

## AMENDMENT 1

The purpose of Amendment 1 is to update the Topic Index (page 9), the chart for topic HR0011SB20224-09 (page 10), and the references for topic HR0011SB20224-09 (page 12). All changes are highlighted.

### **Defense Advanced Research Projects Agency (DARPA) DoD 22.4 Small Business Innovation Research (SBIR) Annual BAA Proposal Submission Instructions Release 6**

#### **INTRODUCTION**

DARPA's mission is to make strategic, early investments in science and technology that will have long-term positive impact on our national security. As part of this mission, DARPA makes high-risk, high-reward investments in science and technology that have the potential to disrupt current understanding and/or approaches. The pace of discovery in both science and technology is accelerating worldwide, resulting in new fields of study and the identification of scientific areas ripe for small business utilization through the SBIR and STTR programs. Small businesses are critical for developing technology to support national security. Proposers are encouraged to consider whether the R/R&D being proposed to DoD Components also has private sector potential, either for the proposed application or as a base for other applications. The topics below focus on technical domains important to DARPA's mission pursuing innovative research concepts that fall within one of its technology offices. More information about DARPA's technical domains and research topics of interest may be found at: <http://www.darpa.mil/about-us/offices>.

Proposers responding to a topic in this BAA must follow all general instructions provided in the Department of Defense (DoD) SBIR Program BAA. DARPA requirements in addition to or deviating from the DoD Program BAA are provided in the instructions below.

Specific questions pertaining to the administration of the DARPA Program and these proposal preparation instructions should be directed to: DARPA Small Business Programs Office at [SBIR\\_BAA@darpa.mil](mailto:SBIR_BAA@darpa.mil). DSIP Topic Q&A will NOT be available for these DARPA topics. Technical questions related to improving the understanding of a topic's requirements must be submitted to [SBIR\\_BAA@darpa.mil](mailto:SBIR_BAA@darpa.mil) by the deadline listed below.

The following dates apply to this DARPA Topic release:

- June 30, 2022:** Topics issued for pre-release
- July 19, 2022:** Topics open; DARPA begins accepting proposals via DSIP
- August 11, 2022:** Deadline for technical question submission
- August 18, 2022:** Deadline for receipt of proposals no later than **12:00 pm ET**

#### **PHASE I PROPOSAL GUIDELINES**

The Defense SBIR/STTR Innovation Portal (DSIP) is the official portal for DoD SBIR/STTR proposal submission. Proposers are required to submit proposals via DSIP; proposals submitted by any other means will be disregarded. Detailed instructions regarding registration and proposal submission via DSIP are provided in Appendix A.

**Current Release Award Structure by Topic**

Topic Number	Phase I		
	Technical Volume	Award Amount	Period of Performance (PoP)
HR0011SB20224-09	25 pages	\$225,000	8 months

**Technical Volume (Volume 2)**

The technical volume is not to exceed 20 pages and must follow the formatting requirements provided in the DoD SBIR Program BAA. Phase I commercialization strategy shall not exceed 5 pages. This should be the last section of the Technical Volume and will not count against the 20-page limit.

**Content of the Technical Volume**

Proposers should refer to the DARPA Phase I Proposal Instructions, provided in Appendix A and on the DARPA Small Business site (<https://www.darpa.mil/work-with-us/for-small-businesses/participate-sbir-sttr-program>).

**Cost Volume (Volume 3)**

Please see the chart above for award amounts listed by topic. Proposers are required to use the Phase I – Volume 3: Cost Proposal Template (Excel Spreadsheet) provided on the DARPA Small Business site (<https://www.darpa.mil/work-with-us/for-small-businesses/participate-sbir-sttr-program>).

**Company Commercialization Report (CCR) (Volume 4)**

Completion of the CCR as Volume 4 of the proposal submission in DSIP is required. Please refer to the DoD SBIR Program BAA for full details on this requirement. Information contained in the CCR will not be considered by DARPA during proposal evaluations.

**Supporting Documents (Volume 5)**

In addition to the documents required by DoD, small businesses may also submit additional documentation to support the Technical Volume (Volume 2) and the Cost Volume (Volume 3) in Volume 5.

**DIRECT TO PHASE II PROPOSAL GUIDELINES**

Proposers should refer to the DARPA Direct to Phase II Proposal Instructions, provided on the DSIP Submission site.

**Current Release Award Structure by Topic**

Topic Number	Direct to Phase II				
	Tech Volume	Award Amount	Period of Performance (PoP)	Option Amount	Option PoP
HR0011SB20224-10	65 pages	\$1,500,000	24 months	\$200,000	12 months

### **Technical Volume (Volume 2)**

If a proposer can provide adequate documentation to substantiate that the scientific and technical merit and feasibility described in the Phase I section of the topic has been met and describes the potential commercial applications, the Direct to Phase II (DP2) authority allows the Department of Defense (DoD) to make an award to a small business concern under Phase II of the SBIR program without regard to whether the small business concern was provided an award under Phase I of an SBIR program. This topic is accepting DP2 proposal submissions.

DP2 Feasibility Documentation shall not exceed 20 pages. DP2 Technical Proposal shall not exceed 40 pages. Phase II commercialization strategy shall not exceed 5 pages. This should be the last section of the Technical Volume and will not count against the 40-page limit.

### **Content of the Technical Volume**

Proposers should refer to the DARPA DP2 Proposal Instructions, provided in Appendix B and on the DARPA Small Business site (<https://www.darpa.mil/work-with-us/for-small-businesses/participate-sbir-sttr-program>).

### **Cost Volume (Volume 3)**

Please see the chart above for award amounts listed by topic. Proposers are required to use the Direct to Phase II – Volume 3: Cost Proposal Template (Excel Spreadsheet) provided on the DARPA Small Business site (<https://www.darpa.mil/work-with-us/for-small-businesses/participate-sbir-sttr-program>).

### **Company Commercialization Report (CCR) (Volume 4)**

Completion of the CCR as Volume 4 of the proposal submission in DSIP is required. Please refer to the DoD SBIR Program BAA for full details on this requirement. Information contained in the CCR will not be considered by DARPA during proposal evaluations.

### **Supporting Documents (Volume 5)**

In addition to the documents required by DoD, small businesses may also submit additional documentation to support the Technical Volume (Volume 2) and the Cost Volume (Volume 3) in Volume 5.

## **PHASE II PROPOSAL GUIDELINES**

Phase II proposals may only be submitted by Phase I awardees. Should DARPA have funding available and decide to proceed with a Phase II, proposers awarded a Phase I contract will be eligible to submit a proposal for Phase II and will be contacted to do so by the DARPA Small Business Programs Office at the appropriate time during their Phase I period of performance. Phase II proposals will be evaluated in accordance with the applicable DoD or DARPA SBIR BAA. Phase II selection(s) are at the sole discretion of the government and are subject to funding availability and Phase I performance.

### **Current Release Award Structure by Topic**

Topic Number	Phase II				
	Tech Volume	Award Amount	Period of Performance (PoP)	Option Amount	Option PoP
HR0011S210002-09	45 pages	\$1,200,000	24 months	\$600,000	12 months

Technical Proposal shall not exceed 40 pages. Phase II commercialization strategy shall not exceed 5 pages. It should be the last section of the Technical Volume and will not count against the 40-page limit.

#### **DISCRETIONARY TECHNICAL AND BUSINESS ASSISTANCE (TAB A)**

DARPA does not offer TABA funding.

#### **EVALUATION AND SELECTION**

All proposals will be evaluated in accordance with the evaluation criteria listed in the DoD SBIR 2022.4 BAA. DARPA will conduct an evaluation of each conforming proposal. Proposals that do not comply with the requirements detailed in this BAA and the research objective(s) of the corresponding topic are considered non-conforming and therefore are not evaluated nor considered for award.

Using the evaluation criteria, the Government will evaluate each proposal in its entirety, documenting the strengths and weaknesses relative to each evaluation criterion, and, based on these identified strengths and weaknesses, determine the proposal's overall selectability. Proposals will not be evaluated against each other during the evaluation process, but rather evaluated on their own individual merit to determine how well the proposal meets the criteria stated in this BAA and the corresponding DARPA topic.

Awards will be made to proposers whose proposals are determined to be the most advantageous to the Government, consistent with instructions and evaluation criteria specified in the DoD SBIR 2022.4 BAA and availability of funding. Given the limited funding available for each topic released, not all proposals considered selectable will be selected for funding.

