NAVAL HEALTH RESEARCH CENTER

BROAD AGENCY ANNOUNCEMENT (BAA)

Solicitation # W911QY-13-R-0063

"NHRC BAA 13-001"

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SECTION I - INTRODUCTION

Naval Health Research Center (NHRC) serves as a leading research and development laboratory for the Department of Defense (DoD). NHRC manages and executes expeditionary operational medical research, development and test and evaluation programs for the Naval Medical Research Center enterprise, the Navy Medicine Research and Development Center, the Navy Bureau of Medicine and Surgery (BUMED) enterprise, and as the designated Department of Defense (DoD) Center for Deployment Health Research by the United States Assistant Secretary of Defense for Health Affairs on September 30, 1999, NHRC also manages and executes programs for the Secretary of Defense and the Assistant Secretary of Defense for Force Health Protection/ Health Affairs and Readiness.

Our Research

Medical Modeling, Simulation & Mission Support

- Navy/Marine Corps Combat Trauma Registry
- Shipboard & Ground Casualty Projection Algorithms
- Estimating Supplies Program (ESP)
- Tactical Medical Logistics Tool (TML+)
- ReSupply Validation Program (RSVP)

Warfighter Performance

- Environmental Stress Studies
- Physical Stress, Load and Impact
- Physical Fitness and Weight Standards
- Cognitive Neuroscience of Stress & Performance

Behavioral Sciences & Epidemiology

- Behavioral Trends That Impact Readiness
- Focused Intervention Strategies
- Behavioral Needs Assessment Survey
- PTSD/TBI Studies
- Career-Span Health & Wellness Studies

Deployment Health Research

- Millennium Cohort Study
- Birth and Infant Health Registry
- Recruit Assessment Program
- Post-Vaccination Epidemiological Studies

Operational Infectious Diseases

- Global Emerging Infections System (GEIS)
- Surveillance of all DoD Training Sites
- Adenovirus Vaccine Clinical Trial

HIV/AIDS Prevention Program

- Military-to-Military Education & Awareness Strategies
- President’s Emergency Plan for AIDS Relief (PEPFAR)
- DHAAP Assistance in Over 70 Countries

This Broad Agency Announcement (BAA) is intended to fulfill requirements for scientific study and experimentation directed toward advancing state-of-the-art technologies, and/or increasing knowledge and understanding as a means of eliminating current technology barriers. This BAA DOES NOT focus on specific systems or hardware solutions. This BAA identifies NHRC research/exploratory development areas of interest, and provides prospective offeror's information on the preparation of proposals, along with proposal evaluation factors. It may be used to support the BUMED enterprise or DoD enterprise, provided that certain approvals are complied with.

The government may award purchase orders, contracts, grants, cooperative agreements or other transactions permitted under this BAA, including Individual Set Aside (ISA) contracts. An ISA is a firm fixed price contract made directly with the researcher individual following streamlined procedures described in the DFARS at Part 237.104. An ISA is specifically to acquire the personal services of experts and consultants included in 10 U.S.C. 129b and related to health care as authorized by 10 U.S.C. 1091. Where a contract has a direct benefit to the government client, an assistance agreement such as a grant or cooperative agreement does not. An assistant agreement having no direct government participation is a grant, otherwise it is a cooperative agreement.

Please note that, typically, research resulting from work executed under this BAA leads to an additional requirement for services being provided by the applicable contractor in support of operational experiments to evaluate the measures of merit and performance enhancement capability to the Warfighters. However, it is not possible at the time of release of this announcement, or at the time of contract award, to accurately anticipate if these services will be required, nor is it possible to anticipate the level of effort required. In addition, the technology explored under this BAA typically has application across the various branches of the Department of Defense (DoD). In order to satisfy the unique needs of these different branches, and to ensure a proper job is done in the evaluation of the applicable technology, contract modifications which add new Contract Line Item Numbers (CLINs), and/or expand on current CLINs, for services providing for flexibility in technology assessment (with technology transition the ultimate goal) may be executed. In the event that this is required, it shall be considered to be within the scope of this BAA and the resulting contract, and therefore will have met the requirements of the Federal Acquisition Regulation (FAR)/Defense Acquisition Regulation System (DFARS) and the Competition in Contracting Act. The benefit of this flexibility to the government, and ultimately the taxpayer, is a significant increase in the R&D return on investment. The flexibility to have multiple users (branches of the military) in the technology evaluation cycle is absolutely critical and allows systems and technologies to be developed in a manner that has broader DoD market applications. These can then be modularly reconfigured to meet goals and objectives for all DoD services.

SECTION II - GENERAL INFORMATION

1. ELIGIBILITY INFORMATION

a. The NHRC will consider concept papers and proposals based on this BAA from the following organizations and firms interested in conducting scientific research: degree- granting colleges and universities, nonprofit research institutes, foreign organizations, and commercial firms (including socio-economic concerns such as defined by the Small Business Administration). Offerors are cautioned that only a duly appointed Contracting Officer or Grant Officer acting within the scope and limits of his/her authority may obligate the government to the expenditure of funds. Proposals from government facilities and organizations WILL NOT be considered under this program announcement.

b. Small Businesses (SBs), Small Disadvantaged Businesses (SDBs), Service-Disabled Veteran Owned Small Businesses (SDVOSB), HUBZone Small Businesses, Historically Black Colleges and Universities (HBCUs) and Minority Institutions (MIs): Although no portion of this BAA has been set aside for SBs, SDBs, HUBZones, HBCUs, or MIs, their participation is highly encouraged. For any topic areas (see Section V) where quality proposals are received that demonstrate a set-aside would be appropriate, NHRC will consider doing so and modifying this BAA accordingly. Therefore, all named business types are encouraged to submit proposals under any topic that they feel they are highly qualified to perform. The applicable North American Industry Classification System (NAICS) code for the majority of work submitted under this BAA will be 541712 with a size standard of 500 employees.

c. To be eligible for award, a prospective recipient (except other governments, including state and local governments) must meet certain minimum standards pertaining to financial resources, ability to comply with the performance schedule, prior record of performance, integrity, organization, experience, operational controls, technical skills, facilities and equipment. (See FAR 9.405)

d. Excluded Parties List: To protect the public interest, the Federal Government ensures the integrity of Federal programs by only conducting business with responsible recipients. The U.S. Army Contracting Command, Aberdeen Proving Ground – Natick Contracting Division uses the System for Award Management (SAM) to exclude recipients ineligible to receive Federal awards. The SAM is online at https://www.sam.gov.

e. Successful registration within System for Award Management (SAM) previously known as the Central Contractor Registration (CCR).

2. RESPONSE INFORMATION

a. This BAA shall remain in effect until 30 April 2015 unless superseded, extended or canceled. Proposals may be submitted at any time after the concept paper has been approved and up until the BAA closing date of 30 April 2015. Awards against this BAA may be made up until 30 July 2015. This period of time is defined as the ordering period. Awards made during this time period may have a period of performance that goes beyond this ordering period.

b. Proposals shall remain valid for a period of ninety (90) calendar days from date of submission. The contractor agrees that if their offer is accepted by the government within ninety (90) calendar days from the date of their proposal, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule. At times, the government may contact a contractor after the ninety (90) day period about a proposal they would like to bring to award. This will occur when a shortage of funds exists during the initial ninety (90) day period. If this does occur, the contractor reserves the right to except or decline the offer, and may also submit a revised proposal with any necessary price/schedule changes, though the technical merit must remain the same.

3. WHERE TO SUBMIT

Concept papers, proposals and inquires shall be submitted to the address indicated under each scientific and technical area of interest as cited in Section V herein. Email attachment is an authorized means for the delivery of such documents, facsimile transmission is not.

4. BAA PROCESS

In an effort to minimize proposal preparation costs, this BAA will utilize a two-step process. The first step will be the submission of a concept paper. This step will preclude unwarranted effort on the part of an offeror whose proposed technology/capability or product is not of interest to the government. Those concept papers found to be consistent with the intent of the BAA and which are of interest to the government will be invited to submit a proposal (step two). Step one may be waived only by the technical POC named herein and in writing. Communication with the technical POCs identified in Section V. Scientific and Technical Areas of Interest is essential in tailoring responses to the specific needs of NHRC. This preliminary communication is especially important because once the formal proposal is accepted by the technical POC and submitted to the Contracting Office, no further communication between the proposed contractor and the government technical POC is allowed.

Requests for conference or symposium support, consultant services, engineering and/or marketing services, and/or training support will not be considered under this announcement. Only concepts for research/exploratory development will be considered.

