Multifunctional Resuscitation Fluid (MRF)

INTRODUCTION:

This publication constitutes a Broad Agency Announcement (BAA) as contemplated in Federal Acquisition Regulation (FAR) 6.102(d)(2). A formal Request for Proposals (RFP), other solicitation, 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 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

2. Research Opportunity Title –

Multifunctional Resuscitation Fluid

3. Program Name –

Casualty Care and Management Research Program

4. Research Opportunity Number –

BAA 10-008

5. Response Dates –

Consideration for FY11 program funding:
White Papers Due Date: 24 March 2010 2PM Eastern Time
Full Proposals Due Date: 19 May 2010 2PM Eastern Time

6. Research Opportunity Description –

The Force Health Protection Program of the Warfighter Performance Department at the Office of Naval Research (Code 342) is soliciting white papers and full proposals for Multifunctional Resuscitation Fluid.

Work funded under this BAA may include applied research and 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 26 June 2008. 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 performed by universities or industry or (b) funded by Budget Activity 2 (Applied Research) and performed on-campus at a university. Advanced Technology Development (ATD) is funded through Budget Activity 3. In conformance with the USD (AT&L) guidance and National Security Decision Directive 189, ONR will place no restriction on the conduct or reporting of unclassified fundamental research, except as otherwise required by statue, regulation or Executive Order. Normally, fundamental research is awarded under grants with universities and under contracts with industry. ATD projects are 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. In regards to the present BAA, the Research & Development efforts to be funded consist of applied research and ATD. The funds available to support awards are Budget Activity 2 and Budget Activity 3.

Statement of Problem: The leading cause of preventable death on the battlefield remains uncontrolled hemorrhage. Current first-responder treatment is to control or stop hemorrhage and to replace lost blood volume with a crystalloid or colloid resuscitation fluid. However, these resuscitation fluids are limited in capability, provide only volume, and are not adequate to sustain casualties for potentially long casualty evacuation (CASEVAC) times that may occur in expeditionary warfare. Further, if over-administered, the use of these fluids may result in dilutional coagulopathy and contribute to development of hypothermia. Whole blood, packed red blood cells, liquid platelets, and thawed frozen plasma are not available in expeditionary medicine due to lack of refrigeration. The requirement is for a resuscitation fluid which does not need refrigeration and which not only provides volume (to replenish lost blood), but also coagulation factors and an oxygen carrier as well to control bleeding and prevent shock, respectively.

Objective: To obtain FDA Investigational New Drug (IND) approval and completion of a Phase I clinical trial for a multifunctional resuscitation fluid (MRF) product. The MRF will replace lost blood volume, provide oxygen to tissues, and replace coagulation factors lost during bleeding to prevent further blood loss. The product will not require refrigeration. The product will have a long shelf-life, be easily reconstituted (if dried) and administered, restore intravascular volume, provide oxygen to tissues, and restore coagulation factors lost due to hemorrhage.

It is anticipated that a product may contain dried plasma, dried platelets, an oxygen carrier (perfluorocarbon, hemoglobin-based, or other) and possibly other components to provide support to ischemic cells/tissues to prevent/mitigate development of hemorrhagic shock. It is also anticipated that no single performer will have all of the required expertise, which will necessitate partnerships between different entities. It is realized that multi-component products have a far more difficult route to obtain Food and Drug Administration (FDA) approval. Therefore a systems approach to administration is possible. However, administration of the product must be corpsman/medic friendly.

Program Structure:

Program Phase I: Refers to (A) the development and testing of biologic components required to provide the required capability, and to (B) the design, fabrication and testing of hardware for production and assembly of units in the required quantities and rates. This phase includes the selection, integration, assembly, test and checkout, as well as technical and management activities associated with individual **biologic** components and **infusion set** components. The selected offer shall:

- Conduct initial meeting with FDA to develop a regulatory approval plan
- Design, development and testing of process to establish sterility compliance per FDA regulations.
- Design, development and testing of quality control process per FDA regulations.
- Data collection and document generation to support an Investigational New Drug (IND) application to the FDA
- Development of special equipment, special tooling, and production planning required to produce the final product.
- All whole and partial prime contractor, subcontractor, and vendor test units.