For the purposes of this proposal evaluation process, a selectable proposal is defined as follows:

Selectable: A selectable proposal is a proposal that has been evaluated by the Government against the evaluation criteria listed in the DoD SBIR 2022.4 BAA and DARPA topic, and the strengths of the overall proposal outweighs its weaknesses. Additionally, there are no accumulated weaknesses that would require extensive negotiations and/or a resubmitted proposal.

For the purposes of this proposal evaluation process, a non-selectable proposal is defined as follows:

Non-Selectable: A proposal is considered non-selectable when the proposal has been evaluated by the Government against the evaluation criteria listed in the DoD SBIR 2022.4 BAA and DARPA topic, and the strengths of the overall proposal do not outweigh its weaknesses.

Proposing firms will be notified of selection or non-selection status for a Phase I award within 90 days of the closing date of the DoD SBIR 2022.4 BAA. It is the policy of DARPA to treat all proposals as source selection information and to disclose their contents only for the purpose of evaluation. Restrictive notices notwithstanding, during the evaluation process, submissions may be handled by support contractors for administrative purposes and/or to assist with technical evaluation. All DARPA support contractors are expressly prohibited from performing DARPA-sponsored technical research and are bound by appropriate nondisclosure agreements. Input on technical aspects of the proposals may be solicited by DARPA from other Government and/or non-Government consultants/experts who are strictly bound by the appropriate non-disclosure requirements. No submissions will be returned. Upon completion of the evaluation and selection process, an electronic copy of each proposal received will be retained at DARPA.

Proposal titles, abstracts, anticipated benefits, and keywords of proposals that are selected for contract award will undergo a DARPA Policy and Security Review. Proposal titles, abstracts, anticipated benefits,

and keywords are subject to revision and/or redaction by DARPA. Final approved versions of proposal titles, abstracts, anticipated benefits, and keywords may appear on the DoD SBIR/STTR awards website and/or the SBA's SBIR/STTR award website (<https://www.sbir.gov/sbirsearch/award/all>).

Refer to the DoD SBIR 2022.4 Program BAA for procedures to protest the Announcement. As further prescribed in FAR 33.106(b), FAR 52.233-3, Protests regarding the selection decision should be submitted to:

DARPA  
Contracts Management Office (CMO)  
675 N. Randolph Street  
Arlington, VA 22203  
E-mail: [scott.ulrey@darpa.mil](mailto:scott.ulrey@darpa.mil) and [sbir@darpa.mil](mailto:sbir@darpa.mil)

## **AWARD AND CONTRACT INFORMATION**

### **1. General Award Information**

Multiple awards are anticipated. DARPA may award FAR-based government contracts (Firm- Fixed Price or Cost-Plus Reimbursement) or Other Transactions for Prototypes agreement (under the authority of 10 U.S.C. § 2371b) subject to approval of the Contracting Officer. The amount of resources made available for each topic issued under this BAA will depend on the quality of the proposals received and the availability of funds.

Small businesses that are owned in majority part by multiple venture capital operating companies (VCOs), hedge funds, or private equity funds are eligible to submit applications or receive awards.

The Government reserves the right to select for negotiation all, some, one, or none of the proposals received in response to this announcement and to make awards with or without communications with proposers. Additionally, the Government reserves the right to award all, some, one, or none of the options on the contract(s)/agreement(s) of the performers based on available funding and technical performance. If warranted, portions of resulting awards may be segregated into pre-priced options. Additionally, DARPA reserves the right to accept proposals in their entirety or to select only portions of proposals for award. In the event that DARPA desires to award only portions of a proposal, negotiations may be opened with that proposer. The Government reserves the right to fund proposals in phases with options for continued work, as applicable.

The Government reserves the right to request any additional, necessary documentation once it makes the award instrument determination. The Government reserves the right to remove a proposal from award consideration should the parties fail to reach agreement on award terms, conditions, and price within a reasonable time, and/or the proposer fails to provide requested additional information within three business days.

In all cases, the Government Contracting Officer reserves the right to select award instrument type, regardless of instrument type proposed, and to negotiate all instrument terms and conditions with selectees. DARPA will apply publication or other restrictions, as necessary, if it determines that the research resulting from the proposed effort will present a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense. Any award resulting from such a determination will include a requirement for DARPA permission before publishing any information or results on the program. For more information on publication restrictions, see the DoD SBIR 2022.4 BAA.

Because of the desire to streamline the award negotiation and program execution process, proposals identified for negotiation will result in negotiating a type of instrument for award that is in the best interest of the Government. In the case of an OT for Prototype agreement under DARPA's authority to award OTs for prototype projects, 10 U.S.C. § 2371b, use of an OT provides significant opportunities for flexible execution to assist in meeting DARPA's aggressive SBIR/STTR program goals.

All proposers that wish to consider an OT award should carefully read the following:

The flexibility of the OT award instrument is beneficial to the program because the Performer will be able to apply its best practices as required to carry out the research project that may be outside of the Federal Acquisition Regulation (FAR) process-driven requirements. Streamlined practices will be used, such as milestone-driven performance, intended to reduce time and effort on award administration tasks and permit performers to focus on the research effort and rapid prototyping. Because of this ability, OTs provide the Agreements Officer the flexibility to create an award instrument that contains terms and conditions that promote commercial transition, reduce some administratively burdensome acquisition regulations, and meet SBIR/STTR program goals.

Proposers must only propose an OT agreement with fixed payable milestones. Fixed payable milestones are fixed payments based on successful completion of the milestone accomplishments agreed to in the milestone plan. Refer to the Other Transactions for Prototypes Fact Sheet and Other Transaction for Prototype Agreement, available at <https://www.darpa.mil/work-with-us/for-small-businesses/participate-sbir-sttr-program>. Specific milestones will be based upon the research objectives detailed in the topic.

Please see <https://www.darpa.mil/work-with-us/for-small-businesses/participate-sbir-sttr-program> for more information on OTs.

## **2. Transition and Commercialization Support Program (TCSP)**

DARPA will provide services to Phase II or DP2 awardees upon contract execution through the Transition and Commercialization Support Program (TCSP) at no cost to awardees. The TCSP goal is to maximize the potential for SBIR/STTR companies to move their technology beyond Phase II, and into other research and development programs for further maturity, or into solutions or products for DoD acquisition programs, other Federal programs, and/or the commercial market. Please visit <https://www.darpa.mil/work-with-us/for-small-businesses/commercialization-continued> for more information on DARPA TCSP.

## **3. Embedded Entrepreneurship Initiative**

Awardees of SBIR funding pursuant to this BAA may be eligible to participate in the DARPA Embedded Entrepreneurship Initiative (EEI) during the Period of Performance. Invitation to participate in EEI is at the sole discretion of the Government based on evaluation of technical and commercial factors and subject to program balance and the availability of funding. EEI is a limited scope program offered by DARPA, at DARPA's discretion, to a small subset of awardees. The goal of DARPA's EEI is to increase the likelihood that DARPA-funded technologies take root in the U.S. and provide new capabilities for national defense. EEI supports DARPA's mission "to make pivotal investments in breakthrough technologies and capabilities for national security" by accelerating the transition of innovations out of the lab and into new capabilities for the Department of Defense (DoD). EEI investment supports development of a robust and deliberate Go-to-Market strategy for selling technology product to the government and commercial markets and positions DARPA awardees to attract U.S. investment. The following is for informational and planning purposes only and does not constitute solicitation of proposals to the EEI.

There are three elements to DARPA's EEI: (1) A Senior Commercialization Advisor (SCA) from DARPA who works with the Program Manager (PM) to examine the business case for the awardee's

technology and uses commercial methodologies to identify steps toward achieving a successful transition of technology to the government and commercial markets; (2) Connections to potential industry and investor partners via EEI's Investor Working Groups; and (3) Additional funding on an awardee's contract for the awardee to hire an embedded entrepreneur to achieve specific milestones in a Go-to-Market strategy for transitioning the technology to products that serve both defense and commercial markets. This embedded entrepreneur's qualifications should include business experience within the target industries of interest, experience in commercializing early stage technology, and the ability to communicate and interact with technical and non-technical stakeholders. Funding for EEI is typically no more than \$250,000 per awardee over the duration of the award. An awardee may apportion EEI funding to hire more than one embedded entrepreneur, if achieving the milestones requires different expertise that can be obtained without exceeding the awardee's total EEI funding. The EEI effort is intended to be conducted concurrent with the research program without extending the period of performance.