Contractors should not submit a proposal until selected government personnel have reviewed the concept paper and the contractor has been invited to submit a formal proposal by government personnel.

a. **STEP ONE**: If the offeror has a novel research approach within an area of interest covered by this BAA, a BAA concept paper should be prepared. Concept papers should be submitted electronically to the technical POCs listed in each area of interest in Section V. Concept papers may not exceed 5 single-sided 8 ½ x 11 inch typed pages (including charts, graphs, photographs, etc.) and shall include the following:

(1) A brief technical explanation of the proposed effort that addresses the major research

thrust, the research goals, and deliverables, a proposed approach to achieve these goals and deliverables, and military relevancy.

(2) A brief "management" description outlining key personnel and experience.
(3) Any past performance the contractor has had with similar research efforts.
(4) An estimated cost/price and performance schedule for the work.

Once an offeror has been invited to submit a formal proposal, the following process must be adhered to by the offeror.

b. **STEP TWO**: Informal exchanges should be held with the technical POC listed under each topical area noted in Section V herein on any proposed research BEFORE the submission of a formal proposal since the BAA is written in such broad terms to cover a wide variety of technical areas.

The offeror's technical, management, cost/price, past performance, subcontracting (if applicable), and company certification sections of the proposal shall be submitted in severable sections as set forth below. All information pertaining to each section shall be confined to the appropriate part. The sections shall be as brief as possible, consistent with complete submission. Pages should not exceed 8-1/2 inches in width and 11 inches in length. Double column pages are not permitted. The proposal shall be evaluated in accordance with the process described in Section IV herein.

PART I - Technical Section
PART II - Management Section
PART III - Cost/Price Section
PART IV - Past Performance Section
PART V - Subcontracting Plans (if applicable)
PART VI - Contractor Representations and Certifications

(1) **Part I - Technical Section:** Offeror is responsible for including sufficient details, without reference to cost/price, to permit a complete and accurate evaluation of the proposal from a strictly technical standpoint. The following information shall be included:

(a) Cover sheet, including (1) BAA number; (2) Topic area by number and title for which the proposal is being submitted under, (3) lead organization submitting proposal; (4) type of business, selected among the following categories: “Large Business”, “SDB”, “Other SB”, “HBCU,” “MI,” “Other Education,”, or “Other Nonprofit”; (5) proposal title; (6) technical point of contact, including salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail (if available); (7) administrative point of contact, including salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail (if available); (8) total funds requested from NHRC; and (9) date proposal prepared and date of proposal expiration.
(b) A summary of the objective/purpose of proposed research - what scientific "problem" do you intend to resolve, advance the state-of-the-art with respect to, or increase the understanding of.
(c) Identification of product(s) or process(es) which you anticipate will result from this

effort. Product(s) may simply be technical data, reports on the feasibility of novel concepts, product samples, etc. Identification of any potential military medical and/or civilian medical applications of the product(s) which may be developed if the work performed under the proposed BAA contract is followed through on, following completion of the proposed contract.

(d) An assessment of the probability for project success.

(e) An explanation of the planned approach, techniques, and/or processes to be used in this effort.

(f) Rationale for the proposed methodology. What, if any, innovative ideas/ techniques will be tried? Identification of the technical risks in completing this project and the approach taken to overcome these risks.

(h) Any planned interactions with NHRC (to include a request for a post-award conference if the contractor so desires) required during the performance of proposed contract.

(i) Any planned collaborative arrangements with other parties (including subcontractors and/or consultants) for the effort. Identification of the responsibilities and contributions of these parties in completing the intended deliverables. If offeror is an academic institution, details of planned interactions with industry (if applicable), and letters from the industries in which they commit themselves to support the effort, should be provided.

(j) A list of the deliverables (technical data, processes, publications, prototypes, etc.) that will result from the effort plus demonstration of a clear pathway from the research to the intended deliverables.

(k) A schedule containing milestones for the performance of the proposed effort.

(2) **Part II - Management Section:** The management section of the proposal shall include the following for the offeror and any collaborators identified in Part I:

(a) Resumes (or some portion of such) of technical personnel detailing relevant education, experience, and technical expertise proposed for this effort and the percentage of time expected to be devoted to this project.

(b) Organization of the offeror's firm.

(c) Facilities and equipment available for the proposed effort. Title for any contractor procured equipment on a Firm-Fixed-Price (FFP) contract shall be defined in the offeror’s proposal. For a FFP contract, if title is to be given to the government, then the offeror shall list it in their proposal as a deliverable end item. In a Cost-Plus type contract, ownership title is given to the government in accordance with FAR 45.4, unless so otherwise agreed to in writing.

(d) Project management systems and controls to be utilized by the contractor.

(e) Human protection assurances (if applicable) such as a DHHS Federalwide Assurance (FWA) or MPA DoD-Navy Addendum and compliance with the DoD Human Research Protection Program.

(f) Data agreements (if applicable) such as a TMA Data Use Agreement or Data Share Agreement or a DoD Business Associate Agreement.

(g) Proof of security clearance (if applicable) from DSS or OPM and any personnel background checks (if applicable) for CAC card / government IT system access.

(h) Indemnification of the government and medical liability insurance (if applicable) for both individual occurrence and aggregate limits.

(i) Animal use (if applicable) assurance and accreditation by the candidate performer (for example IACUC functions and approval, AAALAC accreditation, DHHS OLAW assurances, and USDA site inspections).

(j) Any Organizational Conflicts of Interest (OCI).

(3) **Part III - Cost/Price Section:** The following information shall be included:

(a) Cover sheet, including (1) BAA number; (2) Topic area by number and title for which the proposal is being submitted under, (3) lead organization submitting proposal; (4) type of business, selected among the following categories: "Large Business", "SDB", "Other SB", "HBCU," "MI," "Other Education,", or "Other Nonprofit"; (5) proposal title; (6) technical point of contact, including salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail (if available); (7) administrative point of contact, including salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail (if available); (8) awarded instrument requested: cost-plus-fixed-fee (CPFF), CPFF with a management fee (rather than fee for profite) for nonprofits, cost-sharing contract (no fee), grant, cooperative agreement, or other type of procurement contract (specify), or other transaction; (9) place(s) and period(s) of performance; (10) total proposed cost separated by basic award and option(s) (if any); (11) name, address, and telephone number of the Offeror's cognizant Defense Contract Management Agency (DCMA) or Office of Naval Research (ONR) administration office (if known); (12) name, address, and telephone number of the offeror's cognizant Defense Contract Audit Agency (DCAA) (if known); (13) date proposal prepared and date of proposal expiration; and (14) the offeror's Contractor and Government Entity (CAGE) code, Dun and Bradstreet (DUN) Number, North American Industrial Classification System (NAICS) Number and Tax Identification Number (TIN).

(b) Each proposal must contain a detailed cost breakdown, including (1) total program cost broken down by major cost items such as direct labor, other direct costs (including subcontractors, material, travel), indirect cost rate charges such as fringe, overhead, G&A, fee for profit or fee for management (for non-profit entities); (2) further broken down by each phase; (3) program tasks by year; (4) an itemization of major subcontracts and equipment purchases; (5) an itemization of any information technology (IT) purchases; and (6) a summary of projected funding requirements by months. In addition to the budget, a "Budget Explanation Page" shall be submitted which addresses the different cost factors in the cost proposal. The cost proposal shall be signed and dated.

(c) All cost data must be current and complete. Costs proposed must conform to the following principles and procedures:

- Educational Institutions: OMB Circular A-21
- Nonprofit Organizations: OMB Circular A-122*
- Commercial Organizations: FAR Part 31, DFARS Part 231, FAR Subsection

15.403-5, and DFARS Subsection 215.403-5.

- All offerors (when applicable): DOD Grant and Agreement Regulations (DODGARs), DOD 3210.6-R

**For those nonprofit organizations specifically exempt from the provisions of OMB Circular A-122, FAR Part 31 and DFARS Part 231 shall apply.*

(d) Supporting cost and pricing information in sufficient detail to substantiate the summary cost estimates in (b) above. Include a description of the method used to estimate costs and supporting documentation. NOTE: "COST OR PRICING DATA as defined in FAR Subpart 15.4 shall be required if the offeror is seeking a procurement contract award of $700,000 or greater. Certified cost and pricing data shall be submitted in accordance with Table 15-2 in FAR Subpart 15.408. Sufficient cost/price information is required to allow the Government to make a determination of fair and reasonable price and cost realism. Offeror shall provide any Forward Pricing Rate Agreements, other such Approved Rate Information (e.g. Rate memo's, etc) or such other documentation that may assist in expediting negotiations (if not available, state so). The information shall be submitted at the level of detail described below and may be submitted in the offeror's own format. Examples of cost/price data are as follows:

- Materials, including raw materials and purchased parts and test equipment;
- Labor with engineering, manufacturing and service labor shown as separate elements, each labor category should cite hours of labor, hourly rate of pay, and total labor cost;
- Other direct cost, with supporting documentation;
- Costs for contractors with whom the lead contractor is teaming;
- Specific overhead cost and/or indirect cost rates;
- Facilities capital cost of money (note: if facilities capital cost of money is requested, the offeror shall submit a DD Form 1861;
- Consultant costs, if applicable, shall include the names of the consultant's purpose on the project, number of days to be employed, and rates of pay per day; and
- Profit or fee (if applicable).

