DEFENSE ADVANCED RESEARCH PROJECTS AGENCY
FY2011.1 SBIR Proposal Submission

DARPA's mission is to prevent technological surprise for the United States and to create technological surprise for its adversaries. The DARPA SBIR and STTR Programs are 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
3701 North Fairfax Drive
Arlington, VA 22203-1714
(703) 526-4170
Home Page http://www.darpa.mil/sbpo

Offerors responding to the DARPA topics listed in Section 8.0 of the DoD 11.1 SBIR Solicitation must follow all the instructions provided in the DoD Solicitation Instructions preface. Specific DARPA requirements in addition to or that deviate from the DoD Solicitation Instructions are provided below and reference the appropriate section of the DoD Solicitation Instructions. All proposals must be submitted electronically through the DoD SBIR Web site at http://www.dodsbir.net/submission by the submission deadline. Proposals provided in hard copy or via e-mail will not be accepted. In addition, all topics are UNCLASSIFIED and only UNCLASSIFIED proposals will be accepted.

SPECIFIC DARPA REQUIREMENTS:

Please note – these requirements and guidelines are supplemental to the DoD 11.1 SBIR Solicitation. For additional information, please refer to the corresponding section number in the DoD solicitation (http://www.dodsbir.net/solicitation/sbir111/preface111.htm).

2.15 Foreign National

DARPA topics are unclassified; however, the subject matter may be considered to be a "critical technology" and therefore subject to ITAR restrictions. ALL offerors proposing to use foreign nationals MUST disclose this information regardless of whether the topic is subject to ITAR restrictions. If the offeror proposes to use foreign nationals, identify the foreign national(s) you expect to be involved on this project as a direct employee, subcontractor or consultant, and the individual's country of origin. For these individuals, please specify the type of visa or work permit under which they are performing and an explanation of their anticipated level of involvement on this project. You may be asked to provide additional information during negotiations in order to verify the foreign citizen's eligibility to participate on a contract issued as a result of this solicitation. See **Export Control** requirements below in Section 5.

3.5 Phase I Proposal Format

PHASE I OPTION

PHASE I OPTION MUST BE INCLUDED AS PART OF PHASE I PROPOSAL. DARPA has implemented the use of a Phase I Option that may be exercised to fund interim Phase I activities while a

Phase II contract is being negotiated. Only Phase I companies selected for Phase II will be eligible to exercise the Phase I Option. The Phase I Option, which must be included as part of the Phase I proposal, covers activities over a period of up to four months and should describe appropriate initial Phase II activities that may lead to the successful demonstration of a product or technology. The Phase I Option must be included within the 25-page limit for the Phase I proposal.

A Phase I Cost Proposal ($150,000 maximum) must be submitted in detail online. Proposers that participate in this solicitation must complete the Phase I Cost Proposal, not to exceed the maximum dollar amount of $100,000, and a Phase I Option Cost Proposal (if applicable), not to exceed the maximum dollar amount of $50,000. Phase I and Phase I Option costs must be shown separately but may be presented side-by-side on a single Cost Proposal. The Cost Proposal DOES NOT count toward the 25-page Phase I proposal limitation. Phase I awards and options are subject to the availability of funds.

3.7 Phase II Proposals

DARPA Program Managers may invite Phase I performers to submit a Phase II proposal based upon the success of the Phase I contract to meet the technical goals of the topic, as well as the overall merit based upon the criteria in section 4.3 of the DoD SBIR 11.1 Solicitation. Phase II proposals will be evaluated in accordance with the evaluation criteria provided in section 4.3. Due to limited funding, DARPA reserves the right to limit invitations and awards under any topic. Only those Phase II proposals considered to be of superior quality will be funded. Information regarding Phase II Proposal format will be included in the Phase II Invitation letter.

PHASE II OPTION

PHASE II OPTION MUST BE INCLUDED AS PART OF PHASE II PROPOSAL. 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 or DoD Acquisition Program. The Phase II Option, which must be included as part of the Phase II proposal, covers activities over a period of up to 24 months and should describe Phase II activities that may lead to the successful demonstration of a product or technology. The Phase II Option must be included within the 40-page limit for the Phase II proposal.

A Phase II Cost Proposal ($1,000,000 maximum) must be submitted in detail online. Proposers that submit a Phase II proposal must complete the Phase II Cost Proposal, not to exceed the maximum dollar amount of $1,000,000, and a Phase II Option Cost Proposal (if applicable), not to exceed the maximum dollar amount of $750,000. Phase II and Phase II Option costs must be shown separately but may be presented side-by-side on a single Cost Proposal. The Cost Proposal DOES NOT count toward the 40-page Phase II proposal limitation. Phase II awards and options are subject to the availability of funds.

