Special Notice 14-SN-0002

Special Program Announcement for 2014 Office of Naval Research

"Hypoxia Monitoring, Alert, and Mitigation System"

I. INTRODUCTION:

This announcement describes a research thrust entitled "Hypoxia Monitoring, Alert and Mitigation System" (HAMS) to be launched under the ONR BAA 14-001, Long Range Broad Agency Announcement (BAA) for Navy and Marine Corps Science and Technology which can be found at: http://www.onr.navy.mil/Contracts-Grants/Funding-Opportunities/Broad-Agency-Announcements.aspx. The research opportunity described in this announcement specifically falls under numbered paragraph 2 (item c) of the sub-section entitled Warfighter Performance (Warfighter Protection and Applications). The submission of proposals, their evaluation and potential execution of funds will be carried out as described in that BAA.

The purpose of this announcement is to focus attention of the scientific community on the area to be studied and the planned timetable for the submission of proposals.

II. TOPIC DESCRIPTION:

The Office of Naval Research (ONR) is interested in receiving proposals for the development of a HAMS for 1) ground troops at altitude and 2) casualties during air evacuation (CASEVAC). HAMS will predict/detect/warn warfighters of impending hypoxic events based on individual physiological, environmental, and cognitive monitoring. The goal is to provide optimal protection of military personnel and equipment through intelligent monitoring and adaptive modeling that accounts for individual differences in physiologic tolerance and provides a timely notification/warning such that personnel can take corrective action before missions are compromised or injuries are aggravated.

The primary technology areas of interest for full system development over the lifetime of the program are 1) detection/prediction algorithm, 2) sensing suite, 3) warning modalities, and 4) modes of mitigation. This Special Notice is a follow on to Special Notice 13-SN-0003, published in November 2012.

ONR is currently seeking proposals for algorithm development/refinement, development of the sensing suite, determination of warning modalities, and modes of mitigation. Offerors are invited to respond with proposal(s) for any combination of or all deliverables.

(A) Detection/Prediction Algorithm: An advanced adaptive monitoring algorithm should account for both the textbook predictions of hypoxia based on barometric pressure as well as individual variations in tolerance. It should predict physiologic state, how it changes over time and compute level of risk accordingly. The working environment will have multiple noise sources generated by the warfighter and data drop outs which must be considered. Predicted decrements in physiologic and cognitive/motor responses should factor into the decision algorithm to classify the type of warning issued. Performers will provide a validated algorithm that can be upgraded as the entire system matures.

(B) Determination of Metrics: Animal and/or human testing is expected to determine and validate appropriate physiologic and environmental metrics that can be used to determine negative sequelae associated with hypoxia and/or hypoxia-like events. Detection must be non-invasive, and the metric should provide information with enough lead-time to implement mitigation strategies; automatic or manual. Metrics should be largely consistent across subjects with significant reliability. Detection of such physiologic events should be easily measured with minimal equipment.

(C) Sensing Suite Development and Integration: Physiologic sensors must be miniaturized, selfcontained, low power, unobtrusive, and must require minimal interaction by warfighters. These should be easy to maintain and calibrate without special tooling. Any person-borne system must not present an increased injury risk in an adverse event, such as vehicle crash. Physiologic monitoring should consider oxygen mask breathing air quality/expiration of O2, CO2, flow, and pressure. Tissue responses, such as blood oxygen saturation (SpO2) and cerebral tissue oxygen content (rSO2) should be considered. Blood dyshemoglobins (carboxyhemoglobin (COHb) and methemoglobin (MetHb)) should also be considered for CASEVAC. Respiratory rate and function, as well as physical workload are also key parameters. The system should include environmental measures, such as barometric pressure, acceleration, temperature and humidity. All recommended sensing transducers should specify the necessary calibration methods for error sources.

(D) Warning Modalities: The warning modalities should be physiologically based and provide enough time to take corrective actions or provide automated mitigation.

(E) Modes of Mitigation The basic system shall include a mitigation component (e.g. supplemental oxygen or pharmacological intervention) and should afford the opportunity to account for both altitude and acceleration-induced hypoxia.

