APPENDIX C

PHASE II 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 referring 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 5 pages. The Statement of Work will be attached to the award document. Please do not include confidential or propriety information.

TITLE: [Normally carries the same title as Phase I but may be changed if the previous title no longer accurately describes the project.]

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 II 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 II PROPOSALS

(including Direct to Phase II Proposals and the Phase II Proposal of a Fast Track submission)

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 10 pages.**

Discuss the following elements in the order indicated:

1) Anticipated Results of the Phase I/ Phase I-like Effort –

For Fast Track proposals: Briefly discuss and summarize the objectives of the Phase I effort, the research activities to be carried out, and the anticipated results.

For Direct to Phase II: Summarize the specific aims of the preliminary work that forms the basis for this Direct Phase II proposal, quantitative milestones (a quantitative definition of success) for each aim, the importance of the findings, and emphasize the progress made toward their achievement. Describe the technology developed, its intended use and who will use it. Provide data or evidence of the capability, completeness of design, and efficacy along with the rationale for selection of the criteria used to validate the technology, prototype, or method Describe the current status of the product (e.g., under development, commercialized, in use, discontinued). If applicable, describe the status of FDA approval for the product, process, or service (e.g., continuing pre-IND studies, filed on IND, in Phase I (or II or III) clinical trials, applied for approval, review ongoing, approved, not approved). List the generic and/or commercial names of products.

1) **Detailed Approach and Methodology** - Provide an explicit detailed description of the Phase II approach. This section should be the major portion of the proposal and must clearly show advancement in the project appropriate for Phase II. Indicate not only what is planned, but also how and where the work will be carried out. List all tasks in a logical sequence to precisely describe what is expected of the contractor in performance of the work. Tasks should contain detail to (1) establish parameters for the project; (2) keep the effort focused on meeting the objectives; (3) describe end products and deliverables; and (4) describe periodic/final reports required to monitor work progress under the contract.
   - If a project involves vertebrate animals, include a Vertebrate Animals Section, as discussed in Section X Research Involving Vertebrate Animals.
   - If Section X Dual Use Research of Concern is applicable to your project, address it here.

2) **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.

3) **Key Personnel** - List by name, title, department and organization, the extent of commitment to this Phase II effort, and detail each person's qualifications and role in the project. Provide resumes for all key staff members, describing directly related education, experience, and relevant

publications. Describe in detail any involvement of subcontractors or consultants, and provide resumes for all key subcontractor staff. Also, include letters of commitment with proposed consultants confirming the extent of involvement and hourly/daily rate. (resumes and letters are excluded from the research plan page limit).

4) **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 and identified in the business proposal. In addition, supported by appropriate letters from each individual confirming his/her role in the project must be included (letters are excluded from the research plan page limit).

5) **Resources** - List/describe all equipment, facilities and other resources available for this project, including the offeror's clinical, computer and office facilities/equipment at any other performance site that will be involved in this project. Briefly state their capacities, relative proximity and extent of availability to this effort. (Any equipment specifically proposed as a cost to the contract must be justified in this section as well as detailed in the budget. Equipment and products purchased with Government funds shall be American-made, to the extent possible. Title to the equipment will vest in the Government.)

6) **Commercialization Plan** – **Limited to 4 pages (this is in addition to the 10-page limit for the Research Plan elements above).** The Phase II portion of Fast-Track proposals and all Direct Phase II proposals must include a Commercialization Plan. Be succinct. There is no requirement for offerors to use the maximum allowable pages allotted to the Commercialization Plan. Provide a description in each of the following areas:

    a) **Value of the SBIR Project, Expected Outcomes, and Impact.** Describe, in layperson's terms, the proposed project and its key technology objectives. Clarify the need addressed, specifying weaknesses in the current approaches to meet this need. In addition, describe the commercial applications of the research and the innovation inherent in this proposal. Be sure to also specify the potential societal, educational, and scientific benefits of this work. Explain the non-commercial impacts to the overall significance of the project. Explain how the SBIR project integrates with the overall business plan of the company.

    b) **Company.** Give a brief description of your company including corporate objectives, core competencies, present size (annual sales level and number and types of employees), history of previous Federal and non-Federal funding, regulatory experience, and subsequent commercialization, and any current products/services that have significant sales. Include a short description of the origins of the company. Indicate your vision for the future, how you will

        grow/maintain a sustainable business entity, and how you will meet critical management functions as your company evolves from a small technology R&D business to a successful commercial entity.

    c) **Market, Customer, and Competition.** Describe the market and/or

market segments you are targeting and provide a brief profile of the potential customer. Tell what significant advantages your innovation will bring to the market, e.g., better performance, lower cost, faster, more efficient or effective, new capability. Explain the hurdles you will have to overcome in order to gain market/customer acceptance of your innovation.

Describe any strategic alliances, partnerships, or licensing agreements you have in place to get FDA approval (if required) and to market and sell your product

Briefly describe your marketing and sales strategy. Give an overview of the current competitive landscape and any potential competitors over the next several years. (It is very important that you understand and know the competition.)

d) **Intellectual Property (IP) Protection.** Describe how you are going to protect the IP that results from your innovation. Also note other actions you may consider taking that will constitute at least a temporal barrier to others aiming to provide a solution similar to yours.

e) **Finance Plan.** Describe the necessary financing you will require, and when it will be required, as well as your plans to raise the requisite financing to launch your innovation into commercialization and begin the revenue stream. Plans for this financing stage may be demonstrated in one or more of the following ways:

   i) Letter of commitment of funding.
   ii) Letter of intent or evidence of negotiations to provide funding, should the Phase II project be successful and the market need still exist.
   iii) Letter of support for the project and/or some in-kind commitment, e.g., to test or evaluate the innovation.
   iv) Specific steps you are going to take to secure non-SBIR follow-on funding.

f) **Production and Marketing Plan.** Describe how the production of your product/service will occur (e.g., in-house manufacturing, contract manufacturing). Describe the steps you will take to market and sell your product/service. For example, explain plans for licensing, internet sales, etc.

g) **Revenue Stream.** Explain how you plan to generate a revenue stream for your company should this project be a success. Examples of

revenue stream generation include, but are not limited to, manufacture and direct sales, sales through value added resellers or other distributors, joint venture, licensing, service. Describe how your staffing will change to meet your revenue expectations.

Offerors are encouraged to seek commitment(s) of funds and/or resources from an investor or partner organization for commercialization of the product(s) or service(s) resulting from the SBIR contract. Your follow-on non-SBIR funding may be from any of a number of different sources including, but not limited to: SBIR firm itself; private investors or "angels"; venture capital firms; investment companies; joint ventures; R&D limited partnerships; strategic alliances; research contracts; sales of prototypes (built as part of this project); public offering; state finance programs; non SBIR-funded R&D or production commitments from a Federal agency with the intention that the results will be used by the United States government; or other industrial firms.

Fast-Track proposals that do not contain all parts described above will be redirected for Phase I

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: