

CHEMICAL AND BIOLOGICAL DEFENSE PROGRAM
FY16.1: Small Business Innovation Research (SBIR)
Proposal Submission Instructions

The approved FY16.1 topics included in the Chemical and Biological Defense (CBD) Small Business Innovation Research (SBIR) Program is listed below. Offerors responding to this Solicitation must follow all general instructions provided in the Department of Defense (DoD) Program Solicitation. Specific CBD SBIR requirements that add to or deviate from the DoD Program Solicitation instructions are provided below with references to the appropriate section of the DoD Solicitation.

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) required 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 Innovation Research (SBIR) Program have the potential to transition to the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) if the appropriate level of technology maturity has been demonstrated. The JSTO-CBD Science & Technology programs and initiatives are improving defensive capabilities against Chemical and Biological Weapons of Mass Destruction. The SBIR 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 that permits 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 regarding the DoD Joint Chemical and Biological Defense Program is available at the DoD Counter-proliferation and Chemical Biological Defense homepage at <http://www.acq.osd.mil/cp>.

The overall objective of the CBD SBIR 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 SBIR 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); information systems technology to include but not limited to modeling and simulation and operational effects & mitigation; medical pre-treatments (e.g., vaccine development and delivery); medical diagnostics & disease surveillance; and medical therapeutics (chemical countermeasures and biological countermeasures).

Submitting Your Phase I CBD SBIR Proposal

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

The Proposal Technical Volume must be 20 pages or less in length. The Cover Sheet, Cost Volume and Company Commercialization Report 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. The proposal must not contain any type smaller than 10-point font size (except as legend on reduced drawings, but not tables).

The Company Commercialization Report must be prepared through the Proposal Submission site and the Report will be included with your electronic submission; however, the Company Commercialization Report does not count against the proposal page limit. Update your commercialization information if it has not been updated in the past year. Note that improper handling of the Commercialization Report may result in the proposal being substantially delayed and that information provided may have a direct impact on the review of the proposal. Refer to Section 5.4.e of this program solicitation for detailed instructions on the Company Commercialization Report.

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. Note also that the U.S. Small Business Administration SBIR/STTR Web site contains information on firm, award, and abstract data for all DoD SBIR Phase I and II awards archived for several years. This information can be viewed on the SBA SBIR/STTR Web site at: <http://www.sbir.gov>

The CBD SBIR Program uses a Phase I Option to enhance the Phase I to Phase II transition process; the Phase I option may be exercised to fund interim Phase II activities while a Phase II contract is being negotiated if selected for a Phase II award. The maximum dollar amount for a Phase I proof-of-concept/feasibility study is \$100,000. The Phase I Option, which **must** be proposed as part of the Phase I proposal, covers activities over a period of up to three months and at a cost not to exceed \$50,000. All proposed Phase I Options must be fully costed and should describe appropriate initial Phase II activities, which would lead, in the event of a Phase II award, to the successful demonstration of a product or technology. **The CBD SBIR Program will not accept Phase I proposals which exceed \$100,000 for the Phase I effort and \$50,000 for the Phase I Option effort (exclusive of Technical Assistance; see below)**. Only those Phase I efforts selected for Phase II awards through the CBD SBIR Program's competitive process will be eligible to exercise the Phase I Option. To maintain the total cost for SBIR Phase I and Phase II activities at a limit of \$1,150,000, the total SBIR funding amount available for Phase II activities from a resulting Phase II contract will be \$1,000,000 (also exclusive of Technical Assistance, if requested).

Companies submitting a Phase I proposal under this solicitation must complete the Cost Volume using the on-line form, within a total cost of \$100,000 over a period of up to six months (plus up to \$50,000 for the Phase I Option over a period of up to three months). Phase I and Phase I Option costs must be shown separately.

Selection of Phase I proposals will be based upon the evaluation criteria discussed in Section 6.0 of this program solicitation. The CBD SBIR 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. The offeror must be responsive to the topic requirements, as solicited. Companies should plan carefully for any research involving animal or human subjects, biological agents, etc. The short Phase I Period of Performance may preclude plans including these elements, unless coordinated before a contract is awarded. However, note that the Chemical and Biological Defense Program is not responsible for any funds expended by the proposer prior to contract award.

Proposals not conforming to the terms of this solicitation, and any unsolicited proposals, will not be considered. Awards are subject to the availability of funding and successful completion of contract negotiations.

CBD Program Phase II Proposal Guidelines

Phase II is the demonstration of the technology that was found feasible in Phase I. The Reauthorization of the SBIR/STTR Program (see Note 1) has resulted in significant changes to the Phase II proposal submission process. 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 at 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://sbir.defensebusiness.org/>.** At the proposal submission Web site, Phase II proposals MUST be submitted to ‘**CBD SBIR**’ regardless of which DoD contracting office negotiated the Phase I contract. Additional instructions regarding Phase II proposal submission process including submission key dates will be provided to Phase I awardees after Phase I contract award and also can be found at <https://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. 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 proposal submission site), and the two-years may be presented side-by-side on a single Cost Volume sheet. 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 year.

