Special Notice 13-SN-0003
Special Program Announcement for 2013 Office of Naval Research
"Hypoxia Monitoring, Alert, and Mitigation System"

The following provides answers to questions submitted in response to the Office of Naval Research Special Notice for Hypoxia Monitoring, Alert, and Mitigation System:

Is the eventual deployment target for this program the in-aircraft aviator? Or is the interest in a broad application to the warfighter in any hypoxic environment? Marines in the field in Afghanistan, medevac personnel in an unpressurized flight at high altitude, and aviators in general use?

ANSWER: The application is for any hypoxic environment including aircraft and high mountain operations.

What is the range of altitude of most interest to you and the program? 10,000 feet, 14,000ft, 18,000.

ANSWER: 8,000 through 50,000 ft.

What is the duration of exposure that you wish to monitor? A few minutes, or hours, or days? Or longer.

ANSWER: For aircraft operations, as long as 12 hours with replacement batteries. For mountain operations, it is days.

What are the critical metrics in the desired system?

ANSWER: The system shall be independent of the vehicle in which the warfighter is operating. The algorithm should account for individual differences in hypoxia tolerance and account for external, e.g., barometric pressure, and internal, e.g., physical workload, variables that degrade tolerance. The algorithm should be applicable from high mountain altitudes for ground operations at 8,000 ft through air operations to 50,000 ft. Warnings should be as close to 100% reliable as possible and be updated as conditions change in "real time." The Special Notice outlines parameters other than SpO2 that should be accounted for in algorithm development.

What is the primary application for the desired system: data collection, warning or automatic recovery?

ANSWER: A full system will have both data collection and warning capabilities. Mitigation techniques may be automatic or manual.

Algorithms addressing physiological state are the only interest? Expanding - Algorithms addressing consciousness or cognition/confusion or psychomotor (since these are not physiological states but may be based in physiological response) are not of interest at this time?

ANSWER: The topic description states "The Hypoxia Monitoring, Alert, and Mitigation System will predict/detect/warn warfighters of impending hypoxic events based on individual physiological, environmental, and cognitive monitoring." As such, algorithms should address physiological and cognitive states. However, there may only be physiologic and environmental sensor data to infer cognitive state in the mature system.

The solicitation notice for "Warning Modalities" specifies that they should be "physiologically based" warnings. Does this mean that the Government does not want interaction effects between physiological responses and/or environment and cognitive impairment metrics factored in to the warning modalities?

ANSWER: Physiologically based means that of the various variables input into the algorithm (environmental and cognitive metrics included) physiologic state is a key criterion. For example, a warning based on altitude alone would be insufficient.

Any algorithm should address the spectrum of operational employment (fixed wing, rotary wing pilot and ground soldier)?

ANSWER: Ideally, the algorithm should be applicable to all three environments. However, not all input data will be pertinent (e.g., acceleration for ground operations).

Hypoxia is stated - this is hypoxic hypoxia of altitude only (barometric pressure reference) or do you consider the hypoxia of acceleration exposure part of this? (i.e. are you interested in GLOC and Altitude LOC or just Altitude hypoxia?)

ANSWER: The algorithm should address detection and prediction of hypoxia, regardless of type.

Beta versions are specified - is it a requirement at the beta level to host this algorithm on a computing platform that could go on to a warfighter ? - (i.e. microcontroller with small memory capability (quite small) versus small computing platform (like a small android tablet) versus a desktop with large capacity (impractical).

ANSWER: Given that this is a 12 month effort, either is acceptable.

Is algorithm validation based on literature results sufficient at beta level?

ANSWER: Yes, though the offeror could propose collecting experimental data under 2(B).

Can the results of 2(B) be made available to further the validation?

ANSWER: Yes.

Is there a preference to have the system be universal and tied only to the pilot life support gear vs. interfaced with the aircraft? From my experience in military aviation, a system that is incorporated into current flight gear and unnoticeable to the pilot is optimum and the ability of the system to be standalone avoids the difficult process of aircraft integration/modification plus will allow the system to be immediately usable in multiple airframes.

ANSWER: Vehicle independence is a program goal.

What do you seen as the scope for this effort? The announcement states that there are currently $1,560,000 in funds allocated to this effort for one year of performance by multiple entities. For example, we could propose to research, develop and build a basic prototype in a year for around $200k, or we could fund a staff of engineers and scientists and be ready to provide a production model in a year for around $1m. Which the most appropriate/desired approach?

ANSWER: We suggest that you propose what you feel most advantageous to both ONR and your organization given the time and scope of the Special Notice.

13-SN-003 states that you are looking for a full proposal, but BAA 13-001 states that you may desire a white paper, an in-person presentation and/or a full proposal. We would be happy to provide any of these. Which formats do you prefer?

ANSWER: Full proposal as stated in Special Notice.

The BAA guidance states to discuss [technical content volume] with the source. Has there been a statement to that fact? Will it include the attachments?

ANSWER: 10 page limit, not including supporting documentation (attachments, CVs, etc).

For the full proposal the format is quite flexible. Do you have any particular desires for our format or proposal length?

ANSWER: 10 page limit, not including supporting documentation (attachments, CVs, etc).

Are there particular sections that we should focus on and is there certain content that you want to make sure is covered?

