

DARPA

SBIR 16.1 DIRECT TO PHASE II
PROPOSAL INSTRUCTIONS

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DARPA DIRECT TO PHASE II (DP2) PROPOSAL INSTRUCTIONS

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IMPORTANT NOTE REGARDING THESE INSTRUCTIONS

THESE INSTRUCTIONS ONLY APPLY TO PROPOSALS SUBMITTED IN RESPONSE TO DARPA 16.1 DIRECT TO PHASE II TOPICS. Please contact our office if you require Phase II Instructions or Direct to Phase II instructions for another solicitation.

Offerors responding to DARPA topics listed in Section 12.0 of this solicitation must follow all the instructions provided in the DoD Program Solicitation AND the supplementary DARPA instructions contained in this section. The section/paragraph numbering in these instructions is intended to correspond with the section/paragraph numbering of the 16.1 DoD Program Solicitation (<http://www.acq.osd.mil/osbp/sbir/index.shtml>).

1.0 INTRODUCTION

DARPA's mission is to prevent technological surprise for the United States and to create technological surprise for its adversaries. The DARPA SBIR Program is designed to provide small, high-tech businesses and academic institutions the opportunity to propose radical, innovative, high-risk approaches to address existing and emerging national security threats; thereby supporting DARPA's overall strategy to bridge the gap between fundamental discoveries and the provision of new military capabilities.

The responsibility for implementing DARPA's Small Business Innovation Research (SBIR) Program rests with the Small Business Programs Office.

DEFENSE ADVANCED RESEARCH PROJECTS AGENCY

Attention: DIRO/SBPO

675 North Randolph Street

Arlington, VA 22203-2114

sbir@darpa.mil

http://www.darpa.mil/Opportunities/SBIR_STTR/SBIR_STTR.aspx

Direct to Phase II (DP2)

15 U.S.C. §638(cc), as amended by NDAA FY2012, Sec. 5106, PILOT TO ALLOW PHASE FLEXIBILITY, allows the DoD to make an award to a small business concern under Phase II of the SBIR program with respect to a project, without regard to whether the small business concern was provided an award under Phase I of an SBIR program with respect to such project.

DARPA is conducting a "Direct to Phase II" pilot implementation of this authority for this 16.1 SBIR solicitation only and does not guarantee the pilot will be offered in future solicitations. Each eligible topic will indicate what documentation is required to determine if Phase I feasibility has been met and the technical requirements for a Direct to Phase II proposal.

ELIGIBILITY

Not all DARPA topics are eligible for a DP2 award. Offerors should read the topic requirements carefully. DP2 topics may accept Phase I and Direct to Phase II proposals or Direct to Phase II proposals only. DARPA reserves the right to not make any awards under the Direct to Phase II pilot. All other instructions remain in effect. Direct to Phase II proposals must follow the DARPA Direct to Phase II Solicitation Instructions.

REQUIREMENTS

Offerors interested in submitting a DP2 proposal in response to an eligible topic must 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 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. Work submitted within the feasibility documentation must have been substantially performed by the offeror and/or the principal investigator (PI).

DARPA will not evaluate the offeror's related Phase II proposal if it determines that the offeror has failed to demonstrate that technical merit and feasibility has been established or the offeror has failed to demonstrate that work submitted in the feasibility documentation was substantially performed by the offeror and/or the principal investigator (PI).

DP2 proposals **MUST NOT** be related to or logically extend from any prior or ongoing federally funded SBIR or STTR work. Offerors interested in submitting a Phase II proposal to DARPA based upon prior or ongoing SBIR or STTR work should contact sbir@darpa.mil for instructions.

DEADLINE FOR 16.1 DP2 PROPOSALS: 6:00 AM (ET) on February 17, 2016.

System Requirements

Use of the DARPA SBIR/STTR Information Portal (SSIP) is MANDATORY. The registered Corporate Official (CO) **MUST** authenticate into the SSIP (via the DARPA Extranet) to retrieve the source selection decision notice, to request debriefings, and to upload reports (awarded contracts only). DARPA SBPO will automatically create an extranet account for new users and send the SSIP URL, authentication credentials, and login instructions AFTER the 16.1 source selection period has closed. DARPA extranet accounts will ONLY be created for the individual named as the CO on the Proposal Cover Sheet. Offerors may not request accounts for additional users at this time.

DARPA contractors who are not eligible to receive a Common Access Card (CAC) are required to obtain a digital certificate from an approved External Certification Authority (ECA) vendor.

- If the SBC has or will register for multiple ECAs, one of the registered ECA e-mail addresses **MUST** match the CO e-mail address (listed on the Proposal Cover Sheet).
- Additional information will be sent to small business concerns (SBCs) selected for contract award

WARNING: The Corporate Official (CO) e-mail address (from the Proposal Cover Sheet) will be used to create a DARPA Extranet account. The same e-mail **MUST** also be used for ECA registration. Updates to Corporate Official e-mail after proposal submission may cause significant delays to communication retrieval and contract negotiation (if selected). Additional information in section 4.0.

3.0 DEFINITIONS

3.4 Export Control

The following will apply to all projects with military or dual-use applications that develop beyond fundamental research (basic and applied research ordinarily published and shared broadly within the scientific community):

- (1) The Contractor shall comply with all U. S. export control laws and regulations, including the International Traffic in Arms Regulations (ITAR), 22 CFR Parts 120 through 130, and the Export Administration Regulations (EAR), 15 CFR Parts 730 through 799, in the performance of this contract. In the absence of available license exemptions/exceptions, the Contractor shall be responsible for obtaining the appropriate licenses or other

approvals, if required, for exports of (including deemed exports) hardware, technical data, and software, or for the provision of technical assistance.

- (2) The Contractor shall be responsible for obtaining export licenses, if required, before utilizing foreign persons in the performance of this contract, including instances where the work is to be performed on-site at any Government installation (whether in or outside the United States), where the foreign person will have access to export-controlled technologies, including technical data or software.
- (3) The Contractor shall be responsible for all regulatory record keeping requirements associated with the use of licenses and license exemptions/exceptions.
- (4) The Contractor shall be responsible for ensuring that the provisions of this clause apply to its subcontractors.

Please visit http://www.pmdotc.state.gov/regulations_laws/itar.html for more detailed information regarding ITAR/EAR requirements.

3.5 Foreign National

Foreign Nationals (also known as Foreign Persons) means any person who is NOT:

- a. a citizen or national of the United States; or
- b. a lawful permanent resident; or
- c. a protected individual as defined by 8 U.S.C. § 1324b

ALL offerors proposing to use foreign nationals MUST follow Section 5.4. c. (8) of the DoD Program Solicitation and disclose this information regardless of whether the topic is subject to ITAR restrictions. There are two ways to obtain U.S. citizenship: by birth or by naturalization. Additional information regarding U.S. citizenship is available at http://travel.state.gov/law/citizenship/citizenship_782.html. Definitions for “lawful permanent resident” and “protected individual” are available under section 3.5 of the DoD instructions.

4.0 PROPOSAL FUNDAMENTALS

4.6 Classified Proposals

DARPA topics are unclassified; however, the subject matter may be considered to be a “critical technology” and therefore subject to Export Control Restrictions. See Export Control requirements in Section 3.3.

4.7/4.8 Human and/or Animal Use

Your topic may have been identified by the program manager as research involving Human and/or Animal Use. In accordance with DoD policy, human and/or animal subjects in research conducted or supported by DARPA shall be protected. Although these protocols were most likely not needed to carry out the Phase I, significant lead time is required to prepare the documentation and obtain approval in order to avoid delay of the DP2 award. Please visit <http://www.darpa.mil/WorkArea/DownloadAsset.aspx?id=2147486611> to review the Human Use PowerPoint presentation to understand what is required to comply with human protocols and <http://www.darpa.mil/WorkArea/DownloadAsset.aspx?id=2147486040> to review the Animal Use PowerPoint presentation to understand what is required to comply with animal protocols. Offerors proposing research involving human and/or animal use are encouraged to separate these tasks in the Technical Volume and Cost Volume in order to avoid potential delay of contract award.

- a. **Human Use:** All research involving human subjects, to include use of human biological specimens and human data, selected for funding must comply with the federal regulations for human subject protection. Further, research involving human subjects that is conducted or supported by the DoD must comply with 32 CFR 219, *Protection of Human Subjects*

- b. DoD Directive 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research* (<http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf>).
- Institutions awarded funding for research involving human subjects must provide documentation of a current Assurance of Compliance with Federal regulations for human subject protection, for example a Department of Health and Human Services, Office of Human Research Protection Federal Wide Assurance (<http://www.hhs.gov/ohrp>). All institutions engaged in human subject research, to include subcontractors, must also have a valid Assurance. In addition, personnel involved in human subjects research must provide documentation of completing appropriate training for the protection of human subjects.
 - For all proposed research that will involve human subjects in the first year or phase of the project, the institution must provide evidence of or a plan for review by an Institutional Review Board (IRB) upon final proposal submission to DARPA. The IRB conducting the review must be the IRB identified on the institution's Assurance. The protocol, separate from the proposal, must include a detailed description of the research plan, study population, risks and benefits of study participation, recruitment and consent process, data collection, and data analysis. Consult the designated IRB for guidance on writing the protocol. The informed consent document must comply with federal regulations (32 CFR 219.116). A valid Assurance along with evidence of appropriate training for all investigators should accompany the protocol for review by the IRB.
 - In addition to a local IRB approval, a headquarters-level human subjects regulatory review and approval is required for all research conducted or supported by the DoD. The Army, Navy or Air Force office responsible for managing the award can provide guidance and information about their component's headquarters-level review process. Note that confirmation of a current Assurance and appropriate human subjects protection training is required before headquarters-level approval can be issued.
 - The amount of time required to complete the IRB review/approval process may vary depending on the complexity of the research and/or the level of risk to study participants. Ample time should be allotted to complete the approval process. The IRB approval process can last between one to three months, followed by a DoD review that could last between three to six months. No DoD/DARPA funding can be used towards human subject research until ALL approvals are granted.
- c. **Animal Use:** Any Recipient performing research, experimentation, or testing involving the use of animals shall comply with the rules on animal acquisition, transport, care, handling and use in: (i) 9 CFR parts 1-4, Department of Agriculture rules that implement the Laboratory Animal Welfare Act of 1966, as amended, (7 U.S.C. 2131-2159); (ii) the guidelines described in National Institutes of Health Publication No. 86-23, "Guide for the Care and Use of Laboratory Animals"; (iii) DoD Directive 3216.01, "Use of Laboratory Animals in DoD Program."
- For submissions containing animal use, proposals should briefly describe plans for Institutional Animal Care and Use Committee (IACUC) review and approval. Animal studies in the program will be expected to comply with the PHS Policy on Humane Care and Use of Laboratory Animals, available at <http://grants.nih.gov/grants/olaw/olaw.htm>.
 - All Recipients must receive approval by a DoD certified veterinarian, in addition to an IACUC approval. No animal studies may be conducted using DoD/DARPA funding until the USAMRMC Animal Care and Use Review Office (ACURO) or other appropriate DoD veterinary office(s) grant approval. As a part of this secondary review process, the Recipient will be required to complete and submit an ACURO Animal Use Appendix, which may be found at https://mrmc-www.army.mil/index.cfm?pageid=Research_Protections.acuro&rn=1.

4.10 Debriefing

DARPA will provide a debriefing to the offeror in accordance with Federal Acquisition Regulation (FAR) 15.505. The source selection decision notice (reference 4.15 Notification of Proposal Status) contains instructions for requesting a proposal debriefing. Please also refer to section 4.10 of the DoD Program Solicitation.

Notification of Proposal Receipt

Within 5 business days after the solicitation closing, the individual named as the “Corporate Official” on the Proposal Cover Sheet will receive a separate e-mail from sbir@darpa.mil acknowledging receipt for each proposal received. Please make note of the topic number and proposal number for your records. The CO should add this address to their address book and whitelist to ensure all communications are received.

Notification of Proposal Status

The source selection decision notice will be available no later than 90 days after the solicitation close date for DP2 offerors. The individual named as the “Corporate Official” (CO) on the Proposal Cover Sheet will receive an email for each proposal submitted, from sbir@darpa.mil with instructions for retrieving their official notification from the SSIP. Please read each notification carefully and note the proposal number and topic number referenced. The CO must retrieve the letter from the SSIP 30 days from the date the e-mail is sent. After 30 days the CO must make a written request to sbir@darpa.mil for the source selection decision notice. The request must explain why the offeror was unable to retrieve the source selection decision notice from the SSIP within the original 30 day notification period. Selections are posted at <https://sbir.defensebusiness.org/>.

Refer to section 1.0 (System Requirements) for information regarding CO registration and DARPA extranet account creation.

4.11 Solicitation Protests

Interested parties may have the right to protest this solicitation by filing directly with the agency by serving the Contracting Officer (listed below) with the protest, or by filing with the Government Accountability Office (GAO). If the protest is filed with the GAO, a copy of the protest shall be received in the office designated below within one day of filing with the GAO. The protesting firm shall obtain written and dated acknowledgment of receipt of the protest.

Agency protests regarding the solicitation should be submitted to:

SBIR/STTR Solicitation Contracting Officer
WHS/Acquisition Directorate
1155 Defense Pentagon
Washington, DC 20301-1155
E-mail: jonathan.l.becker2.civ@mail.mil

Agency protests regarding the source selection decision should be submitted to:

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

4.14 DP2 Award Information

- a. **Number of DP2 Awards.** DARPA reserves the right to select and fund only those proposals considered to be of superior quality and highly relevant to the DARPA mission. As a result, DARPA may fund multiple proposals in a topic area, or it may not fund any proposals in a topic area.
- b. **Type of Funding Agreement.** DARPA DP2 awards are typically Cost-Plus-Fixed-Fee contracts.
 - Offerors that choose to collaborate with a University must highlight the research activities that are being performed by the University and verify that the work is FUNDAMENTAL RESEARCH.

- Offerors are strongly encouraged to implement a government acceptable cost accounting system during the Phase I project to avoid delay in receiving a DP2 award. Phase II contractors MUST have an acceptable system to record and control costs, including procedures for job costing and time record keeping. Items such as overhead and G&A rates WILL require logical supporting documentation during the DCAA review process. Visit www.dcaa.mil and download the “Information for Contractors” guide for more information.
 - Offerors that are unable to obtain a positive DCAA review of their accounting system may on a case-by-case basis, at the discretion of the Contracting Officer, be awarded a Firm Fixed Price Phase II contract or an Other Transaction (OT).
 - More information on Other Transactions is available at: http://www.darpa.mil/Opportunities/Contract_Management/Other_Transactions_and_Technology_Investment_Agreements.aspx.
- c. **Average Dollar Value.** The maximum value of a DARPA DP2 award is \$1,510,000.
- d. **Timing.** The DoD goal for DP2 award is within 180 calendar days from the proposal receipt deadline. Phase II contract award may be delayed if the offeror does not have an adequate accounting system or fails to include sufficient documentation to support its cost proposal.

4.15 Questions/Information

(1) Contact the **DARPA SBIR/STTR Help Desk** via email (sbir@darpa.mil) regarding general questions about these instructions, DP2 proposal preparation and other DARPA SBIR/STTR program-related areas.

(2) Contact the **DoD SBIR/STTR Help Desk** regarding questions about the DoD SBIR/STTR Proposal Submission System. Help Desk hours are 9:00 a.m. to 6:00 p.m. ET, Monday through Friday:

- Phone: 1-800-348-0787
- E-mail Submission: sbirhelp@bytecubed.com

Communication with DARPA Program Managers (PM)

Offerors participating in the DP2 process may only communicate with PMs during the pre-solicitation period, published at <http://www.acq.osd.mil/osbp/sbir/index.shtml> and on SITIS once the solicitation has opened. Information regarding SITIS is available directly from <https://sbir.defensebusiness.org/>.

4.22 Discretionary Technical Assistance (DTA)

DARPA has engaged the Transition and Commercialization Support Program (TCSP) to provide commercialization assistance to *SBIR and/or STTR awardees in Phase I and/or Phase II*. Offerors awarded funding for use of an outside vendor for discretionary technical assistance (DTA) are excluded from participating in TCSP.

DTA requests must be explained in detail with the cost estimate and provide purpose and objective (clear identification of need for assistance), provider’s contact information (name of provider; point of contact; details on its unique skills/experience in providing this assistance), and cost of assistance (clearly identified dollars and hours proposed or other arrangement details). The cost cannot be subject to any profit or fee by the requesting firm. In addition, the DTA provider may not be the requesting firm itself, an affiliate or investor of the requesting firm, or a subcontractor or consultant of the requesting firm otherwise required as part of the paid portion of the research effort (e.g., research partner).

Offerors proposing DTA must complete the following:

1. Indicate in question 17, of the proposal coversheets, that you request DTA and input proposed cost of DTA (in space provided).
2. Provide a one-page description of the vendor you will use and the technical assistance you will receive. The description should be included as the LAST page of the Technical Volume. This description will not count against the 20-page limit of the technical volume and will NOT be evaluated.

3. Enter the total proposed DTA cost, which shall not exceed \$5,000, under the “Discretionary Technical Assistance” line along with a detailed cost breakdown under “Explanatory material relating to the cost proposal” via the online cost proposal.

Approval of DTA is not guaranteed and is subject to review of the Contracting Officer. Please see section 4.22 of the DoD Program Solicitation for additional information.

7.0 DP2 PHASE II PROPOSAL

7.1 Introduction

DoD SBIR/STTR Proposal Submission System (<https://sbir.defensebusiness.org/>) is designed to reduce the time and cost required to prepare a formal proposal. Carefully review the guidance on allowable content.

A complete DP2 proposal consists of four volumes:

Volume 1: Proposal Cover Sheet

Volume 2: Technical Volume

PART ONE: Feasibility Documentation (75 page maximum)

PART TWO: Technical Proposal (40 page maximum)

APPENDICES (20 page maximum – will NOT be evaluated)

Volume 3: Cost Volume

Volume 4: Company Commercialization Report

7.2 Proposal Provisions

Phase II Option

DARPA has implemented the use of a Phase II Option that may be exercised at the DARPA Program Manager's discretion to continue funding Phase II activities that will further mature the technology for insertion into a larger DARPA Program, DoD Acquisition Program, other Federal agency, or commercialization into the private sector. The statement of work for the Phase II Option MUST be included with the Phase II Technical Volume and should describe Phase II activities, over a 12 month period, which may lead to the successful demonstration of a product or technology. The statement of work for the option counts toward the 40-page limit for the Phase II Technical Volume. If selected, the government may elect not to include the option in the negotiated contract.

7.4 Commercialization Strategy

DARPA is equally interested in dual use commercialization of SBIR 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 commercialization strategy part of the proposal. The discussion should include identification of the problem, need, or requirement relevant to a Department of Defense application and/or a private sector application that the SBIR project results would address; a description of how wide-spread and significant the problem, need, or requirement is; and identification of the potential DoD end-users, Federal customers, and/or private sector customers who would likely use the technology.

Technology commercialization and transition from Research and Development activities to fielded systems within the DoD is challenging. Include transition and commercialization activities conducted during Phase I, and how the preliminary transition path or paths may evolve during the Phase II project. That plan should include the Technology Readiness Level (TRL) achieved at the end of the Phase I. The plan should include anticipated business model and

potential private sector and federal partners the company has identified to support transition and commercialization activities. In addition, key proposed milestones anticipated during Phase II such as: prototype development, laboratory and systems testing, integration, testing in operational environment, and demonstrations.

At a minimum, your commercialization strategy must address the following five questions:

- (1) What is the first product that this technology will go into?
- (2) Who will be the customers, and what is the estimated market size?
- (3) How much money will be needed to bring the technology to market, and how will that money be raised?
- (4) Does the company contain marketing expertise and, if not, how will that expertise be brought into the company?
- (5) Who are the offeror's competitors, and what is the price and/or quality advantage over those competitors?

