Technology Development Program

Request for Applications ♦ Month Year

Project Title:

Institution/Department:

Primary Investigator (Name, Title, Telephone, Email):

Disease Space :

Technology Category (Small molecule drug, Biologic drug, Diagnostics device, Therapeutic device, mHealth product, Combination Product, Research tool, other):

Resubmission: Yes____ No____

Was discovery phase of the technology supported by NIH funds: Yes____ No____

Was discovery phase of the technology supported by other Federal funds: Yes____ No____

Instructions
Please complete the required sections below to submit a proposal. Full proposals should not exceed 12 pages for sections 1-14 below and all pages should be numbered. Supporting documents required for full proposals include the completed budget template and justification, NIH format biosketches for key personnel, institutional contact information and authorization, and the compliance form. Supporting documents are not included in the page limit. If you have difficulty answering any of the questions, please work with representatives within the Center for assistance.

I. Basis for Project

1. Background: Describe the scope and nature of the problem the technology will be designed to address and give a brief description of the solution. Some elements to include are the disease burden, market space in which the product would operate, and comparison of your solution to the current and predicted standard of care, including target product profile if applicable.

2. 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).

3. Proposed Product/Solution: Describe the proposed solution, the setting in which it will be utilized (ICU, in-patient, out-patient, primary care physician, etc.), and the primary patient population / indication for use. Characterize the expected benefit from the technology and how it will enhance current or predicted (when this product will be on the market) standard of care or replace the current standard of care. What is the evidence to support the expected benefit? Provide a brief synopsis of your preliminary data.

4. Market Size: Define the total and addressable market size, and target price of the technology. Support your market size and descriptions with evidence about current technologies or approaches to address this

indication. Define a specific patient segment of those suffering from the specific targeted disease. What are the market population trends and projections?

5. 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?

6. Intellectual Property: Describe the extent of interactions with the technology transfer office and how the IP is connected to the commercialization plan. Please include a list of the various types of IP filed or granted, which should include the following information:		
Patent application number, issued patent number, trademark registration number, copyright number, etc.	Title: Status and date	For a patent/patent application the major types of claims

II. Pathways and Requirements for Bringing Product to Market

7. **Differentiation: Explain how the proposed technology is better than current options/technologies and is an advancement in the current market direction. Provide data to support this, and *in lieu* of actual data, describe what data would be needed to justify the differentiation. Describe how it's better than current options/technologies, including those currently in clinical trials.**

8. **Regulatory Path (if applicable): 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. Comment on the clinical trials considerations and how those might impact the regulatory approach. Please also include information on technologies that are currently in development.**

9. **Reimbursement Path (if applicable): 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?**

10. Funding Requirements: Identify how much funding is needed to get the technology to a viable 'exit' or inflection point for commercial investment. Define the funding requirements 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.

III. Project Plan for Bringing Technology Through Program

11. Project Plan: Provide a brief outline of your overall project plan including 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.

12. 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.

13. 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?

14. References
1.

IV. Appendix (These items can be modified to meet the needs of each site)

- **a. Compliance Form (This is the B-BIC sample but each site can adjust as needed)**
- **b. Budget Justification**
- **c. Biosketches**
- **d. Budget pages (by milestone)**
- **e. Other**

Compliance Form

For questions about this form, please contact [Insert Name Here], [Insert Center Here] Administrative Director at [Insert Phone Number Here].

1) **Principal Investigator:**_____

2) **Project Title:**_____

3) **Institution:**_____
(a compliance form must be completed for each performance site)

4) **Financial Overlap:** Yes____ No____

Financial overlap is active or pending funding for the same scope of work and/or budgetary item, and must be resolved prior to award.

5) **Human Subject Use:** Yes____ No____
(includes the prospective or retrospective use of private identifiable data or materials derived from humans)

A human Institution Review Board (IRB) approval letter must be received by B-BIC before funds will be released to awardees. The IRB approval letter should include the protocol title, approval date, the protocol number, and the multiple project or federal wide assurance number.

6) **Animal Use:** Yes____ No____
(includes the use of live animals in research, teaching or testing)

An Animal Care and Use Committee (IACUC) approval letter must be received by B-BIC before funds will be released to awardees. The IACUC letter should include the protocol title, approval date, the protocol number,
and the animal welfare assurance number.

Principal Investigator Signature:_____