Program Phase II: Refers to the development and pre-clinical testing of biologic components, for safety and efficacy, required to provide the required capability in appropriate animal trauma models, and the design, development, and production of complete units (e.g., prototypes) for use in Program Phase III. This phase includes data collection and document generation to support an Investigational Drug Application (IDA) to the Food and Drug Administration (FDA). Data must be handled in a manner consistent with FDA guidelines (security, patient confidentiality, etc). Process must address storage and security of clinical data for a period of time per FDA regulations.

Program Phase III: Refers to the development and human clinical testing of biologic components required to provide the required capability in human volunteers.

- Phase I of clinical tests during Program Phase III will involve human trauma patients to establish safety. See Section VII.2 below for more information on human testing.
- Data collection and document generation to support a New Drug Application (NDA) to the FDA. Data must be handled in a manner consistent with FDA guidelines (security, patient confidentiality, etc). Process must address storage and security of clinical data for a period of time per FDA regulations. Process must address drug inventory records per FDA regulations.

Product Metrics:

(1) Efficacy equal to fresh frozen plasma (FFP) in correcting coagulopathy
(2) If platelet particles a component: cell count and activity =/> single apheresis unit
(3) Total fluid volume less than one (1) unit fresh whole blood (450ml)
(4) Each unit will restore blood volume equal to one (1) unit of fresh whole blood
(5) Oxygen carrying/diffusion capacity equivalent to one unit of packed red blood cells
(6) Coagulation factors not < 80 % of FFP
(7) Storage at ambient temperature > One (1) year (threshold); Three (3) years (objective)
(8) Frozen storage >10 years
(9) Ready for infusion in < 2 minutes when reconstituted
(10) Pathogen inactivated/reduced
(11) No greater immunogenicity or thrombogenicity than current banked blood products.

Exit Criteria: The key performance parameter (KPP) will be the conduct of a Phase I (Safety) clinical trial. This requires that the performer complete development of a Good Laboratory Practices/Good Manufacturing Practices (GLP/GMP) product, complete required documentation, and obtain approval by the FDA of the Investigative New Drug (IND) application. It is anticipated that further clinical evaluation of the product will be supported by the Navy Advanced Medical Development program following this BAA through subsequent awards outside of this BAA.

7. Points of Contact –

Questions of a **technical** nature should be submitted to:

Name: Dr. Michael B. Given
Address: One Liberty Center
875 North Randolph Street
Arlington, VA. 22203-1995
Code: 342
Email: michael.given@navy.mil

Questions of a **business** nature should be submitted to:

Name: Ms. Russelle Dunson
Address: One Liberty Center
875 North Randolph Street
Arlington, VA. 22203-1995
Code: BD254
Email: russelle.dunson@navy.mil

All questions are due no later than 2:00PM Eastern Time 10 days prior to the due dates listed in Section I.5 above.

8. Instrument Type -

Award will be in the form of cost-type contract, specifically Indefinite Delivery Indefinite Quantity (IDIQ) contracts with cost-type Task Orders made off of those IDIQs.

ONR reserves the right to award a different instrument type if deemed to be in the best interest of the Government.

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

12.300

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

Basic and Applied Scientific Research

11. Other Information -

The use of Broad Agency Announcements are restricted to basic and applied research and that portion of advanced technology development not related to the development of a specific system or hardware procurement. Contract awards made under this BAA 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

The amount of funds and period of performance for each proposal will vary depending on the technical approach to be pursued by the offeror. Approximately $20M is anticipated to be available over the 5 year span (FY11-15) for the development of this product. The period of performance for IDIQ shall not exceed a total of four years and 6 months. ONR anticipates a single IDIQ award will result from this BAA.