(e) Cost/Price Realism: A proposal is presumed to represent an offeror's best efforts to respond to the solicitation. Any inconsistency, whether real or apparent, between promised performance and cost/price, should be explained in the proposal. For example, if the intended use of new and innovative production techniques is the basis for an abnormally low estimate, the nature of these techniques and their impact on cost/price should be explained; or, if a corporate policy decision has been made to absorb a portion of the estimated cost, that should be stated in the proposal. Any significant inconsistency, if unexplained, raises a fundamental issue of the offeror's understanding of the nature and scope of work required and of its financial ability to perform the contract, and may be grounds for rejection of the proposal. The contractor shall supply the government with sufficient information to allow the government to assess the reasonableness of the contractor's costs/prices.

Additional information for submitting cost proposals is provided at http://www3.natick.army.mil under the Business Opportunities-Broad Agency Announcement Page, direct link is http://www.natick.army.mil/nhrcbaa.html.

(4) **Part IV - Past Performance Section**: Information should be submitted for all proposed first- tier subcontractors with whom the offeror is teaming, as well as the offeror.

(a) Offeror should submit past performance information on any contracts (as a prime or subcontractor) they worked on during the previous three (3) years which are relevant to the efforts required by this solicitation. In addition, any and all contracts terminated in whole or part during the previous five (5) years, to include those currently in the process of such termination, are considered relevant and the offeror shall provide past performance information for those contracts. The following information should be included: Role as prime or subcontractor; If from past government contract, the contracting activity, address, and the Contracting Officer's name, telephone/facsimile numbers and email address; Contract type; Awarded cost/price; Final, or projected final, cost/price; Original delivery schedule; and Final, or projected final, delivery schedule

(b) For each of the contracts described in the past performance section of the offeror's proposal, a description of the objectives achieved, detailing how the effort is similar to the requirements of this solicitation, shall be included. For any contracts that did not/do not meet the original requirements with regard to original cost/price, schedule, or technical performance, the offeror should provide a brief explanation of the reason(s) for such shortcomings and any demonstrated corrective actions taken to avoid recurrence. For any terminated contracts, the offeror shall indicate the termination type and reasons.

(5) **Part V - Subcontracting Plans (if applicable)**:

Pursuant to Section 8(d) of the Small Business Act (15 U.S.C. 637(d)), it is the policy of the Government to enable small business and small disadvantaged business concerns to be considered fairly as subcontractors to contractors performing work or rendering services as prime contractors or subcontractors under Government contracts, and to ensure that prime contractors and subcontractors carry out this policy. A proposal, other than from a small business, that includes subcontracting and seeks an award in excess of the simplified acquisition threshold is required to include a subcontracting plan IAW FAR 19.702 (a) (1) and (2) and should do so with their proposal. The plan format is outlined in FAR 19.704.

As submitted under this BAA, subcontracting plans will be reviewed for adherence to regulations cited in FAR Part 19 and its supplements and not necessarily for evaluation as a specific evaluation criterion. However, an offeror's refusal to submit a subcontracting plan is grounds for the government to not negotiate award of an offeror's BAA proposal. A sample small business subcontracting plan is provided at http://www3.natick.army.mil under the Business Opportunities-Broad Agency Announcement Page, direct link is http://www.natick.army.mil/nhrcbaa.html.

Conversely, small businesses submitting in the prime position shall submit a plan, where the small business anticipates using a subcontractor, the name of the potential subcontractor, the size of the subcontractor based on the applicable NAICS code herein, and the percentage for that contractor. Including a subcontractor as part of the prime's team does not allow for the use of the subcontractor's experience or qualifications for that of the prime contractor. The exception is if the prime offeror is a joint venture.

(6) **Part VI - Contractor Representations and Certifications:**

Contractor's are encouraged to complete the annual representations and certificates electronically on the System for Award Management (SAM) at http://www.sam.gov and should note in part VI of their proposal what their Dun and Bradstreet Data Universal Numbering System (DUNS) number is and the fact that they are in ORCA. Please note that if a contractor does regular business with DoD, or intends to start, the NHRC strongly recommends they complete the electronic certifications at SAM to ease their business practices with the government.

Note that the applicable NAICS code for the majority of work submitted under this BAA will be 541712 with a size standard of 500 employees. If the offeror feels a different NAICS applies then provision 52.219-1 may be altered by the offeror accordingly.

DFAR Representations and Certifications and Certifications for Grants and Agreements is provided at http://www3.natick.army.mil under the Business Opportunities-Broad Agency Announcement Page, direct link is http://www.natick.army.mil/nhrcbaa.html.

SECTION III - INFORMATION ABOUT PROPOSAL SUBMISSIONS

1. GOVERNMENT FURNISHED PROPERTY (GFP)

Government-furnished property, as defined in FAR Part 45, may be available for contractor use during the performance of a given contract awarded against this BAA.

a. The offeror should clearly request in its proposal what, if anything, it desires as GFP for the given project. It is recommended that a section in the technical or management proposal be set aside to summarize the GFP requirements.
b. The offeror may request, for incorporation in the contract, a GFP delivery schedule NOT based specifically on the date of contract award.
c. Any property furnished to, and accepted by, the government under a resultant contract, and subsequently returned to the contractor for any reason, shall be regarded as government furnished property.
d. Any facilities, including rooms, desks, etc., to be provided to a contractor by the government for the performance of any portion of a contract, is considered to be GFP, and if needed should be specifically requested for the applicable time frames in the offeror's proposal.

2. TYPE OF CONTRACT

The U.S. Army Contracting Command-Aberdeen Proving Ground-Natick Contracting Division and the Research Triangle Park (RTP) have the authority to award procurement contracts, cooperative agreements and grants and reserves the right to use the type of instrument most appropriate for the effort proposed. Offeror’s should familiarize themselves with these instruments and the applicable regulations before submitting a proposal. Following are brief descriptions of the possible award instruments.

a. Procurement Contract. A legal instrument which, consistent with 31 U.S.C. 6303, reflects a relationship between the Federal Government and a State, a local government, or other recipient when the principal purpose of the instrument is to acquire property or services for the direct benefit or use of the Federal Government.

Contract type may vary according to the degree and timing of the responsibility assumed by the contractor for the cost of performance and the amount and nature of the profit incentive offered to the contractor for achieving or exceeding specific standards and goals. See FAR Subpart 16.101(a). Offerors shall identify the type(s) of contract (FAR Part 16) they feel is (are) best suited to the proposed effort. The offeror shall note that, in accordance with FAR Subpart 16.301-3, in order to receive a cost type contract, their accounting system must be adequate for determining costs on a government contract. This is determined by the Defense Contract Audit Agency (DCAA) assigned to the offeror's business location and may take more than thirty (30) to forty (40) days for completion. An offeror's suggestion regarding suitable contract type does not obligate the government to employ the suggested contract type. The selection of the contract type is subject to negotiation. Contracts have a direct benefit to the government client.

b. Grant - A legal instrument that, consistent with 31 U.S.C. 6304, is used to enter into a relationship:

(1) The principal purpose of which is to transfer a thing of value to the recipient to carry out a public purpose of support or stimulation authorized by a law or the United States, rather than to acquire property or services for the DOD's direct benefit or use.
(2) In which substantial involvement is not expected between the DOD and the recipient when carrying out the activity contemplated by the grant.
(3) No fee or profit is allowed.

c. Cooperative Agreement - A legal instrument which, consistent with 31 U.S.C. 6305, is used to enter into the same kind of relationship as a grant (see definition "grant"), except that substantial involvement is expected between the DOD and the recipient when carrying out the activity contemplated by the cooperative agreement. The term does not include "cooperative research and development agreements" as defined in 15 U.S.C. 3710a. No fee or profit is allowed.

