APPENDIX A

PHASE I TECHNICAL PROPOSAL

NAME, ADDRESS, AND TELEPHONE:

TITLE OF PROJECT:

SOLICITATION NUMBER:

TOPIC NUMBER:

FAST-TRACK PROPOSAL: ☐ Yes ☐ No

ATTACHMENT CHECKLIST

Appendix A.1 — Human Subjects & Clinical Trials Form
(If your proposal does not involve Human Subjects or Clinical Trials, you must still note this on the form and submit the form.)

☐ Yes ☐ No

Appendix A.2 — Study Record to Human Subjects & Clinical Trials Form
(If applicable, Appendix A.2. – Study Record must be attached to Appendix A.1)

☐ Yes ☐ No

ABSTRACT OF 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, don't 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 impact of the research. DO NOT EXCEED 50 WORDS.

Provide a brief summary of the potential commercial applications of the research. DO NOT EXCEED 50 WORDS.

PERSONNEL SHEET

TITLE OF PROJECT:

TOPIC NUMBER:

OFFEROR PERSONNEL ENGAGED ON PROJECT

Name (First, Middle, Last)	Degree(s)	Position Title

SUBCONTRACTOR ORGANIZATIONS

(If more than one, list each organization and its personnel separately)

Name (First, Middle, Last)	Degree(s)	Position Title

COLLABORATORS OR CONSULTANTS

Name (First, Middle, Last)	Degree(s)	Position Title

PROPOSED STATEMENT OF WORK

Please limit the proposed Statement of Work to no more than 3 pages. The Statement of Work will be attached to the award document. Please do not include confidential or propriety information.

TITLE: [Phase I title]

BACKGROUND: Provide a general, brief summary of what needs the research on this contract will be addressing. Information from the Topic description may be useful to include for context.

SCOPE: Provide a one to two sentence statement of what is expected to be accomplished under the contract.

OBJECTIVES: State the specific objectives and anticipated end results of the proposed Phase I effort. **Limit responses to 250 words**.

SERVICES TO BE PERFORMED:
Begin this section with the following language: "The contractor shall independently perform all work and furnish all labor, materials, supplies, equipment, and services to perform the following services:"

1. Specific Requirements – List all tasks in a logical sequence, in an outline format, to precisely describe what is expected of the contractor in performance of the work. Tasks should contain enough detail to establish parameters for the project and keep the effort focused on meeting the objectives. Do not include any proprietary information.

2. If the research plan includes the use of human subjects or animals, briefly describe the parameters of this use.

REPORTS & DELIVERABLES: Describe end products and deliverables and describe periodic/final reports required to monitor work progress under the contract in a milestone format (i.e. a kick-off, midterm, and final).

RESEARCH PLAN FOR PHASE I PROPOSAL

Consider whether a list describing abbreviations or providing significant definitions would be helpful to reviewers, and if so, include such a list at the beginning of your Research Plan. **Please limit the Research Plan to no more than 8 pages.** Discuss the following elements in the order indicated:

1) **Identification and Significance of the Problem or Opportunity.** Provide a clear statement of the specific technical problem or opportunity addressed.

2) **Technical Objectives.** State the specific objectives of the Phase I effort, including the technical questions it will try to answer to determine the feasibility of the proposed approach.

3) **Detailed Approach and Methodology.** Provide an explicit, detailed plan for the Phase I R&D to be carried out, including the experimental design, procedures, and protocols to be used. Address how the objectives will be met. Discuss in detail the methods to be used to achieve each objective or task. The plan should indicate what is planned, how, when, and where the work will be carried out, a schedule of major events, the final product to be delivered, and the completion date of the effort. The Phase I effort should determine the technical feasibility of the proposed concept.
    - If a project involves vertebrate animals, include a Vertebrate Animals Section, as discussed in Sections X and X – CONTRACT REQUIREMENTS, Section X Research Involving Vertebrate Animals.
    - If Section X Dual Use Research of Concern is applicable to your project, address it here.

4) **Related Research or R&D.** Describe significant research activities directly related to the proposed effort, including any conducted by the Project Director/Principal Investigator (PD/PI), the proposing firm, consultants, or others. Describe how these activities interface with the proposed project and discuss any planned coordination with outside sources. The PD/PI must persuade reviewers of his or her awareness of recent significant research or R&D conducted by others in the same scientific field.
5) **Relationship with Future R&D.**
    a. State the anticipated results of the proposed approach, assuming project success.
    b. Discuss the significance of the Phase I effort in providing a foundation for the Phase II R/R&D effort.

