CHEMICAL AND BIOLOGICAL DEFENSE PROGRAM
20.A Small Business Technology Transfer (STTR)
Proposal Submission Instructions

The approved FY20.A topic included in the Chemical and Biological Defense (CBD) Small Business Technology Transfer (STTR) Program is listed below. Offerors responding to this Announcement must follow all general instructions provided in the Department of Defense (DoD) Program Announcement. Specific CBD STTR requirements that add to or deviate from the DoD Program Announcement instructions are provided below with references to the appropriate section of the DoD Announcement.

General Information

In response to Congressional interest in the readiness and effectiveness of U.S. Nuclear, Biological and Chemical (NBC) warfare defenses, Title XVII of the National Defense Authorization Act for Fiscal Year 1994 (Public Law 103-160) requires the Department of Defense (DoD) to consolidate management and oversight of the Chemical and Biological Defense (CBD) Program into a single office – Office of the Assistant Secretary of Defense for Nuclear, Chemical and Biological Defense Programs. The Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD), Defense Threat Reduction Agency (DTRA) provides the management for the Science and Technology component of the Chemical and Biological Defense Program. Technologies developed under the Small Business Technology Transfer (STTR) Program have the potential to transition to the Joint Program Executive Office for Chemical Biological Radiological and Nuclear Defense (JPEO-CBRND) if the appropriate level of technology maturity is demonstrated. The JSTO-CBD Science & Technology programs and initiatives improve defensive capabilities against Chemical and Biological Weapons of Mass Destruction. The STTR portion of the CBD Program is managed by the JSTO-CBD.

The mission of the Chemical and Biological Defense Program is to ensure that the U.S. Military has the capability to operate effectively and decisively in the face of chemical or biological warfare threats at home or abroad. Numerous factors continually influence the program and its technology development priorities. Improved defensive capabilities are essential in order to mitigate the impact of Chemical and Biological Weapons. The U.S. military requires the finest state-of-the-art equipment and instrumentation available to permit our warfighters to 'detect to warn' and avoid contamination, if possible – and to be able to sustain operations in a potentially contaminated environment. Further information is available at the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs homepage at https://www.acq.osd.mil/ncbdp/cbd/

The overall objective of the CBD STTR Program is to improve the transition or transfer of innovative Chem-Bio technologies to the end user – the warfighter – in addition to commercializing technologies within the private sector for mutual benefit. The CBD STTR Program targets those technology efforts that maximize a strong defensive posture in a biological or chemical environment using passive and active means as deterrents. These technologies include chemical and biological detection for both point and stand-off capabilities; individual and collective protection; hazard mitigation (decontamination); medical pre-treatments (e.g., vaccine development and delivery); medical therapeutics (chemical countermeasures and biological countermeasures); medical diagnostics; information systems technology to include but not limited to modeling and simulation (e.g., meteorological dispersion), disease surveillance, data fusion, and health & human effects.

Submitting Your Phase I CBD STTR Proposal

Your entire proposal submission (consisting of a Proposal Cover Sheet, the Technical Volume and Cost Volume) must be submitted electronically through the DoD SBIR/STTR Proposal Submission system located at https://www.dodsbirsttr.mil/submissions/. A hardcopy is NOT required and will not be accepted by the Chemical and Biological Defense STTR Program. Hand or electronic signature on the proposal is NOT required.

The Proposal Technical Volume must be 20 pages or less in length. The Cover Sheet and Cost Volume do not count against the 20-page Proposal Technical Volume page limit. Pages in excess of this length will not be evaluated or considered for review. The proposal must not contain any type smaller than 10-point font size (except as legend on reduced drawings, but not tables).

Volume 4, the Company Commercialization Report, will not be available for the 20.A BAA.

If your proposal is selected for award, the technical abstract and discussion of anticipated benefits will be publicly released on the Internet; therefore, do not include proprietary or classified information in these sections. Also note that the DoD website contains timely information on firm, award, and abstract data for all DoD SBIR/STTR Phase I and II awards archived for several years. This information can be viewed on the DoD SBIR/STTR website.

