DEPARTMENT OF THE AIR FORCE (DAF)
23.A SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) Phase I
PROPOSAL PREPARATION INSTRUCTIONS

The DAF intends these Phase I proposal submission instructions to clarify the Department of Defense (DoD) Broad Agency Announcement (BAA) as it applies to the topics solicited herein. **Firms must ensure proposals meet all requirements of the 23.A STTR BAA posted on the DoD SBIR/STTR Innovation Portal (DSIP) at the proposal submission deadline date/time.**

Complete proposals **must** be prepared and submitted via https://www.dodsbirsttr.mil/submissions/ (DSIP) on or before the date published in the DoD 23.A STTR BAA. Offerers are responsible for ensuring proposals comply with the requirements in the most current version of this instruction at the proposal submission deadline date/time.

The DAF recommends early submission, as computer traffic gets heavy near the proposal submission date/time and could slow down the system. **Do not wait until the last minute.** The DAF is not responsible for incomplete proposal submission due to system lag or inaccessibility. Please ensure contact information, i.e., names/phone numbers/email addresses, in the proposal is current and accurate. The DAF is not responsible for ensuring notifications are received by firms for which this information changes after proposal submission without proper notification. Changes of this nature shall be sent to the Air Force SBIR/STTR One Help Desk.

Please ensure all e-mail addresses listed in the proposal are current and accurate. The DAF is not responsible for ensuring notifications are received by firms changing mailing address/e-mail address/company points of contact after proposal submission without proper notification to the DAF. **If changes occur to the company mail or email addresses or points of contact after proposal submission, the information must be provided to the AF SBIR/STTR One Help Desk.** The message shall include the subject line, "23.A Address Change".

Points of Contact:

- General information related to the AF SBIR/STTR program and proposal preparation instructions, contact the AF SBIR/STTR One Help Desk at usaf.team@afsbirsttr.us.
- Questions regarding the DSIP electronic submission system, contact the DoD SBIR/STTR Help Desk at dodsbirsupport@reisystems.com.
- For technical questions about the topics during the pre-announcement and open period, please reference the DoD 23.A STTR BAA.
- Air Force SBIR/STTR BAA Contracting Officers (CO):
    - Mr. Daniel Brewer, Daniel.Brewer.13@us.af.mil

General information related to the AF Small Business Program can be found at the AF Small Business website, http://www.airforcesmallbiz.af.mil/. The site contains information related to contracting opportunities within the AF, as well as business information and upcoming outreach events. Other informative sites include those for the Small Business Administration (SBA), www.sba.gov, and the Procurement Technical Assistance Centers (PTACs), http://www.aptacus.us.org. These centers provide Government contracting assistance and guidance to small businesses, generally at no cost.

PHASE I PROPOSAL SUBMISSION

DoD 23.A STTR BAA, https://www.dodsbirsttr.mil/submissions/login, includes all program requirements. Phase I efforts should address the feasibility of a solution to the selected topic's

requirements. See Chart 1 (DAF-1) for proposal dollar values, periods of performance, and technical volume content.

Limitations on Length of Proposal

The Phase I Technical Volume page limits do not include the Cover Sheet, Cost Volume, Cost Volume Itemized Listing (a-j). The Technical Volume must be no smaller than 10-point on standard 8-1/2" x 11" paper with one-inch margins. Only the Technical Volume and any enclosures or attachments count toward the page limit. In the interest of equity, pages/slides in excess of the stated limits will not be reviewed.. The documents required for upload into Volume 5, "Other", do not count toward the specified limits.

Phase I Proposal Format

Proposal Cover Sheet: If selected for funding, the proposal's technical abstract and discussion of anticipated benefits will be publicly released. Therefore, do not include proprietary information in these sections.

Technical Volume: The Technical Volume should include all graphics and attachments but should not include the Cover Sheet, which is completed separately. Phase I technical volume (uploaded in Volume 2) shall contain the required elements found in Chart 1. Make sure all graphics are distinguishable in black and white.