If selected, the government may elect not to include the option in the negotiated contract.

4.0 Method of Selection and Evaluation Criteria

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 and Rules of Conduct/Conflict of Interest statements. Non-

Government technical consultants/experts will not have access to proposals that are labeled by their proposers as "Government Only."

Please note that additional proposal information provided on Universal Resource Locator (URL) links, computer disks, CDs, DVDs, video tapes or any other medium will not be accepted or considered in the proposal evaluation

Also note that qualified advocacy letters will count towards the proposal page limit and will be evaluated towards criterion C. Advocacy letters are not required for Phase I or Phase II. 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.

4.2 Evaluation Criteria

In Phase I, DARPA will select proposals for funding based on the evaluation criteria contained in Section 4.2 of the DoD 11.1 SBIR Solicitation, including potential benefit to DARPA, in assessing and selecting for award those proposals offering the best value to the Government.

DARPA will use the Phase II Evaluation criteria in Section 4.3 of the solicitation, including potential benefit to DARPA and ability to transition the technology into an identified system, in assessing and selecting for award those proposals offering the best value to the Government.

As funding is limited, 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 more than one proposal in a specific topic area if the quality of the proposals is deemed superior and are highly relevant to the DARPA mission, or it may not fund any proposals in a topic area. Each proposal submitted to DARPA must have a topic number and must be responsive to only one topic.

4.4 Assessing Commercial Potential of Proposals

DARPA is particularly interested in the potential transition of SBIR project results to the U.S. military, and expects explicit discussion of a transition vision in the commercialization strategy part of the proposal. That vision should include identification of the problem, need, or requirement in the Department of Defense that the SBIR project results would address; a description of how wide-spread and significant the problem, need, or requirement is; identification of the potential end-users (Army, Navy, Air Force, SOCOM, etc.) who would likely use the technology; and the operational environments and potential application area(s).

Technology commercialization and transition from Research and Development activities to fielded systems within the DoD is challenging. Phase I is the time to plan for and begin transition specific activities. The small business must convey an understanding of the transition path or paths to be established during the Phase I and II projects. That plan should include the Technology Readiness Level (TRL) at the start and end of the Phase II. The plan should also include a description of targeted

operational environments and priority application areas for initial Phase III transition; potential Phase III transition funding sources; anticipated business model and identified commercial and federal partners the SBIR company has identified to support transition activities. Also include key proposed milestones anticipated during Phase I, II or beyond Phase II that include, but are not limited to: prototype development, laboratory and systems testing, integration, testing in operational environment, and demonstrations.

4.5 SBIR Fast Track

Small businesses that participate in the Fast Track program do not require an invitation to submit a proposal, but must submit an application. The complete Fast Track application must be received by DARPA no later than the last day of the fifth month of the Phase I effort. Once your application is submitted, the DARPA Program Manager will make a determination on whether or not a technical proposal will be accepted for the Phase II effort. If the DARPA Program Manager approves the Fast Track application, the small business will have 30 days to submit the technical proposal.

Any Fast Track applications not meeting these dates may be declined. All Fast Track applications and required information must have a complete electronic submission. The DoD proposal submission site will lead you through the process for submitting your technical proposal and all of the sections electronically.

Firms who wish to submit a Fast Track Application to DARPA must utilize the DARPA Fast Track application template. Failure to follow these instructions may result in automatic rejection of your application. Phase I interim funding is not guaranteed. If awarded, it is expected that interim funding will generally not exceed $50,000. Selection and award of a Fast Track proposal is not mandated and DARPA retains the discretion not to select or fund any Fast Track applicants. NOTE: Phase I firms whose proposals are not accepted for a Fast Track Phase II award are not eligible to receive a Phase II invitation from the agency.

- DARPA encourages Phase I performers to discuss its intention to pursue Fast Track with the DARPA Program Manager prior to submitting a Fast Track application or proposal.
- Fast Track awards are subject to the availability of funds.
- After coordination with the DARPA Program Manager, the performer and the investor should submit a Fast Track application through the DoD Submission Web site no later than the last day of the fifth month of the Phase I effort.
- The Fast Track Interim amount is not to exceed $50,000.
- Additional information regarding the DARPA Fast Track process and application template may be found at: http://www.darpa.mil/sbpo/sbir_program/index.html

4.6 Phase II Enhancement Policy

To encourage transition of SBIR projects into DoD systems, DARPA's Phase II Enhancement Program provides a Phase II performer up to $200,000 of additional Phase II SBIR funding if the performer can match the additional SBIR funds with funds from a DoD acquisition program, a non-SBIR/non-STTR government program or private sector investments. The Phase II Enhancement Program allows for an existing Phase II SBIR to be extended for up to one year per Phase II Enhancement application, to perform additional research and development and further mature the technology. Phase II Transition matching funds will be provided on a one-for-one basis up to a maximum amount of $200,000 of SBIR or funds in accordance with DARPA Phase II Enhancement policy.