The IDIQ minimum quantity will be $10,000 with a period of performance proposed by the offeror for the Phase I effort. Subsequent Task Orders will be issued based on the success of the prior phase and will follow the criteria established in FAR 16.505. The IDIQ maximum quantity will be based on the total program estimate, which should be approximately $20M.

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

For White Papers that propose efforts that are considered of particular value to the Navy but either exceed available budgets or contain certain tasks or applications that aren't desired by the Navy, ONR may suggest a full proposal with reduced effort to fit within expected available budgets or an effort that refocuses the tasks or application of the technology to maximize the benefit to the Navy.

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 either white papers or full proposals in response to this BAA. If any such an organization is interested in one or more of the programs described herein, the organization should contact the ONR Technical POC to discuss its area of interest. 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.

IV. APPLICATION AND SUBMISSION INFORMATION

1. Application and Submission Process -

Each White Paper should state that it is submitted in response to this announcement. White Papers shall be submitted directly to the Technical Point of Contact identified in Section I.7 above. The White Paper due date is listed in Section I.5 above. White Papers

are desired for all offerors seeking FY 2011 initial funding. Each White Paper will be evaluated by the government to determine whether the technology advancement proposed appears to be of particular value to the Department of the Navy. Initial government evaluations of the White Papers for FY 2011 program funding will be issued via e-mail notification from the Technical Point of Contact. The initial White Paper appraisal is intended to give entities a sense of whether their concepts are likely to be funded under this BAA.

Detailed Full Proposal (Technical and Cost proposals) will be subsequently encouraged from those Offerors whose proposed technologies have been identified through the above referenced e-mail as being of "particular value" to the Government. However, any such encouragement does not assure a subsequent award. Full Proposals may also be submitted by any Offeror whose White Paper was not identified as being of particular value to the Government or any Offeror who did not submit a White Paper. 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 White Papers/Full Proposals –

White Papers and Full Proposals submitted under the BAA are expected to be **unclassified**.

Proposal submissions will be protected from unauthorized disclosure in accordance with FAR Subpart 15.207, applicable law, and DoD/DoN regulations. Offerors are expected to appropriately mark each page of their submission that contains proprietary information. The proposal shall include a severable, self-standing Statement of Work, which contains only unclassified information and does not include any proprietary restrictions.

IMPORTANT NOTE: Titles given to the White Papers/Full Proposals should be descriptive of the work they cover and not be merely a copy of the title of this solicitation.

The proposal format and content identified below are applicable to the submission of proposals for contracts.

A. WHITE PAPERS

i. White Paper Format

- Paper Size – 8.5 x 11 inch paper
- Margins – 1 inch
- Spacing – single or double-spaced
- Font – Times New Roman, 12-point
- Copies – One electronic copy to the ONR Technical POC listed in Section I.7 submitted by e-mail on or before the date and time specified in the BAA with attachment (in Microsoft® Word or Excel 2003 compatible or .PDF format). NOTE: 1) Do not send hardcopies of White Papers as only electronic

submissions will be accepted and reviewed. 2) Do not send .ZIP files. 3) Do not send password protected files.
- Page limit – 5 pages (Excluding Cover Page and Biographical Sketches)

ii. White Paper Content

- **Cover Page:** The Cover Page shall be labeled "WHITE PAPER" and shall include the BAA number, proposed title, technical point(s) of contact, telephone number(s), facsimile number(s), and e-mail address(es).
- **Technical Concept:** A description of the technology innovation and technical risk areas.
- **Operational Utility Assessment Plan:** A plan for demonstrating and evaluating the operational effectiveness of the Offeror's proposed products or processes in field experiments and/or tests in a simulated environment.
- **Costs:** Rough Order of Magnitude (ROM) cost estimate segregated by task for all phases.
- **Biographical Sketch:** Use "Biographical Sketch" form PHS 398/2590 (Rev. 11/07) (http://www.grants.nih.gov/grants/funding/phs398/biosketchsample.doc). *NOTE:* Limit 3 pages per investigator