The maximum dollar amount for a Phase I proof-of-concept/feasibility study is $167,500. **The CBD STTR Program will not accept Phase I proposals which exceed $167,500 for the Phase I effort**. The total STTR funding amount available for Phase II activities from a resulting Phase II contract will be $1,100,000.

Companies submitting a Phase I proposal under this Announcement must complete the Cost Volume using the on-line form, within a total cost Not to Exceed (NTE) $167,500 over a period of up to six months.

Selection of Phase I proposals will be based upon the evaluation criteria discussed in Section 6.0 of this Program Announcement. The CBD STTR Program reserves the right to limit awards under any topic, and only those proposals of superior scientific and technical quality in the judgment of the technical evaluation team will be funded. All STTR contract awards are subject to availability of funding.

Companies should plan carefully for any research involving animal or human subjects, chemical agents, biological agents, etc. The brief Phase I Period of Performance available for a Phase I project may preclude plans that include these elements as all DoD requirements and necessary approvals associated with animal and/or human use must be strictly adhered to. See Section below for further information regarding animal and/or human subjects.

If a small business concern receives an STTR award, the firm must negotiate a written agreement between the small business and their selected Research Institution that allocates intellectual property rights and rights to conduct follow-on research, development, or commercialization.

Proposals not conforming to the terms of this Announcement, and any unsolicited proposals, will not be considered. All awards are subject to the availability of funding and successful completion of contract negotiations. The Chemical and Biological Defense Program is not responsible for any funds expended by the proposer prior to contract award.

CBD Program Phase II Proposal Guidelines

Phase II is the demonstration of the technology that was found feasible in Phase I. Phase I awardees may submit a Phase II proposal without invitation; however, it is strongly encouraged that a Phase II proposal not be submitted until sufficient Phase I progress can be evaluated and assessed based on results of the Phase I proof-of-concept/feasibility study Work Plan and no sooner than a recommended five months from date of contract award. **All Phase II proposal submissions must be submitted electronically through the DoD SBIR/STTR Proposal Submission system at https://www.dodsbirsttr.mil/submissions/.** At the proposal submission website, Phase II proposals MUST be submitted to '**CBD** STTR' regardless of which DoD contracting office negotiated and awarded the Phase I contract. Additional instructions regarding the Phase II proposal submission process including submission key dates will be provided to Phase I awardees after the Phase I contract is awarded; additional information may also be found at http://www.cbdsbir.net.

All proposers are required to develop and submit a commercialization plan describing feasible approaches for marketing and manufacturing the developed technology. Proposers are required to submit a budget for the entire 24-month Phase II Period of Performance. During contract negotiation, the Contracting Officer may require a Cost Volume for a base year and an option year; thus, proposers are advised to be aware of this possibility. These costs must be submitted using the Cost Volume format (accessible electronically on the DoD SBIR/STTR submission site). The total proposed amount should be indicated on the Proposal Cover Sheet as the Proposed Cost. At the Contracting Officer's discretion, Phase II projects may be evaluated for technical progress prior to the end of the base year, prior to extending funding for the option (second) year.

The CBD STTR Program is committed to minimizing the funding gap between Phase I and Phase II activities. The CBD STTR Program typically funds a cost plus fixed fee Phase II award, but may award a firm fixed price contract at the discretion of the Contracting Officer.

Technical Assistance

At this time, the CBD STTR Program is not participating in the Technical and Business Assistance (TABA) Program.

CBD STTR Projects Requiring Animal and Human Subjects

Companies should plan carefully for any research involving animal and/or human subjects in addition to the use of any chemical or biological warfare agents, and use of any agents associated with "Dual Use Research of Concern (DURC)". The brief Phase I Period of Performance may preclude plans requiring the use of these materials as well as animal and/or human subjects prior to obtaining all necessary approvals.