The CBD SBIR Program is committed to minimizing the funding gap between Phase I and Phase II activities. All CBD SBIR Phase II proposals will receive timely reviews and be eligible for interim funding (refer above for information regarding the Phase I Option). The CBD SBIR 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

In accordance with the Small Business Act (15 U.S.C. 632), the CBD SBIR Program Office will authorize the recipient of a Phase I and/or a Phase II SBIR award to purchase technical assistance services (Discretionary Technical Assistance, DTA), such as access to a network of scientists and engineers engaged in a wide range of technologies, or access to technical and business literature available through on-line data bases, for the purpose of assisting such concerns as:

- making better technical decisions concerning such projects;

- solving technical problems which arise during the conduct of such projects;
- minimizing technical risks associated with such projects; and
- developing and commercializing new commercial products and processes resulting from such projects.

If you are interested in proposing use of a vendor for technical assistance, you must provide a cost breakdown in the Cost Volume under “Other Direct Costs (ODCs)” and provide a one-page description of the vendor you will use and the technical assistance you will receive. The proposed amount may not exceed \$5,000 for Phase I and \$5000 for each year of a Phase II project. The description should be included as the LAST page of the Technical Volume. This description will not count against the Phase I or Phase II proposal page limit and will NOT be assessed against SBIR proposal evaluation criteria. Approval of technical assistance is not guaranteed and is subject to review of the Contracting Officer.

Key Dates

16.1 Solicitation Pre-Release	11 December 2015 – 10 January 2016
16.1 Solicitation Open/Close	11 January 2016 – 17 February 2016 (submission deadline: 6:00 am Eastern Time on closing date)
Phase I Evaluations	February - April 2016
Phase I Selections	No Later Than 16 May 2016
Phase I Awards	August 2016 (see Note 2)
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 https://www.cbdsbir.net/PhaseII.aspx .

(Note 1) On December 31, 2011, the President of the United States signed into law the National Defense Authorization Act for Fiscal Year 2012 (Defense Reauthorization Act), Public Law 112–81. Section 5001, Division E, of the Defense Reauthorization Act contains the SBIR/STTR Reauthorization Act of 2011 (SBIR/STTR Reauthorization Act), which extends both the SBIR and STTR Programs through September 30, 2017.

(Note 2) Subject to the Congressional Budget process.

CBD SBIR PROPOSAL CHECKLIST

This is a Checklist of Requirements for your proposal. Please review the checklist carefully to ensure that your proposal meets the CBD SBIR 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, Cost Volume, and Company Commercialization Report were submitted via the Internet using the DoD's SBIR Proposal Submission Web site at <https://sbir.defensebusiness.org/>.
- _____ 2. The proposal cost adheres to the CBD SBIR Program criteria specified.
- _____ 3. The proposal is limited to only **ONE** solicitation topic. All required documentation within the proposal references the same topic number.
- _____ 4. The proposal is responsive to the requirements addressed in the topic.
- _____ 5. 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.
- _____ 6. The Technical Volume of the proposal, including the Option (if applicable), includes the items identified in Section 5.3.c of this program solicitation.
- _____ 7. The Proposal Technical Volume must be 20 pages or less in length. The Cover Sheet, Cost Volume and Company Commercialization Report 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.
- _____ 8. The Company Commercialization Report is submitted online in accordance with Section 5.4.e. This report is required even if the company has not received any prior SBIR funding.
- _____ 9. The proposal must not contain any type smaller than 10-point font size (except as legend on reduced drawings, but not tables).

CBD SBIR 16.1 Topic Index

CBD161-001	Dual-Purpose Biocidal and Chemical Warfare Agent/Reactive Textile Finish
CBD161-002	Development of Chemical and Biological Aerosol and Liquid Repellent Coatings
CBD161-003	Dermal Medical Countermeasures for Chemical Weapons Exposure
CBD161-004	Medical Countermeasure Development for Viral Induced Encephalitis Using Single Domain Antibodies
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CBD161-006	Contaminated Materiel Transfer Case

CBD SBIR 16.1 Topic Descriptions

CBD161-001 TITLE: Dual-Purpose Biocidal and Chemical Warfare Agent/Reactive Textile Finish

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

OBJECTIVE: Develop textile finishes that can provide both broad spectrum biocidal activity and chemical warfare agent reactivity. Develop protective finishes for military relevant textiles that provide broad spectrum biocidal activity (Gram-positive bacteria, Gram-negative bacteria, fungi, and viruses) that are compatible with existing and/or emerging durable repellency treatments, are resilient, and provide active protection against nerve and blister agents.

DESCRIPTION: The commercial viability of any technology whose sole purpose is chemical warfare (CW) defense is limited. This limited applicability either drastically increases the cost of focused products or completely prevents their commercial development. However, it is critical that vigilance is maintained while protecting our soldiers from the threat of chemical warfare agents (CWA). An approach that has greater potential for economic and commercial feasibility is to develop technologies possessing utility in both the commercial world and in the chemical warfare defense arena. Although technologies developed for decontamination/reactivity against chemical warfare agents also are generally effective as biocides, the converse is not true for commercial-off-the-shelf biocides. The market for antibacterial/biocidal textiles is a multibillion dollar industry. Producing a dual-use product will take advantage of the commercial market and should reduce the cost of chemical warfare agent protection ensembles.

Protective finishes should provide protection to wearers from CWA as well as commonly encountered, ambient, infectious, highly contagious and debilitating pathogens such as Staphylococcus and Streptococcus (Gram positives), Pseudomonas (Gram negative), Aspergillus (fungus), influenza (virus), etc., as well as more exotic, highly contagious and deadly pathogens, such as Ebola and hantavirus (virus), tularemia and pneumonic plague (Gram negatives), etc. Such finishes also have the potential to reduce commonly encountered casualties caused by inherent limitations associated with field hygiene (e.g. limited availability of clean water for showers, etc.). (NOTE: Bacterial spores are NOT a target of this topic).