Grants and cooperative agreements are governed by the following regulations:
(1) OMB Circular A-21, "Cost Principles for Educational Institutions"
(2) OMB Circular A-87, "Cost Principles for State, Local and Indian Tribal Governments"
(3) OMB Circular A-102, "Grants and Cooperative Agreements with State and Local Governments"
(4) OMB Circular A-110, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations"
(5) OMB Circular A-122, "Cost Principles for Non-Profit Organizations"
(6) OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations"
(7) DOD Grant and Agreement Regulations (DODGARs), DOD 3210.6-R

Copies of OMB regulations may be obtained from:

Executive Office of the President
Publications Service
New Executive Office Building
725 17th Street, N.W., Room 2200
Washington, DC 20503

Telephone: (202) 395-7332
FAX: (202) 395-9068
http://www.whitehouse.gov/OMB/grants

An electronic copy of the DODGARs may be found at
http://www.dtic.mil/whs/directives/corres/html/321006r.htm

NOTE: In accordance with DOD Directive 3210.6, the DODGARs may include rules that apply to other nonprocurement instruments, when specifically required in order to implement a statute, Executive Order, or Government wide rule that applies to other nonprocurement instruments, as well as to grants and cooperative agreements.

d. Other Transaction for Research. A legal instrument, consistent with 10 U.S.C. 2371, which may be used when the use of a contract, grant, or cooperative agreement is not feasible or appropriate for basic, applied, and advanced research projects. The research covered under "an other" transaction shall not be duplicative of research being conducted under an existing DOD program. To the maximum extent practicable, other transactions shall provide for a 50/50 cost share between the government and the offeror. An offeror's cost share may take the form of cash, independent research and development (IR&D), foregone intellectual property rights, equipment, or access to unique facilities, as well as others. Due to the extent of cost share, and the fact that an other transaction does not qualify as a "funding agreement" as defined at 37 CFR 401.2(a), the intellectual property provisions of an other transaction can be negotiated to provide expanded protection to an offeror's intellectual property. No fee or profit is allowed on an other transactions.

e. Individual Set Aside (ISA) Contract. An ISA is a firm fixed price contract made directly with the researcher individual following streamlined procedures described in the DFARS at Part 237.104. An ISA is specifically to acquire the personal services of experts and consultants included in 10 U.S.C. 129b and related to health care as authorized by 10 U.S.C. 1091.

3. PREPARATION COSTS

It must be clearly understood that the receipt and review of concept papers and proposals as described in this BAA by the government is entirely for the purpose of technical evaluation and in no way constitutes an agreement to enter into contractual or other relationships. It must be further understood that the submission of such documents is voluntary and must be done solely at the offeror's expense. The government will in no way be held liable for, nor reimburse, an offeror for any direct expenses incurred in the process of formulating or submitting such documents.

4. AVAILABILITY OF FUNDS

It must be clearly understood that, as of the date of release of this BAA, there are no funds committed for any project. Until such time as funds are released to the Contracting Officer, no contract can, or will, be made for an otherwise acceptable proposal.

5. FAR INFORMATION/REFERENCES

All FAR information/references, plus other related acquisition information may be found on the Internet at any of the following addresses:

http://www.arnet.gov/far/
http://farsite.hill.af.mil/VFFARa.htm
http://web2.deskbook.osd.mil/default.asp

6. SYSTEM FOR AWARD MANAGEMENT (SAM)

By submission of an offer, the offeror acknowledges the requirement that prospective awardees MUST be registered in the SAM database prior to award, during performance, and through final payment of any contract resulting from this solicitation. Lack of registration in the SAM database shall make an offeror ineligible for award. Offerors that are not registered should consider applying for registration immediately upon receipt of this solicitation. To remain registered in the SAM database after the initial registration, the contractor is required to confirm on an annual basis that its information in the SAM database is accurate and complete. For all SAM information (including any exemptions) go to https://www.sam.gov.

7. DATA UNIVERSAL NUMBERING SYSTEM (DUNS) NUMBER

An organization will need a DUNS number. A DUNS number is a unique nine-digit identification number provided by the commercial company Dun & Bradstreet (D&B) (http://fedgov.dnb.com/webform/displayHomePage.do). If an organization does not have a DUNS number, an authorized official of the organization can request one by calling 866-705-5711 or online via web registration (http://fedgov.dnb.com/webform/displayHomePage.do). Organizations located outside of the United States can request and register for a DUNS number online via web registration.

8. INVOICING AND PAYMENTS

All payments by the government under contracts awarded from this BAA shall be made by electronic funds transfer (EFT) or the government purchase card (GPC). If not paid by GPC, then invoices shall be submitted electronically in accordance with DFARs clause #252.232-7003, which will be included in any resulting contract from this BAA. The automated method being used at NHRC is the Wide Area Workflow (WAWF) system found at https://wawf.eb.mil. Contractors are encouraged to view this website and familiarize themselves with the invoicing process. More specific instructions on WAWF will be provided in any BAA award document.

9. RESTRICTED DATA ON PROPOSALS

As stated in FAR clause #52.215-1--Instructions to Offeror's - Competitive Acquisition, the following guidance is provided for contractors desiring to restrict any information in their concept paper or proposal:

Offeror's that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the government except for evaluation purposes, shall --

a. Mark the title page with the following legend:

   This proposal includes data that shall not be disclosed outside the government and shall not be duplicated, used, or disclosed -- in whole or in part -- for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of -- or in connection with -- the submission of this data, the government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This

restriction does not limit the government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [*insert numbers or other identification of sheets*]; and

b. Mark each sheet of data it wishes to restrict with the following legend:

Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.

10. INTELLECTUAL PROPERTY

a. Noncommercial Items (Technical Data and Computer Software)

Proposers responding to this BAA requesting a procurement contract to be issued under the FAR/DFARS, shall identify all noncommercial technical data, and noncommercial computer software that it plans to generate, develop, and/or deliver under any proposed award instrument in which the Government will acquire less than unlimited rights, and to assert specific restrictions on those deliverables. Proposers shall follow the format under DFARS 252.227-7017 for this stated purpose. In the event that proposers do not submit the list, the Government will assume that it automatically has "unlimited rights" to all noncommercial technical data and noncommercial computer software generated, developed, and/or delivered under any award instrument, unless it is substantiated that development of the noncommerical technical data and noncommerical computer software occurred with mixed funding. If mixed funding is anticipated in the development of noncommercial technical data, and noncommercial computer software generated, developed, and/or delivered under any award instrument, then proposers should identify the data and software in question, as subject to Government Purpose Rights. In accordance with DFARS 252.227-7013 Rights in Technical Data-Noncommercial Items, and DFARS 252.227-7014 Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation, the Government will automatically assume that any such General Purpose Rights restriction is limited to a period of five (5) years in accordance with the applicable DFARS clauses, at which time the Government will acquire "unlimited rights" unless the parties agree otherwise. Proposers are admonished that the Government will use the list during the source selection evaluation process to evaluate the impact of any identified restrictions, and may request additional information from the proposer, as may be necessary, to evaluate the proposer's assertions. If no restrictions are intended, then the proposer should state "NONE."

A sample list for complying with this request is as follows:

NONCOMMERCIAL

Technical Data Computer Software To be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Person Asserting
(LIST)	(LIST)	(LIST)	(LIST)

b. Commercial Items (Technical Data and Computer Software)

Proposers responding to this BAA requesting a procurement contract to be issued under the FAR/DFARS, shall identify all commercial technical data, and commercial computer software that may be embedded in any noncommercial deliverables contemplated under the research effort, along with any applicable restrictions on the Government's use of such commercial technical data and/or commercial computer software. In the event that proposers do not submit the lists, the Government will assume that there are no restrictions on the Government's use of such commercial items. The Government may use the list during the source selection evaluation process to evaluate the impact of any identified restrictions, and may request additional information from the proposer, as may be necessary, to evaluate the proposer's assertions. If no restrictions are intended, then the proposer should state "NONE."