B. FULL PROPOSALS

i. Full Proposal Format

- Paper Size – 8.5 x 11 inch paper
- Margins – 1 inch
- Spacing – single or double-spaced
- Font – Times New Roman, 12-point
- There are no page limitations to Volume 1 or 2.
- Copies – Three (3) original paper copies and one electronic copy on a CD-ROM (in Microsoft® Word or Excel 2003 compatible or .PDF format). Proposals shall be submitted via hard copy directly to the ONR Technical POC listed in Section I.7.

ii. Full Proposal Content

a. VOLUME 1: Technical Proposal

Technical Proposals shall consist of two sub-volumes:
Sub-Volume 1: IDIQ proposal (Address All Program Phases)
Sub-Volume 2: Task Order 0001 proposal (Address Only Program Phase I)

- **Cover Page:** This should include the words "Technical Proposal" and the following:

1) BAA number;

2) Title of Proposal;
3) Identity of prime Offeror and complete list of subcontractors, if applicable;
4) Technical contact (name, address, phone/fax, electronic mail address)
5) Administrative/business contact (name, address, phone/fax, electronic mail address)
6) Signature of authorized individual approving the submission of the Full Proposal and;
7) Period of Performance

- **Table of Contents:** (include in both sub-volumes) An alphabetical/numerical listing of the sections within the proposal, including corresponding page numbers.

- **Statement of Work:** (include only in Task Order 0001 sub-volume; Statement of Work for IDIQ will reference this solicitation) A Statement of Work (SOW) clearly detailing the scope and objectives of the effort and the technical approach. It is anticipated that the proposed SOW will be incorporated as an attachment to the resultant award instrument. To this end, the proposals must include a severable, task-oriented, self-standing SOW, without any proprietary restrictions, which can be attached to the contract award. Include a detailed listing of the technical tasks/subtasks organized by Government fiscal year. The SOW shall also include a section on the future naval relevance of the research: A description of potential Naval relevance and contributions of the effort to the agency's specific mission.

  Submission of the SOW without restrictive markings is your entity's affirmation that the SOW is non-proprietary and releasable in response to Freedom of Information Act (FOIA) requests.

- **Technical Approach and Justification:** (include in both sub-volume) The major portion of the proposal should consist of a clear description of the technical approach being proposed. This discussion should provide the technical foundation/justification for pursuing this particular approach/direction and why one could expect it to enable the objectives of the proposal to be met.

- **Operational Utility Assessment Plan:** (include in both sub-volumes) A plan for demonstrating and evaluating the operational effectiveness of the Offeror's proposed products or processes in field experiments and/or tests in a simulated environment.

- **Project Schedule and Milestones:** (include in both sub-volumes) A summary of the schedule of events and milestones.

- **Assertion of Data Rights and/or Rights in Computer Software:** (include as appropriate in either sub-volume) An Offeror may provide with its proposal assertions to restrict use, release or disclosure of data and/or computer software

that will be provided in the course of contract performance. The rules governing these assertions are prescribed in Defense Federal Acquisition Regulation Supplement (DFARS) clauses 252.227-7013, -7014 and - 7017. These clauses may be accessed at the following web address: http://farsite.hill.af.mil/VFDFARA.HTM.

The Government may challenge assertions that are provided in improper format or that do not properly acknowledge earlier federal funding of related research by the Offeror.

If an Offeror determines a data rights assertion is not applicable, indicate that no assertion is being made in the proposal submission.

- **Deliverables:** (include only in Task Order 0001 sub-volume) A detailed description of the results and products to be delivered inclusive of the timeframe in which they will be delivered.