Candidate technologies should balance commercial considerations with DoD requirements.

PHASE I: The research and development goals of Phase I are to identify CW reactive/biocidal compounds that are compatible with existing and/or emerging durable repellency treatments and to demonstrate that textiles treated with the combined formulation retain all desired properties (CWA reactivity via simulants, broad spectrum biocide, and oil/water repellency). The small business firm shall deliver a data package containing data on treated woven textile swatches having starting fabric weights of = 5 oz/yd² for four fabric compositions: Defender-M or equivalent, 100% cotton, 50:50 nylon:cotton, and fire-retardant & fire-resistant (FR) cotton; and 2) a data package that includes measurements of oil repellency (AATCC 118), water-isopropyl alcohol repellency (AATCC 193), water spray rating (AATCC 22), qualitative biocidal efficacy (AATCC 147) for *S. aureus*, *Ps. fluorescens* and *A. niger*, viral efficacy data for an enveloped virus, CWA simulant qualitative efficacy data (detection of higher levels of breakdown products vs. controls) for at least one of the following CWA simulants: 2-chloroethyl ethyl sulfide (2-CEES, HD simulant), Demeton-S (VX simulant), and/or diisopropyl fluorophosphate (DFP, G-agent simulant).

PHASE II: Technologies focused on CWA reactive textile treatments historically do not possess commercially acceptable wash durability and often treatments are not uniform throughout the treatment process e.g. the first ten linear yards may perform well, but the last ten may not. Additionally, while simulants serve a screening purpose, reactivity to simulants does not always correlate well to reactivity to actual chemical warfare agents.

The research and development goals of Phase II (Year 1) are to demonstrate formulations are able to be scaled from the swatch level to a small-scale roll-to-roll process with reasonable quality control maintained from the beginning to the end of the roll-to-roll process. At the conclusion of Phase II (Year 1), the small business firm shall deliver: 1) performance data, as in Phase-I, on roll-to-roll treated cloth having width of 18 inches or more on woven textiles having starting fabric weights of = 5 oz/yd² each, prepared from Defender-M or equivalent, 100% cotton, 50:50

nylon:cotton, and FR-cotton, and 2) performance data, as in Phase-I, taken after twenty washes performed in accordance with AATCC standard practices.

Historically, technologies focused on CWA reactive textile treatments are often so aggressive that they lead to rapid degradation of the textile material or degrade upon exposure to the elements (humidity, sunlight, heat) which is deemed unacceptable for commercial textile products. Additionally, scale-up to full width is never a trivial endeavor, as airflows and temperatures on full textile lines are often vastly different than a pilot scale 18 inch line. This can lead to differences in evaporation rate, crosslink density, etc. that may affect performance compared to swatch and pilot scale materials.

The research and development goals of Phase II (Year 2) are to demonstrate reactivity to actual chemical warfare agents and to demonstrate retention of desired properties after accelerated aging. At the conclusion of Phase II (Year 2), the small business firm shall deliver: 1) a performance data package consisting of chemical warfare agent efficacy data for at least two agents using standard practices from a third party testing agency on one roll-to-roll (18" width) treated fabric and, 2) performance data, as specified in Phase-I, taken after accelerated aging on roll-to-roll (18" width) treated goods for each of the four fabrics specified above.

PHASE III DUAL USE APPLICATIONS: Phase III activities will focus on integration of Phase II full width formulations into existing textile lines at line speeds applicable to large-scale production; Phase III also will include establishing sustainable sources for precursor chemicals and compatibility of precursors, formulations and procedures with commercial textile lines.

PHASE III DUAL-USE APPLICATIONS: Textile finishes that can provide both broad spectrum biocidal activity and chemical warfare agent reactivity will also be effective against pesticides, herbicides, and endogenous bacteria and viruses, implying dual-use applications in agriculture, chemical and outdoor recreation industries, and first-responder organizations.

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KEYWORDS: biocidal, chemical agent, fabric, individual protection, repellent, textile

CBD161-002 TITLE: Development of Chemical and Biological Aerosol and Liquid Repellent Coatings

TECHNOLOGY AREA(S): Chemical/Biological Defense, Materials/Processes

OBJECTIVE: To develop, assess, and optimize Chemical and Biological (CB) aerosol and liquid repellent coatings for use on textiles and solid surfaces.

DESCRIPTION: Chemical and Biological agents can be in the aerosol state (i.e., tiny particles or droplets suspended in the air) or liquid state. It is therefore critical to develop surfaces that can protect soldiers and their equipment by

preventing adhesion and penetration of aerosols and liquids. Resistance to dust, dirt, and aerosol accumulation on a surface is related to three key factors: (1) coefficient of friction, (2) surface energy; and (3) anti-static properties.² The lower the coefficient of friction and surface energy, the higher the anti-static properties a surface will be, and the better its resistance to attraction, repellency, and accumulation of aerosols. Recent research has indicated that surface adhesion with solids (e.g., ice) is very different as compared to that of liquids,³⁻⁵ and aerosolized CB agents could be in the form of CB contaminated aerosols such as ice crystals, air-borne liquid droplets and particulates. Therefore, an in-depth understanding of the interaction, attraction, and repellency between liquid and aerosol and materials with different surface topographies will need to be studied. These materials will include smooth and textured continuous surfaces (e.g., metal and glass surfaces), as well as fibrous surfaces of woven and non-woven textiles.