A sample list for complying with this request is as follows:

COMMERCIAL

Technical Data Computer Software To be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Person Asserting
(LIST)	(LIST)	(LIST)	(LIST)

c. Non-Procurement Contract Proposers – Noncommercial and Commercial Items (Technical Data and Computer Software)

Proposers responding to this BAA requesting a grant or cooperative agreement shall follow the applicable rules and regulations governing these various award instruments, but in all cases should appropriately identify any potential restrictions on the Governments use of any Intellectual Property contemplated under those award instruments in question. This includes both Non-Commercial Items and Commercial Items. Although not required, proposers may use a format similar to that described in (a) and (b) above. The Government may use the list during the source selection evaluation process to evaluate the impact of any identified restrictions, and may request additional information from the proposer, as may be necessary, to evaluate the proposer's assertions. If no restrictions are intended, then the proposer should state "NONE."

d. All Proposers – Patents

Proposer responding to this BAA shall include documentation proving your ownership of or possession of appropriate licensing rights to all patented inventions (or inventions for which a patent application has been filed) that will be utilized under the proposal being submitted. If a patent application has been filed

for an invention that your proposal utilizes, but the application has not yet been made publicly available and contains proprietary information, you may provide only the patent number, inventor name(s), assignee names (if any), filing date, filing date of any related provisional application, and a summary of the patent title, together with either: 1) a representation that you own the invention, or 2) proof of possession of appropriate licensing rights in the invention.

e. All Proposers – Intellectual Property Representations

Proposers shall provide a good faith representation that they either own or possess appropriate licensing rights to all other intellectual property that will be utilized under the proposal being submitted. Additionally, offeror's shall provide a short summary for each item asserted with less than unlimited rights that describes the nature of the restriction and the intended use of the intellectual property in the conduct of the proposed research.

11. PROTECTION OF HUMAN SUBJECTS

Proposals selected for funding are required to comply with provisions of the following

a. Department of Defense Directive 3216.2; Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, March 25, 2002.
b. Section 980 of title 10, United States Code.
c. Common rule (32 CFR 219) on the protection of human subjects in research.

Any proposal for research involving human subjects the Offeror must 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 Federalwide 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. 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.

12. ANIMAL USE

DOD Directive 3216.1, dated April 17, 1995, provides policy and requirements for the use of

animals in DOD-funded research. The DoD definition of animal is any live nonhuman vertebrate. All proposals that involve the use of animals must address DoD compliance with Directive 3216.1.

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. DoD Standard IACUC Protocol Format Instructions, (See Appendix E).

Provisions include rules on animal acquisition, transport, care, handling, and use in 9 CFR Parts 1-4, Department of Agriculture rules implementing the Laboratory Animal Welfare Act of 1966 (7 U.S.C. 2131-2156), and guidelines in the National Academy of Sciences (NAS) "Guide for the Care and Use of Laboratory Animals" (1996), including the Public Health Service Policy and Government Principles Regarding the Care and Use of Animals in Appendix D to the Guide.

13. MILITARY RECRUITING

This is to notify potential offeror's that each grant or cooperative agreement awarded under this announcement to an institution of higher education must include the following term and condition:

"As a condition for receipt of funds available to the Department of Defense (DOD) under this award, the recipient agrees that it is not an institution of higher education (as defined in 32 CFR part 216) that has a policy of denying, and that it is not an institution of higher education that effectively prevents, the Secretary of Defense from obtaining for military recruiting purposes: (A) entry to campuses or access to students on campuses or (B) access to directory information pertaining to students. If the recipient is determined, using the procedures in 32 CFR part 216, to be such an institution of higher education during the period of performance of this agreement, and therefore to be in breach of this clause, the Government will cease all payments of DOD funds under this agreement and all other DOD grants and cooperative agreements to the recipient, and it may suspend or terminate such grants and agreements unilaterally for material failure to comply with the terms and conditions of award."

If your institution has been identified under the procedures established by the Secretary of Defense to implement Section 558, then: (1) no funds available to DOD may be provided to your institution through any grant, including any existing grant, (2) as a matter of policy, this restriction also applies to any cooperative agreement, and (3) your institution is not eligible to receive a grant or cooperative agreement in response to this solicitation.
This is to notify potential offeror's that each contract awarded under this announcement to an institution of higher education shall include the following clause: Defense Federal Acquisition Regulation Supplement (DFARS) clause 252.209-7005, Military Recruiting on Campus.

14. INTERNATIONAL TRAFFIC IN ARMS REGULATION (ITAR)

The offeror and their subcontractors shall comply with the ITAR, 22 CFR Parts 120 through 130. Information regarding ITAR is available at http://www.dtic.mil/mctl. If a question exists regarding ITAR, please contact Mr. Stephen Brackett at Stephen.brackett@us.army.mil. Information pertaining to the Export Administration Regulation (EAR) is available at http://www.gpo.gov/bis/ear/ear_data.html.

15. CLASSIFIED CONTRACT INFORMATION

The offeror and their subcontractors shall comply with FAR Subpart 4.4, Safeguarding Classified Information Within Industry. When applicable the offeror shall complete a DD Form 254, in compliance with the Federal Acquisition Regulation to ensure proper identification of classified information. Information pertaining to the preparation of DD Form 254 can be found at http://www.da.usda.gov/infosec/DD254.pdf.

SECTION IV - EVALUATION PROCESS

1. EVALUATION APPROACH FOR CONCEPT PAPERS

Concept papers will be evaluated by technical/scientific personnel that are knowledgeable within the particular topical area/specific interest area to determine if the paper presented is consistent with the intent of the BAA and is of interest to the government. Concept papers will be evaluated on the scientific/technical merit, the management approach, the importance to agency programs, and the proposed cost/price. Based on these evaluation criteria, the highest rated concept papers will show considerable potential to develop into highly qualified proposals that could likely lead to an award. Concept papers will be evaluated within ninety (90) days of receipt.

2. EVALUATION APPROACH FOR PROPOSALS

a. Proposals submitted in response to this solicitation will be given a scientific/peer review evaluation by NHRC technical personnel in accordance with below evaluation criteria within ninety (90) days after receipt. Each proposal will be evaluated based on the merit and relevance of the specific proposal as it relates to NHRC program requirements / needs, rather than against other proposals. Once a proposal has been submitted by the technical POC to the contracting office, the contractor is to HAVE NO FURTHER CONTACT with the technical POC until the time a contract award exists or unless otherwise authorized by the Contracting Officer or Grant Officer. Inquiries regarding status of the evaluation may be addressed to the administrative POC indicated under each scientific and technical area.
b. Offeror's whose proposals are considered not to have sufficient merit, which are not relevant to a Navy need, or which are in areas where funds are not expected to be available, will be notified as soon as possible after completion of evaluation that their proposal will not be further considered for a contract award.
c. For those proposals that are acceptable, notification will be made within ninety (90) days after receipt of proposal. The offeror will also be notified as to if and when funding is expected to be available for the project. The offeror is cautioned that the availability of funds as of the date of such notice is no guarantee that funds will be available at any given later date.

3. BASIS FOR AWARD

Offers will be selected based upon the outcome of proposal evaluation in accordance with the evaluation criteria cited below, plus the availability and source of funds. Not all highly rated proposals will result in a contract award. The government may elect not to award a contract for every highly rated proposal for each topical area/specific interest area. The government may award more than one contract in a given topical area/specific interest area, or the government may not award a contract at all in a given topical area/specific interest area.

4. FACTORS AND SUBFACTORS TO BE EVALUATED

Evaluation will be broken down into four (4) factors: technical, management, cost/price, and past performance. The technical factor is the most important followed by management, cost/price, and, finally, past performance. The technical factor has at least two (2) and up to three (3) subfactors, and cost/price has two (2) subfactors, each of equal importance. Technical subfactors A and B are of equal importance, and subfactor C is also equal when it is an applicable subfactor. Technical and management, when combined, are significantly more important than cost/price.

Technical personnel will assign an adjectival and risk rating for the technical and cost/price factor and subfactors, as well as the management factor of each proposal. Past performance areas will receive only a performance risk rating.

5. EVALUATION CRITERIA

a. **FACTOR I – Technical**: Each subfactor in this factor will be evaluated and will receive an individual rating. This factor will receive an overall rating based on the ratings of all the technical subfactors combined.
   (1) Subfactor A: Technical Merit: The proposal will be evaluated on the relevance of the proposed effort in response to the topical area/specific interest area and the overall technical feasibility of the technology, capability, the product and/or the technology proposed.
   (2) Subfactor B: Technology Advancement/Warfighting Capability: The proposal will be evaluated on the potential to increase the combat effectiveness of the Navy and the potential for exploiting a capability not likely to be executed elsewhere.

b. **FACTOR II – Management**: The proposal will be evaluated on the quality of the personnel, equipment, facilities, project management systems, controls (i.e., the overall organization) and the milestone schedule being proposed. The overall management plan will be evaluated.

c. **FACTOR III – Cost/Price**: Each subfactor in this factor will be evaluated and will receive an individual rating. This factor will receive an overall rating based on the ratings of both cost/price subfactors combined.
   (1) Subfactor A: Cost/Price Benefit: The proposals will be evaluated to determine the overall benefit to the government. Considerations will include industry contribution and fiscal feasibility. Fiscal feasibility includes the ability to accomplish the proposed project within government fiscal constraints, and includes the requirement for the use of other government contractors to assist in the execution of proposed effort, and the use of government furnished equipment, information, facilities, and other assets. The proposals will be evaluated to determine the extent to which the overall cost/price to the government is reasonable.
   (2) Subfactor B: Cost/Price Realism: The proposals will be evaluated for cost realism to assess the likelihood that the technical and management approaches can be accomplished at the cost/price proposed.

d. **FACTOR IV – Past Performance**: The offeror's and first tier subcontractor's past performance with government and industry in the specific interest area or similar and/or related areas will be evaluated to assess the relative risks associated with the offeror's likelihood of success in meeting the requirements stated in this BAA.

