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

**Long Island Bioscience Hub - Award Application**

|  |  |
| --- | --- |
|  |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Project Title:**  **Principal Investigator:**  Name:  Title:  Department:  Institution: (check one)   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | SBU |  |  | CSHL |  | BNL |  | FIMR |   Address:  Telephone:  Email:  **Disease Space:** *(e.g., Cardiovascular, Brain, Musculoskeletal, Cancer):*  **Technology Category:**   |  |  | | --- | --- | |  | 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 | | **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 company | |  | Letter for Post-Doctoral Advisor giving permission to work on this project (if applicable) |   **Institutional Authorized Official:**  Name:  Title:  Department:  Address:  Telephone:  Email:  **Certification and Signature**  I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.  ***SIGNATURE NOT REQUIRED AT SUBMISSION. SEE RFP.***  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Authorized Official Date |

**Upload the proposal and all attachments as ONE PDF to the** [**submission portal**](https://script.google.com/a/macros/stonybrook.edu/s/AKfycbz4moYtOtniW1s3ZgrxNsPhi0PC2VHOge4C_KRriicEUrIY3uA/exec)**. Approval from your Sponsored Programs Office is NOT required *prior to* submission, but will be required if the project is selected for NIH secondary review.**

**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 Award: Full proposals is limited to **12** pages for sections **4-17**.
* THIS IS A TECHNOLOGY DEVELOPMENT INITIATIVE, and is not appropriate for basic science studies.
* The list of references will not be counted against page limit
* 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.
* **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.”**

Applicants are STRONGLY ENCOURAGED to contact LIBH staff during the submission process for help with any general or business and technology development related questions. Technology Development RFP Contact:

Dr. Li Liu, Assistant Director, Technology & Business Development

Center for Biotechnology, Bioengineering Building

Stony Brook University, Stony Brook, NY 11794-5280

Phone 631.632.8521 Fax 631.632.8577

[li.liu.1@stonybrook.edu](mailto:li.liu.1@stonybrook.edu) [www.centerforbiotechnology.org](http://www.centerforbiotechnology.org)

* 1. PI, Institution, and Project Title (Title should reflect the product and start with “REACH” e.g., “REACH: 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): 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): 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 (*1 page 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, 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**)
  6. A letter of support (if applicable) from the match-funding company stating: 1) the amount of funding they will provide, 2) if the company is considered a “small” company (fewer than 250 employees) and 3) 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.**