The commercialization strategy must also include a schedule showing the anticipated quantitative 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 (see Section 7.5.e) at least annually.

In addition, each Phase II proposal must contain a five-page commercialization strategy as part of the Technical Volume, addressing the following questions:

- (1) Product Description/System Application – Identify the Commercial product(s) and/or DoD system(s) or system(s) under development or potential new systems that this technology will be/or has the potential to be integrated into.
- (2) Advocacy Letters** – Feedback received from potential Commercial and/or DoD customers and other end-users regarding their interest in the technology to support their capability gaps.
- (3) Letters of Intent/Commitment** – 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.
- (4) Business Models/Procurement Mechanisms/Vehicles – Business models, procurement mechanisms, vehicles and, as relevant, commercial channels, and/or licensing/teaming agreements you plan to employ to sell into your targeted markets.
 - a. What is the business model you plan to adopt to generate revenue from your innovation?
 - b. Describe the procurement mechanisms, vehicles and channels you plan to employ to reach the targeted markets/customers.
 - c. If you plan to pursue a licensing model, what is your plan to identify potential licensees?
- (5) Market/Customer Sets/Value Proposition – Describe the market and customer sets you propose to target, their size, and their key reasons they would consider procuring the technology.
- (6) What is the current size of the broad market you plan to enter and the “niche” market opportunity you are addressing?
- (7) What are the growth trends for the market and the key trends in the industry that you are planning to target?
 - a. What features of your technology will allow you to provide a compelling value proposition?
 - b. Have you validated the significance of these features and if not, how do you plan to validate?
- (8) Competition Assessment – Describe the competition in these markets/customer sets and your anticipated advantage (e.g., function, performance, price, quality, etc.)
- (9) Funding Requirements – List your targeted funding sources (e.g., federal, state and local, private (internal, loan, angel, venture capital, etc.) and your proposed plan and schedule to secure this funding. Provide anticipated funding requirements both during and after Phase II required to:
 - mature the technology
 - as required, mature the manufacturing processes

- test and evaluate the technology
- receive required certifications
- secure patents, or other protections of intellectual property
- manufacture the technology to bring the technology to market for use in operational environments
- market/sell technology to targeted customers

(10) Sales Projections – Provide a schedule that outlines your anticipated sales projections and indicate when you anticipate breaking even.

(11) 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 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.)?

**Please note: 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.

DP2 PROPOSAL INSTRUCTIONS

Each DP2 proposal must be submitted through the DoD SBIR/STTR Submission Web site by the solicitation deadline.

1. After authenticating, choose “Phase II Proposal Preparation”
2. When asked to choose a Phase I proposal number, choose Z001

a. Proposal Cover Sheet (Volume One)

On the DoD SBIR/STTR Submission Web site, (<https://sbir.defensebusiness.org/>), prepare the Proposal Cover Sheet. The Cover Sheet must include a brief technical abstract, of no more than 200 words, 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 will be publicly released on the Internet. Once the Cover Sheet is saved, the system will assign a proposal number. You may edit the Cover Sheet as often as necessary until you submit your proposal.

b. Technical Volume (Volume Two)

- The Technical Volume upload must include two parts. Label the Feasibility Documentation “PART ONE: Feasibility Documentation.” Part Two of the Technical Volume should be labeled “PART TWO: Technical Proposal.
- Number all pages of your Technical Volume consecutively. Use no type 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 the DoD SBIR/STTR Submission Web site when the Cover Sheet was created. The header may be included in the one-inch margin.
- The Technical Volume should cover the following items in the order given below.

VOLUME TWO - PART ONE: Feasibility Documentation

- 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 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.

- Maximum page length for feasibility documentation is 75 pages. 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.
- Work submitted within the feasibility documentation must have been substantially performed by the offeror and/or the principal investigator (PI).
- If technology in the feasibility documentation is subject to IP, the offeror must have IP rights. Refer to section 11.5 of these DARPA instructions for additional information.
- 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 and WILL be redacted.

VOLUME TWO - 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.
 - a) **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.
 - b) **Human/Animal Use:** Offerors 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.
 - c) **Phase II OPTION Statement of Work.** 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.
- (3) **Related Work.** Describe significant activities directly related to the proposed effort, including any conducted by the principal investigator, the offeror, 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 offeror'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.
- (4) **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.

- (5) **Commercialization Strategy.** Each DP2 proposal must contain a five-page commercialization strategy as part of the Technical Volume describing the offeror's strategy for commercializing this technology in DoD, other Federal Agencies and/or private sector markets. Provide specific information on the market need the technology will address and the size of the market. See section 7.4 for required strategy elements.
- (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 principal investigator, 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, country of origin and level of involvement.
- (7) **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.
- (8) **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 described in detail and identified in the Cost Volume. A minimum of one-half of the research and/or analytical work in Phase II, as measured by direct and indirect costs, must be carried out by the offeror, unless otherwise approved in writing by the Contracting Officer. No portion of an SBIR award may be subcontracted back to any Federal government agency, including Federally Funded Research and Development Centers (FFRDCs). SBA may issue a case-by-case waiver to this provision after review of the DoD component's written justification that includes the following information: (a) an explanation of why the SBIR research project requires the use of the Federal facility or personnel, including data that verifies the absence of non-federal facilities or personnel capable of supporting the research effort; (b) why the Agency will not and cannot fund the use of the Federal facility or personnel for the SBIR project with non-SBIR money; and (c) the concurrence of the small business concern's chief business official to use the Federal facility or personnel. Award is contingent on the sponsoring agency obtaining a waiver.
- (9) **Prior, Current or Pending Support of Similar Proposals or Awards.** Warning -- While it is permissible, with proposal notification, to submit identical proposals or proposals containing a significant amount of essentially equivalent work for consideration under numerous federal program solicitations, it is unlawful to enter into contracts or grants requiring essentially equivalent effort. If there is any question concerning this, it must be disclosed to the soliciting agency or agencies before award.

c. Cost Volume (Volume 3)

Offerors are REQUIRED to use the online Cost Volume (<https://sbir.defensebusiness.org/>) for the Phase II and Phase II Option costs. Additional details and explanations regarding the Cost Volume may be uploaded as an appendix to the Technical Volume. The Cost Volume (and supporting documentation) DOES NOT count toward the 40-page limit of the Technical Volume. Phase II awards and options are subject to the availability of funds.

The Phase II Cost Volume must not exceed the maximum dollar amount of \$1,000,000 (24 months) or \$1,010,000 if discretionary technical assistance services are proposed. Offerors proposing a Phase II Option must also submit a Phase II Option Cost Volume, not to exceed \$500,000 (12 months).