Key Personnel: Identify in the Technical Volume all key personnel who will be involved in this project; include information on directly related education, experience, and citizenship.

- A technical resume of the Principal Investigator, including a list of publications, if any, must be included.
- Concise technical resumes for subcontractors and consultants, if any, are also useful.
- Identify all U.S. permanent residents to be involved in the project as direct employees, subcontractors, or consultants.
- Identify all non-U.S. citizens expected to be involved in the project as direct employees, subcontractors, or consultants. For all non-U.S. citizens, in addition to technical resumes, please provide countries of origin, the type of visa or work permit under which they are performing and an explanation of their anticipated level of involvement on this project, as appropriate. Additional information may be requested during negotiations in order to verify the foreign citizen's eligibility to participate on a contract issued as a result of this announcement.
- **Note:** Do not upload information such as Permanent Resident Cards (Green Cards), birth certificates, Social Security Numbers, or other PII to the DSIP system.

Phase I Work Plan Outline

NOTE: The DAF uses the Phase I Work Plan Outline in lieu of a Statement of Work (SOW). DO NOT include proprietary information in the Work Plan Outline. To do so will necessitate a request for revision, if selected, and may delay contract award.

In the Work Plan section, start with a Work Plan Outline in the following format:

1) Scope: List the major requirements and specifications of the effort.
2) Task Outline: Provide a brief outline of the work to be accomplished over the span of the Phase I effort.
3) Milestone Schedule
4) Deliverables
    a. Kickoff meeting within 30 days of contract start

b. Progress reports
c. Technical review within 6 months
d. Final report with SF 298

Cost Volume: Cost information should be provided by completing the Cost Volume in DSIP and including the Cost Volume Itemized Listing specified below. The Cost Volume detail must be adequate to enable Air Force personnel to determine the purpose, necessity and reasonability of each cost element. Provide sufficient information (a-i below) regarding funds use if an award is received. The DSIP Cost Volume and Itemized Cost Volume Information will not count against the specified page limit. The itemized listing may be submitted in Volume 5 under the "Other" dropdown option.

a. **Special Tooling, Special Test Equipment, and Material**: The inclusion of equipment and materials will be carefully reviewed relative to need and appropriateness to the work proposed. Special tooling and special test equipment purchases must, in the CO's opinion, be advantageous to the Government and relate directly to the effort. These toolings or equipment should not be of a type that an offeror would otherwise possess in the normal course of business. These may include such items as innovative instrumentation and/or automatic test equipment.

b. **Direct Cost Materials**: Justify costs for materials, parts, and supplies with an itemized list containing types, quantities, prices and where appropriate, purpose. Material costs may include the costs of such items as raw materials, parts, subassemblies, components, and manufacturing supplies.

c. **Other Direct Costs**: This category includes, but it not limited to, specialized services such as machining, milling, special testing or analysis, and costs incurred in temporarily using specialized equipment. Proposals including leased hardware must include an adequate lease vs. purchase justification.

d. **Direct Labor**: Identify key personnel by name and labor category, if possible. Direct labor hours, labor overhead and/or fringe benefits, and actual hourly rates for each individual are also necessary for the CO to determine whether these hours, fringe rates, and hourly rates are fair and reasonable.

e. **Travel**: Travel costs must relate to project needs. Break out travel costs by trip, number of travelers, airfare, per diem, lodging, etc. The number of trips required, as well as the destination and purpose of each, should be reflected. Recommend budgeting at least one trip to the Air Force location managing the contract.

f. **Subcontracts**: Involvement of a research institution in the project is required. Involvement of other subcontractors or consultants may also be desired. Describe in detail the tasks to be performed in the Technical Volume and include information in the Cost Volume for the research institution and any other subcontractors/consultants. The proposing SBC must perform a minimum of 40% of the Phase I R/R&D and the research institution must perform a minimum of 30%. Work allocation is measured by direct and indirect costs AFTER REMOVAL OF THE SBC's PROPOSED PROFIT. This work allocation requirement is codified in statute; therefore, the Government CO cannot waive it. STTR efforts may include subcontracts with Federal Laboratories and Federally Funded Research and Development Centers (FFRDCs). NOTE: Not all Federal Laboratories or FFRDCs qualify as research institutions.

