DEPARTMENT OF HEALTH AND HUMAN SERVICES

SMALL BUSINESS INNOVATION RESEARCH PROGRAM

PHASE I CONCEPT AWARD TECHNICAL PROPOSAL SUBMISSION CHECKLIST

- ☐ Complete Proposal Cover Sheet Page
- ☐ Complete Abstract of the Research Plan and Public Health Relevance Page
- ☐ Complete Technical Proposal Content
  - ☐ Complete Identification and Significance of the Problem or Opportunity Section
  - ☐ Complete Proposed Technological Solution Section
  - ☐ Optionally Attach 1-Page Preliminary Data/Figures Document
  - ☐ Complete Innovation Section
  - ☐ Complete Approach and Methodology Section
  - ☐ Complete Product Discovery and Development Section
  - ☐ Complete Potential Commercial Application Section
  - ☐ Complete Resources Section
  - ☐ Complete Authentication of Key Biological and/or Chemical Resources
  - ☐ Complete Scientific Data Sharing Plan Section
  - ☐ Complete References Section
- ☐ Complete Statement of Work Pages
- ☐ Attach Biosketches Document

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SMALL BUSINESS INNOVATION RESEARCH PROGRAM

PHASE I PROPOSAL COVER SHEET

TOPIC NO.:

PROJECT TITLE:

FAST TRACK PROPOSAL: ☐ YES ☐ NO

SUBMITTED BY (*Firm name, address, and telephone number*):

YEAR FIRM FOUNDED:

NO. OF EMPLOYEES (*Include all affiliations*):

NOTICE TO OFFERORS

The offeror organization and the principal investigator are jointly responsible for the accuracy and validity of all the administrative, fiscal, and scientific information in the proposal. Deliberate withholding, falsification, or misrepresentation of information could result in a determination of non-responsibility [see Federal Acquisition Regulation (FAR) 9.104] which would preclude an award to the offeror. In addition, sanctions such as suspension, debarment, and criminal penalties could apply.

YES	NO	CERTIFICATIONS
☐	☐	1. The above organization certifies that it is a small business concern as defined in this Solicitation.
☐	☐	2. The above organization also certifies that it is one or more of the following small business concerns as defined in FAR 2.101: ☐ 8(a) ☐ HubZone ☐ Service-Disabled Veteran-Owned ☐ Small Disadvantaged Business ☐ Woman-Owned ** Note: Capture of this information is strictly for statistical purposes.*
☐	☐	3. The above organization certifies that, if this proposal results in a contract award, more than one-half of the principal investigator's time will be spent in the employ of the firm.
☐	☐	4. The above organization and / or principal investigator(s) have submitted contract proposals or grant applications for essentially equivalent work (as defined in this Solicitation) under other federal programs, or have received other federal awards containing a significant amount of essentially equivalent work. (If YES, include information required for "**Prior, Current, or Pending Support of Similar Proposals or Awards"** in Appendix C – Pricing Proposal, as described in the solicitation.)
☐	☐	5. If this proposal does not result in an award, is the Government permitted to disclose the title and abstract of your research project, and the name, address and telephone number of the corporate official of your firm, to organizations that may be interested in contacting you for further information or possible investment?
☐	☐	6. This proposed project involves human subjects. (See instructions in Solicitation.) Clinical Trial? ☐ Yes ☐ No Agency-Defined Phase III Clinical Trial? ☐ Yes ☐ No
☐	☐	7. This proposed project involves vertebrate animals. (See instructions in Solicitation.) If YES, identify by common names and circle primates.

NOTICE OF PROPRIETARY INFORMATION

The information identified by asterisks (*) on pages of this proposal constitutes trade secrets or information that is commercial or financial and confidential or privileged. It is furnished to the Government in confidence with the understanding that such information shall be used or disclosed only for evaluation of this proposal; provided that, if a contract is awarded as a result of or in connection with the submission of this proposal, the Government shall have the right to use or disclose information herein to the extent provided by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.