Phase II Enhancement funding can only be applied to an active DoD Phase II SBIR contract. The funds provided by the DoD acquisition program or a non-SBIR/non-STTR government program may be obligated on the Phase II contract as a modification prior to or concurrent with the modification adding

DARPA SBIR funds, OR may be obligated under a separate contract. Private sector funds must be from an "outside investor" which may include such entities as another company, or an investor. It does not include the owners or family members, or affiliates of the small business (13 CFR 121.103).

4.7 Commercialization Pilot Program

DARPA does not participate in the Commercialization Pilot Program (CPP); however, DARPA has established a Transition Support Pilot Program focused on transitioning innovative technologies to the most critical U.S. military end-users as well as key collaboration partners. This program will also support transitions within DARPA, civilian agencies, and private-sector, if deemed critical for technology transition success. The program, administered by the DARPA Small Business Programs Office with support from The Foundation for Enterprise Development (The Foundation), a U.S. owned non-profit organization, consists of the following assistance:

- Transition Assistance. The Foundation will provide DARPA funded SBIR Phase II companies identified to participate in the Pilot with guidance and assistance in identifying and facilitating introductions to potential collaborators, funding sources, and end users, in support of SBIR Company's Phase III technology development activities. Thus, identification of potential funding sources will be primarily focused on enabling the SBIR Company to work towards reaching Technology Readiness Level (TRL) 7 – System prototype demonstration in an operational environment. Specific potential funding sources will be identified throughout a designated period of transition support and may include, but are not limited to:
  - DARPA
  - Other DoD research programs (e.g.: Army, Navy, Air Force, Marine Corps)
  - Prime contractor programs, to include their Independent Research & Development (IR&D) programs
  - Non-DoD Federal research programs in the Intelligence agencies and the Department of Homeland Security
  - Other non-DoD Federal research programs, such as those within National Institutes of Health
  - Other DoD-funded technology transition programs as appropriate (e.g., Technology Transition Initiative, Defense Acquisition Challenge, TechLink and TechMatch)
  - Venture capital funding sources

To be eligible for assistance, the SBIR Company must have an active Phase II, expected technology readiness level of 5 or greater at the completion of Phase II, and understanding of and progress within the expected transition path or paths. DARPA retains the discretion to not select a company. Each identified company will execute a Technology Transition Agreement with the contractor to initiate support. Participation in the DARPA Technology Transition Pilot Program is voluntary.

- All obligations of the SBIR Company shall be carried out <u>at no cost to The Foundation or DARPA and are not billable to any SBIR contract.</u> The SBIR Company shall make relevant experts reasonably available to The Foundation to discuss potential application areas for the technology under development and to support the execution of the technology transition support services described above. The SBIR Company also shall make its relevant experts available for follow-up discussions and briefings with potential collaborators or representatives from federal or other potential funding sources. As appropriate, the SBIR Company will develop appropriate company profiles, briefings and other types of informational materials to support discussions and briefings. SBIR companies involved in the transition pilot will be asked for feedback on the

assistance provided upon completion of the Phase II and on transition outcomes within the year following the Phase II.

- Success Reports: The Foundation will document company Phase III transition successes individualized reports as well as or other printed material for distribution at outreach events and for posting on the DARPA SBPO Web site. SBIR companies that have received Phase III funding are eligible to work with The Foundation to develop the success report. Cleared Success Reports will continue to be posted on the DARPA SBPO Web site. The DARPA SBIR Success Reports can be viewed at this link: http://www.darpa.mil/sbpo/success/index.html

- Outreach/Process Improvement: The Foundation will capture lessons learned, program feedback and best practices from SBIR companies, and will help develop and implement process improvements to increase transition success for DARPA SBIR funded companies. Transition outreach includes panel presentation and one-on-one meetings at relevant SBIR conferences. Additional transition–related documentation and links will be available upon request and via the SBPO web site in the future. All active DARPA SBIR companies are eligible for this outreach support.

- Phase III transition support is subject to the availability of funds.

5.1.b. Type of Funding Agreement (Phase I)

- DARPA Phase I awards will be Firm Fixed Price contracts.
- Companies that choose to collaborate with a University must highlight the research that is being performed by the University and verify that the work is FUNDAMENTAL RESEARCH.
- Companies are strongly encouraged to pursue implementing a government acceptable cost accounting system during the Phase I project to avoid delay in receiving a Phase II award. Visit www.dcaa.mil and download the "Information for Contractors" guide for more information.