Some items in the Cost Breakdown Guidance may not apply to the proposed project. If such is the case, there is no need to provide information on each and every item. What matters is that enough information be provided to allow DARPA to understand how the offeror plans to use the requested funds if the contract is awarded.

1. List all key personnel by name as well as by number of hours dedicated to the project as direct labor.
2. 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 the DoD Component; unless it is determined that transfer of title to the contractor would be more cost effective than recovery of the equipment by the DoD Component.
3. Cost for travel funds must be justified and related to the needs of the project.
4. Cost sharing is permitted for proposals under this solicitation; however, cost sharing is not required nor will it be an evaluation factor in the consideration of a DP2 proposal.
5. The costs for the base and option (if proposed) are clearly separate and identified in the cost volume.

If selected for award, the offeror should be prepared to submit further documentation to the DoD Contracting Officer to substantiate costs (e.g., a brief explanation of cost estimates for equipment, materials, and consultants or subcontractors). For more information about the Cost Volume and accounting standards, see the DCAA publication called "Information for Contractors" available at http://www.dcaa.mil/audit_process_overview.html.

d. Company Commercialization Report (CCR) (Volume 4)

All offerors are required to prepare a CCR through the DoD SBIR/STTR Submission Web Site (<https://sbir.defensebusiness.org/>). List in the CCR, the quantitative commercialization results of the offeror's prior Phase II projects, including the items such as sales revenue, additional investment, as well as other information relative to the offeror's commercialization track record. All prior Phase II projects must be reported, regardless of whether the project has any commercialization to date. The results are compared to the historical averages for the DoD SBIR or STTR Programs to calculate a Commercialization Achievement Index (CAI) value. Only offerors with four or more completed Phase II projects will receive a CAI score; otherwise the CAI is N/A. Offerors with a CAI at the 20th percentile or below may receive no more than half of the evaluation points available for commercial potential criteria. A score of N/A will not affect the offerors ability to be selected for an award.

Offerors may also include at the end of the Report additional, explanatory material (no more than five pages) relating to the offeror's record of commercializing its prior SBIR or STTR projects, such as: commercialization successes (in government and/or private sector markets) that are not fully captured in the quantitative results (e.g. commercialization resulting from the offeror's prior Phase I projects); any mitigating factors that could account for low commercialization; and recent changes in the offeror's organization or personnel designed to increase the offeror's commercialization success. The CCR and additional explanatory material (if any) will not be counted toward the page limit for DP2 proposals.

Appendix Format

An Appendix contains information that is non-essential to understanding of the proposal, but may present information that further clarifies a point without burdening the body of the Technical Volume. An Appendix is optional. Each Appendix should be identified by a Roman numeral in sequence, e.g., Appendix I, Appendix II, etc. Each Appendix should contain different material. The Appendix footer should contain the page number (following

the sequence used for the entire proposal) and the Appendix label (ex. Appendix I). Please note, only that information provided in the Technical Volume (pg. 1-40, including Cover Sheet, Cost Volume and CCR) will be considered by the evaluator. Evaluator review of any Appendix material is optional.

Modifications or Withdrawal of Proposals

Modification

Late modifications of an otherwise scientifically successful proposal, which makes its terms more favorable to the Government, may be considered and may be accepted.

Withdrawal

Proposals may be withdrawn by written notice at any time. Proposals may be withdrawn in person by an offeror or his authorized representative, provided his identity is made known and he signs a receipt for the proposal.

DP2 PROPOSAL CHECKLIST

Complete proposals must contain the following elements. Incomplete proposals will be rejected.

- ___ 1. DP2 is NOT related to or logically extend from prior or ongoing SBIR/STTR work.
- ___ 2. Volume 1: Proposal Cover Sheets
 - ___ a. Completed and checked for accuracy.
 - ___ b. Costs for the base and option (if proposed) are clearly separate and identified on the Proposal Cover Sheet.
- ___ 3. Volume 2: Technical Volume
 - ___ a. Numbered all pages of the proposal consecutively. The Cover Sheets are pages 1 and 2. The Technical Volume begins on page 3.
 - ___ b. Font type is no smaller than 10-point on standard 8½" x 11" paper with one-inch margins. The header on each page of the Technical Volume contains the company name, topic number and proposal number assigned by the DoD SBIR/STTR Submission Web site when the Cover Sheet was created. The header may be included in the one-inch margin.
 - **PART ONE: Feasibility Documentation (75 page maximum)**
 - ___ a. Does not exceed the page limits specified.
 - ___ b. Follows requirements specified in Section 7 (DP2 Proposal Format).
 - **PART TWO: Technical Proposal (40 page maximum)**
 - ___ a. Does not exceed the page limits specified.
 - ___ b. The tasks for the base and option (if proposed) are clearly separate and identified in the Technical Proposal.
 - ___ c. If proposing DTA, one page description submitted in accordance with instructions in section 4.22.
 - ___ d. Follows requirements specified in Section 7 (DP2 Proposal Format).
 - ___ e. Appendices (OPTIONAL) do not exceed the 20 page maximum (appendices will NOT be evaluated).
 - ___ e.1. Appendix contains information that is non-essential to understanding of the proposal, but may present information that further clarifies a point without burdening the body of the Technical Volume.
 - ___ e.2. Each Appendix identified by a Roman numeral in sequence (e.g. Appendix I, Appendix II...). Each Appendix contains different material.
 - ___ e.3. The Appendix footer contains the page number (following the sequence used for the entire proposal) and the Appendix label (ex. Page 78: Appendix I).
- ___ 4. Volume 3: Cost Volume

- ___ a. Used the online Cost Volume.
- ___ b. Subcontractor, material and travel costs in detail. Used the "Explanatory Material Field" in the DoD Cost Volume worksheet for this information, if necessary.
- ___ c. Costs for the base and option (if proposed) are clearly separate and identified in the Cost Volume.
- ___ d. Base effort does not exceed \$1,000,000 or \$1,010,000 if DTA services are proposed.
- ___ e. Option (if proposed) does not exceed \$500,000.
- ___ f. Included the cost of each ECA to be purchased. Reimbursement is limited to a maximum of three ECAs per company. See section 11.0 for additional information.
- ___ g. If proposing DTA, cost submitted in accordance with instructions in section 4.22 and does not exceed \$5,000 per year (\$10,000 total).

___ **5. Volume 4: Company Commercialization Report**

- ___ a. Completed and checked for accuracy. Follow requirements specified in section 5.4(e).

