State Center for Advanced Technology, is pleased to announce a new technology development solicitation under the **Long Island Bioscience Hub**.

The **Long Island Bioscience Hub (LIBH)** fosters the development of therapeutics, preventatives, diagnostics, devices, and research tools 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 focuses 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 “commercially 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.

National Health Security

This solicitation will also accept biomedical technology development proposals related to National Health Security. The CFB has been a part of the Biomedical Research and Development Authority – Division of Research, Innovation, and Ventures (BARDA – DRIVE) Network of 13 Accelerators since 2018, collaborating with the U.S Department of Health and Human Services to support early-stage technologies and companies in the National Health Security space. Our collaboration has provided BARDA with critical insights into the regional biotech innovation ecosystem and connections with innovators and entrepreneurs to develop and commercialize groundbreaking technologies for national health securities.

Working in collaboration with BARDA, we are seeking innovative technologies for the development of effective life-saving medical countermeasures to prepare the nation for any health emergency. Examples

of the areas of interest include but are not limited to: Drug discovery platforms, Alternative delivery platforms for therapeutics/vaccines, Pathogen-agnostic detection of infection, Improvements in pharmaceutical manufacturing, Host-based therapeutics, Regenerative medicine, Infection severity diagnostic tools, Artificial blood and blood products, Home-based testing, Digital health for pandemic preparedness.

Translational Research Initiatives

The LIBH has developed a two-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 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 have 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.

Submission Information – *this funding opportunity includes a pilot project branching out into ‘health security’ and therefore limited to Stony Brook University faculty.*

Proposals are due Monday, July 18, 2022 by 5pm. Proposals submitted after the due date will not be considered. All proposals must be uploaded through the [submission portal](#). Proposals will be evaluated by CFB/LIBH staff and the Center for Biotechnology’s External Advisory Board. A secondary review will be performed by HHS personnel. Final funding announcements will be made on or about October 1, 2022.

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 and its External Review Board, HHS.

Interested applicants are strongly encouraged to schedule a meeting with the CFB’s Technology and Business Development team before writing a full proposal to ensure a thorough understanding of the program’s objectives.

Industry partnerships and collaborations (current or future) in proposal development are highly encouraged.

The two 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, Newco.

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 and presentation are also required every 6 months.
- A member of the technology team is strongly encouraged to participate in the skill development program before or during the funding period.
- Projects involving a corporate partner
 - Proposals for licensed applications of a technology are ineligible for funding
 - Proposals for licensed technology, but new, as-yet unlicensed applications, are 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 contributions are not permitted
- Can subsequently apply for the POC program (below).

Proof of Concept (POC) Award Program (*\$100k total costs for 12 months, 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 over one year, awarded in two \$50K/6 month tranches based upon external review and achievement of predetermined milestones. A written progress report and presentation are also required every 6 months.
- Projects involving a corporate partner
 - Proposals for licensed applications of a technology are ineligible for funding

- Proposals for licensed technology but new, as yet unlicensed applications, are 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
- Proposals for optioned applications of a technology are eligible for funding and \$1:\$1 match funding is required, except for BEIR
- If the corporate partner is not a small entity, a match of \$2:\$1 (corporate partner: LIBH) will be required. A small entity is defined according to NIH guidelines, available at: <https://sbir.nih.gov/about/eligibility-criteria>.
- In-kind contributions are not permitted
- Eligible to apply for an additional year of funding based upon achievement of commercially- relevant milestones, approval of the External Review Board, and availability of funding.

Support for Commercialization & Entrepreneurial Activities

Understanding the issues surrounding the commercialization of academic innovations is critical if the goal is to impact human health. To support faculty, post-doctoral associates', and graduate students' understanding of these issues, and to streamline and improve the success rate of the "translational" process, the LIBH provides 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 provides a "hands-on" workshop for faculty and post-docs interested in taking an active role in commercializing their innovations.
- A Mentor Network provides teams of advisors to guide faculty, post-docs, and graduate students involved in start-up ventures.
- The Fundamentals of the Bioscience Industry program provides comprehensive training to graduate students and post-docs interested in the commercialization process and expanded career paths.
- BioEntrepreneurs-in-Residence (BEIR) develop commercialization strategies in collaboration with faculty innovators, to license the technology for new company formation.
- Access to a network of professional service providers and investors.