5.1.c. Average Dollar Value of Awards (Phase I)

DARPA Phase I proposals **shall not exceed $150,000,** and are generally 6 months in duration.

5.2.b. Type of Funding Agreement (Phase II)

- DARPA Phase II awards are typically Cost-Plus-Fixed-Fee contracts; however, DARPA may choose to award a Firm Fixed Price Phase II contract or an Other Transaction (OT) on a case-by-case basis. Visit http://www.darpa.mil/sbpo/ot/index.html for more information on Other Transactions.
- Companies are advised to continue pursuit of implementation of a government acceptable cost accounting system in order to facilitate their eligibility for future government contracts.
- Companies that choose to collaborate with a university must highlight the research that is being performed by the university and verify that the work is FUNDAMENTAL RESEARCH.

5.2.c. Average Dollar Value of Awards (Phase II)

DARPA Phase II proposals should be structured as a 24 month effort in two equal increments of approximately $500,000 each. The entire Phase II base effort should generally not exceed $1,000,000.

5.3 Phase I Report

All DARPA Phase I and Phase II awardees are required to submit a final report, which is due within 60 days following completion of the technical period of performance and must be provided to the individuals identified in Exhibit A of the contract. Please contact your contracting officer immediately if your final report may be delayed.

5.11.r. 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.pmddtc.state.gov/regulations_laws/itar.html for more detailed information regarding ITAR requirements.

5.11.s. Publication Approval (Public Release)
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/prc/index.html for additional information and applicable publication approval procedures. Visit http://dtsn.darpa.mil/fundamentalresearch/ to verify whether or not your award has a pre-publication review requirement.

5.14.h. Human and/or Animal Use
This solicitation may contain topics that 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 will most likely not be 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 Phase II award. Please visit http://www.darpa.mil/sbpo/docs/SBIR_STTRs_Human_Animal.pdf to review the Human and Animal Use PowerPoint presentation(s) to understand what is required to comply with human and/or animal protocols.

- **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* http://www.access.gpo.gov/nara/cfr/waisidx_07/32cfr219_07.html) and 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 subjects research until ALL approvals are granted.

- **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.

6.3 Notification of Proposal Receipt
DARPA will send each offeror an e-mail acknowledging receipt of proposal after the solicitation closing date.

6.4 Information on Proposal Status
All letters notifying offerors of selection or non-selection will be sent via e-mail to the person listed as the “Corporate Official” on the proposal.

6.5 Debriefing of Unsuccessful Offerors
DARPA will provide debriefings to offerors in accordance with FAR Subpart 15.5. Once the source selection is complete, the Corporate Official (CO) indicated on the Proposal Coversheet will receive an e-mail regarding proposal status. The notification letter will provide instructions regarding the ability to request a proposal debriefing. Small Businesses will receive a notification for each proposal submitted. Please read each notification carefully and note the proposal number and topic number referenced. All communication from the DARPA SBIR/STTR Program management will originate from the sbir@darpa.mil e-mail address. Please white-list this address in your company’s spam filters to ensure timely receipt of communications from our office.

DARPA SBIR 11.1 Topic Index

SB111-001	Sampling and Reagent Technologies for Point of Care Diagnostics
SB111-002	Novel Molecular Approaches to Discover and Identify Bacterial Virulence Factors
SB111-003	Anomaly Detection At Multiple Scales (ADAMS)
SB111-004	VHF/UHF Emitter location from micro Unmanned Aerial Systems

DARPA SBIR 11.1 Topic Descriptions

SB111-001 TITLE: Sampling and Reagent Technologies for Point of Care Diagnostics

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: To develop innovative methods, materials, and devices for improved collection, specificity, and long-term reagent storage for point of care diagnostics.

DESCRIPTION: Advances in miniaturized devices will facilitate development of portable instruments applicable to point of care human diagnostics. State of the art methods still cannot attain clinical grade sensitivity and specificity while having portability, long-term storage capability (e.g., for protein based immunoassays) and minimum sample preparation. In addition, challenges still exist for sample collection without trained medical personnel that minimize loss of analytes. Proposals may address all or one of the following aspects described below: 1) sample collection, 2) highly specific and stable recognition molecules, 3) reagent storage. All proposed methods should enable low/no power operation, Clinical Laboratory Improvement Amendment (CLIA)-waved analysis, and good manufacturing practice (GMP) procedures.

1) Typically, blood is the biological sample of choice for diagnostics. Minimally invasive collection often relies on a finger prick and capillary collection. Since a small volume is collected, any loss of analyte in transfer from collector to transducer decreases probability of detection. Therefore, innovative methods for minimally-invasive, simple to operate, high efficiency sample collection are needed, such as highly non-fouling surfaces or efficient concentration methods. Proposals should address the patient interface, sample collection, and sample delivery to the analysis device. Collection methods that increase the sample volumes that may be collected in a CLIA-waved device are encouraged.