*EEI Application Process:*

After receiving an award under the solicitation, awardees interested in being considered for EEI should notify their DARPA Program Manager (PM) during the period of performance. Timing of such notification should ideally allow sufficient time for DARPA and the awardee to review the awardee's initial transition plan, identify milestones to achieve under EEI, modify the award, and conduct the work required to achieve such milestones within the original award period of performance. These steps may take 9-18 months to complete, depending on the technology. If the DARPA PM determines that EEI could be of benefit to transition the technology to product(s) the Government needs, the PM will refer the performer to DARPA Commercial Strategy.

DARPA Commercial Strategy will then contact the performer, assess fitness for EEI, and in consultation with the DARPA technical office, determine whether to invite the performer to participate in the EEI. Factors that are considered in determining fitness for EEI include DoD/Government need for the technology; competitive approaches to enable a similar capability or product; risks and impact of the Government's being unable to access the technology from a sustainable source; Government and commercial markets for the technology; cost and affordability; manufacturability and scalability; supply chain requirements and barriers; regulatory requirements and timelines; Intellectual Property and Government Use Rights, and available funding.

Invitation to participate in EEI is at the sole discretion of DARPA and subject to program balance and the availability of funding. EEI participants' awards may be subsequently modified bilaterally to amend the Statement of Work to add negotiated EEI tasks, provide funding, and specify a milestone schedule which will include measurable steps necessary to build, refine, and execute a Go-to-Market technology transition plan aimed at delivering new capabilities for national defense. Milestone examples are available at: <https://www.darpa.mil/work-with-us/contract-management>.

Awardees under this solicitation are eligible to be considered for participation in EEI, but selection for award under this solicitation does not imply or guarantee participation in EEI.

For more information please refer to the EEI website <https://eei.darpa.mil/>.

**ADDITIONAL INFORMATION**

DARPA intends to use electronic mail for all correspondence regarding these topics. Questions related to the technical aspect of the research objectives and awards specifically related to a topic should be emailed to [SBIR\\_BAA@darpa.mil](mailto:SBIR_BAA@darpa.mil). Please reference the topic number in the subject line. All questions must be in English and must include the name, email address, and the telephone number of a point of contact.

DARPA will attempt to answer questions in a timely manner; however, questions submitted within seven (7) calendar days of the proposal due date listed herein may not be answered. DARPA will post a consolidated Frequently Asked Questions (FAQ) document. To access the posting please visit: <http://www.darpa.mil/work-with-us/opportunities>. Under the topic number summary, there will be a link to the FAQ. The FAQ will be updated on an ongoing basis until one week prior to the proposal due date.

Technical support for the Defense SBIR/STTR Innovation Portal (DSIP) is available Monday through Friday, 9:00 a.m. – 5:00 p.m. ET. Requests for technical support must be emailed to [DoDSBIRSupport@reisystems.com](mailto:DoDSBIRSupport@reisystems.com) with a copy to [SBIR\\_BAA@darpa.mil](mailto:SBIR_BAA@darpa.mil).



**DARPA SBIR 22.4 Topic Index**  
**Release 6**

HR0011SB20224-09 **Advanced Radiation Shielding**  
HR0011SB20224-10 New Technology for Non-Invasive Intracranial Pressure Monitoring

OUSD (R&E) MODERNIZATION PRIORITY: Directed Energy, Nuclear, Space

TECHNOLOGY AREA(S): Materials/Processes, Nuclear Technology, Space Platform

OBJECTIVE: Develop a new material system capable of more effective high energy gamma-ray shielding than traditional materials such as lead and concrete at comparable cost.

DESCRIPTION: There are various operational environments where shielding is required to protect people and sensitive electronics from ionizing radiation. These include space environments, areas with highly radioactive materials or areas near intense nuclear reactions, such as fission and fusion sources. Although traditional radiation shielding materials have largely been suitable, developing a new material system that provides 10x more effective shielding compared to traditional materials, or that were 10x lighter or more compact than traditional materials while providing equivalent shielding would enable a range of missions where traditional shielding is inadequate. This topic seeks innovation in novel materials for shielding gamma ray radiation at MeV to GeV energies, capable of withstanding high fluences, that can be produced inexpensively and in large quantities, and ideally with flexible form factors. Specifically, at 1 MeV to 100 MeV energy levels, a material that provides twice or greater the linear attenuation coefficient at comparable density to existing shielding materials is being sought. The table below summarizes the mass and linear attenuation coefficients of three common shielding materials, concrete, iron, and lead, and the goal for two-times (or greater) linear attenuation coefficients at these energies:

	Density (g/cm <sup>3</sup> )	mu/rho (cm <sup>2</sup> /g) 1 MeV	mu/rho (cm <sup>2</sup> /g) 100 MeV	mu (cm <sup>-1</sup> ) 1 MeV	mu (cm <sup>-1</sup> ) 100 MeV
Pb	11.35	0.0710	0.0931	0.806	1.057
Fe	7.87	0.0600	0.0433	0.472	0.341
Concrete	2.3	0.0650	0.0221	0.149	0.051
Pb			Goals >x2:	1.612	2.113
Fe				0.944	0.682
Concrete				0.299	0.102

PHASE I: Phase I is a feasibility study that would demonstrate the scientific, technical, and commercial merit and feasibility of the concept resulting in a basic material system and credible material production flow. Activities could include material modeling, basic material synthesis, fabrication experiments, and material system characterization. Key materials characteristics and interfaces should be identified and quantified showing how attenuation goals could be achieved in terms of necessary shielding and high-volume production cost. Challenges and risks in perfecting shielding characteristics, and scaling the shielding material to required volumes for practical applications must be identified and proposed mitigation strategies presented.

Schedule/Milestones/Deliverables. Phase I fixed payable milestones for this program should include:

- Month 1: Initial report on proposed material system, with modeling and empirical data and discussion of Phase 1 goals.
- Month 3: Report on modifying and scaling of proposed material system and required adjustments to achieve program goals supported by experimental, simulated or modeled data

- Month 5: Interim report describing performance and cost of proposed material system
- Month 7: Update to interim report. Given this report needs to support the Phase 2 proposal, it should provide compelling evidence the material system and its synthesis/fabrication can achieve overall program goals.
- Month 8: Final Phase I report summarizing technical approach and status in achieving Phase I goals, and plans to achieve program goals by the end of Ph 2. This should be a culmination of the Phase 1 effort, demonstrating a viable technical path supported by empirical and modeling data to achieving overall program goals, with risks and mitigation strategies fully detailed.

Monthly written technical progress reports (see template under SBIR/STTR BAA DOCUMENTS at <https://www.darpa.mil/work-with-us/for-small-businesses/participate-sbir-sttr-program>).

All proposals must include the following meetings in the proposed schedule and costs:

- Virtual kickoff for Phase 1; and
- Regular monthly teleconference meetings with the Government team for progress reporting as well as problem identification and mitigation. Proposers typically prepare a slide deck to aid in the discussion.

PHASE II: Phase II builds upon feasibility established in Phase I and ultimately produces and demonstrates a TRL 5 prototype material meeting Section II b goals. The Phase II base period (year 1) will focus on overall material system development and characterization and scalable process development. The Phase II increment period (year 2) will refine material production processes, refine shielding performance and conduct initial practical demonstrations. The Phase II option period (year 3) will produce usable quantities of the optimized material system with demonstrated low-cost techniques, and support demonstrations meeting program goals.

Schedule/Milestones/Deliverables. Phase II fixed payable milestones for this program should include:

- Month 1: Phase 2 Kickoff. Slide deck summarizing technical approach to meet overall goals, risks and risk mitigations, and quantified milestone schedule
- Month 9: Preliminary Design Review. Report capturing the refinement of the material system to achieve performance and cost goals
- Month 12: Interim material characterization: Report characterizing the performance of the photon absorbing material produced from a scalable process.
- Month 15: Critical Design Review. Report capturing the final material system design that when realized credibly achieves the overall performance and suitability goals.
- Month 18: Interim Integration Report: Report describing results to date in integrating the absorbing/attenuating material with demonstrations of interest.
- Month 24: Final Report: End of base period report that summarizes >10x attenuation performance and results of initial practical demonstrations.
- Option Schedule/Milestones/Deliverables
- Month 30: Interim Option Period Performance Report.
- Month 36: Final Phase II Report. Summary of material system performance, testing, production at low cost, and demonstrations meeting program goals. Delivery of the prototype material system to the Government or its designee.