The recently commercialized Ultra-Ever Shield® omniphobic coating⁶ that is based on C6 chemistry (perfluorohexanoic acid) had shown about 7.8 times less dirt pickup than an untreated 50% nylon/50% cotton fabric in a control laboratory environment.⁷ Also, it was shown that fan surfaces that were coated with hydrophobic nanoparticles comprising of hexamethylsilazane silica reduced dust particle counts by 7 times.² Previous work has shown that the factors governing the adhesion of a solid particle on a textured substrate, can be very different from a liquid. For example, it was previously found that textured superhydrophobic (SH) surfaces, which can effectively repel water (liquid), do not repel ice (aerosols).³⁻⁵ The underlying problem lies in how superhydrophobic surfaces repel water. By maintaining a high fraction of air (high porosity) within the surface, superhydrophobic surfaces exhibit very high contact angles and low contact angle hysteresis with water,⁸ but in a humid environment, microdroplets of water are formed within the pores in the superhydrophobic surface due to vapor condensation (or frost formation). Once the pores within a superhydrophobic surface are filled with water, the surface is neither superhydrophobic nor icephobic since the interfacial area between the ice and the superhydrophobic surface increases dramatically. Any situation in which ice can form has some humidity; thus practically, superhydrophobic surfaces as they exist today cannot repel ice - which is in the form of an aerosol. The above findings show that it is also necessary to address ice as a separate class of liquid-based aerosol in this topic, since ice particles could also be contaminated with chemical warfare agents, and/or bacteria and viruses.

Current protective clothing can be treated with a durable water repellent (DWR) coating to repel water; however, DWR treated clothing are easily wetted by a range of lower surface tension liquid chemicals including chemical warfare agents [e.g., GD (surface tension of 24.5 mN/m @26.5oC), GB (26.6 mN/m @26.5oC), and VX (32 mN/m @26.5oC)].⁹ Besides, DWR treated clothing attracts dust and minute aerosolized particulates. The desired improvement to current clothing's limited aerosol and liquid repellent capabilities could be realized in the development of a repellent coating based on engineered surfaces containing nanoparticles, which can dramatically reduce the surface area available for dust contact.² Other approaches may include studying surfaces having specific goals with obtaining very low particle/ice-adhesion strength of less than 30 kPa; using surface altering technologies (such as atomic layer deposition (ALD) to deposit multilayers of extremely thin nano-porous, metal oxide coatings in the range of 10 to 100 nm to create material surfaces with ultra-low surface energies;¹⁰ or Langmuir-Blodgett (LB) self-assembly to deposit multiple layers of extremely thin polymer coatings with ultra-low surface energies;¹¹ and other novel and innovative techniques/approaches to achieve surface-modified materials having nano-scale surface topography with or without appropriate surface chemistry may also be useful.^{12,13,14,15} Surface-altering technologies should all possess specific goals of having resulting surface energy less than that of N-Hexane, which has a surface tension of 18.4 dynes/cm.

PHASE I: Effort will be to: (1) study the mechanisms of solid and liquid adhesion on smooth or textured solids and textiles; (2) develop a fundamental understanding of their surface interactions with a range of aerosols having low to high surface energy, and liquids with low to high surface tensions; (3) establish a design of experiments to create a series of coatings to treat surfaces with nanoparticles containing coating formulations, and to identify optimal coating formulations to create effective nano-roughness surfaces or to engineer novel low-surface energy surfaces; (4) produce lab-size surface treated/coated textiles and solid surface templates; and (5) assess these materials' aerosol adhesion strength and liquid repellency with a specific goal of having less than 30 particles count per unit of air/nitrogen volume in an aerosol spray rating test, a spray rating of 100 for water, and an oil rating of 8A, i.e., nonwetting by Heptane which has a surface tension of 14.8 dynes/cm. In addition, physical properties (e.g., tensile strength and abrasion resistance) of the base fabric and solid surface must be maintained or improved. For textiles, coating should be conformal around the fibers and fiber bundles (i.e., yarns) to minimize interference to its base fabric's air permeability (ASTM D 737), which must be less than 0.2 ft³ /min/ft². Its moisture vapor transmission rate (ASTME96-2007, Proc. B), must be maintained, and should be greater than 700 g.m²/24h, and the treated

textiles must be dried within 30 minutes.

Phase I deliverables will be lab-size (e.g., 6"x6") coated fabrics and coated solid surfaces (e.g., metal and polymer plates).

PHASE II: Effort will focus on refining preferred/down-selected processes and materials to produce versatile aerosol and liquid repellent coatings. Finalize high performance, durable coating formulations from Phase I. Establish refined performance goals and parameters through the conduct of experiments. Coatings will be applied to textile and other substrates, and these modified textiles and substrates will be subjected to rigorous testing and evaluation to demonstrate and validate their potential applications. Key comfort and physical properties performance as identified in Phase I will continue to be used in Phase II. Similar and additional metrics will be identified for representative surfaces with collaboration of other DoD personnel. The second year of Phase II efforts will be focused on constructing and demonstrating the operation of prototype garments, producing prototype garments and individual equipment using optimized aerosol and liquid repellent coating, refining processes for producing defect-free coated textiles and solid surface products, and system level testing will be conducted to assess the usability of products as aerosol repellent textiles for clothing. A commercial viability study will be conducted, and effort will be focused on identifying commercial partners for Phase III continued work and technology transition. System level testing and limited field durability testing of CB agent contaminated solid repellent coated clothing and equipment will be planned and conducted under DoD guidance.