2) Development of long-term, stable, reagents is also critical for deployment of analysis devices for point-of-care diagnostics. We seek proposals that exploit recent innovations in high-performance stable molecular recognition elements (e.g., aptamers, pseudo-knots, hairpins, DNA-enzymes) together with labeling scheme internal to the recognition element while exhibiting high stability and signal strength. These molecular structures can be stored for long periods and undergo highly specific conformational changes upon binding of the target analyte, reducing the confounding variable of non-specific adsorption to the transducer, ubiquitous in complex biological matrices. Any transduction scheme is acceptable (e.g., optical, electrical, mechanical magnetic). The requirement of any proposed approach is that the signal change be specifically associated with the conformation change (increasing specificity) and that it can be used with a low power system and with negligible degradation over time (e.g., for optical approaches a pair of gold nanoparticles whose spectral properties change upon binding can have 6 orders of magnitude greater signal strength at the same optical power and detection efficiency vs. organic fluorophores and even larger differential stability).

3) For reagent storage, fluids of interest are those required for commonly used sample preparation methods (lysis, protein purification, nucleic acid purification) and sensing/assay methods (e.g., immunoassays, nucleic acid amplification and/or detection, small molecule detection). Dried reagent storage may be included. Proposals should address methods for dispensing or release of the stored reagents for use in the analysis device. Bioanalysis frequently requires dispensing of reagents at different times and or locations on a device. Therefore, proposals should describe the ability of dispensing methods to address such needs. Storage formats/devices should be compatible with miniaturized analysis devices. Total storage volume will be dependent on analysis to be run. Proposers are encouraged to describe the potential volume-based design variations.

PHASE I:
1) Develop approaches for blood sample collection methods and quantitative recovery of the critical analytes from the sample collector using standard laboratory assays. The proposer should choose a clinically relevant analyte of interest that is currently challenging to recover due to its low concentration in blood (e.g., aM-pM), and demonstrate an increased recovery of this analyte in an appropriate volume as compared to standard collection methods, such as the capillary (using the same collection volume, or a CLIA-waiver compatible larger volume).

2) Demonstrate highly-specific detection of the target analyte with the recognition element in the presence of other "background" molecules that non-specifically adsorb to the surface of the transducer. Quantification of clinically relevant concentration of an analyte in the presence of serum must be demonstrated. The selected target molecules of choice (protein, nucleic acids), should be DoD relevant and not limited to trivial examples such as biotin-streptavidin or BSA. Molecules of interest would include cortisol, toxins, nucleic acids and various proteins.

3) Develop innovative approaches for reagent storage and/or dispersing methods. They should be DoD relevant (see 2 above) and demonstrate progress to suggest feasibility of storage for> 1 month at a variety of temperatures (~20-37 degree C).

PHASE II:
1) Validate feasibility of the method developed in Phase I with a practical protocol that can be used by untrained personnel within a relevant time frame for sample collection and delivery needs for point of care diagnostics (~ 10-20 minutes). Provide a detailed plan for integrating the proposed methods for processing and sample analysis post collection, with other requisite technologies for a point of care diagnostic device. Demonstrate quantification of 2 or more analytes in whole blood previously not quantifiable with existing CLIA-waived collection methods.

2) Demonstrate quantification of 2 or more biomarkers in whole blood over 6 orders of magnitude in concentration with clinically relevant sensitivity and specificity.

3) Design, develop and demonstrate a complete reagent storage unit/device for reagent release/dispensing using standard assays or analyses on the reagents that have been stored at multiple temperatures for at least 1 month in the designed storage packaging/device. Demonstration of integration/compatibility with micro analysis devices is encouraged. Six (6) months storage should be initiated within the two-year performance period and testing plans developed. The stored reagents should be able to quantify at least 2 biomarkers in whole blood with standard analytical techniques and should be compared with fresh reagents to demonstrate equivalent clinical performance (limit of detection, sensitivity, specificity).

PHASE III: The technology to be developed is applicable to deployable medical diagnostics. Transition customers include DTRA and JPEO. There is a significant commercial market for medical diagnostics companies that provide products for glucose monitoring, and pregnancy testing. The developed technology would allow expansion of home diagnostic tests and any steps taken to achieve a CLIA-waiver would greatly facilitate transition to market.

REFERENCES:
1. CLIA: http://wwwn.cdc.gov/clia/regs/toc.aspx

KEYWORDS: Blood, Sample Collection, Microfluidics, Point-of-care, Diagnostics, CLIA-waved

SB111-002 TITLE: Novel Molecular Approaches to Discover and Identify Bacterial Virulence Factors

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Establish rapid approaches to identify novel or previously undiscovered mechanisms utilized by bacteria that promote pathogenesis.