Specific areas of past experience and performance examined will include demonstrated technical and schedule performance, cost control, general responsiveness to contract requirements, customer satisfaction, and customer focus. Emphasis will be on recent, relevant experience (see past performance area under section II of this BAA).

6. RATING METHOD

a. Adjectival Ratings: The adjectival ratings that will be utilized for evaluating individual technical, management, and cost/price factors and subfactors are defined as follows:
   (1) Excellent: Evaluation of the factor/subfactor indicates the offeror's proposal meets or exceeds all stated criteria by demonstrating a firm grasp of the requirements and translating the requirements into a well defined and preferred approach. Innovative approaches that push the state of the art are present. The proposal exhibits strengths, and does not contain any weaknesses or deficiencies.
   (2) Very Good: Evaluation of the factor/subfactor indicates the offeror's proposal meets or exceeds all stated criteria by demonstrating an understanding of the requirements and translating the requirements into a well defined and feasible approach. Innovative approaches that are, at a minimum, state of the art, are present. The proposal exhibits some strengths and might contain one or more weaknesses but does not contain any deficiencies.
   (3) Acceptable: Evaluation of the factor/subfactor indicates the offeror's proposal meets all stated criteria by demonstrating an understanding of the requirements and translating the requirements into a feasible approach. Limited innovation beyond the norm is present. The proposal may exhibit some strengths and might contain some weaknesses but does not contain any deficiencies.
   (4) Marginal: Evaluation of the factor/subfactor indicates the offeror's proposal meets the majority of the stated criteria but either demonstrates a limited understanding of the requirements or translates the requirements in an approach which may not be feasible. The proposal may exhibit some strengths and might contain several weaknesses but does not contain any deficiencies.
   (5) Unacceptable: Evaluation of the factor/subfactor indicates the offeror's proposal does not meet the stated criteria or contains one or more deficiencies which indicate a lack of understanding of the requirements. The stated criteria can only be met with major changes to the proposal.
b. Risk Assessment:
   (1) The proposal risk assessment ratings for technical, management, and cost/price factors and subfactors are defined as follows:
      (a) High: Likely to cause serious disruption of contract effort or increase in cost/price of performance even with special contractor emphasis and government monitoring.
      (b) Moderate: Has some potential to cause minor disruption of contract effort or increase in cost/price of performance. Normal government monitoring will probably be able to overcome most difficulties.

(c) Low: Has very little potential to cause disruption of contract effort or increase in cost/price of performance. Minimal government monitoring will probably be able to overcome difficulties.

(2) The performance risk assessment ratings for past performance are defined as follows:

(a) High: Based on the offeror's performance record, substantial doubt exists that the offeror will successfully perform the required effort.

(b) Moderate: Based on the offeror's performance record, some doubt exists that the offeror will successfully perform the required effort.

(c) Low: Based on the offeror's performance record, little doubt exists that the offeror will successfully perform the required effort.

(d) Unknown: No performance record identifiable. This is essentially a neutral rating, which will neither directly benefit nor negatively impact the offeror.

c. Definitions:

(1) Strength: An aspect of a proposal that appreciably decreases the risk of unsuccessful contract performance or that represents a significant benefit to the government.

(2) Weakness: A flaw in the proposal that increases the risk of unsuccessful contract performance. A "significant weakness" in the proposal is a flaw that appreciably increases the risk of unsuccessful contract performance.

(3) Deficiency: A material failure of a proposal to meet a government requirement or a combination of significant weaknesses in a proposal that increases the risk of unsuccessful contract performance to an unacceptable level.

SECTION V - SCIENTIFIC AND TECHNICAL AREAS OF INTEREST

A. MEDICAL MODELING, SIMULATION & MISSION SUPPORT

M&S products are designed to assist operational commanders, medical logisticians, and field medical personnel in both the Navy and Marine Corps, and most recently, the Air Force. Specifically, M&S tools are used by both Navy and Marine Corps commands that include: Headquarters, US Marine Corps; Marine Corps Systems Command; Marine Corps Combat Development Command; Marine Corps Warfighting Laboratory; Chief of Naval Operations; Commander, Naval Surface Force, US Pacific Fleet; Naval Medical Logistics Command; Navy Warfare Development Command; and the Joint Readiness Clinical Advisory Board.

M&S works with medical planners, providers, and logisticians to develop projects that assist in field medical services planning, systems analysis, operational risk assessment, and determining the best course of action for treating a particular patient stream with the available resources. In addition, M&S works with the Navy, Marine Corps, Army, and Air Force to provide a joint view of medical mission support, helping to standardize across the Services medical assemblages, medical transport equipment, and specialized training programs.

<u>Scientific and Technological Areas of Interest:</u>

A comparison of current capabilities versus future battlefield requirements dictates interest in the following major areas of scientific knowledge and technological capabilities.

Technology is needed for:

1. Surveillance of treatment profiles for over 400 patient conditions.
2. Medical decision support tools for assessing, planning and implementing treatment times and personnel profiles for medical treatment tasks required for each patient condition.
3. Use, update and availability of supply requirements including weight, cube, and cost, for casualties treated at far-forward areas of care for both ground and shipboard platforms.
4. Measurement, collection and use of mortality data related to died of wounds due to treatment delay and died of wounds due to complications.
5. Development, configuration, and use of a casualty records repository that provides an objective source of clinical data from which to establish theater medical requirements.
6. Tools to enable forecasts of the types and numbers of casualties expected to occur in different types of contingency environments.
7. Technology that enables estimations of the supplies required to treat a particular patient stream at both ground and shipboard levels of care and functional areas.
8. Modeling the delivery and consumption of a medical supply inventory over a series of time intervals.
9. Modeling patient arrivals, treatment, and outcomes as they flow from the point of injury through a network of care facilities.

Some of the research for the above topics may include human and animal use regulations and data restrictions.

Communication with the Technical POC prior to submission of a formal proposal is essential.

Technical POC: Dr. Edward Gorham, TEL: 619-524-9876, edward.gorham@med.navy.mil

All concept papers, proposals, and administrative inquires should be submitted to:

Naval Health Research Center
Scientific Support Directorate
ATTN: Dr. Edward Gorham
140 Sylvester Rd, San Diego, CA 92106
619-524-9876, edward.gorham@med.navy.mil

B. WARFIGHTER PERFORMANCE

The Warfighter Performance department conducts research related to the measurement, maintenance, restoration, enhancement, and modeling of human performance in military operational environments. Emphasis is on the measurement and understanding of the processes that lead to physical and mental performance degradation, development of countermeasures to maintain or enhance performance, and the development of standards which allows safe and effective performance of Navy and Marine Corps personnel. This program focuses on optimizing Navy and Marine Corps operational performance through assessment of personnel performance and quantification of mission stressors that negatively influence mission success. Areas of emphasis include heat and cold stress, fatigue, effects of altitude, effects of acute operational stress, and effects of exertion on cognitive and physical performance. The program also engages in research to demonstrate alternatives for determining the physical readiness of Navy personnel. Research quantifies the effects of exposure to environmental stressors (e.g., heat and cold forces) and identifies, develops, and evaluates countermeasures to performance degradation.

Scientific and Technological Areas of Interest:

Concept papers and proposals are requested in the following areas and are not necessarily limited to the specific area of interest indicated:

1. Determinations and treatments to decrease environmental stress
2. Determinations and understanding of physical stressors, load and impact effects on warfighter performance
3. Physical fitness and weight standards for improved warfighter performance
4. Cognitive neuroscience of stress & its affect on performance and performance improvement

Some of the research for the above topics may include human and animal use regulations and data restrictions.

Communication with the Technical POC prior to submission of a formal proposal is essential.

