**SMALL BUSINESS INNOVATION RESEARCH**

**phase ii statement of objectives**

**for**

**CANINE REMOTE PHYSIOLOGIC MONITORING**

**TOPIC: SOCOM193-D004**

**23 August 2019**

I. **BACKGROUND**:

Special Operations Forces (SOF) Multi-purpose canines (MPC) fulfill a number of critical battlefield missions, ranging from attack and sentry activities to olfactory detection of explosives or other contraband. Dogs’ greater sensory acuity combined with their athleticism makes them indispensable in their roles. However, the use of MPCs in combat situations necessarily exposes them to multiple battlefield threats that may lead to traumatic injuries, impaired athletic performance, or environmental injuries.

The ability to provide continuous physiologic monitoring of an MPC at rest, as well as during high levels of performance in all environmental conditions will significantly improve their operational effectiveness, recovery, and overall care.

II. **OVERALL OBJECTIVE**:

The objective of this Statement of Objectives is to develop the ability to remotely monitor the physiology of SOF MPCs, with the ability to collect and transmit data real-time in all environmental conditions utilizing an implantable device. Software must be designed and provided to analyze the transmitted data and send alerts immediately when abnormalities are detected.

III. **Requirements:**

1. **General:** The Contractor shall develop and deliver an implantable canine remote physiologic monitoring device for Government follow-on testing and demonstration.
2. **Detailed Tasks**: The Contractor shall design, develop, fabricate, test, demonstrate, and deliver six (6) prototype implantable canine remote physiologic monitoring devices that meet the following performance requirements:
3. Size of implantable device must not cause harm to the SOF MPC or interfere with performance.
4. Ability for multiple users to access and review the data for each SOF MPC at the same time on a secure system.
5. Ability to access and review the data from various locations.
6. Ability for data to be analyzed and immediately send alerts when abnormalities are detected.
7. Able to effectively operate in harsh environmental conditions.
8. Able to provide real-time monitoring of dog’s heart rate.
9. Able to provide real-time monitoring of dog’s body temperature.
10. Able to provide real-time monitoring of dog’s respiratory rate.
11. Able to transmit data in various environments including buildings, outdoors, etc.
12. Implant must be durable enough to last for a minimum of one year before replacement is necessary.
13. **UNIQUE ITEM IDENTIFICATION:** The Contractor shall include the DoD unique item

identifications or a DoD recognized unique identification equivalent for the prototypes delivered. This includes a description and cost breakout as applicable. Information on unique item identifier types is at http://www.acq.osd.mil/dpap/UID/uid\_types.html. The guide is at http://www.acq.osd.mil/dpap/UID/guides.htm. This is in accordance with DFARS 252.211-7003.

1. **SHIP TO ADDRESS:** The Contractor shall deliver the six prototypes developed under this contract to the following address:

Attn: Mr. Simpson/SOF AT&L-ST (DoDAAC: F2VUG0)

HQ USSOCOM

7701 Tampa Point Blvd

MacDill AFB, FL 33621-5323

(813) 826-3827

1. **SHIPPING COSTS:** The Contractor shall pay all costs to ship all product deliverables

to and from the validation testing /demonstration sites and to the final delivery location.

B. **DOCUMENT DELIVERABLES:** The Contractor shall provide the following documents to the respective specified addresses during the Phase II Period of Performance:

1. Kick-Off/System Requirements Review: (See CDRL A001).
2. Monthly Progress Reports: (See CDRL A002).
3. Financial Status Report: (See CDRL A003).
4. Developmental Test Plan for Performance Validation: (See CDRL A004).
5. Developmental Test Report for Performance Validation: (See CDRL A005).
6. Business Plans: (See CDRL A006).
7. Final Technical Report: (See CDRL A007).
8. Preliminary Design Review: (See CDRL A008).
9. Critical Design Review: (See CDRL A009).

IV. **TESTS AND DEMONSTRATIONS:** The Contractor shall conduct tests and demonstrations to validate that the implantable canine remote physiologic monitor meets or exceeds all the requirements specified in this Statement of Objectives. (See CDRL A004 and CDRL A005).

V. **ENVIRONMENTAL AND SAFETY:** The Contractor shall ensure the implantable canine remote physiologic monitor developed under this Statement of Objectives meets the following environmental and safety standards:

A. MIL-I-45607 entitled “Acquisition, Maintenance, and Disposition of Inspection Equipment” (dated 20 Dec 2002), As required

VI. **GOVERNMENT FURNISHED PROPERTY (GFP) / GOVERNMENT FURNISHED PROPERTY (GFE) / GOVERNMENT FURNISHED INFORMATION (GFI):** The Government does not intend to provide the Contractor any GFP, GFE or GFI. However, the Contractor shall specify by stock number and nomenclature any GFP/GFE/GFI the Contractor believes is needed to successfully complete the requirements specified in this Statement of Objectives.