DESCRIPTION: The number of multi-resistant microorganisms and the dwindling pipeline of efficacious antibiotics pose a substantial threat to human health. We are now entering a post-antibiotic era where alternative strategies need to be investigated to discover inhibitors of bacterial virulence rather than bacterial growth. This strategy will exert mild evolutionary pressure on bacteria and subsequently lower probability of resistance. The discovery of new virulence factors of bacteria is key to the understanding of pathogenesis and to the identification of new targets for therapeutics, vaccines and drugs. This is true for known pathogens as well as emerging and genetically modified organisms. With the emergence of the genomic era, the field of bacterial pathogenesis has advanced rapidly over the last two decades. Microbial genomic investigations have identified traditional virulence

factors for many pathogens. However, genomic investigations can only identify factors of known virulence importance and are dependent on whole genome analysis. For many organisms, the exact mechanisms of pathogenesis still remain a mystery. Thus new methods and platforms for the rapid identification of virulence factors using post-genomic technologies are needed.

Virulence factors comprise a broad range of bacterial components from proteins and peptides to polysaccharides. Many of these function in bacterial adherence, colonization, interaction with host immune factors and invasion of the host mucosal surface - among others. They may be attached to the surface of the pathogen or released into the extracellular environment. Current studies in the identification of virulence mechanisms can be slow and tedious. The development of rapid, preferably high throughput methods for the identification of potential virulence factors would significantly speed the pace of discovery and the development of new treatment options.

An innovative solution that will rapidly identify mechanisms of virulence for pathogenic bacteria is requested. The ideal system would be one that isolates and identifies virulence factors without bias with consideration that such factors often directly interact with the host or host environment. The solution will identify lead candidate factors across a wide range of functions (i.e., bacterial adherence, host immune interaction, resistance to host effects, etc). It will utilize state-of-the-art methods in a rapid and cost effective manner and will result in a detailed characterization of each candidate virulence factor that can be used for follow-on validation and development. The proposed team should have expertise in infectious diseases, especially agents of biodefense significance, microbial pathogenesis, and virulence factor discovery.

PHASE I: Develop an approach to rapidly identify virulence factors of pathogenic bacteria. Determine technical feasibility of the approach using a model bacterium of DoD relevance and demonstrate identification of known virulence factors. The feasibility platform should focus on at least one virulence mechanism (i.e., bacterial adherence, toxin activity, stimulation or suppression of host immune factors, etc). Proposed approaches may use a combination of known techniques not currently combined into a single system or may utilize novel techniques.

PHASE II: Expand the platform developed in Phase I to include screening of multiple virulence mechanisms and/or multiple bacteria. Establish a plan and implement high throughput methods and cataloging of results. Phase II should culminate in an operational platform/system for rapid virulence factor discovery with a target TRL 4-5.

PHASE III: Final development of an integrated technology platform to screen for virulence factors of submitted bacteria, bacterial components, or recombinant bacterial proteins. Civilian and military efforts would benefit from this integrated solution as a commercial source of novel virulence factor discovery for screening of new therapeutic and drug targets. Treatment of antibiotic resistant infections.

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KEYWORDS: Antibiotic resistance, virulence factors, bacteria, biodefense, drug target discovery

SB111-003 TITLE: Anomaly Detection At Multiple Scales (ADAMS)

TECHNOLOGY AREAS: Information Systems

The technology within this topic is restricted under the International Traffic in Arms Regulation (ITAR), which controls the export and import of defense-related material and services. Offerors must disclose any proposed use of foreign nationals, their country of origin, and what tasks each would accomplish in the statement of work in accordance with section 3.5.b.(7) of the solicitation.

OBJECTIVE: Develop methods, tools, and techniques to model, measure, monitor and mitigate insider threat. For the purpose of this topic, we define insider threat as malevolent (or possibly inadvertent) actions by an already trusted person in a secure environment with access to sensitive information and information systems and sources.

DESCRIPTION: Information systems security and counter-intelligence personnel are drowning in ever expanding oceans of observational data from heterogeneous sources and sensors from which they must extract indicators of increasingly sophisticated malicious insider behavior. They are currently only able to use this data reactively – they can use the data to help investigate and resolve suspicions they develop by more traditional means. A major goal of this topic is to enable investigators to use the data proactively as a basis for developing suspicions and to observe precursors to malicious behavior and potentially stop it before it occurs. The fundamental challenge is one of finding a poorly understood, subtle, or hidden signal (indicators of malicious behavior) buried in enormous amounts of noise (observational data of no immediate relevance) under the constraint that the measures of significance are themselves moving targets (based on dynamic context) that must be continually monitored and updated. A significant part of that challenge is detecting deceptive behavior that is characteristic of malicious intent. The first step in meeting this challenge is to create a scalable, distributed infrastructure to securely collect, store, access, process, and correlate relevant data from heterogeneous sources over extended periods of time. The next step is to determine whether an individual or group of individuals is exhibiting anomalous behavior that is also malicious. However, this analysis is very heavily dependent on the context of the individual, groups of individuals and any data involved. Furthermore, context (e.g., location, time, roles and relations) is dynamic and so must be continually inferred, managed and applied automatically.