___ **6. Submission**

- ___ a. Upload four completed volumes: Volume 1: Proposal Cover Sheet; Volume 2: Technical Volume; Volume 3: Cost Volume; and Volume 4: Company Commercialization Report electronically through the DoD submission site by 6:00 AM (ET) on February 17, 2016.
- ___ b. Review your submission after upload to ensure that all pages have transferred correctly and do not contain unreadable characters. Contact the DoD Help Desk immediately with any problems (see section 4.15).
- ___ c. Submit your proposal before 6:00 AM (ET) on February 17, 2016. DARPA will NOT accept proposals that have NOT been submitted by the solicitation deadline.

8.0 PHASE II EVALUATION CRITERIA

DP2 proposals will be evaluated based on the criteria outlined below. Selections will be based on best value to the Government considering the following factors which are listed in descending order of importance:

- a. The soundness, technical merit, and innovation of the proposed approach and its incremental progress toward topic or subtopic solution.
- b. The qualifications of the proposed principal/key investigators, supporting staff, and consultants. Qualifications include not only the ability to perform the research and development but also the ability to commercialize the results.
- c. The potential for commercial (Government or private sector) application and the benefits expected to accrue from this commercialization.

Evaluators will base their conclusions only on information contained in the proposal. Do not assume that evaluators are acquainted with the offeror or key individuals or any referenced experiments. Relevant supporting data such as journal articles, literature, including Government publications, etc., should be contained or referenced in the proposal and will count toward the page limit. Where technical evaluations are essentially equal in merit, cost to the Government will be considered in determining the successful offeror.

The offeror's attention is directed to the fact that non-Government advisors to the Government may review and provide support in proposal evaluations during source selection. Non-government advisors may have access to the offeror's proposals, may be utilized to review proposals, and may provide comments and recommendations to the Government's decision makers. These advisors will not establish final assessments of risk and will not rate or rank offeror's proposals. They are also expressly prohibited from competing for DARPA SBIR or STTR awards in the SBIR/STTR topics they review and/or provide comments on to the Government. All advisors are required to comply with procurement integrity laws and are required to sign Non-Disclosure Agreement and Rules of Conduct/Conflict of Interest statements. Non-Government technical consultants/experts will not have access to proposals that are labeled by their offerors as "Government Only."

Advocacy Letters

Please note that qualified advocacy letters will count towards the proposal page limit and will be evaluated towards criterion C. Advocacy letters are not required. Consistent with Section 3-209 of DoD 5500.7-R, Joint Ethics Regulation, which as a general rule prohibits endorsement and preferential treatment of a non-federal entity, product, service or enterprise by DoD or DoD employees in their official capacities, letters from government personnel will NOT be considered during the evaluation process.

A qualified advocacy letter is from a relevant commercial procuring organization(s) working with a DoD or other Federal entity, articulating their pull for the technology (i.e., what need the technology supports and why it is important to fund it), and possible commitment to provide additional funding and/or insert the technology in their acquisition/sustainment program. If submitted, the letter should be included as the last page of your technical upload. Advocacy letters which are faxed or e-mailed separately will NOT be considered.

Limitations on Funding

DARPA reserves the right to select and fund only those proposals considered to be of superior quality and highly relevant to the DARPA mission. As a result, DARPA may fund multiple proposals in a topic area, or it may not fund any proposals in a topic area. All awards are subject to the availability of funds.

11.0 CONTRACTUAL CONSIDERATIONS

External Certification Authority (ECA)

Offerors must include, in the Cost Volume, the cost of each ECA proposed to be purchased in order to be reimbursed for the cost of ECAs. Reimbursement is limited to a maximum of three ECAs per company. The cost cannot be subject to any profit or fee by the requesting firm.

Offerors should consider purchasing the ECA subscription to cover the Phase II period of performance, to include the option year. Offerors will only be reimbursed for ECA costs once per subscription. Offerors that previously obtained a DoD-approved ECA may not be reimbursed under any potential SBIR/STTR Phase II contract. Likewise, offerors that are reimbursed for ECAs obtained as a requirement under an SBIR/STTR Phase II contract, may not be reimbursed again for the same ECA purchase under any subsequent government contract. Additional information regarding ECA requirement may be found in section 1.0, System Requirements.

Security Requirements

If a proposed effort is classified or classified information is involved, the offeror must have, or obtain, a security clearance in accordance with the Industry Security Manual for Safeguarding Classified Information (DOD 5220.22M).

Payment Schedule

Payment will be made in accordance with General Provisions FAR 523.216-7, *Allowable Cost and Payments*.

11.4 Patents

Include documentation proving your ownership of or possession of appropriate licensing rights to all patented inventions (or inventions for which a patent application has been filed) that will be utilized under your proposal. If a patent application has been filed for an invention that your proposal utilizes, but the application has not yet been made publicly available and contains proprietary information, you may provide only the patent number, inventor name(s), assignee names (if any), filing date, filing date of any related provisional application, and a summary of the patent title, together with either: (1) a representation that you own the invention, or (2) proof of possession of appropriate licensing rights in the invention. Please see section 11.4 of the DoD Program Solicitation for additional information.

11.5 Intellectual Property Representations

Provide a good faith representation that you either own or possess appropriate licensing rights to all other intellectual property that will be utilized under your proposal. Additionally, proposers shall provide a short summary for each item asserted with less than unlimited rights that describes the nature of the restriction and the intended use of the intellectual property in the conduct of the proposed research. Please see section 11.5 of the DoD Program Solicitation for information regarding technical data rights.

11.1 (r) Publication Approval (Public Release)

National Security Decision Directive (NSDD) 189 established the national policy for controlling the flow of scientific, technical, and engineering information produced in federally funded fundamental research at colleges, universities, and laboratories. The directive defines fundamental research as follows: "Fundamental research' means basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons."

It is DARPA's goal to eliminate pre-publication review and other restrictions on fundamental research except in those exceptional cases when it is in the best interest of national security. Please visit http://www.darpa.mil/NewsEvents/Public_Release_Center/Public_Release_Center.aspx for additional information and applicable publication approval procedures.

11.7 Phase II Reports

All DARPA SBIR awardees are required to submit reports in accordance with the Contract Data Requirements List – CDRL and any applicable Contract Line Item Number (CLIN) of the Phase II contract. Reports must be provided to the individuals identified in Exhibit A of the contract.

Reports are uploaded to the DARPA SBIR/STTR Information Portal (SSIP). See section "Retrieval of DARPA SBPO Notifications" on page 4 of these instructions.

DARPA SBIR 16.1 Topic Index

*These instructions **ONLY** apply to **Direct to Phase II Proposals**. For Phase I, refer to the **DARPA 16.1 Phase I Topics and Proposal Instructions** available at (<http://www.acq.osd.mil/osbp/sbir/index.shtml>).*

All DARPA SBIR awardees are required to submit reports in accordance with the Contract Data Requirements List – CDRL and any applicable Contract Line Item Number (CLIN) of the Phase II contract. Reports must be provided to the individuals identified in Exhibit A of the contract.

