1) **Project Objective:** The Joint Science and Technology Office (JSTO) within the Defense Threat Reduction Agency (DTRA) is charged with addressing the potential threat to the armed services posed by a wide range of bacterial, viral and toxin agents. The current technology and animal use and care guidelines limit the number of blood samples that can be taken in the period between vaccine administration and the fully developed immunological response. The objective of this project is to identify and develop technologies that can expand the range of in vivo micro sampling to comprehensively assess the extended developmental immune response to vaccination. These nascent technologies are expected to allow increased or continuous in vivo or in vitro micro sampling and in parallel utilize detection technologies that can characterize post-vaccination immune maturation in small samples.

2) Performance Objectives (required results)

a. **Project Objectives:**
Develop compact wearable devices that allow increased or continual blood micro sampling of test animals.
b. Develop minimally invasive, periodic blood sampling technologies for increased sample acquisition within IACUC guidelines.
c. Utilize micro physiological systems (or "organs on a chip") that can mimic the entire in vivo immune response repertoire, and highly sensitive detection technology to accurately detect innate and adaptive immune components in the blood using minimal sample size.
d. Utilize highly sensitive detection technology that can characterize pos-vaccination immune development in small quantities of blood.

e. **Regulatory Objectives:** Any successful device or technology developed for continual blood sampling would need to be compliant with all Animal Use and Care standards and be validated for use in vaccine development and monitoring studies by the FDA.

f. **Project Management Objectives:** The project will be managed by a Government IPT including a Science and Technology Program Manager (STM), Program Management Office (PMO) and Subject Matter Expert (SME) support. The offeror will be expected to participate in monthly progress meetings as well as quarterly and annual programmatic, milestone and financial reports.

g. Logistics Objectives: Any devices would be required to be packaged in a unform fashion that guarantees consistent, replicative results and is in compliance with all IACUC and FDA device regulatory guidelines.

3) **Performance Requirements:** Any device technologies should have a shelf life of one year at room temperature.

Operational constraints/Limitations/Restrictions: NA

2.1.3 PERIOD AND PLACE OF PERFORMANCE:

The anticipated Period of Performance for this effort is up to five (5) years from date of award. Specific dates to be negotiated. It is anticipated that the primary place of performance will be the Agreement Holders' facilities or a suitable subcontractor, however this aspect can be negotiated as part of each Offerors' submission.

2.1.4 DELIVERABLES:

2.1.4.1 DATA DELIVERABLE(S): <Data deliverables include meeting minutes, financial reports, technical progress reports, annual reports, GFP inventory, patents and invention reports, regulatory documentation and technical data packages, forecasts, WBS, IMS, copies of FDA submissions (IND, BLA, eIND, etc) FDA correspondence, ORTA correspondence, Regulatory Strategy, TPP, and any other data necessary to document the product development.>

Note: Technical data deliverables described herein shall be delivered to the Government with Government Purpose Rights

2.1.4.2 PROTOTYPE DELIVERABLE(S): Deliverable will be compact wearable devices and concurrent ability to analyze minute blood samples. The quantity to be delivered should be limited to only that needed to prove technical or manufacturing feasibility or evaluate military utility.

2.1.5 SPECIAL REQUIREMENTS:

2.1.5.1 Export Control: NA

2.1.5.2 Security and Classified Data: All information/data generated under this agreement will be designated as non-classified.

2.1.5.3 Acceptance of Deliverables: The Government will provide acceptance of all data deliverables within 30 days of delivery. The Government will provide acceptance of all prototype deliverables within 60 days of delivery.

2.1.5.4 Travel: The offeror will travel for Government purposes, including annual project meetings with DTRA and travel to project-relevant conferences. This will include two annual trips within the continental United States (CONUS) but may include non-directed travel the offeror thinks are necessary for the effort.

2.1.6 GOVERNMENT FURNISHED PROPERTY/SERVICE: NA

2.1.7 FUNDING CONFIDENCE LEVEL and PROJECT AWARD MONTH or FY QUARTER:

CL-3 Funding Availability is Unknown at this time

This effort is anticipated for award: April FY2025

2.1.8 FOLLOW-ON PRODUCTION: This prototype project will be awarded after a competitive solicitation, evaluation and award process. As such, in accordance with 10 U.S.C. 4022 and upon a determination that the prototype project for this transaction has been successfully completed, or at the accomplishment of particularly favorable or unexpected results that would justify transitioning to production, any competitively awarded prototype OTA as a result of this RPP may result in the award of a follow-on production contract or transaction without the use of competitive procedures. A follow-on production effort may include the delivery of up to 2 Prototypes annually over a 1 fiscal year period year period.

2.1.9 AGREEMENTS OFFICER REPRESENTATIVE (AOR):

Name: Robert P. Webb, Ph.D.
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E-mail: robert.p.webb6.civ@mail.mil
Office Symbol: DTRA CBM

2.1.9.1 ALTERNATE AOR:

Name: Mary Zoepfl, Ph.D.
Telephone: 571-616-6373
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2.1.9.2 Requiring Activity:

DTRA Joint Science and Technology Office Chem-Bio Medical (CBM)