Technical POC: Dr. Edward Gorham, TEL: 619-524-9876, edward.gorham@med.navy.mil

All concept papers, proposals, and administrative inquires should be submitted to:

Naval Health Research Center
Scientific Support Directorate
ATTN: Dr. Edward Gorham
140 Sylvester Rd, San Diego, CA 92106
619-524-9876, edward.gorham@med.navy.mil

C. BEHAVIORAL SCIENCES AND EPIDEMIOLOGY

Epidemiologists and psychologists in this program examine the manner in which stress reactivity, exposure to stressful situations, and mental health trends affect the performance of military personnel. Lifestyle trends and substance use/abuse are studied, and awareness/educational interventions are developed to modify behaviors and improve quality of life. Topics under study include individual stress reactivity, drug and alcohol abuse prevention, tobacco cessation, risk factors for suicide attempts, combat operational stress reactions and controls, posttraumatic stress disorder, and mental disorders, affects of amputations or blindness on rehabilitation and function of wounded warriors, and the prevention of domestic violence in Navy and Marine Corps families. Current epidemiological studies also address cancer, diabetes and other diseases as a function of occupational and demographic factors including prevention and treatment of cancer in active duty, dependent and veteran populations.

Scientific and Technological Areas of Interest:

A comparison of current capabilities versus future battlefield requirements dictates interest in the following major areas of scientific knowledge and technological capabilities. Concept papers and proposals are requested in the following areas and are not necessarily limited to the specific area of interest indicated:

1. Behavioral Trends That Impact Readiness
2. Focused Intervention Strategies
3. Behavioral Needs Assessment Survey
4. PTSD/TBI Studies
5. Career-Span Health & Wellness Studies
6. Wounded Warrior rehabilitation Studies
7. Investigate the efficacy of hyperbaric oxygen treatment for moderate to chronic traumatic brain injury
8. Proton Beam Therapy and Treatment
9. National Functional Genomics Center (NFGC) & Cancer Research
10. Cancer Prevention and Control

11. Pandemic Influenza and Vaccine Studies
12. Islet Cell Transplantation and Cell based therapies
13. Genetic & immunological causes of Diabetes

Some of the research for the above topics may include human and animal use regulations and data restrictions.

Communication with the Technical POC prior to submission of a formal proposal is essential.

Technical POC: Dr. Edward Gorham, TEL: 619-524-9876, edward.gorham@med.navy.mil

All concept papers, proposals, and administrative inquires should be submitted to:

Naval Health Research Center
Scientific Support Directorate
ATTN: Dr. Edward Gorham
140 Sylvester Rd, San Diego, CA 92106
619-524-9876, edward.gorham@med.navy.mil

D. DEPLOYMENT HEALTH RESEARCH

NHRC was designated as the United States Department of Defense (DoD) Center for Deployment Health Research on September 30, 1999, by the Assistant Secretary of Defense for Health Affairs. To execute this mission, NHRC established the Deployment Health Research Department. The mission of the department includes conducting epidemiological studies on the health of service members and their families, and developing and evaluating health surveillance strategies. An experienced department staff and flexible framework provide the ability to quickly adapt and confront novel health concerns of the public and DoD beneficiary populations. Staff members have expertise in complex data management, biostatistics, epidemiology, reproductive health, large mail and telephone surveys, and occupational health. The accomplishments of department staff on these and other efforts have resulted in numerous publications in leading peer-reviewed medical journals and receipt of competitive funding. Included among the core programs of the Deployment Health Research Department are the Millennium Cohort Study, the DoD Birth and Infant Health Registry, and the Recruit Assessment Program.

1. Millennium Cohort Study

In response to concerns about the health effects of deployments following the 1991 Gulf War, the US Congress and the US Institute of Medicine recommended that the DoD conduct prospective epidemiological research to evaluate the impact of military exposures, including deployment, on long-term health outcomes. The Millennium Cohort Study, the largest prospective health study in the military with more than 140,000 participants at present, meets this critical need. Although the original designers of the Millennium Cohort Study could not foresee the post-2001 military conflicts, the project is perfectly positioned to address health

outcomes related to these operations. Deployment of more than 40% of Millennium Cohort participants in support of the wars in Iraq and Afghanistan will enable investigators to prospectively evaluate detailed data from before, during, and long after these deployments.

Scientific and Technological Areas of Interest:

A comparison of current capabilities versus future battlefield requirements dictates interest in the following major areas of scientific knowledge and technological capabilities. Concept papers and proposals are requested in the following areas and are not necessarily limited to the specific area of interest indicated:

a. Methods of identifying, treating and dealing with posttraumatic stress disorder
b. Identification and treatment of depression
c. Prevention of alcohol misuse
d. Diseases and treatments for respiratory illnesses
e. Identification, treatment and rehabilitation of traumatic brain injury
f. Determining and understanding the long-term health of future generations of military members

Some of the research for the above topics may include human and animal use regulations and data restrictions.

Communication with the Technical POC prior to submission of a formal proposal is essential.

Technical POC: Dr. Edward Gorham, TEL: 619-524-9876, edward.gorham@med.navy.mil

All concept papers, proposals, and administrative inquires should be submitted to:

Naval Health Research Center
Scientific Support Directorate
ATTN: Dr. Edward Gorham
140 Sylvester Rd, San Diego, CA 92106
619-524-9876, edward.gorham@med.navy.mil

2. DoD Birth and Infant Health Registry

Established in 1998 at the direction of the Assistant Secretary of Defense for Health Affairs, the DoD Birth and Infant Health Registry aims to better understand the reproductive health effects of military service. To accomplish this goal, the Registry provides systematic surveillance of DoD beneficiary births, following infants for 1 year after birth to assess health outcomes, including birth defects. In 2003, the Birth and Infant Health Registry team developed a highly visible collaboration with the CDC on the National Smallpox Vaccine in Pregnancy Registry. Smallpox Registry staff receive vaccine adverse event reporting system (VAERS) forms for women inadvertently vaccinated in pregnancy, or within 42 days prior to conception. Unique to the Smallpox Registry is the ability to use active case follow-up to evaluate pregnancy losses. The DoD Birth and Infant Health Registry addresses the

reproductive health concerns of military families with strong science and surveillance, thus contributing to progress in the prevention of birth defects and other infant health challenges.

Scientific and Technological Areas of Interest:

A comparison of current capabilities versus future battlefield requirements dictates interest in the following major areas of scientific knowledge and technological capabilities. Concept papers and proposals are requested in the following areas and are not necessarily limited to the specific area of interest indicated:

a. Identification and establishment of the prevalence of birth defects in military populations
b. Evaluating associations of various birth outcomes with specific exposures, such as smallpox vaccination or deployment.

Some of the research for the above topics may include human and animal use regulations and data restrictions.

Communication with the Technical POC prior to submission of a formal proposal is essential.

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E. DEPARTMENT OF DEFENSE HIV/AIDS PREVENTION PROGRAM

As Executive Agent, the Navy manages the Department of Defense HIV/AIDS Prevention Program (DHAPP) from NHRC. DHAPP began as the Leadership and Investment in Fighting an Epidemic (LIFE) Initiative in fiscal year 2001 to combat the HIV/AIDS epidemic in Africa and India, and has served as a key implementing partner for the President's Emergency Plan for AIDS Relief (PEPFAR) since 2003.

Scientific and Technological Areas of Interest:

A comparison of current capabilities versus future battlefield requirements dictates interest in the following major areas of scientific knowledge and technological capabilities. Concept papers and proposals are requested in the following areas and are not necessarily limited to the specific area of interest indicated:

1. Assist in the development and implementation of military-specific HIV prevention, care and treatment programs in foreign military partners around the world
2. Integrate with and utilize other USG programs, and programs managed by allies and

the United Nations, dedicated to HIV/AIDS prevention, care and treatment
3. Establish HIV/AIDS as a standard Security Cooperation activity. DHAPP currently oversees military HIV prevention programs in 75 countries.

Communication with the Technical POC prior to submission of a formal proposal is essential.

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F. OPERATIONAL INFECTIOUS DISEASES

The Operational Infectious Diseases department conducts active, laboratory-based surveillance of US military populations in unique global environments to quantify and study the etiology of illnesses that afflict military personnel. The initial focus of this work is an in-depth surveillance for respiratory pathogens among deployed troops, at 8 DoD recruit training sites, and on 20 large platforms ships in three fleets. Other areas of interest include malaria (including dengue), enteric diseases, viral and rickettsial diseases, and wound infection. This work contributes directly to force health protection by defining critical respiratory pathogen threats and directing appropriate intervention strategies.