PHASE III: Identify commercial partnerships and opportunities to transition and commercialize the new aerosol and liquid repellent coating technology to specific fielded applications such as the ECWCS Gen III, and dual-use applications such as, for example, clothing for mountain climbers, arctic oil drill handlers, and soldiers operating in extreme cold areas, Naval and Air Force vehicles and personnel working in extreme cold environments, and other relevant individual equipment. The SBIR contractor and its commercial partners will also seek dual-use applications of novel aerosol and liquid repellent coating for commercial clothing and non-clothing applications such as reducing ice-load in automobiles, aircraft, ships; nonstick surfaces, frictionless mechanical system components, parts; high-efficiency snowmobiles, sleds, skis, snow boards; oil drills, swim wear, mountaineers' protective clothing, divers, mariners, amphibious operations suits, etc. Transition of solid/aerosol coating technology to commercial and military applications. (TRL 6 - System/subsystem model or prototype demonstration in a relevant environment.)

PHASE III DUAL USE APPLICATIONS: Spinoff technologies will also address reduced ice adhesion strength for reduced snow load and ice buildup on textile structures, etc.

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KEYWORDS: Solid/aerosol repellent, low surface tension, surface roughness, solid adhesion strength, superomniphobic, chemical/biological agent protection

CBD161-003 **TITLE:** Dermal Medical Countermeasures for Chemical Weapons Exposure

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

OBJECTIVE: To develop low-cost, FDA-cleared toxic chemical neutralizing countermeasures for use on abraded skin or whole body

DESCRIPTION: Current formulations of dermal medical countermeasures to chemical warfare agents (CWAs) are only approved by the FDA for small area applications on intact skin. This severely restricts usefulness since warfighters in some chemical weapons combat scenarios may be exposed over large regions of the body including areas with wounds or skin abrasions. In addition, these countermeasures require storage in climate controlled areas. Together with other factors, this complicates logistics and increases supply costs. Lower-cost methods of skin decontamination, such as water washing, lead in some cases to more rapid onset of toxicity, attributed to a phenomenon known as the "wash in" effect, in which some hydrophobic/lipophilic compounds exhibit enhanced percutaneous penetration and partitioning into the lipid components of the skin in the presence of aqueous media. New countermeasure formulations and strategies are needed which minimize injuries resulting from cutaneous exposure to CWAs up to 50% of the skin surface, including wounded regions and regions containing hair follicles.

This effort will result in the development of practical interventions that neutralize the CWA and/or treat the associated site-specific and systemic toxicity resulting from such large area dermal exposures to wounded warfighters. CWAs of primary focus are persistent threats such as VX, GD, HD, and related classes of molecules. Countermeasures which have applicability to numerous such threats are favored over more specifically-targeted approaches, with the goal of reducing logistical burden, enabling the potential to respond to CWAs prior to full identification, and increasing the potential for application to exposure scenarios within industrial and agricultural contexts. Ideally, such countermeasures would be stable to a large range of environmental and temperature extremes representative of potential field conditions. The ideal dermal countermeasure strategy would also incorporate facile means to reveal activity after application. In addition, low production and supply costs are desired,

with a target reduction in cost of 50% over relevant current countermeasures, as well as a detailed and realistic plan for gaining FDA licensure of new non-licensed compounds or new indications for licensed products for the treatment of chemical warfare casualties.

PHASE I: Demonstrate the efficacy of a lab-scale prototype formulation with an appropriate in-vitro/ex-vivo skin model. Provide experimental evidence suggesting the potential for improvements over existing dermal countermeasures such as Reactive Skin Decontamination Lotion (RSDL) in applications to wounds, as well as enhanced thermal and environmental stability. These improvements could be indicated, for example, through preliminary experiments showing significantly accelerated activity relative to baseline against chemical simulants such as paraoxon, half-mustard, or other chemical warfare simulants in representative in-vitro environments, together with preliminary accelerated stability tests.

Use of human or animal subjects is not intended, or expected, in order to establish/achieve the necessary proof-of-concept in Phase I.

PHASE II: Demonstrate product therapeutic efficacy using an appropriate in-vivo animal wound model supported by limited scope qualitative in-vitro testing, together with a reasonable correlation to expectations in humans. Demonstrate extended storage life as well as stability within a range of environmental and temperature extremes, including accelerated climate testing with cycles between 120oF and -25oF. Provide a projection of scale-up costs. Draft a target product profile. Conduct a pre-IND meeting with the FDA and other relevant stakeholders, and establish a regulatory plan.

PHASE III: Implement appropriate testing, according to the regulatory plan, necessary to gain FDA clearance. Establish ability to perform large scale production and low cost to supply warfighter needs. Demonstrate storage life exceeding three years. Optimize thermal and environmental stability within military operational settings.