- **Management Approach:** (include only in IDIQ sub-volume) A discussion of the overall approach to the management of this effort, including brief discussions of the total organization; use of personnel; project/function/subcontractor/subrecipient relationships; government research interfaces; and planning, scheduling and control practice. Identify which personnel and subcontractors/subrecipients (if any) will be involved. Include a description of the facilities that are required for the proposed effort with a description of any Government Furnished Equipment/Hardware/Software/Information required, by version and/or configuration.

- **Other Agencies:** (include only in IDIQ sub-volume) Include the name(s) of any other agencies to which the proposal has also been submitted.

- **Current and Pending Projects and Proposal Submissions:** (include only in IDIQ sub-volume) Offerors are required to provide information on all current and pending support for ongoing projects and proposals, include subsequent funding in the case of continuing contracts, grants and other assistance agreements. Offerors shall provide the following information of any related or complementary proposal submissions from whatever sources (e.g., ONR, Federal, State, local or foreign government agencies, public or private foundations, industrial or other commercial organizations).

  This information must be provided for all proposals already submitted or submitted concurrently to other possible sponsors, including ONR. Concurrent submission of a proposal to other organizations will not prejudice its review by ONR:

  1) Title of Proposal and Summary;

2) Source and amount of funding (annual direct costs; provide contracts and or/grant numbers for current contracts/grants);
3) Percentage effort devoted to each project;
4) Identity of prime Offeror and complete list of subcontractors, if applicable;
5) Technical contact (name, address, phone/fax, electronic mail address);
6) Administrative/business contact (name, address, phone/fax, electronic mail address);
7) Duration of effort;
8) The proposed project and all other projects or activities requiring a portion of time of the PI and other senior personnel must be included, even if they receive no salary support from the project(s);
9) The total award amount for the entire award period covered (including indirect costs) must be shown as well as the number of person-months per year to be devoted to the project, regardless of source of support; and
10) State how projects are related to the proposed effort and indicate degree of overlap.

- **Qualifications:** (include only in IDIQ sub-volume) A discussion of the qualifications of the proposed Principal Investigator and any other key personnel. Include resumes for the Principal Investigator and other key personnel and full curricula vitae for Principal Investigators and consultants. The resumes and curricula vitae shall be attached to the proposal.

- **Biographical Sketch:** (include only in IDIQ sub-volume) Use "Biographical Sketch" form PHS 398/2590 (Rev. 11/07) (http://www.grants.nih.gov/grants/funding/phs398/biosketchsample.doc).

b. VOLUME 2: Cost Proposal

INSTRUCTIONS FOR PROPOSALS FOR CONTRACT

The following information is provided to assist contractors in preparing and submitting an adequate and compliant cost proposal. The purpose of the submission of other than cost or pricing data is to enable Government personnel to perform cost or price analysis and ultimately negotiate a fair and reasonable cost. Offerors are reminded that the responsibility for pricing adequate supporting data and attachments lies solely with the offeror. Further, the offeror must also bear the burden of proof in establishing reasonableness of proposed costs; therefore, it is the contractor's best interest to submit a fully supportable and well-prepared cost proposal. The basis and rationale for all proposed costs should be provided as part of the proposal so that Government personnel can place reliance on the information as current, complete, and accurate. Further, FAR 15.403-4 sets forth those circumstances in which offerors are required to submit certified cost or pricing data.

Although not required and provided for informational purposes only, using the cost proposal format spreadsheet (spreadsheet.xls) that is an attachment to this document and the accompanying instructions (spreadsheetinstructions.doc) as the basis of the cost proposal may **significantly decrease** the time required to review and award proposals submitted in response to this announcement.

For pricing purposes, assume that performance will start no earlier than six (6) months after submission of the cost proposal.

Only submit a cost proposal for Task Order 0001; the minimum IDIQ amount will be $10,000.

The Cost Proposal shall consist of a cover page and two parts: Part 1 will provide a detailed cost breakdown of all costs by cost category by Contractor fiscal year and Part 2 will provide a cost breakdown by task/sub-task corresponding to the task numbers in the proposed Statement of Work. Any proposed options must be separately priced.

• **Cover Page:** The use of the SF 1411 is optional. The words "Cost Proposal" should appear on the cover page in addition to the following information:

- BAA number
- Title of Proposal
- Identity of prime Offeror and complete list of subcontractors, if applicable
- Technical contact (name, address, phone/fax, electronic mail address)
- Administrative/business contact (name, address, phone/fax, electronic mail address) and
- Period of Performance

i. Part 1

Detailed breakdown of all costs by cost category by calendar or Government fiscal year:

- Direct Labor – Individual labor categories or persons, with associated labor hours and unburdened direct labor rates. Provide escalation rates for out-years, if escalation is desired;

- Indirect Costs – Fringe Benefits, Overhead, G&A, COM, etc. and their applicable allocation bases. If composite rates are used, provide the calculations used in deriving the composite rates.

- Travel – The proposed travel cost should include the following for each trip: the purpose of the trip, origin and destination, the duration, the number of travelers, and the estimated cost per trip must be justified based on the organizations historical average cost per trip or

other reasonable basis for estimation. Such estimates and the resultant costs claimed must conform to the applicable Federal cost principals.

- Subcontracts – A cost proposal as detailed as the Offeror's cost proposal will be required to be submitted by the subcontractor. The subcontractor's cost proposal can be provided in a sealed envelope with the Offeror's cost proposal or may be sent directly to the Government. A proposal and supporting documentation must be received and reviewed before the Government can complete its cost analysis of the proposal and enter negotiations. The prime contractor should perform and provided a cost/price analysis of each subcontractor's cost proposals.* Offerors are required to obtain competition to the maximum extent practicable when selecting subcontractors if the offeror has obtained competitive quotes, copies should be provided. If the offeror has selected other than the low bid for inclusion in their proposal or intends to award the subcontract on a sole-source basis, the offeror should provide rationale for their decisions. Certified cost or pricing data may be required for subcontractor proposals over $650,000.

  * Note: Federal Acquisition Regulation (FAR) provisions 52.215-22 and 52.215-23 are incorporated into this solicitation by reference. The offeror is to exclude excessive pass-through charges from subcontractors. The offeror must identify in its proposal the total cost of the work to be performed by the offeror and the total cost of the work to be performed by each subcontractor. If more than 70 percent of the total cost of the work will be performed by subcontractors, the offeror must include the additional information required by the above-cited clauses.

- Consultants – Provide a breakdown of the consultant's hours, the hourly rate proposed, any other proposed consultant costs, a copy of the signed Consulting Agreement or other documentation supporting the proposed consultant cost, and a copy of the consultant's proposed statement of work.

- Materials & Supplies – Provide an itemized list of all proposed materials and supplies including quantities, unit prices, proposed vendors (if known), and the basis for the estimate (e.g., quotes, prior purchases, catalog price lists).

- Contractor Acquired Equipment or Facilities – Equipment and/or facilities are normally furnished by the Contractor. If acquisition of equipment and/or facilities is proposed, a justification for the purchase of the items must be provided. Provide an itemized list of all equipment and/or facilities costs and the basis for the estimate (e.g.,

quotes, prior purchases, catalog price lists).

- Other Direct Costs – Provide an itemized list of all other proposed other direct costs and the basis for the estimate (e.g., quotes, prior purchases, catalog price lists).

- Options – If any options are proposed, then the options must be priced at the submission of the proposal. Any proposal containing unpriced options will not be included in the contract.

- Fee/Profit – Profit or fee will not be allowed on direct costs for facilities or in cost-sharing contracts.

Note: Indicate if you have an approved Purchasing/Estimating System and/or describe the process used to determine the basis of reasonableness (e.g., competition, market research, best value analysis) for subcontractors, consultants, materials, supplies, equipment/facilities, and other direct costs.

ii. Part 2

Cost breakdown by task/sub-task corresponding to the same task breakdown in the proposed statement of work. When options are contemplated, options must be separately identified and priced by task/subtask.