The offeror is expressly forbidden to use or subcontract for the use of laboratory animals in any manner without the express written approval of the U.S. Army Medical Research and Material Command's (USAMRMC), Animal Care and Use Review Office (ACURO). Written authorization to begin research under the applicable protocol(s) proposed as part of the CBD STTR program will be issued after contract award in the form of an approval letter from the USAMRMC ACURO to the recipient. Furthermore, modifications to already approved protocols require approval by ACURO prior to implementation.

Research under CBD STTR awards involving the use of human subjects, to include the use of human anatomical substances or human data, shall not begin until the DTRA Research Oversight Board (ROB) provides authorization that the research protocol may proceed. Written approval to begin research

protocol will be issued from the ROB, under separate notification to the recipient. Written approval from the ROB is also required for any sub-recipient that will use funds obtained from any CBD STTR awards to conduct research involving human subjects.

Changes in research involving human subjects shall be conducted in accordance with the protocol submitted to and approved by the ROB. Non-compliance with any provision may result in withholding of funds and or termination of the award.

Key Dates

20.A Announcement Pre-Release	10 December 2019 – 13 January 2020
20.A Announcement Open/Close	14 January 2020 – 12 February 2020 (submission deadline: 8:00 pm Eastern Time on closing date)
Phase I Evaluations	February – April 2020
Phase I Selections	No Later Than 11 May 2020
Phase I Awards	August 2020 (see Note 1)
Phase II Proposal Submission	Recommend proposal submission no earlier than approximately five months from date of Phase I contract award. Additional instructions regarding Phase II proposal submission process including key dates will be provided to Phase I awardees after Phase I contract award and also can be found at http://www.cbdsbir.net.

(Note 1) Subject to the Congressional Budget process.

CBD STTR PROPOSAL CHECKLIST

This is a Checklist of Requirements for your proposal. Please review the checklist carefully to ensure that your proposal meets the CBD STTR requirements. **Failure to meet these requirements will result in your proposal not being evaluated or considered for award**.

_____ 1. The Proposal Cover Sheet along with the Technical Volume, and Cost Volume were submitted via the Internet using the DoD's SBIR/STTR Proposal Submission Web site at https://www.dodsbirsttr.mil/submissions/.

_____ 2. The proposal cost adheres to the CBD STTR Program criteria specified.

_____ 3. The proposal is limited to only **ONE** Announcement topic. All required documentation within the proposal references the same topic number.

_____ 4. The Project Abstract and other content provided on the Proposal Cover Sheet does not contain any proprietary or classified information and is limited to the space provided.

_____ 5. The Phase I Proposal Technical Volume must be 20 pages or less in length. The Cover Sheet and Cost Volume do not count against the 20-page Proposal Technical Volume page limit. Pages in excess of this length will not be evaluated and will not be considered for review.

_____ 6. The proposal must not contain any type smaller than 10-point font size (except as legend on reduced drawings, but not tables).

CBD STTR 20.A Topic Index

CBD STTR 20.A Topic Descriptions

CDB20A-T001 TITLE: Opioid Contamination Identification for Military Surfaces

TECHNOLOGY AREA(S): Biomedical, Chemical/Biological Defense

RESEARCH & TECHNOLOGY AREA(S):

ADVANCED CAPABILITIES:

ACQUISITION & SUSTAINMENT AOR:

OBJECTIVE: To develop solution based receptors capable of binding trace concentrations of opioid(s) in the environment and providing amplified, visible signal for immediate large area contamination identification.