PRINCIPAL INVESTIGATOR/PROJECT MANAGER	CORPORATE OFFICIAL
NAME:	NAME:
SIGNATURE:	SIGNATURE:
DATE:	DATE:
TITLE:	TITLE:
PHONE:	PHONE:
E-MAIL ADDRESS:	E-MAIL ADDRESS:

ABSTRACT OF RESEARCH PLAN

NAME, ADDRESS, AND TELEPHONE NUMBER OF OFFEROR ORGANIZATION	AGENCY NAME: SOLICITATION NUMBER: TOPIC NUMBER:

TITLE OF PROJECT

KEY PERSONNEL ENGAGED ON PROJECT

Name (First, Middle, Last)	POSITION TITLE	ORGANIZATION

ABSTRACT OR RESEARCH PLAN: State the proposal's long-term objectives and specific aims, making reference to the health-relatedness of the project. Describe concisely the research design and methods for achieving these goals, and discuss the potential of the research for technological innovation. Summarize the results that are expected. Avoid summaries of past accomplishments and the use of the first person. This abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the proposal is funded, this description, as is, will become public information. **Therefore, do not include proprietary/confidential information. DO NOT EXCEED 200 WORDS.**

Provide key words (8 maximum) to identify the research or technology.

Provide a brief summary of the potential commercial applications of the research.

Technical Proposal Content

Technology/Product Overview

- ☐ Small Molecule
- ☐ Biologics/Vaccine
- ☐ Cell/Gene Therapy
- ☐ Surgical or Ablative Device
- ☐ Hospital Device
- ☐ Drug Delivery Device
- ☐ Imaging Device
- ☐ Imaging Agent
- ☐ In Vitro Diagnostic
- ☐ Bioinformatics/Health IT/Digital Health
- ☐ Research Tool

Targeted Pediatric/Rare Cancer (Please state the rare/pediatric cancer your technology addresses)

A) Identification and Significance of the Problem or Opportunity. Provide a clear statement of the specific technical problem or opportunity to be addressed in the proposed research. Use this section to demonstrate the scientific rationale behind the proposed technology, including identification of the clinical problem and cancer type(s) that the proposal will focus on. Limit your response to 4500 characters at 10pt font.

B) Proposed Technological Solution. Describe the proposed solution to the identified unmet medical need. Justify how the proposed technology is ideally suited to solve the stated problem using the offeror's own research or by citing appropriate literature evidence. Limit your response to 4500 characters at 10pt font. Preliminary data are not required but can be included/referred to in an attached one-page (maximum) document (Attachment 1) to establish project feasibility.

C) Innovation. Highlight the disruptive innovation of the proposed research project in developing approaches to change research, diagnosis, and treatment paradigms in rare and/or pediatric cancers. Discuss the transformative potential of the project for significant change compared to current research and/or clinical practice paradigms, considering consequences for the field and size of the community affected. Include subsections that discuss creative thinking approaches and project risk reward ratio analyses. Limit your response to 4500 characters at 10pt font.

C) Innovation Continued. Limit your response to 4500 characters at 10pt font.

D) Approach and Methodology. Set forth technical objectives and describe a logical approach for meeting the objectives through clearly identified tasks, in a well-developed experimental design. Technical Objectives and Milestones shall be included at a high level in the **Statement of Work section**. However, in this section of the proposal, the offeror should include more detailed and/or confidential information that is not appropriate for inclusion in the summary Statement of Work document, to allow for sufficient technical evaluation of the proposed project. Discuss the methods to be used to achieve each objective/task. Discuss anticipated challenges and plans to address weaknesses in prior research. Identify potential problems and alternative strategies. Define measurable benchmarks for success which will establish feasibility and mitigate risks for future development efforts. Milestones should include quantitative parameters so that the progress and success of the project can be assessed. Explicitly describe the role and time allocated towards the project for each key personnel. If a co-PI/PD is proposed, include a Multiple PI/PD Leadership Plan. Limit your response to 4500 characters at 10pt font.

D) Approach and Methodology Continued. Limit your response to 4500 characters at 10pt font.

D) Approach and Methodology Continued. Limit your response to 4500 characters at 10pt font.

E) Product Discovery & Development. Clearly define a deliverable (expectation is not to have an immediate short-term commercial product) to be achieved with the Concept Award funding and how this deliverable will fit into the whole long-term product development strategy. Successful execution of Concept Award proposals should help derisk the technology for potential future Phase I and/or Phase II SBIR awards through standard funding opportunity announcements. Limit your response to 4500 characters.

F) Potential Commercial Application. Define the unmet medical need that exists in the identified rare or pediatric cancer space for which the proposed technology may solve. Use this section to identify a plausible commercial path and need for a product to be developed. Describe the market as it currently exists and how your product/service may enter and compete. Include the potential barriers to market entry and how you expect to overcome them. Describe the strategy for protecting your innovation (such as status of and/or potential for intellectual property or market exclusivity, etc.). Limit your response to 4500 characters.