Monthly written technical progress reports (see template under SBIR/STTR BAA DOCUMENTS at <https://www.darpa.mil/work-with-us/for-small-businesses/participate-sbir-sttr-program>).

All proposals must include the following meetings in the proposed schedule and costs:

- Virtual kickoff for Phase II;
- Regular monthly teleconference meetings with the Government team for progress reporting as well as problem identification and mitigation. Proposers typically prepare a slide deck to aid in the discussion; and

- Depending on travel conditions, proposers should anticipate at least one site visit during Phase 2 by the DARPA Program Manager during which they will have the opportunity to demonstrate progress towards agreed-upon milestones.

PHASE III DUAL USE APPLICATIONS: Successful development of the subject material system will be applied in demonstration of relevant DoD and commercial applications, with commercialization strategies developed for each. Military electronics in space environments would be one such example. For commercial applications, targeting applications where traditional shielding poses challenges to effective implementation will be targeted. These may include irradiation facilities, reactor applications, and high energy physics applications.

REFERENCES:

1. NIST X-Ray Mass Attenuation Coefficients:  
<https://physics.nist.gov/PhysRefData/Xcom/html/xcom1.html>;  
<https://physics.nist.gov/PhysRefData/XrayMassCoef/tab2.html>

KEYWORDS: Radiation, Shielding, Gamma-rays, X-rays, Nanomaterials, Quantum dots, High Z materials

HR0011SB20224-10 TITLE: New Technology for Non-Invasive Intracranial Pressure Monitoring

OUSD (R&E) MODERNIZATION PRIORITY: Biotechnology

TECHNOLOGY AREA(S): Biomedical

OBJECTIVE: Develop a non-invasive, real-time intracranial pressure (ICP) monitor suitable for use by medical personnel in resource-limited settings that distinguishes normal from elevated ICP with high accuracy.

DESCRIPTION: Traumatic brain injury (TBI), resulting from blast exposure or blunt or penetrating trauma, is a significant threat to service member health, readiness, and retention. About 450,000 military service members have been diagnosed with traumatic brain injury (TBI) during 2000-2020, including more than 16,000 in 2020 alone (Military Health System, 2022). Service members with TBI are at markedly increased risk of disability (MacDonald et al., 2022).

In moderate and severe TBI, intracranial pressure (ICP) elevation from brain swelling or bleeding may lead to significant brain injury or death. Clinical management entails measures to lower ICP, but ICP-based therapy requires invasive ICP probes that carry risk of infection and bleeding, and can only be administered in hospital settings.

A non-invasive ICP monitor could enable evaluation of TBI severity and ICP-based therapy in field settings. While non-invasive ICP-monitoring approaches have been attempted, they have not demonstrated ability to track ICP over time and are highly operator-dependent, with significant training requirements (Whiting et al., 2020), making them challenging for austere military settings.

This SBIR seeks to develop a device that accurately measures ICP non-invasively, is simple to operate, and is suitable for both in-hospital and pre-hospital settings.

PHASE I: This topic solicits Direct to Phase II proposals only. Proposers must provide data demonstrating that the following pre-clinical, in vivo validation of non-invasive ICP methodology has been achieved outside of the SBIR program: (1) Real-time, continuous waveform measures of ICP; (2) Accurate measurements of ICP as validated by concurrent established methods (fluid catheter or fiberoptic systems) across a broad range of physiological ICP pressure ( $\pm 10\%$  across 0-60 mm Hg); and (3) Faithful tracking of changes in ICP during increasing or decreasing pressure changes ( $\pm 20\%$  at peak and trough).

Proposers interested in submitting a Direct to Phase II (DP2) proposal must provide documentation to substantiate that the scientific and technical merit and feasibility described above has been met and describes the potential commercial applications. Documentation should include all relevant information including, but not limited to: technical reports, test data, prototype designs/models, and performance goals/results.

PHASE II: Performers will build on the pre-clinical demonstrations noted above (Phase I) to extend the non-invasive technology to a clinical setting and deliver a prototype system suitable for use in field military settings. Performers must meet progressively challenging performance criteria in larger numbers of patients. The interim and end-phase goals for the base period are:

	6 months	12 months	18 months	24 months
Cohort size (brain-injured patients who have episodes of pathologically elevated ICP)	≥ 5	≥ 10	≥ 25	≥ 50
Percentage of cohort in which Phase I (pre-clinical) metrics are achieved	≥ 60%	≥ 80%	≥ 80%	≥ 90%
Device	Benchtop	Benchtop	Preliminary integrated	Final integrated*

\*Includes software that registers real-time ICP in units of mm Hg as well as “normal” vs “elevated”, stores data with retrieval option, and depicts ICP trends over time. Device is portable (< 3 kg), ruggedized (meeting MIL-STD-810 shock, vibration, altitude, blowing rain, sand and dust, salt, fog, and immersion specifications), and suitable for use in diverse settings, including Role 1 and higher medical facilities, Emergency Departments, and Intensive Care Units.

Schedule/Milestones/Deliverables. Phase II fixed payable milestones for this program should include:

- Month 1: Report on: Current device and design plan to achieve Phase II goals; progress towards month 6 goals; IRB and HRPO approvals or patient enrollment when approvals obtained.
- Month 3: Report on: Progress towards month 6 goals; IRB and HRPO approvals or patient enrollment when approvals obtained.
- Month 6: Report on: Month 6 demonstration; IRB and HRPO approvals or patient enrollment when approvals obtained.
- Month 9: Report on: Progress towards month 12 goals; IRB and HRPO approvals or patient enrollment when approvals obtained.
- Month 12: Report on: Month 12 demonstration; IRB and HRPO approvals or patient enrollment when approvals obtained.
- Month 15: Report on: Progress towards month 18 goals; IRB and HRPO approvals or patient enrollment when approvals obtained.
- Month 18: Report on: Month 18 demonstration; IRB and HRPO approvals or patient enrollment when approvals obtained.
- Month 21: Report on: Progress towards month 24 goals; IRB and HRPO approvals or patient enrollment when approvals obtained; preliminary transition strategy, including plan for regulatory approvals.
- Month 24: Report on: Month 24 demonstration; prototype architecture, operation, and output interpretation, with sufficient detail to enable clinicians to incorporate the device into their practice with minimal additional training; strategy for regulatory approval, including additional development and experiments needed to strengthen the submission.

Option period: Proposals may include a 12-month option period to execute the regulatory strategy developed during the Phase II base period, culminating in submission for Food and Drug Administration (FDA) clearance.

Schedule/Milestones/Deliverables. Phase II option period fixed payable milestones for this program should include:

- Month 27: Report on: Progress in execution of regulatory strategy, including additional enabling studies, IRB and HRPO approvals, and FDA engagement, as appropriate.

- Month 30: Report on: Progress in execution of regulatory strategy, including additional enabling studies, IRB and HRPO approvals, and FDA engagement, as appropriate.
- Month 33: Report on: Progress in execution of regulatory strategy, including additional enabling studies, IRB and HRPO approvals, and FDA engagement, as appropriate.
- Month 36: Report on: Progress in execution of regulatory strategy, including additional enabling studies, IRB and HRPO approvals, and FDA engagement, as appropriate.

PHASE III DUAL USE APPLICATIONS: While this SBIR application focuses on non-invasive measurement of ICP, technology that is capable of measuring pressure waves through scalp and skull interface may also be able to track other physiological waveforms of medical importance non-invasively, creating opportunities for a broader set of non-invasive diagnostic and monitoring tools for use in military and civilian settings. It is desirable for performers to consider such additional applications; for example, to tissue fluid pressures, vascular integrity, and organ and limb perfusion.