6) **Innovation.** Discuss how the end product or technology being developed would offer significant advantages over existing approaches, methodologies, instrumentation, or interventions on the market currently being utilized in research or clinical practice, such as meaningful improvements in quality, capability, cost, speed, efficiency, etc.

7) **Potential Commercial Applications.** Describe why the proposed project is deemed to have potential commercial applications (for use by the Federal Government and/or private sector markets.) Describe the market as it currently exists and how your product may enter and compete in this market. 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.).

8) **Senior/Key Personnel and Bibliography of Directly Related Work.** Identify senior/key personnel, including their directly related education, experience, and bibliographic information. Provide summaries of the most relevant experience or publications, dates and places of employment and some information about the nature of each position or professional experience. The summaries must identify the current or most recent position.

9) **Subcontractors/Consultants.** Identify all investigator/collaborators by name and organization. Involvement of a university or other subcontractors or consultants in the project may be appropriate and is permitted. If such involvement is intended, it should be described in detail, identified in the business proposal, and supported by appropriate letters from each individual confirming his/her role in the project which must be included (letters are excluded from the research plan page limit).

10) **Facilities and Equipment.** Indicate where the proposed research will be conducted. One of the performance sites must be the offeror organization. Describe the facilities to be used; identify the location; and briefly indicate their capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Include clinical, computer, and office facilities of the offeror and those of any other performance sites to be used in the project. For facilities other than those of the applicant, a letter must be submitted with the proposal stating that leasing/rental arrangements have been negotiated and will be available for the use of the SBIR applicant.

    List the most important equipment items already available for this project, noting location and pertinent capabilities of each. Title to equipment purchased with Government funding by the SBIR awardee in relation to project performance vests upon acquisition in the Federal Government. However, the Government may transfer such title to an SBIR awardee upon expiration of the project where the transfer would be more cost-effective than recovery of the property. Any equipment and products purchased with Government funds shall be American-made, to the extent possible.

DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH PROPOSAL SUMMARY AND DATA RECORD

RFP NUMBER/CONTRACT NUMBER:

PROJECT TITLE (Title of RFP or Contract Proposal):

LEGAL NAME AND ADDRESS OF OFFEROR:

PLACE OF PERFORMANCE (Full address including ZIP):

TYPE OF CONTRACT PROPOSED: Fixed Price

ESTIMATED TIME REQUIRED TO COMPLETE PROJECT:

PROPOSED STARTING DATE:

ESTIMATED DIRECT COSTS IN PROPOSED YEAR (From Budget):

DOES THIS PROPOSAL INCLUDE A SUBCONTRACT? ☐ Yes ☐ No

(If yes, please furnish name and location of organization, description of services, basis for selection, responsible person employed by subcontractor and cost information.) (Use attachment if necessary.)

NAME AND TITLE OF PRINCIPAL INVESTIGATOR:

EST. HOURS WEEKLY:

AREA CODE/TEL. NO.:

NAME AND TITLE OF CO-INVESTIGATOR (Use attachment if necessary):

EST. HOURS WEEKLY:

AREA CODE/TEL. NO.:

NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO NEGOTIATE CONTRACTS:

NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO EXECUTE CONTRACTS:

DOES THIS PROPOSAL INVOLVE HUMAN SUBJECTS RESEARCH? ☐ Yes ☐ No

EXEMPTION NUMBER (IF APPLICABLE):

If YES to Human Subjects, is the IRB review Pending? ☐ Yes ☐ No

If IRB Review Not Pending, IRB Approval Date:

Human Subjects Assurance Number:
An example of the informed consent for this study is enclosed: ☐ Yes ☐ No ☐ N/A
A Clinical Protocol is enclosed: ☐ Yes ☐ No ☐ N/A

Are Vertebrate Animals Used? ☐ Yes ☐ No
If YES to Vertebrate Animals, is the IACUC review Pending? ☐ Yes ☐ No
If IACUC Review Not Pending, IRB Approval Date:
Animal Welfare Assurance Number:

OFFEROR'S ACKNOWLEDGEMENT OF AMENDMENTS TO THE RFP
(use attachment if necessary)
AMENDMENT:
DATE:
AMENDMENT:
DATE:

NAME, ADDRESS, AND PHONE NUMBER OF COGNIZANT GOVERNMENT AUDIT AGENCY:

NUMBER OF EMPLOYEES CURRENTLY EMPLOYED:

DOLLAR VOLUME OF BUSINESS PER ANNUM:

FOR THE INSTITUTION

SIGNATURE OF PRINCIPAL INVESTIGATOR:

TYPED NAME AND TITLE:

SIGNATURE OF BUSINESS REPRESENTATIVE:

TYPED NAME AND TITLE:

EMPLOYER IDENTIFICATION NUMBER:

DATE OF OFFER: