ONR BAA Announcement # 11-012

BROAD AGENCY ANNOUNCEMENT (BAA)
Autonomous Critical Care System (ACCS)

INTRODUCTION:

This publication constitutes a Broad Agency Announcement (BAA) as contemplated in Federal Acquisition Regulation (FAR) 6.102(d)(2), the Department of Defense Grants and Agreements regulations (DoDGARS) 22.315(a) and 35.106, and DoD's Other Transaction Guide for Prototypes Projects, USD(AT&L), OT Guide, Jan 2001. A formal Request for Proposals (RFP), solicitation, and/or additional information regarding this announcement will not be issued.

The Office of Naval Research (ONR) will not issue paper copies of this announcement. The ONR reserves the right to select for award all some or none of the proposals in response to this announcement. The ONR reserves the right to fund all, some or none of the proposals received under this BAA. ONR provides no funding for direct reimbursement of proposal development costs. Technical and cost proposals (or any other material) submitted in response to this BAA will not be returned. It is the policy of ONR to treat all proposals as sensitive competitive information and to disclose their contents only for the purposes of evaluation.

I. GENERAL INFORMATION

1. Agency Name -

Office of Naval Research,
One Liberty Center
875 N. Randolph Street
Arlington, VA 22203-1995

2. Research Opportunity Title -

Autonomous Critical Care System

3. Program Name -

Force Health Protection Casualty Care and Management Research Program

4. Research Opportunity Number -

ONR BAA 11-012

5. Response Date -

Full Proposals: 16 May 2011

6. Research Opportunity Description -

The Office of Naval Research (ONR) is interested in receiving proposals for *development of an Autonomous Critical Care System.*

Background: The ONR Force Health Protection program has been researching use of autonomous (closed-loop-control) systems for fluid resuscitation and mechanical ventilation since 2005 which demonstrated improved medical situational awareness and safety while reducing logistical requirements for fluids and oxygen. As a continuation of these studies ONR approved a Science and Technology (S&T) research program to develop a prototype Autonomous Critical Care System (ACCS).

Need Statement: To support naval combat and humanitarian assistance/disaster relief missions there is a need for a modular, automated, critical care system for close management of hemodynamically unstable patients. The system may be employed in both land-based and shipboard medical treatment facilities and during medical evacuation to a sea-base, as a means to increase survivability and improve patient outcomes. Minimally-supervised patient transport may be accomplished by ground vehicle, rotary or fixed wing aircraft, or by high-speed vessel, and the system will need to provide continuous monitoring and medical management of patients to prevent any degradation in clinical status. It is also anticipated that unmanned ground or air vehicles may be used in the future for patient transport and the system will validate effective patient monitoring and control in an unmanned vehicle during transport.

Objective: Advances in machine learning and associated development of computer-based automated control algorithms, device integration, and wireless communications enable improved pre-hospital and hospital patient care capabilities. The goal of this program is to develop a prototype system that will provide complete medical management of a critically injured casualty for a period $\geq$ 6 hrs without human intervention and to demonstrate the ability of the system to correctly diagnose and manage a series of scripted, medically complex, life-threatening clinical events. The prototype system will

have both decision-assist and fully-autonomous (i.e. closed-loop-control) capabilities, or mixed modes selected by the caregiver. Decision-assist algorithms provide treatment recommendations based on the real-time assessment of the physiology of the patient which can either be accepted or rejected by the caregiver; closed-loop-control algorithms manage the patient without caregiver input. The development and implementation of closed-loop algorithms must be done in accordance with 21 CFR 820.30 Design Controls.

The ACCS can be thought as "system of systems" which contains both hardware and software components and requires near infallibility and redundancy to prevent loss of life. Selection of components must be based on performance, reliability, usability and maintainability. The ACCS should be scalable, i.e. modular in design to allow addition/removal of components to meet mission requirements; components should be plug-and-play to the greatest extent possible. Software will be assessed as to efficiency, integrity, reliability, survivability, usability, correctness, maintainability, verifiability, expandability, flexibility, and interoperability. A spiral development process is desired to incorporate changes resulting from experimentation as well as technology opportunities.