3. Significant Dates and Times –

Schedule of Events

Event	**Date**
FY11 White Paper Due Date	See Section I.5
Notification of Initial Evaluation of FY11 White Papers	Approximately 07 APR 2010
FY11 Proposal Due Date	See Section I.5
Notification of Selection for FY11 Award	Approximately 21 JUL 2010

NOTE: Due to changes in security procedures since 11 September 2001, the time required for hard-copy written material to be received at the Office of Naval Research has increased. Thus, it is strongly recommended that any hard-copy proposal be mailed several days 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 –

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 1) received before award is made, 2) the contracting officer determines that accepting the late proposal would not unduly delay the acquisition and:

- 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 4:00 P.M. one working day prior to the date specified for receipt of proposals; or
- 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
- 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 extended 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 White Papers and Hard Copy Full Proposals

All white papers shall be **emailed** to the Technical Point of Contact identified in Section I.7 above.

All hard copies of full proposals shall be **mailed** to the Technical Point of Contact located in Section I.7 above.

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.

Overall, the technical factors (1 – 3 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.

For proposed awards to be made as contracts to large businesses, nonprofit organizations, and universities, the socio-economic merits of each proposal will be evaluated based on the extent of the Offeror's commitment in providing meaningful subcontracting opportunities for small businesses, small disadvantaged businesses, woman-owned small businesses, HUBZone small businesses, veteran-owned small businesses, service disabled veteran-owned small businesses, historically black colleges and universities, and minority institutions.

If proposal includes any options, the Government will evaluate the 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 and non-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. Similarly, support contractors may be utilized to evaluate cost proposals. 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 –

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

• Central Contractor Registry (CCR) – Successful Offerors not already registered in the CCR will be required to register in CCR prior to award of any grant, contract, cooperative agreement, or other transaction agreement. Information on CCR registration is available at http://www.bpn.gov/ccr/default.aspx..

• Subcontracting Plans – Successful contract proposals that exceed $550,000 submitted by all but small business concerns will be required to submit prior to award a Small Business Subcontracting Plan in accordance with FAR 52.219-9.

• Certifications – Proposals for contracts should be accompanied by a completed certification package.

- Online Representations and Certifications Application (ORCA) – In accordance with FAR 4.1201, prospective contractors shall complete and submit electronic annual representations and certifications available at https://orca.bpn.gov.

- ONR Contract Specific Representations and Certifications – Completed ONR contract specific representations and certifications, i.e., Section K, may be accessed under the Contracts and Grants Section of the ONR Home Page at http://www.onr.navy.mil/Contracts-Grants/submit-proposal/contracts-proposal.aspx.

2. Reporting/Deliverables -

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 under Program Phase III of this effort shall include up to five (5) prototype packaging and up to two (2) multifunctional resuscitation fluid packages with a preference for a Food Drug Administration (FDA) approved product in addition to the reporting requirements listed in Section VI.2 below.

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 explain as part of their proposals which of these facilities are critical for the project's success.

2. 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 AALAC 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 documentation, contact the ONR Animal/Human 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 number. 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. [Note: for research involving human subjects that is greater than minimal risk, administrative procedures to protect human subjects from medical expenses (not otherwise provided or reimbursed) that are the direct result of participation in a research project must be addressed. Additional supporting documentation may be requested.] For assistance with submission of human subject research related documentation, contact the ONR Human Research Protection Official at (703) 696-4046.

The award and execution of the contract or a modification to an existing contract 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.

3. Recombinant DNA

Proposals which call for experiments using recombinant DNA must include documentation of compliance with Department of Human and Health Services (DHHS) recombinant DNA regulations, approval of the Institutional Biosafety Committee (IBC), and copies of the DHHS Approval of the IBC letter.

4. 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 70% of these meetings will be at or near ONR, Arlington VA and 30% 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. Offerors should also assume attendance at one conference per year of effort.

5. 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 Government 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.