#### REFERENCES:

1. MacDonald CL, Barber J, Johnson A, et al. Global disability trajectories over the first decade following combat concussion. *J Head Trauma Rehab* 2022; 37:63.
2. Military Health System. DoD TBI worldwide numbers 2022. <https://www.health.mil/Military-Health-Topics/Centers-of-Excellence/Traumatic-Brain-Injury-Center-of-Excellence/DOD-TBI-Worldwide-Numbers>
3. Whiting MD, Dengler BA, Rodriguez CL, et al. Prehospital detection of life-threatening intracranial pathology: an unmet need for severe TBI in austere, rural, and remote areas. *Front Neurol* 202; 11:599268.

KEYWORDS: Intracranial Pressure (ICP), Traumatic Brain Injury (TBI), Intracerebral Edema, Brain Herniation, Tissue Perfusion, Vascular Integrity, Non-Invasive Physiological Monitoring, Physiological Software Design

## Appendix A: DARPA PHASE I PROPOSAL INSTRUCTIONS

### I. Introduction

A complete proposal submission consists of:

- Volume 1: Proposal Cover Sheet
- Volume 2: Technical Volume
- Volume 3: Cost Volume
- Volume 4: Company Commercialization Report
- Volume 5: Supporting Documents
- Volume 6: Fraud, Waste and Abuse Training

The Defense SBIR/STTR Innovation Portal (DSIP) provides a structure for building the proposal volumes and submitting a consolidated proposal package. If this is your first time submitting an SBIR or STTR proposal using DSIP, please review detailed training guides at <https://www.dodsbirsttr.mil/submissions/learning-support/training-materials>. It is the responsibility of the proposing firm to ensure that a complete proposal package is certified and submitted by the close date listed in the TOPIC to which they are responding.

To assist in proposal development, templates for Volume 2: Technical Volume and Volume 3: Cost Volume have been provided as attachments to the announcement posted at <https://www.darpa.mil/work-with-us/for-small-businesses/participate-sbir-sttr-program>. Use of these templates is mandatory.

### II. Proprietary Information

Proposers that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall follow instructions in the DoD SBIR 2022.4/STTR 2022.D BAA regarding marking propriety proposal information.

### III. Phase I Proposal Instructions

#### a. Proposal Cover Sheet (Volume 1)

The Cover Sheet must include a brief technical abstract of no more than 3000 characters that describes the proposed R&D project with a discussion of anticipated benefits and potential commercial applications. **Do not include proprietary or classified information in the Proposal Cover Sheet.** If your proposal is selected for award, the technical abstract and discussion of anticipated benefits may be publicly released.

#### b. Format of Technical Volume (Volume 2)

1. Type of file: The Technical Volume must be a single Portable Document Format (PDF) file, including graphics. Perform a virus check before uploading the Technical Volume file. If a virus is detected, it may cause rejection of the proposal. **Do not lock or encrypt the uploaded file. Do not include or embed active graphics such as videos, moving pictures, or other similar media in the document.**



2. Length: The length of the technical volume will be specified by the corresponding topic. The Government will not consider pages in excess of the page count limitations.
3. Layout: Number all pages of your proposal consecutively. Font size should not be smaller than 10-point on standard 8-1/2" x 11" paper with one-inch margins. The header on each page of the Technical Volume should contain your company name, topic number, and proposal number assigned by DSIP when the Cover Sheet was created. The header may be included in the one-inch margin. Please refer to the attachment titled Phase I Template – Volume 2: Technical Volume at <https://www.darpa.mil/work-with-us/for-small-businesses/participate-sbir-sttr-program> for additional details.

**c. Content of the Technical Volume (Volume 2)**

The Technical Volume should cover the following items in the order given below:

1. **Identification and Significance of the Problem or Opportunity.** Define the specific technical problem or opportunity addressed and its importance.
2. **Phase I Technical Objectives.** Enumerate the specific objectives of the Phase I work, including the questions the research and development effort will try to answer to determine the feasibility of the proposed approach.
3. **Phase I Statement of Work (including Subcontractors' Efforts)**
  - a) Provide an explicit, detailed description of the Phase I approach. The Statement of Work should indicate what tasks are planned, how and where the work will be conducted, a schedule of major events, and the final product(s) to be delivered. The Phase I effort should attempt to determine the technical feasibility of the proposed concept. The methods planned to achieve each objective or task should be discussed explicitly and in detail. This section should be a substantial portion of the Technical Volume section.
  - b) The topic may have been identified by the Program Manager as research or activities involving Human/Animal Subjects and/or Recombinant DNA. In the event that Phase I performance includes performance of these kinds of research or activities, please identify the applicable protocols and how those protocols will be followed during Phase I. Please note that funds cannot be released or used on any portion of the project involving human/animal subjects or recombinant DNA research or activities until all of the proper approvals have been obtained (see DoD SBIR 2022.4/STTR 2022.D BAA).
4. **Related Work.** Describe significant activities directly related to the proposed effort, including any conducted by the 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 technical volume must persuade reviewers of the proposer's awareness of the state-of-the-art in the specific topic. Describe previous work not directly related to the proposed effort but similar. Provide the following: (1) short description, (2) client for which work was performed (including individual to be contacted and phone number), and (3) date of completion.

5. **Relationship with Future Research or Research and Development**

- a) State the anticipated results of the proposed approach if the project is successful.
- b) Discuss the significance of the Phase I effort in providing a foundation for Phase II research or research and development effort.
- c) Identify the applicable clearances, certifications and approvals required to conduct Phase II testing and outline the plan for ensuring timely completion of said authorizations in support of Phase II research or research and development effort.

6. **Key Personnel.** Identify key personnel who will be involved in the Phase I effort including information on directly related education and experience. A concise technical resume of the PI, including a list of relevant publications (if any), must be included (Please do not include Privacy Act Information). All resumes will count toward the page limit for Volume 2, as specified in the topic.

7. **Foreign Citizens.** Identify any foreign citizens or individuals holding dual citizenship expected to be involved on this project as a direct employee, subcontractor, or consultant. For these individuals, please specify their country of origin, the type of visa or work permit under which they are performing and an explanation of their anticipated level of involvement on this project. Refer to DoD SBIR 2022.4/STTR 2022.D BAA for more information.

Supplemental information provided in response to this paragraph will be protected in accordance with the Privacy Act (5 U.S.C. 552a), if applicable, and the Freedom of Information Act (5 U.S.C. 552(b)(6)).

8. **Facilities/Equipment.** Describe available instrumentation and physical facilities necessary to carry out the Phase I effort. Justify equipment purchases in this section and include detailed pricing information in the Cost Volume. State whether or not the facilities where the proposed work will be performed meet environmental laws and regulations of federal, state (name), and local Governments for, but not limited to, the following groupings: airborne emissions, waterborne effluents, external radiation levels, outdoor noise, solid and bulk waste disposal practices, and handling and storage of toxic and hazardous materials.

9. **Subcontractors/Consultants.** Subcontractor means any supplier, distributor, vendor, firm, academic institution, research center, or other person or entity that furnishes supplies or services pursuant to a subcontract, at any tier. Involvement of a university or other subcontractors or consultants in the project may be appropriate. If such involvement is intended, it should be identified and described according to the Cost Breakdown Structure at <https://www.dodsbirsttr.mil/submissions/learning-support/firm-templates>. Please refer to DoD SBIR 2022.4/STTR 2022.D BAA for detailed eligibility requirements as it pertains to the use of subcontractors/consultants.

10. **Prior, Current, or Pending Support of Similar Proposals or Awards.** If a proposal submitted in response to a corresponding topic is substantially the same as another proposal that was funded, is now being funded, or is pending with another Federal Agency, or another DoD Component or DARPA, you must reveal this on the Proposal Cover Sheet and provide the following information:

- a) Name and address of the Federal Agency(s) or DoD Component to which a proposal was submitted, will be submitted, or from which an award is expected or has been received.
- b) Date of proposal submission or date of award.
- c) Title of proposal.
- d) Name and title of the PI for each proposal submitted or award received.
- e) Title, number, and date of BAA(s) or solicitation(s) under which the proposal was submitted, will be submitted, or under which award is expected or has been received.
- f) If award was received, state contract number.
- g) Specify the applicable topics for each proposal submitted or award received.