Table 1: Key Performance Parameters

Key Performance Parameters (KPPs)	**Development Objectives**
System Performance	1. Successful demonstration of ACCS ability to manage a large animal poly-trauma model (hemorrhagic shock, bone fracture, muscle damage and moderate/severe traumatic brain injury) under controlled (laboratory) and operational conditions for a minimum of six (6) hours. As part of the evaluation process the system must be able to demonstrate ability to successfully manage induced clinical events to insure survival of the patient. 2. Demonstrate remote monitoring and control of the ACCS. 3. Demonstrate remote monitoring and control of the ACCS in an unmanned ground or air vehicle using combatant communication network.

Table 2: Key System Attributes

Attribute	**Development Objectives**
Weight	< 30 lbs; The objective is to make the system as small and as light as possible.
Size	Must be able to fit in all current naval air platforms (CH46 & CH53, and MV22).
Attachment	Integral attachment to NATO litter; allows 80% accessibility to patient.
Low Heat Transmission	Can be safely touched with bare skin.

Power	The system: (1) must operate from 110/220 VAC, 60 Hz, or 8-48 VDC; (2) will have a rechargeable battery capable of operating for 8 hours; (3) will have a recharge time < 3 hrs; (4) allow renewing or change of power sources without interrupting operations; (5) will display total power received, time to full charge, time to full discharge, useable power life; (6) must have back-up power source capable of 8-hr autonomous operation.
Alternate Monitor Display	The system will have redundant monitor capability.
System Notification	The system will have manually adjustable audible and visual alarms over an intensity range of 0-100% with 99% effectiveness and accuracy while operating.
Patient Data and Documentation	The system will: (1) use industry standard data storage and data transfer technology; (2) capture, store, and display both patient and system information at a minimum of 48 hours; (3) have an open architecture to log and store patient clinical parameters and waveforms at a minimum of 48 hours; (4) provide for data transferable between device and remote medical treatment facility; (5) have simulation and training software to familiarize medical personnel with operation and maintenance of device.
Telemedicine and Wireless Capability	The system will: (1) provide for physician monitoring of patient status and system override capability from a remote medical treatment facility; (2) have wireless patient monitoring capability.
Central Control Processing Unit	Has interface point and unified control/integrated display
Internet Accessibility	Must be Net Ready as defined in CJCSI 6212.01; 15-Dec-08
Peripheral Hardware Interface	The system will capture, store, and display both patient and system information from attached clinical components with 99% accuracy.
Patient Warming	Closed-loop-control maintenance of body temperature +/-1^{o}F.
Physiological and Hemodynamic Monitoring	The system will: (1) monitor, record and display heart rate (derived from ECG, NIBP, or other); (2) have wireless 3-12 lead ECG monitoring capability; (3) have arrhythmia detection and alarm capability; (4) capture and record respiratory rate, pulse-oximetry, and non-invasive cardiac output, total peripheral resistance, stroke volume; (5) have four separate channels for intravascular catheters.; (6) have clinical parameters and waveforms that are parameters and waveforms that are visualized with 99% accuracy during movement; (7) have wireless patient monitoring capability to include $SPO_{2.}$
Fluid and Drug Therapy	The system will: (1) be decision-assist and closed-loop control capable; (2) record (date and time stamp) patient measurements and interventions, and cumulative total fluid received (infused

	and net volumes); (2) have decision-assist and closed-loop control algorithms control rate and volume of multiple fluids (crystalloids, colloids, blood/blood products); (3) have fluid warming to 40^{o}F capability; (4) be rapid fluid infuser capable (6L/hr) with free-flow protection and vented bubble detection/removal; (5) have industry standard alarms (audio and visual), including low battery alarm; (6) provide a library of medications of commonly used drugs to treat trauma patients (e.g. epinephrine, phenylephrine, dopamine, vasopressin, paralytics, etc), and a system to allow drug calculations.
Oxygen Generating	The system will: (1) provide 6L/min of 93% United States Pharmacopeia (USP) oxygen (+/-) 5%; (2) provide inspired oxygen (FiO_2) range of 21% to 100%; (3) control low flow oxygen source to maintain stable FiO_2.
Ventilation	The system will: (1) have decision-assist and closed-loop algorithms for delivery of FiO_2 (21-100%) and positive end-expiratory pressure (PEEP) (0-25 +/- 1 cm H_2O); (2) have a flow capable ventilator (100L/min at 40 cm H_2O); (2) control low flow oxygen source to maintain stable FiO_2 +/- 5% and alarm; (3) have pressure- and volume-controlled ventilation modes for pediatric and adults; (4) accept oxygen input pressure of 35-70 psi; (5) display and monitor inspired oxygen concentration (FiO_2) and end tidal CO_2; (6) provide humidified oxygen (100% saturation); (7) allow administration of aerosolized medications; (8) have programmable standard of care alarms: low pressure, high pressure, apnea, low source gas pressure, power supply low, low minute ventilation, high respiratory rate; Decision-assist algorithms for all alarm conditions; (9) automatically restarts after unexpected loss of power with user approved settings before reinitiating; (10) create exportable records of ventilator performance; (11) displays operational time remaining for battery life; (12) have time stamp, capture and playback capability for waveforms and significant events.
Suction	The system will: (1) be capable of suctioning with variable digital control and intermittent and constant suction capable of high/low endotracheal tube, gastic, and chest tube; (2) have controlled suction capability (10-300 mm Hg); (3) have pop-off valves.
Analgesia/Anesthesia	System will have (1) standard of care and total intravenous anesthesia (TIVA) capability; BIS monitoring capable.
Documentation	Manuals and simulation and training software to familiarize medical personnel with operation and maintenance of system.
Environmental	Must meet MIL-STD 810F; MIL-STD 202G for environment exposure.

CBRN Filtration	The device will have a filter system for ventilation that is 100% CBRN effective.
Airworthiness release (AWR) for rotary and fixed wing evacuation aircraft	Function of Navy Advanced Development Program

Offerors are encouraged to submit proposals for the entire system, or for the development of decision-assist and closed-loop algorithm-controlled component devices for:

- Mechanical ventilation
- Fluid and drug therapy
- Anesthesia/analgesia
- Patient warming
- Suction (endotracheal, gastric and chest tubes)
- Oxygen production

Offerors are also encouraged to submit proposals for:

- Communication/telemedicine capabilities
- System integration

Validation\integration of decision-assist and closed-loop algorithms for the control of mechanical ventilation, suction, oxygen production, fluid and drug therapy, anesthesia and analgesia, and management of core temperature may be the responsibility of a Prime contractor or of a lead System Integrator; the approach is TBD.

Exit Criteria: Successful completion of the tasks as described in Table 1 resulting in the development of the ACCS to Technology Readiness Level (TRL) 6, "System tested with interfaces and support systems in relevant or simulated operational environment. Configuration Management Approach developed". It is anticipated that further development, clinical evaluation, and regulatory approval of the entire system will be supported by the Navy Advanced Medical Development Program through subsequent awards outside of this BAA. As the device must ultimately be approved by the FDA records must be kept in compliance with GLP/GMP guidelines to support an FDA IDE application per regulations under 21 CFR 812 and Pre-Market Approval (PMA) as a Class III medical device under 21 CFR 814.3.

7. Point(s) of Contact -

Questions of a technical nature shall be directed to the cognizant Technical Point of Contact, as specified below:

Dr. Michael B. Given
Program Officer, Casualty Care and Management
Warfighter Protection and Applications Division, Code 341
One Liberty Center, 875 North Randolph Street, Arlington, VA 22203-1995

Email Address: michael.given@navy.mil

Questions of a business nature shall be directed to the cognizant Contract Specialist (business point of contact), as specified below:

Mr. Patrick Sisk
Contract Specialist
Contracts & Grants Division, Code 254
One Liberty Center, 875 North Randolph Street, Arlington, VA 22203-1995
Email Address: patrick.sisk@navy.mil

Note: All UNCLASSIFIED communications shall be submitted via email. All questions of an UNCLASSIFIED nature to the Technical Point of Contract (POC) shall be sent via email with a copy to the designated Business POC.
Questions submitted within 2 weeks prior to a deadline may not be answered, and the due date for submission of the white paper and/or full proposal will not be extended.

Amendments will be posted to one or more of the following web pages:

- Federal Business Opportunities (FEDBIZOPPS) Webpage – https://www.fbo.gov/
- ONR Broad Agency Announcement (BAA) Webpage – http://www.onr.navy.mil/en/Contracts-Grants/Funding-Opportunities/Broad-Agency-Announcements.aspx

8. Instrument Type(s) -

Awards will take the form of contracts only.

9. Catalog of Federal Domestic Assistance (CFDA) Numbers -

12.300

10. Catalog of Federal Domestic Assistance (CFDA) Titles -

DOD Applied Scientific Research

11. Other Information -

Work funded under a BAA may include basic research, applied research and some Advanced Technology Development (ATD). With regard to any restrictions on the conduct or outcome of work funded under this BAA, ONR will follow the guidance on and definition of "contracted fundamental research" as provided in the Under Secretary of Defense (Acquisition, Technology and Logistics) Memorandum of 24 May 2010.

As defined therein the definition of "contracted fundamental research", in a DoD contractual context, includes [research performed under] grants and contracts that are (a) funded by Research, Development, Test, and Evaluation Budget Activity 1 (Basic Research), whether performed by universities or industry or (b) funded by Budget

Activity 2 (Applied Research) and performed on campus at a university. The research shall not be considered fundamental in those rare and exceptional circumstances where the applied research effort presents a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense, and where agreement on restrictions have been recorded in the contract or grant.

Pursuant to DoD policy, research performed under grants and contracts that are a) funded by Budget Category 6.2 (Applied Research) and NOT performed on-campus at a university or b) funded by Budget Category 6.3 (Advanced Research) does not meet the definition of "contracted fundamental research." In conformance with the USD(AT&L) guidance and National Security Decision Direction 189, ONR will place no restriction on the conduct or reporting of unclassified "contracted fundamental research," except as otherwise required by statute, regulation or Executive Order. For certain research projects, it may be possible that although the research being performed by the prime contractor is restricted research, a subcontractor may be conducting "contracted fundamental research." In those cases, it is the ***prime contractor's responsibility*** in the proposal to identify and describe the subcontracted unclassified research and include a statement confirming that the work has been scoped, negotiated, and determined to be fundamental research according to the prime contractor and research performer.

Normally, fundamental research is awarded under grants with universities and under contracts with industry. Non-fundamental research is normally awarded under contracts and may require restrictions during the conduct of the research and DoD pre-publication review of research results due to subject matter sensitivity.

Regarding the present BAA, the Science and Technology (S&T) efforts to be funded will consist of applied research and advanced technology development. The funds available to support awards are Budget Activities 2 and 3.

FAR Part 35 restricts the use of the Broad Agency Announcements (BAAs), such as this, to the acquisition of basic and applied research and that portion of advanced technology development not related to the development of a specific system or hardware procurement. Contracts and grants and other assistance agreements made under BAAs are for scientific study and experimentation directed towards advancing the state of the art and increasing knowledge or understanding.

THIS ANNOUNCEMENT IS NOT FOR THE ACQUISITION OF TECHNICAL, ENGINEERING AND OTHER TYPES OF SUPPORT SERVICES.

II. AWARD INFORMATION

*Total Amount of Funding Anticipated: $20M
*Anticipated Number of Awards: Multiple (sub-systems)
*Anticipated Range of Individual Award Amounts: $2-10M
*Previous Year(s) Average Individual Award Amounts: N/A
*Anticipated Period of Performance: Dec. 16, 2011 – Dec. 16, 2016

It is anticipated that two awards will be made and that the awardees will act not only as developers but also as a system integrator to produce functional prototypes to be used in the pre-clinical testing using the large animal polytrauma model. A down-selection will be made, and the further development of the selected contractor will be completed by the Navy's Advanced Medical Development program.

In the case of funded proposals for the production and testing of prototypes, ONR may during the contract period add a contract line item or contract option for the provision of advanced component development or for the delivery of additional prototype units. However, such a contract addition shall be subject to the limitations contained in Section 819 of the National Defense Authorization Act for Fiscal Year 2010.

III. ELIGIBILITY INFORMATION

All responsible sources from academia and industry may submit proposals under this BAA. Historically Black Colleges and Universities (HBCUs) and Minority Institutions (MIs) are encouraged to submit proposals and join others in submitting proposals. However, no portion of this BAA will be set aside for HBCU and MI participation.

Federally Funded research & Development Centers (FFRDCs), including Department of Energy National Laboratories, are not eligible to receive awards under this BAA. However, teaming arrangements between FFRDCs and eligible principal bidders are allowed so long as they are permitted under the sponsoring agreement between the Government and the specific FFRDC.

Navy laboratories and warfare centers as well as other Department of Defense and civilian agency laboratories are also not eligible to receive awards under this BAA and should not directly submit full proposals in response to this BAA. If any such organization is interested in one or more of the programs described herein, the organization should contact an appropriate ONR POC to discuss its area of interest. The various scientific divisions of ONR are identified at http://www.onr.navy.mil/. As with FFRDCs, these types of federal organizations may team with other responsible sources from academia and industry that are submitting proposals under this BAA.