PHASE III DUAL-USE APPLICATIONS: Potential alternative applications include exposures of laboratory personnel and first responders working within CWA-contaminated environments. In addition, therapeutics for accidental exposures to pesticides or other toxic chemicals, within the agricultural and chemicals industries, could be addressed.

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KEYWORDS: individual protection, dermal therapeutic, wound care, chemical countermeasure, chemical agent

CBD161-004 TITLE: Medical Countermeasure Development for Viral Induced Encephalitis Using Single Domain Antibodies

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

OBJECTIVE: The objective of this effort is to identify single domain antibodies that demonstrate the capability to cross the blood brain barrier and neutralize encephalitic viruses.

DESCRIPTION: Currently there is a capability gap for the effective treatment of viral induced encephalitis. It is widely acknowledged that viruses such as those represented in the Alphavirus family, e.g. Eastern, Western, and Venezuelan equine encephalitis viruses, pose significant risk to the warfighter. The Alphaviruses are recognized as potential biological warfare agents. There are no approved or licensed medical countermeasures against diseases caused by Alphaviruses. In fact, the only Medical Countermeasure (MCM) is supportive care. Alphavirus infections can cause two distinct clinical presentations. In the mode of lesser concern, the infection can exhibit symptomology from virtually asymptomatic to typical 'flu-like' symptoms. However, Alphavirus infections can also lead to encephalitis and it is this manifestation that is of grave concern as viral encephalitis often leads to death.

Single domain antibodies (sdAb), or nanobodies, are part of a class of recombinant antibody fragments, including Fab, scFv, diabodies and microbodies and offer a new approach to generating antibody-based therapeutics, diagnostics, and tool reagents. With a molecular weight of roughly 13 kDa, single domain antibodies, which consists only of a single heavy-chain variable domain, are significantly smaller than common antibodies, which are 150-160 kDa. Because of its small size and high stability, single domain antibodies are easier to engineer over traditional antibodies. Numerous sdAbs have already proven useful for basic research and as improved diagnostic and biosensor tools. In vivo studies have highlighted the favorable biodistribution of sdAbs, including deep penetration into dense tissues, ability to transcend the blood brain barrier (BBB), and rapid elimination via the kidney. These features make sdAbs particularly amenable for delivery across the BBB.

Single domain antibodies are gaining in popularity for therapeutic applications. Their small size and high stability gives the antibody fragment the advantage of being able to access "hidden" epitopes, to which larger antibodies may not be able to bind. Advantages of single domain antibodies include small size (improved access), amenability to engineering (conventional antibodies are less forgiving due to complexity), maintenance of stability and potency at extreme pH and temperatures, multiple routes of administration, and are easy to manufacture in yeast or microbial systems. It is also easier to engineer bi-specific and tri-specific sdAbs, using sdAb building blocks. Antibody based approaches are likely to result in lower overall costs for development to approval/licensure and concomitant reduction in time to licensure, as compared to small molecules or novel approaches not widely recognized as generally safe for use in humans. There are currently several sdAb-based antibody therapeutics in clinical trials for thrombosis in acute coronary syndrome, arthritis, and lower respiratory tract infection.

The specific approach of the study and the pathogenic targets are to be determined by the individual investigators.

PHASE I: The Phase I proof of concept (POC) must demonstrate the offeror can produce a high binding (pM) sdAb that has the ability to cross the blood brain barrier. Successful Phase I POC is defined as a demonstration that a sdAb directed at either Eastern, Western, or Venezuelan equine encephalitis virus can cross either an artificial or an actual BBB. The offeror need not show efficacy against a challenge in vivo, just that the antibody can cross the BBB.

The most significant obstacle for drug delivery into the brain is the presence of the blood brain barrier, which limits the traffic of substances between the blood and the nervous tissue. Due to fiscal, physical, and time constraints, in

vitro models of efficacy are adequate for successful demonstration of the technology. A variety of in vitro models have been described that are designed to mimic the BBB and characterize the penetration properties of drug candidates into the central nervous system. Most of these in vitro BBB models are based on the culture of brain endothelial cells. The specific model to be employed is at the discretion of the offeror. The offeror may also use in vivo models to demonstrate POC, if that is within their capabilities.

PHASE II: Building upon a successful Phase I POC technology demonstration, Phase II requires the use of an in vivo animal model for viral encephalitis. The offeror will need to use a well-defined animal model that mimics human disease. The development of the animal model is outside the scope of this topic. There is a preference for technologies that facilitate longitudinal studies, such as magnetic resonance imaging (MRI) or computed tomography positron emission tomography (CT-PET). Documenting changes in intracranial pressure with sensors would be a plus. More specifically, the Phase II technology demonstration should be focused on encephalitic Alphavirus species such as Eastern, Western, or Venezuelan equine encephalitis virus. The successful demonstration could be for one or more of the encephalitic Alphaviruses. The offeror's chosen animal model should develop encephalitis analogous to the encephalitis observed in humans. A candidate is considered successful if a statistically significant increase in survival of animals exhibiting encephalitis is demonstrated. The specific timing of medical countermeasure application is at the discretion of the offeror but should be no sooner than the onset of encephalitis symptoms. Delayed time to treat will be evaluated in Phase III.

Phase II work should include a trigger to treat study, chemistry, manufacturing, and controls (CMC) considerations, pilot lot production POC experiment that successfully demonstrates the feasibility to manufacture the MCM, and a preliminary stability study. Other considerations for Phase II work include formulation (route of administration), tissue cross reactivity (TCR), and pharmacokinetics (PK) evaluation.