Reports are uploaded to the DARPA SBIR/STTR Information Portal (SSIP). See section “Retrieval of DARPA SBPO Notifications” on page 4 of these instructions.

<i>Proposals Types Accepted</i>			
Topic Number	Topic Title	Phase I	DP2
SB161-001	Rapid Assembly and Transfer Techniques for Large DNA Constructs	YES	NO
SB161-002	Miniaturized Wireless Microscope and Tissue Diagnostics	YES	YES
SB161-003	Rugged, chip scale, optical frequency combs for real-world applications	YES	NO
SB161-004	Building Trustworthy Software Systems using Big Code	YES	YES
SB161-005	High Dynamic Range Atomic Magnetic Gradiometer	YES	YES
SB161-006	Long Link Range Maritime Communications	YES	NO
SB161-007	Persistent Platform in Geosynchronous Orbit	YES	NO

DARPA SBIR 16.1 Direct To Phase II Topic Descriptions

SB161-002 TITLE: Miniaturized Wireless Microscope and Tissue Diagnostics

PROPOSALS ACCEPTED: Phase I and DP2. Please see the 16.1 DoD Program Solicitation and the DARPA 16.1 Phase I Instructions for Phase I requirements and proposal instructions.

TECHNOLOGY AREA(S): Biomedical, Human Systems

OBJECTIVE: Develop an injectable system no greater than one cubic-millimeter in size to identify and characterize tissue adjacent to the device at cellular resolution. Establish approaches to inject and remotely position this medical device near internal trauma or tumors.

DESCRIPTION: Diagnosis of damaged tissue traditionally involves a biopsy or complex laproscopic techniques. While both of these approaches are relatively non-destructive and can produce an accurate diagnosis, they require a significant amount of training, expert knowledge and equipment to operate. In addition, due to the surgical nature of these procedures, they carry a small but not insignificant risk of infection and hemorrhage. Under battlefield conditions, combat medics do not have the time, hand-held equipment or antiseptic environment required to quickly and accurately identify a wounded service member’s condition using these techniques. For example, the majority of potentially survivable combat deaths occur due to inadequate hemorrhage control.

Recent developments in hyperspectral imaging techniques have demonstrated a path to accurate and automated identification of tissue types and foreign objects. Furthermore, modern photonic design and integrated optics platforms can be used to construct complex imaging systems at the millimeter scale with micron resolution. This objective of this topic is to develop such an imaging system and demonstrate its safe and effective operation.

PHASE I: Design a concept for the millimeter-cube in vivo imaging and characterization system consistent with eventual use in humans for diagnosis of internal tissue. Perform modeling and simulation of the precision and

imaging properties of the proposed system. Define key component technological milestones and metrics, such as spectral sensitivity and spatial resolution. Establish minimum performance goals necessary to achieve practical imaging and characterization of cellular tissue adjacent to the system. Included in the Phase I deliverables is a Phase II plan to construct, validate, and verify the performance of the system in vitro. This phase will demonstrate the feasibility of producing a demonstration of the proposed system and outline demonstration success criteria using integrated product and process design techniques.

PHASE II: Finalize the design from Phase I, produce prototype hardware, validate and verify the performance of the system to meet the key metrics. Establish performance parameters and the efficacy of tissue diagnosis using in vitro models or other relevant operational environments. It is expected that the imaging and characterization system will be manufactured using quality systems appropriate for eventual use in humans for medical applications. Select a target application and develop a credible translation pathway, and attain feedback from the Food and Drug Administration's Early Feasibility Study program. In addition, design and demonstrate at the benchtop level a method to control the position of the untethered wireless microscope in all three dimensions in an in vitro or cadaveric environment.

PHASE III DUAL USE APPLICATIONS: The successful development of this technology will provide a solution to diagnose internal tissue damage and thus potentially enable treatment. Such a capability would be translated to broad medical use through development of FDA-approved technology for use in civilian emergency rooms and cancer diagnosis.

The injectable system to characterize and image internal tissue will enable rapid diagnosis of internal trauma, tumors and other kinds of tissue damage. This new sub-millimeter imaging tool would not require a physical connection to the external world or require highly skilled doctors to operate, as with laproscopic equipment. The primary application for this technology would be in battlefield medicine.

REFERENCES:

1. Asimov, I., & Kleiner, H. (1966). *Fantastic voyage; a novel*. Boston: Houghton Mifflin.
2. Kim, M., D. Kang, T. Wu, N. Tabatabaei, R.W. Carruth, R.V. Martinez, G.M. Whitesides, Y. Nakajima, and G.J. Tearney, Miniature objective lens with variable focus for confocal endomicroscopy. *Biomed Opt Express*, 2014. 5(12): p. 4350-61. doi:10.1364/BOE.5.004350
3. Eisenberger U, Wüthrich RP, Bock A, et al. Medication Adherence Assessment: High Accuracy of the New Ingestible Sensor System in Kidney Transplants. *Transplantation*. 2013;96(3):245-250. doi:10.1097/TP.0b013e31829b7571
4. Ozbay, Baris N., et al. "Miniaturized fiber-coupled confocal fluorescence microscope with an electrowetting variable focus lens using no moving parts." *Optics Letters* 40.11 (2015): 2553-2556. doi:10.1364/OL.40.002553
5. Abel, D., Farb, A., "Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies." Food and Drug Administration. <http://www.fda.gov/downloads/medicaldevices/deviceregulationand%20guidance/guidancedocuments/ucm27910>

KEYWORDS: nondestructive evaluation, design for manufacture, integrated product and process design, quality systems, in vivo imaging, untethered medical diagnostics

SB161-004

TITLE: Building Trustworthy Software Systems using Big Code

PROPOSALS ACCEPTED: Phase I and DP2. Please see the 16.1 DoD Program Solicitation and the DARPA 16.1 Phase I Instructions for Phase I requirements and proposal instructions.

TECHNOLOGY AREA(S): Information Systems

OBJECTIVE: Create tools and techniques that use Big Code for developing trustworthy software systems.

DESCRIPTION: As computing devices become more pervasive in our daily lives, the software systems that control them have become increasingly more complex and sophisticated. Consequently, ensuring that programs are correct, especially at scale, remains a difficult and challenging endeavor. Poorly designed or incorrectly implemented software can lead to unwitting ingestion of malware that can result in potentially crippling security violations, which can in turn have profound negative consequences on the reliability of mission-critical systems, and the correct operation of important and sensitive cyber-infrastructure. Identifying flawed software structure necessary for malware infiltration is critical to ensuring the trustworthiness of modern-day DoD software systems.