Teams are also encouraged and may submit proposals in any and all areas. However, Offerors must be willing to cooperate and exchange software, data and other information

in an integrated program with other contractors, as well as with system integrators, selected by ONR.

IV. APPLICATION AND SUBMISSION INFORMATION

1. Application and Submission Process -

Full Proposals only will be solicited due to time constraints.

Full proposals shall be submitted directly to the Technical Point of Contact identified in Section I.7 above. The Full Proposal due date is listed in Section I.5 above.

2. Content and Format of Full Proposals -

The Proposals submitted under this BAA are expected to be unclassified.

INSTRUCTIONS FOR CONTRACTS

NOTE: *Submission instructions for BAAs issued after FY2010 have changed significantly from previous requirements. Potential Offerors are advised to carefully read and follow the instructions below. The new format and requirements have been developed to streamline and ease both the submission and review of proposals. Both the Template and the Spreadsheet have instructions imbedded into them that will assist in completing the documents. Also, both the Template and the Spreadsheet require completion of cost-related information – both documents must be fully completed to constitute a valid proposal.*

All *proposals must use ONR's Technical and Cost Proposal Template and Cost Proposal Spreadsheet. The Template can be found by following this link: http://www.onr.navy.mil/Contract-Grants/submit-proposal/contracts-proposal/cost-proposal.aspx. Please note that all the attachments listed in Section III.8 of the Template can be incorporated into the Template file for submission.*

The Cost Proposal Spreadsheet can be found by following this link: http://www.onr.navy.mil/Contracts-Grants/submit-proposal/contracts-proposal/cost-proposal.aspx. Click on the "proposal spreadsheet" link and save a copy of the spreadsheet. Instructions for completion have been embedded into the spreadsheet. Any proposed options that are identified in the Technical and Cost Proposal Template, but are not fully priced out in the Cost Proposal Spreadsheet, will not be included in any resulting contract or other transaction. If proposing options, they **must** be separately priced and separate spreadsheets should be provided for the base period and each option period.

For proposed subcontracts or interorganizational transfers over $150,000, Offerors must provide a separate fully completed Cost Proposal Spreadsheet in support of the proposed costs. This spreadsheet, along with supporting documentation, must be provided either in a sealed envelope with the prime's proposal or via email directly to both the Program

Officer and the Business Point of Contact at the same time the prime proposal is submitted. The email should identify the proposal title, the prime Offeror and that the attached proposal is a subcontract, and should include a description of the effort to be performed by the subcontractor. Offerors should also familiarize themselves with the new subcontract reporting requirements set forth in Federal Acquisition Regulation (FAR) clause 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards. From October 1, 2010 through February 28, 2011, any newly awarded subcontract must be reported if the prime contract award amount is $550,000 or more. Starting March 1, 2011, any newly awarded subcontract must be reported if the prime contract award amount was $25,000 or more. The pertinent requirements can be found in Section VII, Other Information, of this document.

Offerors should submit one original, two hard copies, and one electronic copy on a DVD (in Microsoft® Word or Excel 2007 compatible format).

Offerors shall follow the Technical and Cost Proposal Template. The electronic Technical and Cost Proposal should be submitted in a secure, pdf compatible format, save for the electronic file for the Cost Proposal Spreadsheet which should be submitted in a Microsoft Excel 2007 compatible format. All attachments should be submitted in a secure, pdf compatible format.

The secure pdf compatible format is intended to prevent unauthorized editing of the proposal prior to any award. A password should not be required for opening the proposal document, but the Government must have the ability to print and copy text, images, and other content. Offerors may also submit their Technical and Cost Proposal in an electronic file that allows for revision (preferably in Microsoft Word) to facilitate the communication of potential revisions. Should an Offeror amend its Technical and Cost Proposal package, the amended proposal should be submitted following the same hard and electronic copy guidance applicable to the original proposal.

The electronic submission of the Excel spreadsheet should be in a "useable condition" to aid the Government with its evaluation. The term "useable condition" indicates that the spreadsheet should visibly include and separately identify within each appropriate cell any and all inputs, formulas, calculations, etc. The Offeror should not provide "value only spreadsheets" similar to a hard copy.

3. Significant Dates and Times -

Anticipated Schedule of Events		
Event	**Date (MM/DD/YEAR)**	**Time (Local Eastern Time)**
Full Proposals Due Date	16 May 2011	4:00 PM EST
Notification of Selection for Award*	24 June 2011	N/A
Contract Awards*	16 December 2011	N/A

***These dates are estimates as of the date of this announcement.**

NOTE: Due to changes in security procedures since September 11, 2001, the time required for hard-copy written materials to be received at the Office of Naval Research has increased. Materials submitted through the U.S. Postal Service, for example, may take seven days or more to be received, even when sent by Express Mail. Thus any hard-copy proposal should be submitted long enough before the deadline established in the solicitation so that it will not be received late and thus be ineligible for award consideration.

4. Submission of Late Proposals (Applicable to Full Proposals)

Any proposal, modification, or revision, that is received at the designated Government office after the exact time specified for receipt of proposals is "late" and will not be considered unless it is received before award is made, the contracting officer determines that accepting the late proposal would not unduly delay the acquisition and

(a) If it was transmitted through an electronic commerce method authorized by the announcement, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(b) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of proposals and was under the Government's control prior to the time set for receipt of proposals; or

(c) It was the only proposal received.

However, a late modification of an otherwise timely and successful proposal, that makes its terms more favorable to the Government will be considered at any time it is received and may be accepted.

Acceptable evidence to establish the time or receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the Government office designated for receipt of proposals by the exact time specified in the announcement, and urgent Government requirements preclude amendment of the announcement closing date, the time specified for receipt of proposals will be deemed to be extend to the same time of day specified in the announcement on the first work day on which normal Government processes resume.

The contracting officer must promptly notify any offeror if its proposal, modifications, or revision was received late and must inform the offeror whether its proposal will be considered.

5. Address for the Submission of Full Proposals for Contracts

Hard copies of Full Proposals for Contracts should be sent to the Office of Naval Research at the following address:

Office of Naval Research
Attn: Dr. Michael B. Given,
ONR Department Code 341
875 North Randolph St.
Arlington, VA 22203-1995

Telephone Number: 703-696-4055

NOTE: PROPOSALS SENT BY FAX OR EMAIL WILL NOT BE CONSIDERED.

V. EVALUATION INFORMATION

1. Evaluation Criteria –

Award decisions will be based on a competitive selection of proposals resulting from a scientific and cost review. Evaluations will be conducted using the following evaluation criteria:

1) Overall scientific and technical merits of the proposal;
2) The offeror's capabilities, related experience, facilities, techniques or unique combinations of these which are integral factors for achieving the proposal objectives;
3) The qualifications, capabilities and experience of the proposed Principal Investigator (PI), team leader and key personnel who are critical in achieving the proposal objects; and
4) The realism of the proposed costs and availability of funds.
5) Programmatic relevance

Overall, the technical factors (1 – 3 & 5 above) are significantly more important than the cost factor, with the technical factors all being of equal value. The degree of importance of cost will increase with the degree of equality of the proposals in relation to the other factors on which selection is to be based, or when the cost is so significantly high as to diminish the value of the proposal's technical superiority to the Government.

The Office of Naval Research is strongly committed to providing meaningful subcontracting opportunities for small businesses, small disadvantaged businesses, woman-owned small businesses, HUBZone small businesses, veteran-owned small business, service disabled veteran-owned small businesses, historically black colleges and universities, and minority institutions through its awards. For proposed awards to be made as contracts (that exceed $650,000) to other than small businesses, the Offeror is required to submit a Small Business Subcontracting Plan in accordance with FAR 52.219-9. For proposed awards made as contracts to small businesses at any value or to other than Small Businesses that are less than $650,000, the Offeror shall provide a

statement which demonstrates how it intends to provide meaningful subcontracting opportunities to support this policy.

The Government will evaluate options for award purposes by adding the total cost for all options to the total cost for the basic requirement. Evaluation of options will not obligate the Government to exercise the options during contract performance.

2. Evaluation Panel -

Technical and cost proposals submitted under this BAA will be protected from unauthorized disclosure in accordance with FAR 3.104-4 and 15.207. The cognizant Program Officer and other Government scientific experts will perform the evaluation of technical proposals. Restrictive notices notwithstanding, one or more support contractors may be utilized as subject-matter-expert technical consultants. However, proposal selection and award decisions are solely the responsibility of Government personnel. Each support contractor's employee having access to technical and cost proposals submitted in response to this BAA will be required to sign a non-disclosure statement prior to receipt of any proposal submissions.

VI. AWARD ADMINISTRATION INFORMATION

1. Administrative Requirements –

- North American Industry Classification System (NAICS) code – The NAICS code for this announcement is 541712 with a small business size standard of 500 employees.

- Central Contractor Registration: All Offerors submitting proposals or applications must:

  (a) be registered in the Central Contractor Registration (CCR) prior to submission;
  (b) maintain an active CCR registration with current information at all times during which it has an active Federal award or an application under consideration by any agency; and
  (c) provide its DUNS number in each application or proposal it submits to the agency.

Subcontracting Plans shall be submitted by all but small business concerns for proposals that exceed $650,000 in accordance with FAR 52.219-9.

NOTE: Central Contractor Registry (CCR), Subcontracting Plan requirements and Certification requirements are all set forth in the ONR Technical and Cost Proposal Template for those submitting contract proposals.

2. Reporting -

The following are samples of data deliverables that are typically required under a research effort:

*Mandatory Monthly Technical and Financial Progress Reports
*Presentation Materials
*Final Report

Additional data deliverables may be proposed and finalized during negotiations. Research performed under contracts may also include the delivery of software, prototypes, and other hardware deliverables.

The final deliverables of this effort shall include up to three (3) prototypes in addition to the reporting requirements. These prototypes will be used to solicit end-user comments/input to be considered in the final design of a pre-production prototype.

VII. OTHER INFORMATION

1. Government Property/Government Furnished Equipment (GFE) and Facilities

Government research facilities and operational military units are available and should be considered as potential government-furnished equipment/facilities. These facilities and resources are of high value and some are in constant demand by multiple programs. It is unlikely that all facilities would be used for any one specific program. The use of these facilities and resources will be negotiated as the program unfolds. Offerors should indicate in the Technical and Cost Proposal Template, Section II, Blocks 8 and 9, which of these facilities are critical for the project's success.

2. Security Classification

Reserved.

3. Use of Animals and Human Subjects in Research

If animals are to be utilized in the research effort proposed, the Offeror must complete a DoD Animal Use Protocol with supporting documentation (copies of AAALAC accreditation and/or NIH assurance, IACUC approval, research literature database searches, and the two most recent USDA inspection reports) prior to award. For assistance with submission of animal research related documents, contact the ONR Animal Use Administrator at (703) 696-4046.

Similarly, for any proposal for research involving human subjects, the Offeror must submit or indicate an intention to submit prior to award: documentation of approval from an Institutional Review Board (IRB); IRB-approved research protocol; IRB-approved informed consent form; proof of completed human research training (e.g., training certificate or institutional verification of training); an application for a DoD-Navy Addendum to the Offeror's DHHS-issued Federal wide Assurance (FWA) or the Offeror's DoD-Navy Addendum. In the event that an exemption criterion under 32 CFR.219.101 (b) is claimed, provide documentation of the determination by the Institutional Review Board (IRB) Chair, IRB vice Chair, designated IRB administrator or official of the human research protection program including the category of exemption

and short rationale statement. This documentation must be submitted to the ONR Human Research Protection Official (HRPO), by way of the ONR Program Officer. Information about assurance applications and forms can be obtained by contacting ONR_343_contact@navy.mil. If the research is determined by the IRB to be greater than minimal risk, the Offeror also must provide the name and contact information for the independent medical monitor. For assistance with submission of human subject research related documentation, contact the ONR Human Research Protection Official at (703) 696-4046.

For contracts and orders, the award and execution of the contract, order, or modification to an existing contract or order serves as notification from the Contracting Officer to the Contractor that the HRPO has approved the assurance as appropriate for the research under the Statement of Work and also that the HRPO has reviewed the protocol and accepted the IRB approval or exemption determination for compliance with the DoD Component policies. See, DFARS 252.235-7004.

4. Recombinant DNA

Reserved.

5. Department of Defense High Performance Computing Program

Reserved.