G) Resources. Discuss the resources available and accessible to the offeror that will enable the team to successfully complete the proposed research project, including facilities, equipment, and research environment. Limit your response to 4500 characters.

H) Authentication of Key Biological and/or Chemical Resources. Outline below the main biological/chemical resources to be utilized in this project and any authentication procedures. Limit your response to 1500 characters. Further guidance is available at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-068.html

I) Scientific Data Sharing. NIH has a longstanding commitment to making the results of NIH-funded funded research available. Responsible data management and sharing has many benefits, including accelerating the pace of biomedical research, enabling validation of research results, and providing accessibility to high-value datasets. Further guidance is available here: https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policies/data-management-and-sharing-policy-overview

SBIR and STTR recipients may retain the rights to data generated during the performance of an SBIR or STTR award for up to 20 years after the award date, per Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program Policy Directive. An acceptable Data Management and Sharing (DMS) Plan can reference and incorporate these data rights. Further information about SBIR and STTR data rights are enumerated here: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_18/18.5.5_administrative_requirements.htm#Intellec
Discuss the Data Management and Sharing Policy of the proposal below. Limit your response to 1500 characters.

J) References. List all relevant supporting data such as journal articles, literature, and government publications. Limit your response to 4500 characters.

NCI SBIR Innovative Concept Award

Statement of Work

Title of the Project:

Principal Investigator(s):

Offeror Small Business Name:

Subcontractors and Collaborators:

I. Technology and Product (Scope)

(Please provide one sentence description of your technology and final product; up to 250 characters with spaces)

II. Significance and Potential Impact

*(Please identify the clinical need that you are addressing and significance of your technology and the impact of your technology for rare or pediatric cancer populations. This section will be displayed on the **public** databases such as NIH RePORTER; up to 1500 characters with spaces)*

III. Technical Objectives and Milestones

The contractor shall independently perform all work and furnish all labor, materials, supplies, equipment, and services (except as otherwise specified in the contract) to perform the following services:

*(List all tasks in a logical sequence. Tasks should contain enough detail to establish parameters for the project and keep the effort focused on meeting the objectives. Provide clear, quantitative, measurable, testable milestones or success criteria to accompany each of the technical objectives. Correlate objectives and milestones with the TIMELINE section, below. Do not include proprietary information. Technical objectives, but not milestones, will be displayed on **public** databases such as NIH RePORTER; up to 2000 characters with spaces)*

IV. Timeline

(Please put (×) next to the month when you anticipate working on this objective. Please fill in the information only for your number of objectives and milestones.)

Objective/Sub-Objective	Milestones	Timeline in Months											
		1	2	3	4	5	6	7	8	9	10	11	12
Kick-off Call													
Objective 1	Milestone 1												

Submission of Final Report													

V. I-Corps™ at NIH

☐ **Offeror agrees to participate in the I-Corps Program at NIH**

The Contractor will complete the I-Corps™ at NIH program, including the requirements below.

A. The Contractor's 3-member I-Corps™ team shall participate at all lectures and sessions for a 3-day Opening workshop and a 2-day Closing workshop for the I-Corps™ at NIH program.

B. The Contractor's 3-member I-Corps™ team shall prepare and submit Customer Discovery Interviews and Team Presentations in accordance with the I-Corps™ at NIH program and in accordance with the REPORTING REQUIREMENTS and DELIVERIES articles of this contract.

C. The Contractor's 3-member I-Corps™ team shall participate in weekly faculty meetings during the 8-week I-Corps™ program.

D. The Contractor's 3-member I-Corps™ team shall participate in 6 I-Corps™ Webex sessions.

E. The Contractor's 3-member I-Corps™ team shall prepare an I-Corps™ at NIH Lessons Learned Video and incorporate an I-Corps™ section into the Commercialization Plan within the SBIR Phase I Final Report, in accordance with the REPORTING REQUIREMENTS and DELIVERIES articles of this contract.

Any changes to the Contractor's 3-member I-Corps™ at NIH team must be approved in advance by the Government for the requirements and deliverables associated with I-Corps to be considered satisfactory and I-Corps Payment Schedule items to be authorized.

VI. Vertebrate Animals Section

(If the project will involve Vertebrate Animals, fill out this section in accordance with instructions set forth in Section 8.8 of the solicitation. If the project will not involve Vertebrate Animals, leave as "N/A".)