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| National Heart Lung and Blood Institute Logo | NIH REACH/LIBH |

**Long Island Bioscience Hub - Award Application**

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**Project Title:**

**Principal Investigator:**

Name:

Title:

Department:

Institution: (check one)

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| --- | --- | --- | --- | --- | --- | --- |
|  | SBU |  |  | CSHL |  | BNL |

Address:      

Telephone:

Email:

**Disease Space:** *(e.g., Cardiovascular, Brain, Musculoskeletal, Cancer):*

**Technology Category:**

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| --- | --- |
|  | Small molecule drug |
|  | Biologic drug |
|  | Diagnostics device |
|  | Therapeutic device |
|  | mHealth product |
|  | Combination product (ie. Diagnostic + Therapeutic) |
|  | Research tool |
|  | Other: |

**Indicate program you are applying for:**

|  |  |
| --- | --- |
|  | Feasibility Award |
|  | Proof of Concept (POC) Award Program |
|  | Commercialization Award |

**Attachment Checklist:**

|  |  |
| --- | --- |
|  | Compliance Forms (pending/approved) |
|  | NIH-Biosketches of PI and primary co-sponsor (if applicable) |
|  | Budget pages |
|  | Project Plan Form |
|  | Intellectual property documentation |
|  | A letter of support (if applicable) from the match-funding NYS company |
|  | Letter for Post-Doctoral Advisor giving permission to work on this project (if applicable) |

**Submit one PDF of the proposal to corresponding Tech Transfer Office. Applications do not require prior approval by the Office of Sponsored Programs. Post-Doctoral Associates serving as Principal Investigator must receive written permission from their respective Lab Director. Only projects recommended for funding will be required to obtain institutional approvals.**

Technology Development RFP Contact:

Dr. Li Liu, Manager, Technology & Business Development

Center for Biotechnology

([li.liu.1@stonybrook.edu](mailto:li.liu.1@stonybrook.edu))

Bioengineering Building

Stony Brook University, Stony Brook, NY 11794-5281

Phone 631.632.8521 Fax 631.632.8577

[www.centerforbiotechnology.org](http://www.centerforbiotechnology.org)

**NIH REACH/LIBH Application**

Instructions: Please complete the required sections below to submit a proposal.

* Feasibility Award: Full proposal is limited to **5** pages for section **4-17**. You **DO NOT** have to address section **9 and 10** for feasibility award.
* POC & Commercialization Award: Full proposals is limited to **12** pages for sections **4-17**.
* Applicants are STRONGLY ENCOURAGED to contact LIBH staff during the submission process.
* THIS IS A TECHNOLOGY DEVELOPMENT INITIATIVE, and is not appropriate for basic science studies.
* Reference will not be counted against page limit

Please use the resources within LIBH to help with business and technology development related questions. Supporting documents required for full proposals include the completed budget template, NIH format biosketches for key personnel, institutional contact information, the compliance forms (pending or approved), project plan form, previous funding record and existing applications, intellectual property documentation and letter of support from corporate co-sponsor and/or lab director (as applicable). Please use Arial font size 11 points or larger, and at least one inch margins for all pages. Supporting documents are not included in the page limit. If you have difficulty answering any of the questions,please contact LIBH representatives for assistance.