PHASE III: With successful completion of Phase II, Phase III will focus on refinement and expansion of the concept. A successful Phase III effort will culminate in a product that is "tri-valent" for use as an Eastern, Western, and Venezuelan equine encephalitis virus medical countermeasure. The tri-valent capability can be from a single sdAb or may be a cocktail of sdAbs. A dosing regime in line with an FDA Phase I human safety trial will be determined, as will delayed time to treat. The technology will be evaluated in animal models using lethal doses of Eastern, Western, or Venezuelan equine encephalitis virus, separately. Time points for delayed time to treat should include 24, 48, 72 hrs post encephalitic symptoms, with statistically significant target rescue rates of 80%, 40%, and 20%, respectively.

After the successful completion of the Phase III activities, additional tasks required to make the product marketable will include pre-investigational new drug (IND) meeting with the FDA, and IND filing. This would require completion of all necessary IND enabling toxicology, PK studies required and cGMP manufacturing to support Phase I safety trials in healthy human volunteers.

PHASE III DUAL USE APPLICATIONS: Beyond DoD use, the product would most certainly have world-wide acceptance in the medical community for a treatment, or possibly prevention as a passive immunization, for encephalitis caused by Eastern, Western, or Venezuelan equine encephalitis virus infection. Moreover, the product would likely prove effective against treating infection of the aforementioned pathogens prior to the encephalitic stage.

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KEYWORDS: Alphavirus, BBB, Blood Brain Barrier, Eastern Equine Encephalitis Virus, Encephalitis, Nanobody, sdAb, Single Domain Antibody, Venezuelan Equine Encephalitis Virus, Western Equine Encephalitis Virus

CBD161-005 TITLE: Smartphone Application for Mask Sizing and Projecting Quantitative Fit

TECHNOLOGY AREA(S): Chemical/Biological Defense

OBJECTIVE: Design and develop a software application ('app') for rapid identification of the appropriate size of a respiratory protective mask facepiece and to reliably predict the quantitative protective fit once the size has been determined.

DESCRIPTION: Military respirators used for protection against chemical, biological, radiological and nuclear (CBRN) threat agents must be properly sized and fitted to the individual wearer to provide adequate protection. Full facepiece respirators are sized based on facial anthropometric measurements including face length and width. A significant degree of expertise is required to properly use the anthropometric calipers and to identify proper alignment of the respirator on the face (e.g., eyes fall in correct location of a visor or eye lenses). A mask quantitative fit test is then performed to verify that the respirator has been properly sized and donned, and to measure the protective fit for the wearer afforded by the respirator. The fit test is performed using the CBRN Mask Protection Assessment Test System 8020M. (Ref. 1) The user dons the respirator and performs a series of standing exercises including normal breathing, deep breathing, moving the head side to side, moving the head up and down, and grimacing the face. A fit factor is provided for each exercise and for the overall fit. This process is cumbersome and very time consuming and must be repeated at least annually or more frequently if a respirator user has any significant gain or loss of body weight, major dental work performed, or if there are any injuries or scarring of the face.

An innovative smartphone app is desired that could quickly and accurately perform respirator sizing and reliably predict the protective fit of a properly donned respirator. Additionally, the readily acquired anthropometric data from the app can be used to enhance existing anthropometric databases of military personnel to support sizing tariffs and inventory control for production of respirators and head borne equipment items. The smartphone could be used to take a sequence of 2-D photos of a prospective respirator wearer. A 3-D face and head reconstruction could then be performed. The app could be used to determine common facial anthropometric measurements (Ref. 2) as well as coronal arc and head and neck circumferences. The proper size respirator for the user could be provided along with predicted protective fit (i.e., quantitative fit factor) for a properly donned respirator. (Ref. 3, 4, 5 & 6)

PHASE I: Design and develop a computer program to accurately size a full-facepiece respiratory protective mask to include the nose cup and peripheral seal of the mask. Perform a 3-D face and head reconstruction using a video or series of provided 2-D photos of five headforms⁷ taken with a smartphone camera. Demonstrate the ability to identify common face and head anthropometric measurements of the headforms with $\pm 10\%$ accuracy. Use the software to predict which size of an Avon Protection C50 respirator would best accommodate each of the five headforms.

PHASE II: Refine and optimize the sizing software. Transition the software to the iOS and Android operating systems so that it can be operated on a smartphone or tablet using WiFi. Take photos of human subjects with the smartphone camera. The number of subjects shall comply with applicable standards for respirator fit testing.⁶ Use the app to determine the anthropometric measurements in Table 2 of the International Organization for Standardization (ISO) Technical Specification (TS) 16976-2.⁷ Compare these measurements to those made manually and demonstrate accuracy of $\pm 5\%$. Identify the hair line and incorporate an accommodation in the sizing. Determine the anthropometric parameters necessary to predict fit. Demonstrate the ability to predict size and protective fit⁶ for a panel of wearers (1st to 99th percentile) for the Avon Protection C50 respirator. The measured quantitative fit for each respirator wear trial shall exceed 2000 to be considered an acceptable fit.

PHASE III: Expand the database of respirators to include all fielded military respirators. Demonstrate the ability of the device to accurately size and fit a range of respirators including half-mask filtering facepiece and elastomeric respirators. Demonstrate the ability to commercialize the technology and establish technology transition partners to expand commercialization.