Support subcontract costs with copies of executed agreements. The supporting agreement documents must adequately describe the work to be performed. At a minimum, each planned subcontractor's information must include a SOW with a corresponding detailed cost proposal.

g. **Consultants**: Provide a separate agreement letter for each consultant. The letter should briefly state what service or assistance will be provided, the number of hours required, and hourly or daily rate.

h. **DD Form 2345**: For proposals submitted under export-controlled topics, either by International Traffic in Arms or Export Administration Regulations (ITAR/EAR), a copy of a certified DD Form 2345, Militarily Critical Technical Data Agreement, or evidence of application submission must be included. The form, instructions, and FAQs may be found at the United States/Canada Joint Certification Program website, http://www.dla.mil/HQ/InformationOperations/Offers/Products/LogisticsApplications/JCP/DD2345Instructions.aspx. The DD Form 2345 must be approved prior to award if proposal is selected for negotiations and funding.

NOTE: Restrictive notices notwithstanding, proposals may be handled for administrative purposes only, by support contractors TEC Solutions, Inc., APEX, Oasis Systems, Riverside Research, Peerless Technologies, HPC-COM, Mile Two, Montech, Wright Brothers Institute, and MacB (an Alion Company). In addition, only Government employees and technical personnel from Federally Funded Research and Development Centers (FFRDCs) MITRE and Aerospace Corporations working under contract to provide technical support to AF Life Cycle Management Center and Space and Missiles Centers may evaluate proposals. All support contractors are bound by appropriate non-disclosure agreements. Please contact one of the Contracting Officer identified on A-1 with any concerns.

i. **Cost Sharing**: Cost share is not accepted as part of Phase I proposals.

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

DISCRETIONARY TECHNICAL AND BUSINESS ASSISTANCE (TABA)

The DAF does not participate in the Discretionary Technical and Business Assistance (TABA) Program. Proposals in response to Air Force topics should not include TABA.

PHASE I PROPOSAL SUBMISSION CHECKLIST

Firms shall register in the System for Award Management (SAM) at https://www.sam.gov/, to be eligible for proposal acceptance. Follow instructions located in SAM to obtain a Commercial and Government Entity (CAGE) code and Unique Entity Identifier (UEI) number. Firms shall also verify "Purpose of Registration" is set to "I want to be able to bid on federal contracts or other procurement opportunities. I also want to be able to apply for grants, loans, and other financial assistance programs", NOT "I only want to apply for federal assistance opportunities like grants, loans, and other financial assistance programs." Firms registered to compete for federal assistance opportunities only at the time of proposal submission will not be considered for award. Addresses must be consistent between the proposal and SAM at award. Previously registered firms are advised to access SAM to ensure all company data is current before proposal submission and, if selected, award.

Please note the FWA Training must be completed prior to proposal submission. When training is complete and certified, DSIP will indicate completion of the Volume 6 requirement. The proposal cannot be submitted until the training is complete. The AF recommends completing submission early, as site traffic is heavy prior to solicitation close, causing system lag. **Do not wait until the last minute.** The DAF will not be responsible for proposals not completely submitted prior to the deadline due to system inaccessibility unless advised by DoD. The DAF will not accept alternative means of submission outside of DSIP, and transmission of proposal materials by way of alternative means will not constitute successful submission on the applicant's part.

AIR FORCE PROPOSAL EVALUATIONS

The DAF will utilize the Phase I proposal evaluation criteria in the DoD 23.A STTR BAA with the factors in descending order of importance.

The DAF will utilize Phase II evaluation criteria in the DoD 23.A STTR BAA with the factors in descending order of importance.

Proposal Status and Feedback

The Principal Investigator (PI) and Corporate Official (CO) indicated on the Proposal Cover Sheet will be notified by e-mail regarding proposal selection or non-selection. Small Businesses will receive a notification for each proposal submitted. Please read each notification carefully and note the Proposal Number and Topic Number referenced.

Automated feedback will be provided for Phase I proposals determined Not Selected. Additional feedback may be provided at the sole discretion of the DAF.

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IMPORTANT: Proposals submitted to the DAF are received and evaluated by different organizations, handled topic by topic. Each organization operates within its own schedule for proposal evaluation and selection**.** Updates and notification timeframes will vary. If contacted regarding a proposal submission, it is not necessary to request information regarding additional submissions. Separate notifications are provided for each proposal.

It is anticipated all the proposals will be evaluated and selections finalized within approximately 90 calendar days of solicitation close. Please refrain from contacting the BAA COs for proposal status before that time.

Refer to the DoD STTR Program BAA for procedures to protest the Announcement.
As further prescribed in FAR 33.106(b), FAR 52.233-3, Protests after Award should be submitted to: Air Force SBIR/STTR BAA Contracting Officer Daniel Brewer, Daniel.Brewer.13@us.af.mil.

AIR FORCE SUBMISSION OF FINAL REPORTS

All final reports will be submitted to the awarding DAF organization in accordance with the purchase order or contract. Companies will not submit Final Reports directly to the Defense Technical Information Center (DTIC).

PHASE II PROPOSAL SUBMISSIONS

DAF organizations may request Phase II proposals while technical performance is on-going. This decision will be based on the contractor's technical progress, as determined by an AF TPOC's review using the DoD 23.A STTR BAA Phase I review criteria. All Phase I awardees will be provided an opportunity to submit a Phase II proposal unless the Phase I purchase order has been terminated for default or due to non-performance by the Phase I company.

Phase II is the demonstration of the technology found feasible in Phase I. Only Phase I awardees are eligible to submit a Phase II proposal. All Phase I awardees will be sent a notification with the Phase II proposal submittal date and detailed Phase II proposal preparation instructions. If the physical or email addresses or firm points of contact have changed since submission of the Phase I proposal, correct information shall be sent to the AF SBIR/STTR One Help Desk as instructed on A-1. Phase II dollar values, performance periods, and proposal content will be specified in the Phase II request for proposal.

NOTE: The DAF primarily awards Phase I and II contracts as Firm-Fixed-Price . However, awardees are strongly urged to work toward a Defense Contract Audit Agency (DCAA)-approved accounting system. If the company intends to continue work with the DoD, an approved accounting system will allow for competition in a broader array of acquisition opportunities, including award of Cost-Reimbursement types of contracts. Please address questions to the Phase II CO, if selected for award.

All proposals must be submitted electronically via DSIP by the date indicated in the Phase II request for proposal. Note: Only ONE Phase II proposal may be submitted for each Phase I award.

AIR FORCE STTR PROGRAM MANAGEMENT IMPROVEMENTS

The DAF reserves the right to modify the Phase II submission requirements. Should the requirements change, all Phase I awardees will be notified. The DAF also reserves the right to change any administrative procedures at any time to improve management of the DAF STTR Program.

Air Force STTR 23.A Topic Index

Topic Number	Topic Title	Maximum Value	Maximum Duration (in months)	Technical Volume Page Limit
SF23A-T001	Integrated Navigation, Communication, and Authentication	$180,000	9	20
AF23A-T002	Hybrid biological systems/biomaterials for in-body sensing	$180,000	9	20
AF23A-T003	Smart Contact Lens Sensor Integrated with AI to Monitor Physiological Signals in Deployed Extreme Operational Stress Environments	$180,000	9	20

SF23A-T001 TITLE: Integrated Navigation, Communication, and Authentication

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Trusted AI and Autonomy; Integrated Network Systems-of-Systems

The technology within this topic is restricted under the International Traffic in Arms Regulation (ITAR), 22 CFR Parts 120-130, which controls the export and import of defense-related material and services, including export of sensitive technical data, or the Export Administration Regulation (EAR), 15 CFR Parts 730-774, which controls dual use items. Offerors must disclose any proposed use of foreign nationals (FNs), their country(ies) of origin, the type of visa or work permit possessed, and the statement of work (SOW) tasks intended for accomplishment by the FN(s) in accordance with the Announcement. Offerors are advised foreign nationals proposed to perform on this topic may be restricted due to the technical data under US Export Control Laws.