Additional considerations: Overall, HAMS must be compatible with multiple operational environments. The intent is to develop a modular prototype, with capabilities for 1) ground troops at altitude and 2) CASEVAC. Proposals shall include a thorough description of the associated supporting power requirements, electronics, personal protective equipment and life support systems integration details, procedures for using the recommended system, and how such a system would impact the maintenance and life-cycle costs associated with a potential deployment of the system. Technologies should demonstrate that they meet and ideally exceed the current state of the art in quantitative metrics, such as (but not limited to) size, weight, efficiency, effectiveness, manufacturability, power and interface requirements, term of expected availability, suitability for the industrial and military marketplace, initial cost, and life-cycle costs. Note that programmatic considerations for approval by the Food and Drug Administration (FDA) for the CASEVAC prototype should be included in the proposal. This includes costs for FDA approval, meeting with FDA consultants, and any other costs associated with the FDA process.

III. FULL PROPOSAL SUBMISSION AND AWARD INFORMATION

Full proposals should be submitted under ONRBAA14-001 by November 22, 2013. Full Proposals received after that date will be considered as time and availability of funding permit. Full instructions are outlined at the following link <u>http://www.onr.navy.mil/~/media/Files/Funding-Announcements/BAA/2014/14-001.ashx</u>. Proposal formats/templates must be consistent with the BAA.

ONR anticipates that both grants and contracts will be issued for this effort. Full proposals for contracts should be submitted in accordance with the instructions at Section IV, Application and Submission Information, item 2.b, Full Proposals and item 6, Submission of Full Proposals for Contracts, Cooperative Agreements, and Other Transactions. Full proposals for grants should be submitted in accordance with the instructions at Section IV, Application and Submission Information, item 5, Submission of Grant Proposals through Grants.gov. All full proposals for grants <u>must</u> be submitted through <u>www.grants.gov</u>. The following information must be completed as follows in the SF 424 to ensure that the application is directed to the correct individual for review: Block 4a, Federal Identifier: Enter N00014; Block 4b, Agency Routing Number, Enter the three (3) digit Program Office Code (342) and the Program Officer's name, last name first, in brackets [Steele, Chris]. All attachments to the application should also include this identifier to ensure the proposal and its attachments are received by the appropriate Program Office.

The period of performance for projects is for up to 48 months. ONR anticipates funding multiple awards for this effort totaling approximately \$6M over this period. It is envisioned that a CASEVAC prototype would be completed for transition to advanced product development by Q4 of FY16, and the ground prototype in Q4 of FY17. Budgets for multi-year proposals should align yearly funding requests with government fiscal years (01OCT-30SEP).

For contract proposals (i.e., non-grants) that include animal and/or human studies it is suggested, although not required, to structure as a base that is without animal/human studies. Animal and/or human studies can be added as options to the proposal if desired. Overall, if selected for funding, this will allow for expedited processing of funds. To be clear, offerors are not required to do so, and this WILL NOT be used as selection criteria for proposals.

Although ONR expects the above described program plan to be executed, ONR reserves the right to make changes.

Funding decisions should be made by December 17, 2013. Selected projects will have an estimated award date of April 1, 2014.

IV. SIGNIFICANT DATES

Event Recommended Full Proposal Submission Notification of Selection: Full Proposals * Awards * <u>Date</u> November 22, 2013 December 17, 2013 April 1, 2014

Note: * These are approximate dates.

V. POINTS OF CONTACT: In addition to the points of contact listed in ONR BAA 14-001, the specific points of contact for this announcement are listed below:

LCDR Christopher Steele E-mail: <u>Christopher.steele4@navy.mil</u> Phone: (703) 696-0618

Business and Contractual Point of Contact: Patrick Sisk E-mail: <u>Patrick.sisk@navy.mil</u> Phone: 703-696-6804

VI. Submission of Questions

Any questions regarding this announcement must be provided to the Technical Points of Contact and/or the Business Point of Contact listed above. All questions shall be submitted in writing by electronic mail.

Questions regarding this special notice must be submitted via email to LCDR Chris Steele (<u>Christopher.steele4@navy.mil</u>) no later than 1700 ET, November 01, 2013. Title the subject line "14-SN-0002 Questions." Questions after this date may not be answered.

Answers to questions submitted in response to this Special Notice will be addressed in the form of an Amendment and will be posted to the following web pages:

Federal Business Opportunities (FEDBIZOPPS) Webpage – <u>https://www.fbo.gov/</u> Grants.gov Webpage – <u>http://www.grants.gov/</u> ONR Special Notice Webpage - <u>http://www.onr.navy.mil/Contracts-</u> <u>Grants/Funding-</u> <u>Opportunities/Special-Notices.aspx</u>