* 1. PI, Institution, and Project Title (Title should reflect the product e.g., “Small molecule drug to treat patients with X”)
  2. Corporate Co-Sponsor Contact (If applicable), include name, title, company name, address, contact info, total number of employees and total number of NYS employees. (A company with an existing license and/or option to intellectual property directly related to the proposed project is considered a corporate co-sponsor)
  3. Non-Confidential Abstract of Research Plan: A succinct and accurate description of the proposed work addressing the unmet need, intended customer, envisioned technology, proposed work, milestones and deliverables, and team strength. The description should be suitable for public disclosure. (Not to exceed 200 words).
  4. Unmet Need: Clearly state the unmet need being addressed by the technology and provide evidence to support the need from multiple stakeholder perspectives (ex. patient, clinician, payer).
  5. Proposed Product/Solution: Describe the proposed solution, identify the product category for the technology (Small molecule drug, Biologic drug, Diagnostics device, Therapeutic device, mHealth product, Combination Product, Research tool, other), and the primary patient population / indication for use. Characterize the expected benefit from the technology and how it will enhance current or predicted standard of care or replace the current standard of care. What is the evidence to support the expected benefit?
  6. Market Size: Define the total and addressable market size. Support your market size and descriptions with evidence about current technologies or approaches to address this indication. Define an appropriate patient segment of those suffering from the specific targeted disease
  7. Competitive Landscape: Define the competition mix (companies, products, substitutes and shifting landscape) for the technology. Think particularly about how the disease will be treated when the technology/product gets to market. How is the landscape shifting or projected to shift?
  8. Differentiation: Explain how the proposed technology is better than current technologies, including those currently in clinical trials. Provide data to support this, and in lieu of actual data, describe what data would be needed to justify the differentiation
  9. Regulatory Path (required for POC and Commercialization proposals): Describe the expected regulatory pathway for the technology and identify which FDA division will regulate the technology. Describe foreseeable regulatory risks or accelerated programs that could impact the technology development. Please also include information on technologies that are currently in development.
  10. Reimbursement Path (required for POC and Commercialization proposals): Define similar product(s)/service(s) that is (are) currently being covered for the indication your technology targets and identify relevant CPT/DRG/APC Codes and their reimbursement rates. If no code exists, how will the technology be paid for?
  11. Project Plan: Provide an outline of your overall project plan including specific aims, key intermediate milestones and the final goal to be achieved at the completion of the project. Identify go/no-go decision points and potential pivot points within the plan. Explain how this project plan fits into the overall product development plan? Explain how achievement of each milestone increases the value of the technology. Summarize the project plan in the template in appendix (*1page maximum*).
  12. Experimental Design and Methods: Discuss the experimental design, and the means by which the data will be analyzed and interpreted. (*2 page maximum for POC and Commercialization Award, 1 page maximum for feasibility*)
  13. Funding Requirements and Timeline: Identify how much funding is needed to get the technology to a viable ‘exit’ or inflection point for commercial investment. Define the funding requirements and timeline to achieve each milestone and each go/no-go decision point for the proposed project. Projecting beyond the completion of the proposed project, estimate the key milestones that need to be achieved and the total funding required to bring the product to a commercial exit. Include an estimate of the long-term return on the overall investment. Use the budget in the appendix to provide full details.
  14. Budget justification: Explain the budget in terms of what will be funded (e.g., salaries, equipment, animal models/testing, services).
  15. Intellectual Property: Explain why proposed research will generate new IP or enhance existing IP. Explain how proposed IP is connected to the commercialization plan. Please include a list of any disclosure and/or existing IP related to proposed project.
  16. Potential Risks and Mitigations: Define the potential risks (scientific, technical, personnel, market, and commercialization) that exist for the product development and the mitigation processes available to the innovator team or in place to correct for these.
  17. Personnel: Provide the institutional affiliation, relevant background and expertise of the individuals on the team and explain how their backgrounds inform their ability to succeed at this stage of the product development. Consider how they will impact future product development. What will be needed for future product development?

**Appendices**

* 1. Compliance Forms (pending/approved)
  2. NIH-Biosketches of PI and primary co-sponsor (if applicable)
  3. Budget pages
  4. Project Plan Form
  5. Intellectual property documentation (patent applications or issued patents – **must be included for POC or Commercialization proposals**)
  6. A letter of support (if applicable) from the match-funding NYS company stating: 1) the amount of funding they will provide, 2) that the company has a presence in NYS 3) if the company is considered a “small” company (fewer than 250 employees) and 4) how this project will benefit the company
  7. Where applicable, letter for Post-Doctoral Advisor giving permission to work on this project.

**No additional attachments beyond those listed above will be accepted. Failure to comply may result in application being returned without benefit of review.**