OBJECTIVE: Develop enabling technologies for providing high data rates and precise position, navigation, and timing services with high assurance and reduced hardware/software complexity by leveraging functional synergies of navigation and communication and their hardware/software similarities.

DESCRIPTION: With the growing demand for high communication rate and navigation accuracy, different approaches for integrating the navigation and communication system have been explored for next-generation navigation and communication applications. If successful, a prospective integrated design could provide improved utilization of the spectrum and orbit resources by sharing the spectrum for navigation and communication. Moreover, it would reduce hardware/software complexity and power consumption by sharing radio frequency (RF) front end and signal processing unit, which are common to both communication and navigation. Also relevant is that it would leverage functional synergies of communication and navigation to improve the positioning speed via higher communication rate and alleviate the signal synchronization burden via timing information. However, the key challenge is to meet different requirements, namely high data rate and precise and trustworthy positioning/timing, with a single signaling system. Most previous efforts have explored these requirements in isolation. Navigation and communication functions are implemented independently without deep integration, and the spectrum resources are used separately. Furthermore, the message authentication mechanisms for secure and trustworthy satellite navigation and communication are implemented in isolation. The isolated design inevitably results in a waste of radio resources, increased hardware/software complexity, and degradation of network performance. This topic solicitation seeks a proof of concept to meet all the communication, navigation, and authentication requirements in a single design framework. Signaling solutions that provide: i) high data rates with low transmission power, ii) trustworthy position, navigation, and timing services with reduced hardware/software complexity and power consumption, and iii) reduced spectrum usage, are desirable. Solutions that are backward compatible with the existing navigation system, i.e., providing navigation services with the existing navigation receiver without any modification, are of interest under this call. Signal designs that support various services for users with different data rates, are also of interest. Theoretical performance analysis is highly encouraged as it can provide important guidance and insight for optimum system design.

PHASE I: Identify and explore options for the integration of navigation, communication, and authentication, conduct trade analysis and simulations, define operating concepts, and provide justification for proposed solutions. Integrated solutions should offer potential advantages over state-of-the-art and demonstrate technical feasibility.

PHASE II: Develop prototype hardware and software and demonstrate a proof of concept for trustworthy navigation and communication services. Evaluate the data transmission rate, navigation accuracy, and

authentication error rate in the presence of spoofing attacks to support instantiations and deployments of the proposed concept.

PHASE III DUAL USE APPLICATIONS: Integrate with prospective follow-on transition partners to provide an improved operational capability to a broad range of potential Government and civilian applications such as non-dedicated positioning, navigation, and timing (PNT) services (e.g. through communications systems) as can be derived from the NASA-funded HelioSwarm flight experiment consisted of multi-satellite missions by flying a swarm of nine spacecraft (8 nodes, 1 hub) to make measurements at multiple scales simultaneously, in which a large hub is utilized for transport of the smallsat nodes to the mission orbit and data relay. Government organizations such as Air Force Research Laboratory and Space Systems Command could sponsor a government reference design for PNT over communications flight integration, in collaboration with small business and industry partners. Successful contractor technology demonstrations will inform the technical requirements of future acquisitions by Primes and subcontractors.