Necessary content covered should follow the Special Notice description. Guidelines for full proposals should be submitted under ONRBAA13-001 by January 18, 2013. Full instructions

are outlined at the following link http://www.onr.navy.mil/~/media/Files/Funding-Announcements/BAA/2013/13-001.ashx

How many hard copies of the proposal documents does the Government want delivered?

ANSWER: No hard copies need be submitted.

Does the Government want electronic copies of all proposal document files sent via email? If so, to LCDR Steele, Mr. Pollack or both? If not, the transmittal media preference CD-ROM?

ANSWER: All full proposals for Grants must be submitted through www.grants.gov and follow the instructions found there - not via e-mail.

Under the Special Notice, 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. **You may e-mail the proposal to LCDR Chris Steele at Christopher.steele4@navy.mil.**

Additionally, for Department of Defense applicants, proposals may be sent via email to LCDR Steele (christopher.steele4@navy.mil) vice via www.grants.gov.

The BAA instructions indicate that full proposals for Contracts should be mailed to a street address, but the instructions also request files in Excel, PDF and Word format.

ANSWER: No hard copies need be submitted.

If the proposal is to be submitted via regular mail, how many paper copies are required? Is delivery by courier (Fed Ex or UPS) acceptable?

ANSWER: No hard copies need be submitted.

Should the electronic files be emailed (and if so, to which address?) or included with the mailed hardcopies on a CD?

ANSWER: You may e-mail the proposal to LCDR Chris Steele at Christopher.steele4@navy.mil.

If email is acceptable, can the entire proposal be submitted by email?

ANSWER: Yes.

Section III of ONRBAA13-001 indicates that some topics cover export controlled technologies limiting research efforts to "U.S. persons" only per ITAR. Is this research

effort considered an export controlled technology? If the research is ITAR controlled, does this preclude using researchers or facilities in Canada?

ANSWER: The year one program does not involve ITAR.

RE: 13-SN-003, Section II 2 (A), first sentence, what does the Government mean by "adaptive" monitoring algorithm? Adaptive to aircraft, individual pilots? Does this statement imply the use of a learning algorithm (e.g., artificial intelligence – perhaps pattern recognition)?

ANSWER: Adaptive refers to the individual wearing the system. As the individual's physiologic state and environmental conditions change, the algorithm should account for these and modify its assessment and potential warnings accordingly. A learning algorithm certainly is one but not the only possible approach.

RE: 13-SN-003, Section II 2 (A), second sentence, the algorithm is to predict physiologic state and how it changes "over time"…what time frame is being indicated here (a specific flight or mission time, a tour, or life of pilot, other.)?

ANSWER: Over the course of a mission.

Should this proposal consider only the 1 year time frame discussed in the solicitation or should a vision for the four year effort be described with detailed statement of work to cover just the one year funding period?

ANSWER: The emphasis should be on the first year topic as outlined in the Special Notice, including a plan for sensing suite integration to be implemented in a 2nd year. However, the outcome of the 1st year effort should directly apply to the subsequent tasks as provided for reference in the Special Notice.

Is the Navy interesting in funding additional development work on the sensor suite in the upcoming 1-year effort? Should this work be proposed as an option, so that it may be elected into the contract or should it be proposed integral to the core proposal?

ANSWER: First year funding is for algorithm development and verification/validation, not hardware development.

Can you clarify what is meant by "(Beta version development sought under this Special Notice)." Looking up the definition of "beta version" suggests a version that sufficiently well-developed that it can be distributed to multiple users for evaluation. How does the Navy envision evaluating the algorithm? At this time, we have only one copy of hardware which can create human data for the algorithm to operate on. Consequently other evaluators will not be to evaluate the algorithm with input from the hardware. Is the Navy looking for an algorithm that can be evaluated using artificially created data input files? If so does the Navy

have a data input format in mind or is it up to the proposer to design the input data file format? Does this statement mean that the algorithm is to be coded into runnable software? If yes, is there a preferred software language?

ANSWER: Beta meant that ONR is looking for something more advanced than simply coding an algorithm based on symptom tables published in aeromedical textbooks. Any algorithm submitted should be in a format that can be readily used by Navy labs to test it as well as use government furnished data as test inputs for contractor use. Details on data format and language are not necessary to include in this proposal.

Also, the BAA proposal format calls for some discussion based on whether the work is Basic Research or Applied research and Advanced Technology Development - does this apply and if so which is it??

ANSWER: Funding is 6.2/6.3.

Is a firm fixed price [contract] the most appropriate model for this proposal?

ANSWER: Cost type contracts are expected considering the nature (e.g., Research & Development) of the work to be performed.

The contract provides the ability to include options. Is there a desire to include contract option(s) in this case versus a single funding for one year?

ANSWER: The Special Notice describes up to one year funding. As such, the base effort should be for just the first year. Vendors may include any combination or all of a Detection/Prediction Algorithm, Determination of Physiologic Metrics, and Sensing Suite Integration. Option years or option tasks may be included in the proposal.

Could you provide some insight into how much of a factor set-asides are in this funding?

ANSWER: Set-asides are not a factor.

In the special notice, it is referenced that there is a total funding amount of $1,560,000 for all awards. Is this funding for direct costs or for direct and indirect costs?

ANSWER: Total award, including both direct and indirect costs.

The BAA indicates that there is no fee allowed under special agreements. As I believe this would be a contract, I assum fee is aloowable. Can you confirm?

ANSWER: Yes, fee is allowable.