Trying to ascertain whether a given piece of software contains vulnerabilities that make it an attractive malware target is problematic in isolation, however, given the large number of malware variants, and the well-known limitations of static and dynamic program analyses, with respect to their high false negative and false positive rates, resp. Indeed, security specialists AV-Test [1] recently reported that new malware was up 72 percent in 2014 from the previous year, despite tremendous investment in software security, suggesting that it is easy to create and sustain diverse malware variants resistant to existing analysis and patching techniques.

Rather than examining a single program in isolation, we posit that a potentially more fruitful approach would be to leverage the results of mining a large corpus of programs for common semantic patterns that can be used to assess the trustworthiness of software components. Limitations in existing analysis techniques can be thus mitigated using statistical methods and machine learning approaches, i.e., “Big Code”. To explore this thesis in the context of automated repair and program synthesis, DARPA’s Mining and Understanding Software Enclaves (MUSE) program [2] has already produced a large publically available corpus of open source software, currently containing over 200K projects, reflecting over 600GBs of source code.

By extending and labeling this corpus with known malware (source and binary) artifacts, along with a precise representation of their attack vectors, we envision the construction of an evolving semantic database that effectively relates these artifacts with potentially vulnerable software components. New programs can now be compared against these components to gauge the likelihood they are vulnerable to a specific malware attack.

PHASE I: Develop a plan for creating tools and techniques that leverage Big Code to create trustworthy software systems. Required Phase I deliverable includes a final report that details the proposed techniques, how the technology would leverage the MUSE corpus, and the anticipated amount of software development required.

PHASE II: Demonstrate that the techniques from Phase I can be practically and effectively applied to a DoD relevant system. Required Phase II deliverables include all documentation and software for the techniques and a proof-of-concept demonstration of the techniques on a DoD relevant system.

PHASE III DUAL USE APPLICATIONS: Phase III Commercial App: SCADA systems, medical devices, computer peripherals, communication devices, and vehicles.

Phase III DoD/Military App: Unmanned ground, air and underwater vehicles, weapons systems, satellites, and command and control devices.

REFERENCES:

1. <https://www.av-test.org/en/statistics/malware/>
2. <http://www.darpa.mil/program/mining-and-understanding-software-enclaves>

KEYWORDS: Big code, trustworthy software systems, malware, program analysis, software mining, big data analytics

SB161-005 TITLE: High Dynamic Range Atomic Magnetic Gradiometer

PROPOSALS ACCEPTED: Phase I and DP2. Please see the 16.1 DoD Program Solicitation and the DARPA 16.1 Phase I Instructions for Phase I requirements and proposal instructions.

TECHNOLOGY AREA(S): Biomedical, Sensors

OBJECTIVE: Develop atomic magnetometers capable of high-sensitivity magnetic field gradient detection in unshielded environments.

DESCRIPTION: State-of-the-art magnetometers are utilized for diverse civilian and DoD applications, ranging from biomedical imaging to navigation and North-finding, unexploded ordnance detection, and underwater and underground anomaly detection. Commercially-available magnetometers range from inexpensive Hall probes, to highly sensitive Fluxgate and atomic magnetometers, to high precision SQUIDs and SERF atomic magnetometers. In general, however, all of these devices have limited dynamic range; the lower-performing devices operate comfortably in the background ambient field of the earth, while the highest performing sensors only operate in highly-shielded special purpose laboratory facilities. Emerging applications require highly sensitive detection of magnetic fields in non-laboratory environments. As many of these applications require cancelling of the background field in order to isolate the signal of interest, it is expected that significant application gain will be realized through gradient detection.

The objective of this SBIR is to develop a high dynamic range atomic magnetic gradiometer (HDRAMG), with sensitivity below 10 femtoTesla/cm/sqrt(Hz) in background fields exceeding 100 microTesla. Possible geometries include a dual sensor, with some displacement between the atomic vapor cells but with common laser sources and electronics, which will enable simplification of design and enhancement of sensitivity, due to common-mode cancellation of noise sources.

A HDRAMG meeting the objectives of this solicitation has potential to revolutionize diagnostics and research of brain injuries and seizures by enabling diagnostic magnetoencephalography outside of costly dedicated facilities, as well as field and emergency diagnostics.

PHASE I: Perform modelling and experiments to validate predicted performance of the proposed technology. Develop an architecture and model of the final product and evaluate component technologies for performance and availability, particularly laser sources, vapor cells, and other unique components. The Phase I final report shall include a detailed design and performance specifications for a sensor to be fabricated and tested in Phase II.

PHASE II: Develop and test prototype fully-integrated sensors, suitable for subsequent transfer to manufacturing. Phase-II prototypes will initialize and operate autonomously and be compactly packaged in a form factor suitable for commercial sale. At the conclusion of the Phase-II base period, a minimum of three sensors will be tested, across a relevant operating temperature range, in a laboratory environment. If proposed, a Phase-2 option period should include the fabrication and test of a minimum of ten additional sensors as well as demonstration in an operationally relevant system application.

PHASE III DUAL USE APPLICATIONS: Phase III Commercial App: Unshielded magnetoencephalography and/or magnetocardiography for medical diagnostic applications. Non-invasive direct brain control of prosthetics.

Phase III DoD/Military App: Perimeter monitoring/detection. Underground cave/tunnel detection. Submarine detection. Navigation aiding. Hands-free command and control.

REFERENCES:

1. Allred J C, Lyman R N, Kornack T W and Romalis M V 2002 High-sensitivity atomic magnetometer unaffected by spinexchange relaxation Phys. Rev. Lett. 89 130801
2. Fukuma R, Yanagisawa T, Yorifuji S, Kato R, Yokoi H, Hirata M, et al. (2015), "Closed-Loop Control of a Neuroprosthetic Hand by Magnetoencephalographic Signals." PLoS ONE 10(7): e0131547. doi:10.1371/journal.pone.0131547
3. Hassanien, Aboul Ella, Azar, Ahmad Taher , "Noninvasive Electromagnetic Methods for Brain Monitoring: A Technical Review", in Brain-Computer Interfaces,74, 10.1007/978-3-319-10978-7_3, Springer International Publishing, p. 51-95.
4. Pradhan, S. and Mishra, S. and Behera, R. and Poornima and Dasgupta, K., "An atomic magnetometer with autonomous frequency stabilization and large dynamic range," Review of Scientific Instruments, 86, 063104 (2015), DOI:http://dx.doi.org/10.1063/1.4921901
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6. Wyllie R, Kauer M, Wakai R T and Walker T G 2012 Optical magnetometer array for fetal magnetocardiography Opt. Lett. 37 2247–9.

KEYWORDS: Atomic Magnetometer, Magnetometer, magnetoencephalography, magnetocardiology, magnetic navigation, north-finding, perimeter monitoring, anti-submarine warfare