REFERENCES:

1. S. Han, Z. Gong, W. Meng, C. Li and X. Gu, "Future Alternative Positioning, Navigation, and Timing Techniques" A Survey, "IEEE Wireless Communications, vol. 23, no. 6, pp. 154-160, December 2016;
2. Zou, Deyue, and Shouchuan Ma. & "Satellite Navigation and Communication Integration Based on Correlation Domain Indefinite Pulse Position Modulation Signal. "Wireless Communications and Mobile Computing 2021;
3. X. Xu, L. Li, M. Zhao, and C. Fan, "A flexible design of waveform for communication and navigation, "IEEE Wireless Communications and Networking Conference (WCNC), 2018;
4. Zou, Deyue, and Shouchuan Ma. "Satellite Navigation and Communication Integration Based on Correlation Domain Indefinite Pulse Position Modulation Signal. "Wireless Communications and Mobile Computing 2021;
5. Yin, Lu, et al. "A novel positioning-communication integrated signal in wireless communication systems. "EEE Wireless Communications Letters, pp. 1353-1356, 2019;
6. Wang, Yu, et al. "Integrated Communication and navigation for ultra-dense LEO satellite networks: vision, challenges and solutions "arXiv preprint arXiv 2105.08985, 2021;
7. Zou, Deyue, Xinyue Li, and Ruofei Ma. "A signal optimization strategy for next-generation navigation and communication integration applications. "Physical Communication, 2022;
8. Wang, Lei, et al. "LEO-augmented GNSS based on communication navigation integrated signal. "Sensors 19.21, 2019;
9. Hein, Guenter W. "Status, perspectives and trends of satellite navigation. "Satellite Navigation 1.1, 2020

KEYWORDS: Communications; navigation; authentication; trustworthy position, navigation, and timing services; reduced hardware and software complexity; low power consumption; reduced spectrum usage

TPOC-1: Khanh Pham
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AF23A-T002 TITLE: Hybrid biological systems/biomaterials for in-body sensing

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Biotechnology

The technology within this topic is restricted under the International Traffic in Arms Regulation (ITAR), 22 CFR Parts 120-130, which controls the export and import of defense-related material and services, including export of sensitive technical data, or the Export Administration Regulation (EAR), 15 CFR Parts 730-774, which controls dual use items. Offerors must disclose any proposed use of foreign nationals (FNs), their country(ies) of origin, the type of visa or work permit possessed, and the statement of work (SOW) tasks intended for accomplishment by the FN(s) in accordance with the Announcement. Offerors are advised foreign nationals proposed to perform on this topic may be restricted due to the technical data under US Export Control Laws.

OBJECTIVE: The goal of this topic is the development of "soft" implantable, biocompatible and biodegradable sensors that can measure multiple biomarkers of interest continuously, and provide a signal that can be interrogated either with an external device or internally, as part of the implantable device itself.

DESCRIPTION: Implantable sensors are emerging as a promising means to perform a wide variety of diagnostic and therapeutic functions. In these types of applications, the hydrogel-based biocompatible polymer matrix containing photosensitized molecule probes must be properly designed to accurately measure biomarker levels under the skin. The most noticeable example of a flexible micro-sensor was reported by Profusa with Lumee, a tissue implantable device for monitoring the levels of oxygen in the surrounding tissues [1]. Applications of such implantable sensors include monitoring of peripheral artery disease, wound healing, and muscle performance. Recently, implanted sensors were reported for detecting the presence of oral cancers [2], as well as for battery-less recording of deep brain neuropotentials [3]. Research advances in tissue-injectable biopolymer matrix continue to develop for more advanced applications. For example, implantable temperature-sensitive sensors for infection biomarkers such as pH, carbon dioxide and viscosity of synovial fluid were recently developed for early detection of prosthetic joint infections [4]. Overall, with technological advances in biocompatible material development, implantable biosensors will have the potential to improve the management of patient health and quality of life, increasing survival rates while reducing health care costs. To respond to this topic, the performer should design implantable sensors with components that will assemble into soft materials able to interact transiently with analytes of interest and provide a readable signal that allows analytical quantification over time. Soft materials are defined here as made of biological components (proteins, peptides, nucleic acids and the like) in combination with biocompatible and biodegradable polymers that offer an optimal environment for sensing, with no electronics or other hardware required to be implanted. These materials will be in the micro- or nano-size scale in order to be implanted with no compatibility issues and/or major inflammatory reactions. The end deliverable will detect at least two biomarkers of military relevance when implanted in a model system (animal, tissue model, organ-on-chip platform) or in human subjects. The sensors will be active for at least 24 h without any user intervention or regeneration steps to maintain sensor function.