In both the real and virtual world, it is very difficult to do anything without leaving some evidence behind. Attempts to conceal or remove evidence generally create new evidence that, if detected, could be a strong indication of the perpetrator's intent. Looking for such evidence could potentially be easier than recognizing explicit attacks. Forensic-like techniques can be used to find clues, gather and evaluate evidence and combine them deductively. Security is often difficult because the defenses must be perfect, while the attacker needs to find only one flaw. An emphasis on forensics could reverse the burden by requiring the attacker and his tools to be perfect, while the defender needs only a few clues to recognize an intrusion is underway. Techniques of interest to this topic include, but are not limited to, techniques to (a) derive information about the relationship between deductions, the likely intent of inferred actions, and suggestions about what evidence might mean and (b) dynamically forecast context-dependent behaviors – both malicious and non-malicious. Also of interest are on-line and off-line algorithms for feature extraction and detection in enormous graphs (as in billions of nodes) as well as hybrid engines where deduction and feature detection mutually inform one another and novel host based sensors.

Sensors developed for this topic might have, but are not limited to, the following characteristics:

- Unobtrusive and host-based in order to capture the comprehensive range of human interaction with computer endpoints, to include all keystroke activity, communication vectors, application usage, processes and use of removable media.
- Provide unambiguous and irrefutable attribution of all computer end-user activity and context to discern malicious and benign intent as well as detect concealment techniques.
- Enable researchers to apply tailored, policy-based rule sets against the computer endpoints and seamlessly reconfigure them to ensure the quality and integrity of data collected and to dynamically test and evaluate new hypotheses. These granular controls are critical in helping an organization employ a risk management model to prioritize audit of the highest risk behaviors, individuals and assets in the enterprise and eliminate false positives to ensure the analyst is not overwhelmed by a "data dump" of information.

NOTE: This topic is considered sensitive under the International Traffic in Arms Regulation (ITAR) and the technology developed under this topic is subject to the Export Control Act. Please visit www.pmddtc.state.gov/regulations_laws/itar.html for more detailed information regarding ITAR requirements.

PHASE I: Define the scope of the proposed effort by identifying, describing, justifying, designing and prototyping software with capabilities in one or more of the following areas: (1) host based sensors, (2) cyber and behavioral sensor data alignment, correlation, fusion, and information extraction, (3) behavioral modeling and anomaly detection to enable understanding normal patterns and to detect deviations characteristic of activities at individual, group and organizational levels, and (4) sensor data processing, exploitation, and understanding that leverage the complementary strengths of humans and machines in order to proactively reduce the enormous volumes of data to actionable information. Proposers should describe the types of data that they will provide and use to facilitate the development and evaluation of their proposed prototypes.

PHASE II: Develop and optimize, using analytic and computational techniques as appropriate, detailed algorithmic approaches and implementations of software prototypes developed in Phase I. Plan, design, construct, execute and evaluate verification and validation testing (evaluation methods and metrics) of developed software under realistic conditions of load and scale. Proposers should describe the types of data that they will provide and use to facilitate the development and evaluation of their proposed software. At the conclusion of Phase II algorithms and software should meet or exceed Transition Readiness Level 5 (System/subsystem/component validation in relevant environment).

PHASE III: In Phase III, delivery of mature software to targeted intelligence and military systems is expected. The techniques developed under this topic will also have direct applicability to insider threat detection in critical infrastructure systems such as financial systems.

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KEYWORDS: counter-intelligence, intelligence, insider, threat, sensor, information, process, detect, track, classify, exploit, correlate, cue

SB111-004 TITLE: VHF/UHF Emitter location from micro Unmanned Aerial Systems

TECHNOLOGY AREAS: Sensors, Electronics

The technology within this topic is restricted under the International Traffic in Arms Regulation (ITAR), which controls the export and import of defense-related material and services. Offerors must disclose any proposed use of foreign nationals, their country of origin, and what tasks each would accomplish in the statement of work in accordance with section 3.5.b.(7) of the solicitation.

OBJECTIVE: Develop and demonstrate a tactical emitter-location system that could be flown on a miniature unmanned aircraft system (UAS) such as the WASP-III micro-UAV (MAV) or Scan Eagle and detect and locate VHF/UHF emitters in real-time.