Proposal Guidelines

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The LIBH translational research programs provide a tiered structure that allows for progressive funding as ideas move from the feasibility stage to proof of concept. 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 before submission. The proposal form, 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 the Sponsored Programs Office is *NOT* required *before* submission but will be required if the project is selected for funding. Further details can be found within the application form.

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 uploaded to the submission portal by the established deadline. Access the submission portal [here](#) or on our website. **The submitted document should be named as follows: last name_first name_type of application** (Feasibility or POC). e.g., Smith_John_POC. **The project title must begin with the word “REACH” or “NHS.”**

Technology Transfer Contact: Valery Matthys Valery.Matthys@stonybrook.edu

SBU Sponsored Programs Contact: contact your departmental grants administrator at the [Office of Sponsored Programs](#)

Center for Biotechnology Contact: center_for_biotechnology@stonybrook.edu

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 the achievement of commercially relevant milestones. 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 a calculated annual salary cap of \$203,700 for *non-state personnel only*. Faculty members who are full-time on New York State payroll cannot request salary reimbursement for their effort. Post-doctoral fellows who apply as a Principal Investigator must receive written permission from their host lab director and are subject to the 20% limit on salary and fringe. Please note that students and Postdoctoral trainees that are supported by a third-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 necessary to add commercial value is allowed on a case-by-case basis with prior approval by the Center for Biotechnology. Budgets should include the appropriate fringe benefit rate as established by your sponsored programs office. Graduate students working on the project should receive tuition reimbursement at the appropriate rate. The budget for these technology development programs is Total Direct Cost (TDC) only.

Projects conducted in partnership with industry partners are required to provide a letter of support from the corporate partner demonstrating the commitment to matching funding as outlined in the technology development programs. Only non-grant funds are considered 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: <http://centerforbiotechnology.org/who-we-are/long-island-bioscience-hub/>

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 CFB/LIBH staff, Technology Transfer, and the LIBH External Review Board, comprised of academic scientists and commercialization experts. All external members will sign a confidentiality agreement to protect the information provided in the application. A secondary review will be performed by HHS personnel.

Award Implementation and Administration

PIs should have the necessary animal research, human subject protocols, and any other compliance/regulatory issues processed for approval as soon as possible, ideally, at the time they are notified that their application has been recommended to proceed to secondary review, which will include HHS personnel. Once submitted to HHS for secondary review, a description of the use of human subjects and/or animal subjects will be requested. These descriptions are to be prepared according to the requirements for a typical NIH grant application. Amendments to existing approvals are acceptable. In those cases where LIBH grants are approved for an 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 corporate funding. Funding obtained through LIBH is not transferrable to any institution beyond partner institutions.

Funding will be awarded in 6-month tranches based upon the 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 External Review Board, 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 technology transfer office 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 the technology transfer and grants management offices.

PIs will also be required to make a formal presentation every 6 months to the LIBH. 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.

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. Any New Technology Disclosures resulting from funded projects should acknowledge LIBH funding. 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:

Research reported in this publication was support by the Center for Biotechnology, a New York State Center for Advanced Technology, Stony Brook University, and in collaboration with the Biomedical Advanced Research and Development Authority – Division of Research, Innovation and Ventures.

Faculty are reminded of Stony Brook University Export Control Policy P212 and are expected to be knowledgeable about federal export control regulations as they apply to their area of research, equipment, supplies, technology and technical data used in their laboratories and/or research. Information and links to the regulations are located on the OVPR website at: <https://www.stonybrook.edu/commcms/export-controls/>. Faculty should not share confidential or third-party proprietary information that is, or that they suspect may be, export controlled in their grant applications without first consulting with the SBU's Export Compliance Officer.

Disclosure of non-public, export controlled technology or technical data to Stony Brook University (SBU) faculty, staff or students that are non-U.S. persons may require a U.S. federal agency authorization. Companies are responsible for determining, and if necessary securing, the appropriate authorizations prior to sharing any non-public, export controlled technology or technical data with SBU.