VII. **MEETINGS AND REVIEWS**: The Contractor shall attend the following meetings and reviews:

A. Phase II Kick-Off meeting shall be conducted in Tampa, Florida not later than thirty (30) calendar days after contract award. The Contractor shall provide the Government:

1. A Phase II Kick-Off Meeting System Requirements Review Read-Ahead no less than seven (7) calendar days prior to the Phase II Kick-Off Meeting / System Requirements Review Meeting (See CDRL A001).

2. An initial Program Management Plan / Financial Status Report for accomplishing all objectives specified in this Statement of Objective. (See CDRLs A002 and A003).

3. Conceptual Design Drawings no less than ten (10) calendar days prior to the Phase II Kick-Off/System Requirements Review Meeting (See CDRL A001).

B. Preliminary Design Review (PDR) - This meeting shall be conducted at the Contractor’s facility no more than one hundred and eighty (180) calendar days after Phase II contract award. The Contractor shall provide teleconference capability for those participants unable to travel. The Contractor shall provide the Government:

1. A Preliminary Design Review and Materials Read-Ahead Briefing no less than ten (10) calendar days prior to the PDR (See CDRL A008).

2. A Detailed Design Report (See CDRL A008).

3. Trade off considerations for the design. (See CDRL A008).

4. Results of any testing to date. (See CDRL A005).

5. Resolution to any Contractor/Government issues or concerns.

6. An assessment of other potential benefits / impacts of the implantable canine remote physiologic monitor, and a recommendation of any changes for consideration / incorporation into the subsequent design that will be provided to the Government at the follow-on Critical Design Review. (See CDRL A008).

C. Critical Design Review (CDR): This teleconference meeting shall be arranged by the Contractor two (2) weeks prior to the end of the contract completion date. The Contractor shall provide the Government:

1. A Critical Design Review and Materials Read-Ahead Briefing no less than ten (10) calendar days prior to the CDR (See CDRL A009).

2. A Detailed Design Report (See CDRL A009).

3. Trade off considerations for the design. (See CDRL A009).

4. Results of any testing to date. (See CDRL A005).

5. Resolution to any Contractor/Government issues or concerns.

D. Phase II Close-Out Meeting: The Phase II Close-Out Meeting shall be conducted in Tampa, Florida no earlier than seven (7) calendar days prior to the conclusion of the Phase II Period of Performance. The Contractor shall provide the Government:

1. A briefing on the test verification (See CDRL A005).

2. An update of the progress to date. (See CDRL A002)

3. Resolution to any Contractor/Government issues or concerns.

VIII. **NOTIFICATION:** The Contractor shall notify USSOCOM no less than thirty (30) calendar days prior to tests, demonstrations and reviews at the Contractor’s facilities to ensure USSOCOM representatives can attend should they desire to do so.

VIX. **TRAVEL REQUIREMENTS:** The costs associated with the below travel requirements will be included in a separate Contract Line Item Number as a cost reimbursable expense. The Contractor shall comply with the Federal Acquisition Regulation 31.205-46 (<http://www.gsa.gov/perdiem>) on proposing all travel related costs. The Contractor shall include the costs associated with the following travel requirements in the proposal:

A. Phase II Kick-Off Meeting: Tampa, Florida; one (1) overnight, no more than three (3) Contractor representatives.

B. Phase II Close-Out Meeting: Tampa, Florida; one (1) overnight, no more than three (3) Contractor representatives.

X. **MANDATORY REPORTING:**

A. The Contractor shall report ALL contractor labor hours (including subcontractor labor hours) required for performance of services provided under this contract for the U.S. Special Operations Commands via a secure data collection site. The Contractor is required to completely fill in all required data fields using the following web address: <http://www.ecmra.mil/>.

B. Reporting inputs will be for the labor executed during the period of performance during each Government fiscal year (FY), which runs October 1 through September 30. While inputs may be reported any time during the FY, all data shall be reported no later than October 31 of each calendar year, beginning with 2014. Contractors may direct questions to the help desk at help desk at: http://www.ecmra.mil.

XI. **DISCLOSURE OF UNCLASSIFIED INFORMATION:**

A. On September 21, 2001, the Department of Defense designated Headquarters US Special Operations Command (USSOCOM) a sensitive unit, as defined by Title 10 United States Code (USC) Section 552 (10 USC 552). In keeping with this designation, unclassified information related to USSOCOM military technology acquisitions managed by USSOCOM or any of its component commands, will be designated Controlled Unclassified Information (CUI). As such, the contractor hereby unequivocally agrees that it shall not release to anyone outside the Contractor’s organization any unclassified information, regardless of medium (e.g., film, tape, document, Contractor’s external website, newspaper, magazine, journal, corporate annual report, etc.), pertaining to any part of this contract or any program related to this contract, unless the Contracting Officer has given prior written approval. Furthermore, any release of information which associates USSOCOM, Special Operation Forces (SOF), or any component command with an acquisition program, contractor, or this contract is prohibited unless specifically authorized by USSOCOM.