PHASE III DUAL USE APPLICATIONS: Enhancement of existing anthropometric databases of military personal to support sizing tariffs and inventory control for production of respirators and head borne items such as army combat uniform hats and ballistic helmets. Potential alternative applications include health care, industrial, international, and commercial respiratory protection systems.

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KEYWORDS: Individual protection, respirator, anthropometrics, respirator sizing, respirator fit, facial reconstruction, 3-D, smartphone app

CBD161-006 TITLE: Contaminated Materiel Transfer Case

TECHNOLOGY AREA(S): Chemical/Biological Defense, Materials/Processes

OBJECTIVE: The overall objective is to develop a high strength/low weight chemically and biologically impermeable container capable of being opened to allow the insertion of the maximum sized contents of 85” x 24” x 18” and up to 335 lbs of chemical or biological hazardous materials. After loading contents, the container would never be re-opened. The container must also be puncture resistant, leak-proof at a hydrostatic load of 36 pounds of hydrostatic pressure per square inch (psi), and remain leak-proof after a 30 foot drop at 0 degrees Fahrenheit to enable air transport without a method for pressure relief. The container will allow the safe repatriation of chemically or biologically contaminated human remains, animal remains, protective equipment, or other material in accordance with Department of Defense (DoD), federal, and international standards.

DESCRIPTION: Current international standards impose strict requirements on air transport of chemical and biological hazards. While the requirements are attainable on a small scale, large scale containers encounter significantly increased stresses at high pressures due to increased volume and significantly increased stresses during drop and puncture tests due to higher weights. The standards also require a leak-proof seal without allowance for pressure relief. While the system would never need to be re-opened after insertion of contents, ease of use in terms of portability (low weight) and time to seal the container (less than 30 minutes) are desired. Current existing solutions are designed for small samples rather than large contents, and the maximum stress and stress distribution on large containers varies greatly based on the size, shape and thickness of the vessel. The container may employ multiple layers to meet requirements. As such, the term “container” shall refer to the single or combination of layers utilized as a single system. Molded thermoplastic composites, high molecular weight plastics, or multi-layered silicone/Kevlar systems may demonstrate promise in achieving the stated requirements.

PHASE I: Proof-of-concept computer modeling of the proposed design should demonstrate a container capable of being opened to allow the insertion of the maximum sized contents of 85”L x 24”W x 18”H and up to 335 lbs of inserted contaminated materials. The content shape will be more elliptical than squared. The proposed design should represent a full-scale hydrostatic leak-proof system at a minimum of 36 psi of hydrostatic pressure for one hour, a 30 foot drop at 0 degrees Fahrenheit, and a 3.3 foot drop on a 1.5 inch diameter cylindrical steel rod without leakage. The rod must protrude from the surface a distance at least equal to that between the primary container and the outer surface of the outer packaging with a minimum of 7.9 inches. The drop test requirements also include a 98% capacity (by volume) fill with water. Vapor leakage shall not exceed 0.001 cm³/s at 4 psi. The system is desired, but not required, to be sealed in 30 minutes or less, be transportable by a 463L pallet, and be less than 200 lbs. The system must also be designed and configured to have a redundant container with equivalent leak-proof characteristics. Due to the significant altered stresses at smaller volumes and thicknesses, small scale prototypes are not viable for proof-of-concept. Performance requirements of Phase I activities should be demonstrated by the contractor through computer modeling and/or full-scale concept construction and will be verified by the Government.

PHASE II: The desired outcome of the first year of Phase II Period of Performance is a pre-production prototype of a chemically and biologically impermeable container capable of withstanding Phase I parameters of 36 psi of hydrostatic pressure for one hour, a 30 foot drop at 0 degrees Fahrenheit without leakage, and a 3.3 foot drop on a 1.5 inch diameter cylindrical steel rod without leakage. The rod must protrude from the surface a distance at least equal to that between the primary container and the outer surface of the outer packaging with a minimum of 7.9 inches. In the second year of Phase II Period of Performance, drop tests will be conducted with a 98% fluid/antifreeze mixture to provide a means for leak-proof verification during the test. Vapor leakage shall not exceed 0.001 cm³/s at 4 psi. The prototype solution must include a secondary container with equivalent leak-proof characteristics. A redundant container is necessary to meet hazardous materials standards included in the Air Force Manual 24-204, the International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air, and the International Air Transportation Association Dangerous Goods Regulations for chemical warfare agents and Centers for Disease Control and Prevention (CDC) Category A Infectious Substances. The system (without its cargo) is desired, but not required, to weigh 200 lbs or less. The contractor would be responsible for verifying the additional performance parameters in Phase II for the redundant combined system of two nested containers and conducting operationally-relevant testing.

PHASE III: The container would be certified through testing by the United States Army Logistics Support Activity and the United States Transportation Command through an operational assessment on a C-17 aircraft and air worthiness testing. A minimum of three tests per requirement are necessary for certification. After certification, the DoD will assist with coordination with the CDC for Category A Hazardous Substance Import Permit using the packaging as designed.

PHASE III DUAL USE APPLICATIONS: Dual use applications include large volume chemical or biological contaminated evidence transfer, large volume hazardous laboratory specimen transfer, heavily degraded or contaminated human remains transfer, or chemical/biological waste containment.

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KEYWORDS: human remains, chemical agent, biological agent, transport, contaminated remains