DESCRIPTION: Miniature UASs such as WASP-III and Scan Eagle are platforms that have the potential to provide situational awareness at the tactical level by detecting and locating emitters in the UHF band. Of particular concern are UHF push-to-talk radios and high power cordless phones. There are no systems that can provide accurate emitter location at the tactical level. The goal is to develop and demonstrate an emitter location system that operates on one or more UAS aircraft such as the WASP-III or Scan Eagle and to provide the tactical user with real-time day/night all-weather alerting and cuing capability to prevent surprise and enable timely countermeasures. The ultimate goal is for an emitter location system that can cover a radius of at least 2 km, over which it can detect VHF/UHF emitters and provide an emitter geo-location accuracy of 100 m with 95% confidence in approximately 10 seconds. Single platform and multiple platform solutions are both of interest. This effort will require innovative antenna designs to provide the desired bandwidth and antenna coverage and fit within the extremely limited space available on a small UAS. Novel emitter location algorithms will also be required to provide the required geo-location accuracy. The design will also require advanced extremely low power high dynamic range receiver technology and computationally efficient processing approaches to fit within the power budget available on a small UAS.

PHASE I: Develop a system concept for a VHF/UHF emitter detection and location system that can be flown on a WASP-III or Scan Eagle class small UAS aircraft. Single aircraft and multiple aircraft systems are both of interest. Vehicle payload interface control documents for these UAS aircraft will be provided as government furnished information. The Phase I tasks include:

• Task 1: Develop a variety of system architecture concepts, such as using a pair of WASP-III vehicles or a single Scan Eagle.

• Task 2: Develop a design for an innovative lightweight antenna that can be installed on the small UAS and provide coverage over the VHF/UHF band at a nominal vertical polarization with coverage of 360 in azimuth and from 75 to 15 degrees grazing angle. Figures of merit for the antenna include bandwidth, gain, angular coverage and ability to direction find.

• Task 3: Develop signal processing concepts for an emitter location system and predict achievable accuracy. Design considerations include on board processing, the amount of data that must be transmitted down the WASP data link, methods of maintaining positional and clock alignment required, time to achieve required direction-finding accuracy and the impact of environmental noise and the density of the signals in regions where these aircraft would operate.

• Task 4: Develop a hardware design concept for the airborne system, including receiver and onboard signal processor. Design considerations include size, weight and power budget.

• Task 5: Identify key risks or hardware considerations.

Deliverable is a final report that describes the system architecture content, the antenna design and predicted performance, a description of the emitter algorithm and predicted detection and location accuracy, the system hardware concept (including size, weight and power budgets), and identification of key risks and hardware considerations.

PHASE II: Develop and demonstrate a prototype airborne emitter location system. The prototype emitter location system will be designed, fabricated and installed on the target UAS and then flown in a proof of principle test to validate the design and demonstrate the feasibility of the approach. The prototype system will not necessarily have the entire suite of capabilities desired in the objective system, but will have sufficient capability to verify performance and demonstrate the feasibility of the approach. Based on the results of the proof of principle test, develop the hardware and software design for an objective system that would meet all the objective system requirements. The government may have a UAS aircraft available, and if so this will be provided to the performer as government furnished equipment, however the performer must plan the contingency that no aircraft is available and thus the performer must purchase or rent the appropriate UAS.

• Task 1: Design, fabricate and integrate the prototype emitter detection system components, including airborne and ground subsystems, and conduct laboratory tests to validate the prototype subsystems function properly in the laboratory.

• Task 2: Install the prototype airborne payload on the target UAS and conduct airborne data collections to validate performance models and demonstrate the feasibility of the approach. As noted above, the prototype system is not required to meet the entire suite of objective system requirements, but must validate the overall design and demonstrate that the desired objective requirements are achievable.

• Task 3: Develop system design for the objective system that has the capability of meeting all system requirements.

Deliverables include: Interface Control Document for the airborne payload interface to the UAS, laboratory test plan, laboratory test report, integration plan, data collection plan, data collection report, objective system design, and prototype emitter payload and ground system.

PHASE III: The most likely transition path is that the Army would develop an operation system that could provide airborne VHF/UHF emitter location at the tactical level. This may take the form of a single payload on a Scan Eagle

class UAS, or multiple payloads on two or more WASP-III class UAS platforms. Additional possibilities include development of emitter location system for homeland security operations such as border surveillance or perimeter surveillance for important facilities. For example, a potential commercial system might be a airborne emitter location system that could around perimeter of a large facility or property and provide autonomous detection and location of emitters to detect intruders or other unauthorized access.

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KEYWORDS: UAS, ELINT, SIGINT, UHF, DF, Direction Finding, WASP-III, Scan Eagle