PHASE I: The performer should identify/design: i) biological components or systems that can interact with identified biomarkers and produce a readable signal to sense their physiological levels over time, and ii) biopolymers with properties allowing for implantation into soft body tissues. At the end of the Phase I effort, the performer should provide a detailed plan for building the sensor prototype, test it for selectivity, sensitivity and biodegradability and the models/platforms to be used for these tests. The performer should also provide a detailed assessment of the rationale for their design considering inflammatory response, biofluid access, reader function and biodegradability bioproducts toxicity.

PHASE II: Multiple biological sensing components or systems should be incorporated into the implantable biopolymer formulation allowing for detection of at least two biomarkers of interest. The performer should investigate cross-reactivity and sensitivity of incorporated sensing components and demonstrate that the implantable biosensor can be used for simultaneous and continuous monitoring of at least two biomarkers of interest. The performer should utilize existing or develop new technologies allowing for the sensor's signal interrogation either with an external device or internally, as part of the implantable device itself, with no electronics or other hardware required to be implanted. At the end of Phase II, the performer should demonstrate that the implantable sensor can be used for monitoring physiological level of at least two biomarkers of interest and produce signals that can be remotely detected and converted into biomarker quantifying units.

PHASE III DUAL USE APPLICATIONS: The performer should test the functionality of the implantable sensor using animal models, tissue models or organ-on-chip platforms. The performer may conduct human studies. At the end of Phase III, the performer should demonstrate that the developed sensing device can be implanted into soft body tissues and can be used for continuous monitoring of at least two biomarkers of interest. The implantable device should be active for at least 24 hours, biocompatible (e.g., without production of toxic or immunological response), and biodegradable over time. The performer should assess marker options for medical use in different areas (tissue regeneration, a self-contained theranostics system, wound healing, etc.) and sports medicine (tissue regeneration/injury recovery, etc.).

REFERENCES:

1. http://profusa.com/lumee/;
2. O.K. Hammouda and A.M.M. Allam, "Utilizing implanted antennas to detect the presence of oral cancers," Res. J. Eng. Scien., vol. 3, pp. 22-27, Jul. 2014.;
3. A. Kiourti, C. Lee, J. Chae, and J.L. Volakis, "A wireless fully-passive neural recording device for unobtrusive neuropotential monitoring," IEEE Trans. Biomed. Eng., vol. 63, pp. 131-137, Jan. 2016.;
4. Wijayaratna, U. N.; Kiridena, S. D.; Adams, J. D.; Behrend, C. J.; Anker, J. N. "Synovial Fluid PH Sensor for Early Detection of Prosthetic Hip Infections." Adv. Funct. Mater. 2021, 31 (37), 2104124. https://doi.org/10.1002/adfm.202104124.

KEYWORDS: implantable sensor; biomarkers; biodegradable; continuous sensing

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AF23A-T003 TITLE: Smart Contact Lens Sensor Integrated with AI to Monitor Physiological Signals in Deployed Extreme Operational Stress Environments

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Trusted AI and Autonomy; Space Technology

OBJECTIVE: The objective of this topic is to design contact lenses integrated with sensitive sensors to monitor physiological parameters as an innovative tool for the detection of stress biosignatures in body fluids in extreme operational environments (e.g., the arctic [i.e., extreme cold temperatures], heat, exposure to unknown contaminants, directed energy radiation, etc.).