B. Requests for approval shall identify the specific information to be released, the medium to be used, and the purpose for the release. The Contractor shall submit its request to the Contracting Officer at least 45 days before the proposed date for release for approval. No release of any restricted information shall be made without specific written authorization by the Contracting Officer.

C. The Contractor shall include a similar requirement in each subcontract under this contract. Subcontractors shall submit requests for authorization to release through the prime contractor to the Contracting Officer.

D. The Contractor further understands that Title 18 USC Section 701 specifically prohibits the use of the USSOCOM emblem or logo in any medium (e.g., corporate website, marketing brochure, newspaper, magazine, etc.) unless authorized in writing by USSOCOM. Forward any requests to use the USSOCOM emblem or logo through the Contracting Officer.

XII. **ANIMAL WELFARE**

(a) (1) The Contractor shall register its research, development, test, and evaluation or training facility with the Secretary of Agriculture in accordance with Section 7 of the United States Code (U.S.C.) 2136 and section 9 of the Code of Federal Regulations (CFR) subpart C, and section 2.30, unless otherwise exempt from this requirement by meeting the conditions in 7 U.S.C. 2136 and 9 9 CFR parts 1 through 4 for the duration of the activity. The Contractor shall have its proposed animal use approved in accordance with Department of Defense Instruction (DoDI) 3216.01, Use of Animals in DoD Programs, by a DoD Component Headquarters Oversight Office. The Contractor shall furnish evidence of such registration and approval to the Contracting Officer before beginning work under this contract.

 (2) The Contractor shall make its animals, and all premises, facilities, vehicles, equipment, and records that support animal care available during business hours and at other times mutually agreeable to the Contractor and the United States Department of Agriculture Office of Animal and Plant Health Inspection Service (USDA/APHIS) representative, personnel representing the DoD component oversight offices, as well as the Contracting Officer, to ascertain that the Contractor is compliant with 7 U.S.C. 2131- 2159 9 CFR parts 1 through 4.

(b) The Contractor shall acquire animals in accordance with DoDI 3216.01, current at time of award (https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321601p.pdf).

(c) The Contractor agrees that the care and use of animals will conform with the pertinent laws of the United States, regulations of the Department of Agriculture, and policies and procedures of the Department of Defense (see 7 U.S.C. 2131et seq., and 9 CFR subchapter A, parts 1 through 4, DoDI 3216.01, Army Regulation 40-33/SECNAVINST 3900.38C/AFMAN 40-401(I)/DARPAINST 18/USUHSINST 3203). The Contractor shall also comply with DoDI 1322.24, Medical Readiness Training, if this contract includes acquisition of training, https://www.health.mil/Reference-Center/Policies/2019/06/18/DHA-MSR-6025-02 .

(d) The Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract for failure to comply with the requirements of paragraphs (a) through (c) of this clause.

 (1) The suspension will stay in effect until the Contractor complies with the requirements.

 (2) Failure to complete corrective action within the time specified by the Contracting Officer may result in termination of this contract and, if applicable, removal of the Contractor's name from the approved vendor list for live animals used in medical training.

(e) The Contractor may request registration of its facility by contacting USDA/APHIS/AC, 4700 River Road, Unit 84, Riverdale, MD 20737-1234, or via the APHIS Animal Care Web site at: http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare.

(f) The Contractor shall include the substance of this clause, including this paragraph (f), in all subcontracts involving research, development, test, and evaluation or training that use live vertebrate animals.

XIII. **PROHIBITION OF USE OF LABORATORY ANIMALS**

Notwithstanding any other terms and conditions contained in this SOO or incorporated by reference herein, the contractor is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the USSOCOM, Veterinary Review Office. Written authorization to begin research under the applicable protocol(s) proposed for this effort will be issued in the form of an approval letter from the USSOCOM Veterinary Review Office to the contractor with a copy to the USSOCOM Contracting Office. Furthermore, modifications to already approved extramural protocols require approval by Veterinary Review Office prior to implementation. Once approved, notification must be given immediately to USSOCOM contracting. For each fiscal year, the contractor shall maintain, and upon request from Veterinary Review Office, submit animal usage information. Non-compliance with any of these terms and conditions may result in withholding of funds and/or the terminations of the award.

The USSOCOM Veterinary Review Office requirements can be accessed at https://www.socom.mil/SOF-ATL/Pages/HRPO.aspx