**Note: If this does not apply, state in the proposal "No prior, current, or pending support for proposed work."**

**11. Transition and Commercialization Strategy.** DARPA is equally interested in dual use commercialization of SBIR/STTR project results to the U.S. military, the private sector market, or both, and expects explicit discussion of key activities to achieve this result in the transition and commercialization strategy part of the proposal. Phase I is the time to plan for and begin transition and commercialization activities. The small business must convey an understanding of the market, competitive landscape, potential stakeholders and end-users, and preliminary transition path or paths to be established during the Phase I project. The Phase I transition and commercialization strategy shall not exceed 5 pages.

It should be the last section of the technical volume and include the following elements:

- a) **A summary of transition and commercialization activities conducted during prior SBIR/STTR efforts if applicable, and the Technology Readiness Level (TRL) achieved.**
- b) **Problem or Need Statement.** Briefly describe the problem, need, or requirement, and its significance relevant to a Department of Defense application and/or a private sector application that the SBIR/STTR project results would address. Is there a broader societal need you are trying to address? Please describe.
- c) **Description of Product(s) and/or System Application(s).** Identify the commercial product(s) and/or DoD system(s), or system(s) under development, or potential new system(s). Identify the potential DoD end- users, Federal customers, and/or private sector customers who would likely use the technology.
- d) **Business Model(s)/Procurement Mechanism(s).** Discuss your current business model hypothesis for bringing the technology to market. Describe plans to license, partner, or self-produce your product. How do you plan to generate revenue? Describe the resources you expect will be needed to implement your business models. Discuss your plan and expected timeline to secure these resources. Understanding DARPA's goal of creating and sustaining a U.S. military advantage, describe how you intend to develop your product and supply chains to enable this differentiation.
- e) **Target Market.** Describe the market and addressable market for the innovation. Describe the customer sets you propose to target, their size, their growth rate, and their key reasons they would consider procuring the

technology. Discuss the business economics and market drivers in the target industry. Describe competing technologies existent today on the market as well as those being developed in the lab. How has the market opportunity been validated? Describe the competition. How do you expect the competitive landscape may change by the time your product/service enters the market?

- f) **Funding Requirements.** Describe your company's funding history. How much external financing have you raised? Describe your plans for future funding sources (internal, loan, angel, venture capital, etc.).
- g) **Transition and Commercialization Risks.** Describe the major technology, market and team risks associated with achieving successful transition and commercialization of the DARPA funded technology. DARPA is not afraid to take risks but we want to ensure that our awardees clearly understand the risks in front of them. What are the key risks in bringing your innovation to market? What are actions you plan to undertake to mitigate these risks?
- h) **Expertise/Qualifications of Team/Company Readiness.** Describe the expertise and qualifications of your management, marketing/business development and technical team that will support the transition of the technology from the prototype to the commercial market and into government operational environments. Has this team previously taken similar products/services to market? If the present team does not have this needed expertise, how do you intend to obtain it? What is the financial history and health of your company (e.g., availability of cash, profitability, revenue growth, etc.)?
- i) **Anticipated Transition and Commercialization Results.** Include a schedule showing the anticipated quantitative transition and commercialization results from the Phase II project at one year after the start of Phase II, at the completion of Phase II, and after the completion of Phase II (i.e., amount of additional investment, sales revenue, etc.). After Phase II award, the company is required to report actual sales and investment data in its Company Commercialization Report at least annually.

Advocacy Letters (OPTIONAL)\* Feedback received from potential Commercial and/or DoD customers and other end-users regarding their interest in the technology to support their capability gaps. Advocacy letters that are faxed or e-mailed separately will NOT be accepted.

Letters of Intent/Commitment (OPTIONAL)\* Relationships established, feedback received, support and commitment for the technology with one or more of the following: Commercial customer, DoD PM/PEO, a Defense Prime, or vendor/supplier to the Primes and/or other vendors/suppliers identified as having a potential role in the integration of the technology into fielded systems/products or those under development. Letters of Intent/Commitment that are faxed or e-mailed separately will NOT be accepted.

\*Advocacy Letters and Letters of Intent/Commitment are optional, and should ONLY be submitted to substantiate any transition or commercialization claims made in the commercialization strategy. Please DO NOT submit these letters just for the sake of including them in your proposal. These letters DO NOT count against any page limit.

In accordance with section 3-209 of DOD 5500.7-R, Joint Ethics Regulation, letters from government personnel will NOT be considered during the evaluation process.

#### d. Format of Cost Volume (Volume 3)

Proposers are required to use the Phase I – Volume 3: Cost Proposal Template (Excel Spreadsheet) provided at <https://www.darpa.mil/work-with-us/for-small-businesses/participate-sbir-sttr-program>.

**e. Content of the Cost Volume (Volume 3)**

Some items in the Cost Breakdown Guidance below may not apply to the proposed project. If such is the case, there is no need to provide information on each and every item.

ALL proposed costs should be accompanied by documentation to substantiate how the cost was derived. For example, if you proposed travel cost to attend a project-related meeting or conference, and used a travel website to compare flight costs, include a screen shot of the comparison. Similarly, if you proposed to purchase materials or equipment, and used the internet to search for the best source, include your market research for those items. You do not necessarily have to propose the cheapest item or supplier, but you should explain your decision to choose one item or supplier over another. It's important to provide enough information to allow contracting personnel to understand how the proposer plans to use the requested funds.

If selected for award, failure to include the documentation with your proposal will delay contract negotiation, and the proposer will be asked to submit the necessary documentation to the Contracting Officer to substantiate costs (e.g., cost estimates for equipment, materials, and consultants or subcontractors). It is important to respond as quickly as possible to the Contracting Officer's request for documentation.

Cost Breakdown Guidance:

- List all key personnel by name as well as by number of hours dedicated to the project as direct labor.
- Special tooling and test equipment and material cost may be included. The inclusion of equipment and material will be carefully reviewed relative to need and appropriateness for the work proposed. The purchase of special tooling and test equipment must, in the opinion of the Contracting Officer, be advantageous to the Government and should be related directly to the specific topic. These may include such items as innovative instrumentation and/or automatic test equipment. Title to property furnished by the Government or acquired with Government funds will be vested with DARPA; unless it is determined that transfer of title to the contractor would be more cost effective than recovery of the equipment by the DARPA.
- Cost for travel funds must be justified and related to the needs of the project.
- Cost sharing is permitted for proposals under this announcement; however, cost sharing is not required nor will it be an evaluation factor in the consideration of a proposal.
- All subcontractor costs and consultant costs must be detailed at the same level as prime contractor costs in regard to labor, travel, equipment, etc. Provide detailed substantiation of subcontractor costs in your cost proposal. Enter this information in the Explanatory Material section of the on-line cost proposal form. The Supporting Documents Volume (Volume 5) may be used if additional space is needed.

For more information about cost proposals and accounting standards associated with contract

awards, see the DCAA publication titled “Audit Process Overview – Information for Contractors” available at <http://www.dcaa.mil>.

**f. Company Commercialization Report (Volume 4)**

The Company Commercialization Report (CCR) allows companies to report funding outcomes resulting from prior SBIR and STTR awards. The Company Commercialization Report (CCR) is required for Phase I and Direct to Phase II proposals. Please refer to the DoD STTR Program BAA for full details on this requirement. Information contained in the CCR will not be considered by DARPA during proposal evaluations.

**g. Supporting Documents (Volume 5)**

In addition to required DoD documentation and certifications, small businesses may also submit additional documentation to support the Technical Volume (Volume 2) and the Cost Volume (Volume 3) in Volume 5.

**h. Fraud Waste and Abuse (Volume 6)**

The Fraud, Waste and Abuse (FWA) training is required for Phase I and Direct to Phase II proposals. FWA training provides information on what represents FWA in the SBIR/STTR program, the most common mistakes that lead to FWA, as well as the penalties and ways to prevent FWA in your firm. This training material must be thoroughly reviewed once per year. Plan ahead and leave ample time to complete this training based on the proposal submission deadline. Knowingly and willfully making any false, fictitious, or fraudulent statements or representations may be a felony under the Federal Criminal False Statement Act (18 U.S.C. Sec 1001), punishable by a fine of up to \$10,000, up to five years in prison, or both. Understanding the indicators and types of fraud, waste, and abuse that can occur is critical for the SBIR/STTR awardees’ role in preventing the loss of research dollars.