6. Organizational Conflicts of Interest

All Offerors and proposed subcontractors must affirm whether they are providing scientific, engineering, and technical assistance (SETA) or similar support to any ONR technical office(s) through an active contract or subcontract. All affirmations must state which office(s) the offeror supports and identify the prime contract numbers. Affirmations shall be furnished at the time of proposal submission. All facts relevant to the existence or potential existence of organizational conflicts of interest (FAR 9.5) must be disclosed. The disclosure shall include a description of the action the offeror has taken or proposes to take to avoid, neutralize, or mitigate such conflict. In accordance with FAR 9.503 and without prior approval, a contractor cannot simultaneously be a SETA and a research and development performer. Proposals that fail to fully disclose potential conflicts of interests or do not have acceptable plans to mitigate identified conflicts will be rejected without technical evaluation and withdrawn from further consideration for award. If a prospective offeror believes that any conflict of interest exists or may exist (whether organizational or otherwise), the offeror should promptly raise the issue with ONR by sending his/her contact information and a summary of the potential conflict by e-mail to the Business Point of Contact in Section I, item 7 above, before time and effort are expended in preparing a proposal and mitigation plan. If, in the sole opinion of the Contracting Officer after full consideration of the circumstances, any conflict situation cannot be effectively avoided or mitigated, the proposal may be rejected without technical evaluation and withdrawn from further consideration for award under this BAA.

7. Project Meetings and Reviews

Individual program reviews between the ONR sponsor and the performer may be held as necessary. Program status reviews may also be held to provide a forum for reviews of the latest results from experiments and any other incremental progress towards the major demonstrations. These meetings will be held at various sites throughout the country. For costing purposes, offerors should assume that 40% of these meetings will be at or near ONR, Arlington, VA and 60% at other contractor or government facilities. Interim meetings are likely, but these will be accomplished via video telephone conferences, telephone conferences, or via web-based collaboration tools.

8. Executive Compensation and First-Tier Subcontract Reporting

Section 2(d) of the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. No. 109-282), as amended by section 6202 of the Government Funding Transparency Act of 2008 (Pub. L. 110-252), requires the Contractor to report information on subcontract awards. The law requires all reported information be made public, therefore, the Contractor is responsible for notifying its subcontractors that the required information will be made public.

Unless otherwise directed by the Contracting Officer, by the end of the month following the month of award of a first-tier subcontract with a value of $25,000 or more, (and any modifications to these subcontracts that change previously reported data), the Contractor shall report the following information at http://www.fsrs.gov for each first-tier subcontract:

(a) Unique identifier (DUNS Number) for the subcontractor receiving the award and for the subcontractor's parent company, if the subcontractor has one.

(b) Name of the subcontractor.

(c) Amount of the subcontract award.

(d) Date of the subcontract award.

(e) A description of the products or services (including construction) being provided under the subcontract, including the overall purpose and expected outcomes or results of the subcontract.

(f) Subcontract number (the subcontract number assigned by the Contractor).

(g) Subcontractor's physical address including street address, city, state, and country. Also include the nine-digit zip code and congressional district.

(h) Subcontractor's primary performance location including street address, city, state, and country. Also include the nine-digit zip code and congressional district.

(i) The prime contract number, and order number if applicable.

(j) Awarding agency name and code.

(k) Funding agency name and code.

(l) Government contracting office code.

(m) Treasury account symbol (TAS) as reported in FPDS.

(n) The applicable North American Industry Classification System (NAICS) code.

By the end of the month following the month of a contract award, and annually thereafter, the Contractor shall report the names and total compensation of each of the five most highly compensated executives for the Contractor's preceding completed fiscal year at http://www.ccr.gov, if –

(a) In the Contractor's preceding fiscal year, the Contractor received –

(i) 80 percent or more of its annual gross revenues from Federal contracts (and subcontracts), loans, grants (and subgrants) and cooperative agreements; and

(ii) $25,000,000 or more in annual gross revenues from Federal contracts (and subcontracts), loans, grants (and subgrants) and cooperative agreements; and

(b) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at http://www.sec.gov/answers/execomp.htm.).

Unless otherwise directed by the Contracting Officer, by the end of the month following the month of a first-tier subcontract with a value of $25,000 or more, and annually thereafter, the Contractor shall report the names and total compensation of each of the five most highly compensated executives for each first-tier subcontractor for the subcontractor's preceding completed fiscal year at http://www.fsrs.gov, if –

(a) In the subcontractor's preceding fiscal year, the subcontractor received –

(i) 80 percent or more of its annual gross revenues from Federal contracts (and subcontracts), loans, grants (and subgrants) and cooperative agreements; and

(ii) $25,000,000 or more in annual gross revenues from Federal contracts (and subcontracts), loans, grants (and subgrants) and cooperative agreements; and

(b) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at http://www.sec.gov/answers/execomp.htm.).

If the Contractor in the previous tax year had gross income, from all sources, under $300,000, the Contractor is exempt from the requirement to report subcontractor awards. Likewise, if a subcontractor in the previous tax year had gross income from all sources under $300,000, the Contractor does not need to report awards to that subcontractor.