DESCRIPTION: Currently, there is no technology in the commercial marketspace that is capable of identification of trace quantities of opioids in large contaminated areas (i.e. military vehicles, individual protective equipment, clandestine labs, etc.). Modern lateral flow immunoassays (LFIs) can rapidly detect various opioid analogues in many bio-samples (e.g., blood, saliva, urine) through the use of colorimetric changes or colored-line appearance as the readout, but are not able to be used for gross contamination identification of large areas [1]. Engineered protein binders [2] and mu-opioid receptors [3] have potential to be used as environmental sensors for opioids, but there have not been any advances in commercialization of a solution-based product using these technologies. The current single use environmental opioid sample collection and identification kits can only cover small areas per wipe, and utilizes either a separate detector [DetectaChem Seeker] to identify the sample, or a Mecke reagent that requires strong acid chemistry [Sirchie Nark II] with the opioid compound. These commercial-off-the-shelf (COTS) kits are not suitable for the Concept of Operation (CONOPS) where large areas of contaminated surfaces need to be rapidly mapped for potential trace amounts of contaminants, which can then be rendered safe through decontamination procedures or through avoidance. There is an immediate need for the U.S. Department of Defense to provide a solution of rapid identification technologies to identify areas contaminated by opioids in order to reduce the risk of exposure to military personnel and first responders.

PHASE I: Describe the potential technologies that could be leveraged to discover or engineer molecular probes/receptors that can bind to the current set of opioids and related compounds. These molecular probes must be amenable to a wide range of chemical and biological conditions and susceptible to chemical modification, as they are expected to elicit an amplified, visible response themselves, or be part of a cascade of reactions that result in an amplified, visible response. The molecular probes must also be able to function in a solution, as the final product will be a solution-based spray. There is an immediate need to develop one type of molecular probe or receptor that can bind and recognize a broad spectrum class of opioids, rather than a unique probe per opioid compound. The synthesis of the molecular probes must be scalable. The deliverable in Phase I should be a proof of concept batch scale formulation that can be demonstrated on operationally relevant surfaces (e.g., green or tan Chemical Agent Resistant Coating (CARC), dark colored carpet, military uniforms, stainless steel, etc.) at the laboratory level, using opioid or opioid simulants as contamination.

PHASE II: For one or more of the prototype molecular probes investigated in Phase I, the offeror is to develop and deliver a batch scale formulation to the Government for independent evaluation using actual opioids and related compounds. Iterative feedback and formulation optimization should occur during Phase II between the offeror and the Government to finalize a formulation that produces an eye-readable response with Limit of Detection at 0.1 mg/m2 (milligram per square meter) surface concentration levels within 10-minutes of application, shelf-life stable for 1-year (shorter term accelerated studies are acceptable), and ready for pre-production. A list of interferents and potential false positive compounds should be included in the final formulation as well as cross-reactivity amongst fentanyl analogues. The formulation needs to be able to recognize the target opioids and elicit an eye-visible response when in the presence of interferents.

PHASE III DUAL USE APPLICATIONS: PHASE III: Offerors will need to explore low rate initial manufacturability and the operability of the final product form factor using the down-selected formulation. The offerors should have facilities available for low rate initial production during Phase III. The offeror should be able to transition to mid-scale production after Phase III. All products produced from mid-scale production should be validated for activity and shelf-life stability.

PHASE III DUAL USE APPLICATIONS: Beyond contamination mapping for military applications, products derived from this topic can be used by homeland defense and first responders when encountering unknown areas that are suspected to be contaminated by opioids and related compounds.

REFERENCES:
1. Angelini DA, Biggs TD, Maughan MN, Feasel MG, Sisco E, Sekowski JW. Evaluation of a lateral flow immunoassay for the detection of the synthetic opioid fentanyl. Forensic Science International. 2019; 300:75-81.

2. Bick MJ, Greisen PJ, Morey KJ, Antunes MS, La D, Sankaran B, Reymond L, Johnsson K, Medford JI, Baker D. Computational design of environmental sensors for the potent opioid fentanyl. eLife. 2017; 6:e28909.

3. Lerner MB, Matsunaga F, Han GH, Hong SJ, Xi J, Crook A, Perez-Aguilar JM, Park YW, Saven JG, Liu R, Johnson ATC. Scalable Production of Highly Sensitive Nanosensors Based on Graphene Functionalized with a Designed G Protein-Coupled Receptor. Nano Letters. 2014, 2709-2714.

KEYWORDS: opioids, molecular probe, hazard mitigation, contamination mapping, receptors