## **APPENDIX B: DARPA DIRECT TO PHASE II (DP2) PROPOSAL INSTRUCTIONS**

### **I. Introduction**

A complete proposal submission consists of:

Volume 1: Proposal Cover Sheet

Volume 2: Technical Volume (feasibility documentation and technical proposal) Volume 3: Cost Volume

Volume 4: Company Commercialization Report

Volume 5: Supporting Documents

Volume 6: Fraud, Waste and Abuse Training

The Defense SBIR/STTR Innovation Portal (DSIP) provides a structure for building the proposal volumes and submitting a consolidated proposal package. If this is your first time submitting an SBIR or STTR proposal using DSIP, please review detailed training guides at <https://www.dodsbirsttr.mil/submissions/learning-support/training-materials>. It is the responsibility of the proposing firm to ensure that a complete proposal package is certified and submitted by the close date listed in the TOPIC to which they are responding.

To assist in proposal development, templates for Volume 2: Technical Volume and Volume 3: Cost Volume have been provided as attachments to the announcement posted at <https://www.dodsbirsttr.mil/submissions/login>. Use of these templates is mandatory.

NOTE: All proposers are required to submit Volume 4: Company Commercialization Report (CCR).

### **II. Proprietary Information**

Proposers that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall follow instructions in section 4.5 regarding marking propriety proposal information.

### **III. DP2 Proposal Instructions**

#### **a. Proposal Cover Sheet (Volume 1)**

The Cover Sheet must include a brief technical abstract of no more than 3000 characters that describes the proposed R&D project with a discussion of anticipated benefits and potential commercial applications. Do not include proprietary or classified information in the Proposal Cover Sheet. If your proposal is selected for award, the technical abstract and discussion of anticipated benefits may be publicly released.

#### **b. Format of Technical Volume (Volume 2)**

1. The Technical Volume must include two parts, PART ONE: Feasibility Documentation and PART TWO: Technical Proposal.
2. Type of file: The Technical Volume must be a single Portable Document Format (PDF) file, including graphics. Perform a virus check before uploading the Technical Volume file. If a virus is detected, it may cause rejection of the proposal. Do not lock or encrypt the uploaded file. Do not

include or embed active graphics such as videos, moving pictures, or other similar media in the document.

3. Length: The length of each part of the technical volume (Feasibility Documentation and Technical Proposal) will be specified by the corresponding TOPIC. The Government will not consider pages in excess of the page count limitations.
4. Layout: Number all pages of your proposal consecutively. Font size should not be smaller than 10-point on standard 8-1/2" x 11" paper with one-inch margins. The header on each page of the Technical Volume should contain your company name, topic number, and proposal number assigned by DSIP when the Cover Sheet was created. The header may be included in the one-inch margin.

**c. Content of the Technical Volume (Volume 2)**

**PART ONE: Feasibility Documentation**

1. Provide documentation to substantiate that the scientific and technical merit and feasibility described in the Phase I section of the TOPIC has been met and describe the potential commercial applications. Documentation should include all relevant information including, but not limited to: technical reports, test data, prototype designs/models, and performance goals/results.
2. Maximum page length for feasibility documentation will be specified by the TOPIC. If you have references, include a reference list or works cited list as the last page of the feasibility documentation. This will count towards the page limit.
3. Work submitted within the feasibility documentation must have been substantially performed by the proposer and/or the PI.
4. If technology in the feasibility documentation is subject to Intellectual Property (IP), the proposer must either own the IP, or must have obtained license rights to such technology prior to proposal submission, to enable it and its subcontractors to legally carry out the proposed work. Documentation of IP ownership or license rights shall be included in the Technical Volume of the proposal.
5. Include a one-page summary on Commercialization Potential addressing the following:
  - i. Does the company contain marketing expertise and, if not, how will that expertise be brought into the company?
  - ii. Describe the potential for commercial (Government or private sector) application and the benefits expected to accrue from this commercialization.

DO NOT INCLUDE marketing material. Marketing material will NOT be evaluated.

**PART TWO: Technical Proposal**

1. Significance of the Problem. Define the specific technical problem or opportunity addressed and its importance.
2. Phase II Technical Objectives. Enumerate the specific objectives of the Phase II work, and describe the technical approach and methods to be used in meeting these objectives.
3. Phase II Statement of Work. The statement of work should provide an explicit, detailed description of the Phase II approach, indicate what is planned, how and where the work will be carried out, a schedule of major events and the final product to be delivered. The methods planned to achieve each objective or task should be discussed explicitly and in detail. This section should be a substantial portion of the total proposal.
  - a. Human/Animal Use: Proposers proposing research involving human and/or animal use are encouraged to separate these tasks in the technical proposal and cost proposal in order to avoid potential delay of contract award.



- b. Phase II Option Statement of Work (if applicable, specified in the corresponding TOPIC). The statement of work should provide an explicit, detailed description of the activities planned during the Phase II Option, if exercised. Include how and where the work will be carried out, a schedule of major events and the final product to be delivered. The methods planned to achieve each objective or task should be discussed explicitly and in detail.
4. Related Work. Describe significant activities directly related to the proposed effort, including any conducted by the PI, the proposer, consultants or others. Describe how these activities interface with the proposed project and discuss any planned coordination with outside sources. The proposal must persuade reviewers of the proposer's awareness of the state of the art in the specific topic. Describe previous work not directly related to the proposed effort but similar. Provide the following: (1) short description, (2) client for which work was performed (including individual to be contacted and phone number) and (3) date of completion.
5. Relationship with Future Research or Research and Development.
  - i. State the anticipated results of the proposed approach if the project is successful.
  - ii. Discuss the significance of the Phase II effort in providing a foundation for Phase III research and development or commercialization effort.
6. Key Personnel. Identify key personnel who will be involved in the Phase II effort including information on directly related education and experience. A concise resume of the PI, including a list of relevant publications (if any), must be included. All resumes count toward the page limitation. Identify any foreign nationals you expect to be involved on this project.
7. Foreign Citizens. Identify any foreign citizens or individuals holding dual citizenship expected to be involved on this project as a direct employee, subcontractor, or consultant. For these individuals, please specify their country of origin, the type of visa or work permit under which they are performing and an explanation of their anticipated level of involvement on this project. Refer to section 3.2 of this BAA for more information. Supplemental information provided in response to this paragraph will be protected in accordance with the Privacy Act (5 U.S.C. 552a), if applicable, and the Freedom of Information Act (5 U.S.C. 552(b)(6)).
8. Facilities/Equipment. Describe available instrumentation and physical facilities necessary to carry out the Phase II effort. Items of equipment to be purchased (as detailed in the cost proposal) shall be justified under this section. Also state whether or not the facilities where the proposed work will be performed meet environmental laws and regulations of federal, state (name) and local Governments for, but not limited to, the following groupings: airborne emissions, waterborne effluents, external radiation levels, outdoor noise, solid and bulk waste disposal practices and handling and storage of toxic and hazardous materials.
9. Subcontractors/Consultants. Involvement of a university or other subcontractors or consultants in the project may be appropriate. If such involvement is intended, it should be identified and described according to the Cost Breakdown Guidance. Please refer to section 3 of this BAA for detailed eligibility requirements as it pertains to the use of subcontractors/consultants.
10. Prior, Current or Pending Support of Similar Proposals or Awards. If a proposal submitted in response to this topic is substantially the same as another proposal that was funded, is now being funded, or is pending with another Federal Agency, or another or the same DoD Component, you must reveal this on the Proposal Cover Sheet and provide the following information:
  - a. Name and address of the Federal Agency(s) or DoD Component to which a proposal was submitted, will be submitted, or from which an award is expected or has been received.

- b. Date of proposal submission or date of award.
- c. Title of proposal.
- d. Name and title of the PI for each proposal submitted or award received.
- e. Title, number, and date of BAA(s) or solicitation(s) under which the proposal was submitted, will be submitted, or under which award is expected or has been received.
- f. If award was received, state contract number.
- g. Specify the applicable topics for each proposal submitted or award received.

Note: If this does not apply, state in the proposal "No prior, current, or pending support for proposed work."

- 11. Transition and Commercialization Strategy. DARPA is equally interested in dual use commercialization of SBIR/STTR projects that result in products sold to the U.S. military, the private sector market, or both. DARPA expects explicit discussion of key activities to achieve this result in the transition and commercialization strategy part of the proposal. The Technical Volume of each Direct to Phase II proposal must include a transition and commercialization strategy section. The Phase II transition and commercialization strategy shall not exceed 5 pages, and will NOT count against the proposal page limit.