DESCRIPTION: In recent years, contact lenses as flexible and wearable sensing devices have shown significant progress in identifying potential biomarkers related to human disease. However, there exists a giant leap in creating these contact lenses with sensor chips integrated with unique functionalities to accomplish non-invasive detection of physiological biosignatures. Recent technological advances in material science, microelectronics, artificial intelligence, and digital engineering have enabled contact lenses as promising sensing devices for non-invasive monitoring systems of human performance in stressful operational environments. Despite significant efforts, the use of smart contact lenses remains limited because of their mechanical biocompatibility, detection sensitivity, and challenging integration process. Many characteristics are required for the successful development of smart contact lenses. First, they must maintain a high degree of transparency within the visual field, including the electronic materials for the embedded sensors and circuitry. Second, smart lenses must be comfortable to wear daily without interrupting the wearer's routine mission in stressful environments. This generates several challenges relating to substrate mechanical stiffness, biocompatibility, lens shape, and surface irregularities that, if not controlled, could lead to eye inflammation and irritation. This challenge requires a multidisciplinary approach that leverage many technologies including biomaterials, microfluidics, biosensor circuits, energy supply, data transmission, and display. All these electronic components must be sandwiched within the lens substrate to prevent harming the eye surface, but it also obstructs direct contact with the tear fluid. A potential solution in this case is to use microfluidic channels for tear sampling and transport. Similarly, it is necessary to use flexible and biologically stable electrode materials to display relevant information on smart lenses with wireless communication capabilities and stable power supply. The proposed topic on wearable contact lenses integrated with biosensors can provide real-time noninvasive monitoring of physiological parameters and increase combat effectiveness in Airmen without interrupting or limiting the wearer's motions. The biosensor components as well as the contact lens should be made of a transparent, opaque, flexible, and biocompatible material to be placed around the healthy pupil without obstructing the field of vision. The proposed contact lens designs must overcome the limitations of current contact lens sensors by continuously monitoring multiple analytes, such as the stress biosignatures cortisol and dehydroepiandrosterone (DHEA), without obstructing the user's field of vision.

PHASE I: A transparent sensor platform will be designed and fabricated to detect a panel of biomarkers (e.g., oxygen, glucose, cortisol, lactate, urea, etc.). Sensor components and their connections must be protected from mechanical deformations due to the soft and stretchable nature of the contact lens. The success for the first phase of this project would be to provide a proof-of-concept for the proposed prototype, demonstrating its multi-functional sensing ability with wireless and battery-free operation. The key deliverables are proof of concept data, specific detection of stress biosignatures, and an initial proof of concept prototype. The final report consisting of a detailed description is required to determine if the result of Phase I feasibility technology is currently at an acceptable stage.

PHASE II: The work completed in Phase II should demonstrate the successful operation of a contact lens prototype with integrated sensor components wireless communication capabilities. The biocompatibility data should be conducted using in vitro or in vivo models to demonstrate the safety of the contact lens

without producing toxicity. The smart lens must be comfortable to wear on daily basis without interrupting the routine mission. The contact lens substrate, mechanical stiffness, lens shape, and surface irregularities should be considered very carefully to not produce any inflammation or irritation to the human eye. The deliverable is the functional smart contact lens sensor with a wireless communication capability to transmit information collected from contact lenses to a receiver for analysis.

PHASE III DUAL USE APPLICATIONS: Phase III should demonstrate dual use primarily for military applications in the field. A wearable contact lens integrated with biosensors must provide real-time noninvasive monitoring of physiological parameters (e.g., cortisol, DHEA, oxygen, glucose, lactate, etc.) and increase combat effectiveness in Airmen without interrupting or limiting the wearer's motions or obstructing their vision. The second application is for commercialization to use to detect key biomarkers for diagnostic and clinical purposes.

REFERENCES:

1. 1. S. Lee, I. Jo, S. Kang, B. Jang, J. Moon, J. B. Park, S. Lee, S. Rho, Y. Kim, B. H. Hong, ACS Nano 2017, 11, 5318.;
2. G. Z. Chen, I. S. Chan, L. K. Leung, D. C. Lam, Med. Eng. Phys 2014, 36, 1134.;
3. M. Falk, V. Andoralov, M. Silow, M. D. Toscano, S. Shleev, Anal. Chem. 2013, 85, 6342.;
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