Information contained in the commercialization strategy section will be used to determine suitability for participation in EEI. Selection for participation in EEI will be made independently following selection for SBIR/STTR award. Please refer to section 2.6 of this BAA for more information on the DARPA EEI and additional proposal requirements.

The transition and commercialization strategy should include the following elements:

- a. A summary of transition and commercialization activities conducted during Phase I, and the Technology Readiness Level (TRL) achieved. Discuss the market, competitive landscape, potential stakeholders and end-users, and how the preliminary transition and commercialization path or paths may evolve during the Phase II project. Describe key proposed technical milestones during Phase II that will advance the technology towards product such as: prototype development, laboratory and systems testing, integration, testing in operational environment, and demonstrations.
- b. Problem or Need Statement. Briefly describe what you know of the problem, need, or requirement, and its significance relevant to a Department of Defense application and/or a private sector application that the SBIR/STTR project results would address. Is there a broader societal need you are trying to address? Please describe.
- c. Description of Product(s) and/or System Application(s). Identify the commercial product(s) and/or DoD system(s), or system(s) under development, or potential new system(s). Identify the potential DoD end- users, Federal customers, and/or private sector customers who would likely use the technology.
- d. Business Model(s)/Procurement Mechanism(s). Discuss your current business model hypothesis for bringing the technology to market. Describe plans to license, partner, or self-produce your product. How do you plan to generate revenue? Describe the resources you expect will be needed to implement your business models. Discuss your plan and expected timeline to secure these resources. Understanding DARPA's goal of creating and sustaining a U.S. military advantage, describe how you intend to develop your product and supply chains to enable this differentiation.
- e. Target Market. Describe the market and addressable market for the innovation. Describe the customer sets you propose to target, their size, their growth rate, and the key reasons they would consider procuring the technology. Discuss the business economics and market drivers in the target industry. Describe competing technologies existent today on

- the market as well as those being developed in the lab. How has the market opportunity been validated? Describe the competition. How do you expect the competitive landscape may change by the time your product/service enters the market?
- f. Funding Requirements. Describe your company's funding history. How much external financing have you raised? Describe your plans for future funding sources (internal, loan, angel, venture capital, etc.).
  - g. Transition and Commercialization Risks. Describe the major technology, market and team risks associated with achieving successful transition of the DARPA funded technology. DARPA is not afraid to take risks but we want to ensure that our awardees clearly understand the risks in front of them. What are the key risks in bringing your innovation to market? What are actions you plan to undertake to mitigate these risks?
  - h. Expertise/Qualifications of Team/Company Readiness. Describe the expertise and qualifications of your management, marketing/business development and technical team that will support the transition of the technology from the prototype to the commercial market and into government operational environments. Has this team previously taken similar products/services to market? If the present team does not have this needed expertise, how do you intend to obtain it? What is the financial history and health of your company (e.g., availability of cash, profitability, revenue growth, etc.)?
  - i. Anticipated Transition and Commercialization Results. Include a schedule showing the anticipated quantitative transition and commercialization results from the Phase II project at one year after the start of Phase II, at the completion of Phase II, and after the completion of Phase II (i.e., amount of additional investment, sales revenue, etc.). After Phase II award, the company is required to report actual sales and investment data in its Company Commercialization Report at least annually.

Advocacy Letters (OPTIONAL)\* Feedback received from potential Commercial and/or DoD customers and other end-users regarding their interest in the technology to support their capability gaps. Advocacy letters that are faxed or e-mailed separately will NOT be accepted.

Letters of Intent/Commitment (OPTIONAL)\* Relationships established, feedback received, support and commitment for the technology with one or more of the following: Commercial customer, DoD PM/PEO, a Defense Prime, or vendor/supplier to the Primes and/or other vendors/suppliers identified as having a potential role in the integration of the technology into fielded systems/products or those under development. Letters of Intent/Commitment that are faxed or e- mailed separately will NOT be accepted.

\*Advocacy Letters and Letters of Intent/Commitment are optional, and should ONLY be submitted to substantiate any transition or commercialization claims made in the commercialization strategy. Please DO NOT submit these letters just for the sake of including them in your proposal. These letters DO NOT count against any page limit.

In accordance with section 3-209 of DOD 5500.7-R, Joint Ethics Regulation, letters from government personnel will NOT be considered during the evaluation process.

#### **d. Format of Cost Volume (Volume 3)**

Proposers are required to use the Direct to Phase II – Volume 3: Cost Proposal Template (Excel Spreadsheet) provided as an attachment to this announcement. The Cost Volume (and supporting documentation) DOES NOT count toward the page limit of the Technical Volume.

#### **e. Content of the Cost Volume (Volume 3)**

Some items in the Cost Breakdown Guidance below may not apply to the proposed project. If such is the case, there is no need to provide information on each and every item.

ALL proposed costs should be accompanied by documentation to substantiate how the cost was derived. For example, if you proposed travel cost to attend a project-related meeting or conference, and used a travel website to compare flight costs, include a screen shot of the comparison. Similarly, if you proposed to purchase materials or equipment, and used the internet to search for the best source, include your market research for those items. You do not necessarily have to propose the cheapest item or supplier, but you should explain your decision to choose one item or supplier over another. It's important to provide enough information to allow contracting personnel to understand how the proposer plans to use the requested funds. If selected for award, failure to include the documentation with your proposal will delay contract negotiation, and the proposer will be asked to submit the necessary documentation to the Contracting Officer to substantiate costs (e.g., cost estimates for equipment, materials, and consultants or subcontractors). It is important to respond as quickly as possible to the Contracting Officer's request for documentation.

#### Cost Breakdown Guidance:

1. List all key personnel by name as well as by number of hours dedicated to the project as direct labor. Special tooling and test equipment and material cost may be included. The inclusion of equipment and material will be carefully reviewed relative to need and appropriateness for the work proposed. The purchase of special tooling and test equipment must, in the opinion of the Contracting Officer, be advantageous to the Government and should be related directly to the specific topic. These may include such items as innovative instrumentation and/or automatic test equipment. Title to property furnished by the Government or acquired with Government funds will be vested with DARPA; unless it is determined that transfer of title to the contractor would be more cost effective than recovery of the equipment by the DARPA.
2. Cost for travel funds must be justified and related to the needs of the project.
3. Cost sharing is permitted for proposals under this announcement; however, cost sharing is not required nor will it be an evaluation factor in the consideration of a proposal.
4. All subcontractor costs and consultant costs must be detailed at the same level as prime contractor costs in regard to labor, travel, equipment, etc. Provide detailed substantiation of subcontractor costs in your cost proposal. Enter this information in the Explanatory Material section of the on-line cost proposal form. The Supporting Documents Volume (Volume 5) may be used if additional space is needed.

For more information about cost proposals and accounting standards, see the DCAA publication titled "Audit Process Overview – Information for Contractors" available at: <http://www.dcaa.mil>.

#### **f. Company Commercialization Report (Volume 4)**

The Company Commercialization Report (CCR) allows companies to report funding outcomes resulting from prior SBIR and STTR awards. The Company Commercialization Report (CCR) is required for Phase I and Direct to Phase II proposals. Please refer to the DoD STTR Program BAA for full details on this requirement. Information contained in the CCR will not be considered by DARPA during proposal evaluations.

#### **g. Supporting Documents (Volume 5)**

In addition to required DoD documentation and certifications, small businesses may also submit additional documentation to support the Technical Volume (Volume 2) and the Cost Volume (Volume 3) in Volume 5.

**h. Fraud Waste and Abuse (Volume 6)**

The Fraud, Waste and Abuse (FWA) training is required for Phase I and Direct to Phase II proposals. FWA training provides information on what represents FWA in the SBIR/STTR program, the most common mistakes that lead to FWA, as well as the penalties and ways to prevent FWA in your firm. This training material must be thoroughly reviewed once per year. Plan ahead and leave ample time to complete this training based on the proposal submission deadline. Knowingly and willfully making any false, fictitious, or fraudulent statements or representations may be a felony under the Federal Criminal False Statement Act (18 U.S.C. Sec 1001), punishable by a fine of up to \$10,000, up to five years in prison, or both. Understanding the indicators and types of fraud, waste, and abuse that can occur is critical for the SBIR/STTR awardees' role in preventing the loss of research dollars.