Scientific and Technological Areas of Interest:

A comparison of current capabilities versus future battlefield requirements dictates interest in the following major areas of scientific knowledge and technological capabilities. Concept papers and proposals are requested in the following areas and are not necessarily limited to the specific area of interest indicated:

1. Conduct outbreak investigations
2. Develop studies to understand infectious diseases
3. Test rapid diagnostic assays and platforms
4. Conduct clinical trials of potential vaccines and therapeutics
5. Test specimens from ongoing surveillance programs and from special investigations of febrile illness and pneumonia among military personnel or civilians (recruits, forces afloat, deployed forces, and outbreaks of concern, border populations
6. Address the safety and efficacy of drugs, vaccines, and new diagnostics as they impact operational health concerns

Communication with the Technical POC prior to submission of a formal proposal is essential.

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G. MEDICAL SCIENCE

1. Expeditionary Medicine

In Expeditionary Medicine, we are looking at personnel survivability and performance, including immediate and pre/post deployment, in the context of operational medicine. We must understand/model the personnel prerequisites before entering into the engagement zone, while in the hot zone, and the effects on personnel way after exiting the service. Understanding of these environments/scenarios requires the application/advancement of expertise, science, and technology in basic, applied, and developmental research associated with topics such as mental status (e.g., combat trauma, PTSD, etc.) and physical condition (e.g., infectious diseases, TBI, etc.). Then we must develop and deploy solutions quickly (e.g., virus vaccines, medical procedures, patient support environments, etc.).

Scientific and Technological Areas of Interest:

a. Innovative applications of modeling and simulation technologies in support of Navy operational medicine.
b. New scientific approaches to medically understanding/improving Warfighter performance in and post deployment from a military operational environment.
c. Advancement of Navy Medicine based on epidemiology and behavioral science research.
d. Developing cures/vaccines for infectious diseases

Communication with the Technical POC prior to submission of a formal proposal is essential.

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H. BIOMEDICAL TRANSLATIONAL INITIATIVE

The goal of this program is to identify and fund research projects that are likely to yield clinical diagnostics, therapies, or procedures for improving the clinical outcome of injured soldiers, enabling their return to duty, their restoration of form or function, or their reclamation of independence in daily living tasks. Diagnostics, therapies, or procedures for supporting the caregivers and/or family members of injured soldiers are also eligible for funding within this program.

Scientific and Technological Areas of Interest:

1. Polytrauma - This program defines polytrauma as multiple, simultaneous, traumatic injuries, *e.g.*, loss of limb as well as burns.
2. Blood Substitutes - Proposals are encouraged to focus on:
   a. Oxygen carrying, temperature stable, universally compatible agents for treating hemorrhagic shock, or
   b. Human derived, pathogen inert, temperature stable, lipid reduced plasma products for trauma-induced coagulopathy.
3. Inflammation - Proposals are encouraged to focus on products or procedures that reduce inflammation limiting tissue injury and promoting healing.
4. Infection and Healing - Proposals are encouraged to focus on:
   a. Novel treatments to reduce bacterial load, including load-hyperbaric oxygen and nitric oxide applications, or
   b. Technology to assess total bacterial load in blast wounds, or
   c. Identification of biomarkers to predict outcomes related to wound infection, or
   d. Supplements or products to enhance immune status and accelerate healing.
5. Burns and Compartment Syndrome - Proposals are encouraged to focus on:
   a. Skin substitutes to minimize morbidity from repeated or extensive donor-site harvesting and delayed closure, or
   b. Adipose derived therapies for wound healing, tissue repair, and scar management.
6. Massive Tissue Loss - Proposals are encouraged to focus on:
   a. Salvage and reconstruction of damaged tissue, including bone substitutes, composite tissue allografts, novel reconstruction materials, and dynamic facial restoration capabilities, or
   b. Improved techniques for inducing immune tolerance after transplants in order to preclude a lifelong need for immunosuppressant therapies, or
   c. Replacement of lost tissue, including prostheses, exoskeletons, and novel assistive devices, or
   d. Regeneration of lost tissue, including tissue engineering based on stem cells.
7. Traumatic Brain Injury - This program defines Traumatic Brain Injury (TBI) as damage to the structure and function of the brain. Of particular interest is TBI resulting from blast overpressure.

a. Differential Diagnoses Proposals are encouraged to focus on diagnostic procedures for the early identification and assessment of cognitive impairment, including the use of biomarkers, radiological studies, rapid psychometric assessments, or symptom pattern algorithms that could be used to differentiate between the functional impairment often resulting from blast overpressure trauma (*i.e.*, mTBI) versus psychological trauma
b. Early Interventions Projects are encouraged to focus on:
   - Evidence-based pharmacological agents for the immediate treatment of TBI, or
   - Evidence-based approaches for the rehabilitation of TBI, including products or procedures to treat cognitive dysfunction, affective dysregulation and aggression, altered self-identify, and problems with social re-integration, or
   - Novel approaches to rehabilitation (*e.g.*, the use of virtual reality), or
   - Integrated approaches to treatments for TBI, psychological trauma, and/or physical trauma, or
   - Methods to integrate the assessment of both physical and cognitive capacities in order to more objectively monitor and assess rehabilitation and return-to-duty status.

8. Psychological Trauma - This program defines psychological trauma as the disruption of normal cognitive and emotional processes, often with physiologic sequelae, resulting from an experience that overwhelms psychological coping mechanisms.
   a. Post Traumatic Stress Disorder Proposals are encouraged to focus on: Evidence-based approaches to improve the referral, retention, and return-to-duty of soldiers with Post Traumatic Stress Disorder (PTSD), or
   b. Primary care interventions to attenuate the physical, social, relational, and emotional sequelae of psychological health issues (*e.g.*, PTSD, depression, etc).
   c. Suicidal Intent – Proposals are encouraged to focus on the early diagnosis of suicidal intent, the assessment of its degree of risk, its treatment, or its prevention.
   d. Caregiver Factors – Research has shown that health care providers and chaplains treating veterans of Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) are at a higher risk of developing mental health disorders.[1] Proposals are encouraged to focus on technologies for screening and treating caregivers for mental health disorders.
   e. Family Factors Proposals are encouraged to focus on:
      - Methods to improve the resiliency and wellness of family members during deployment of a soldier, or
      - Methods to minimize depression, anxiety, and deteriorating physical health of family members after the injury of a soldier, due to the stresses attendant to care giving, changing roles in a relationship, and loss.

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[1] Tanielian, T. and Jaycox, L.H. Invisible Wounds of War: Psychological and Cognitive Injuries, Their Consequences, and Services to Assist Recovery. Rand Corporation Monograph, 2008.

Some of the research for the above topics may include human and animal use regulations and data restrictions.

Communication with the Technical POC prior to submission of a formal proposal is essential.

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I. WARFIGHTER SYSTEMS TECHNOLOGIES

1. Integrated Protective Head Borne Equipment and Injury Diagnostic/Assessment Tools

Head borne protection for the individual combatant involves protection of the head (to include the eyes, neck and throat) against fragmentation munitions, handgun projectiles, blunt trauma impact and behind armor effects including injuries caused by kinetic energy and blast waves. New materials, designs including modeling and simulation design tools, survivability models, treatments and diagnosis technologies are required to meet this broad range of threats while also providing in-depth consideration to the appropriate ergonomics, comfort, hearing, mission requirements, thermal/vapor management and other cognitive functions necessary for the combatant to fully execute his/her operational duties without extensive physical or mental impairments.

New diagnostic and assessment tools/methods that medically evaluate the combatant are needed in order to more fully characterize specific warrior populations at risk and requiring further clinical intervention. In order to support this requirement new diagnostic and assessment methods and tools for Post-Traumatic Stress Disorder (PTSD) and Traumatic Brain Injury (TBI) are required. In addition, research data needs to be collected in a systematic manner for the various services, compiled and analyzed in order to develop a baseline for a requirements document. The injury data is a key element in developing treatment and diagnosis tools and new protection/survivability models so that troops maybe better protected in future engagements and injuries treated at the front lines.

Marine Corps personnel, both Navy Active and Reserve personnel are deploying in unprecedented numbers to the CENTCOM AOR as Individual Augmentee personnel in support of Army missions. This large movement of Navy personnel to extreme environments in a non-traditional combat role presents unique medical readiness requirements.

Scientific and Technological Areas of Interest:

A comparison of current capabilities versus future battlefield requirements dictates interest in

the following major areas of scientific knowledge and technological capabilities.

Technology is needed for:

a. New and improved polymers for fiber reinforced plastics and resins which can provide increased ballistic protection and lighter weight.
b. New fibers and materials for energy absorption and moisture vapor permeability/cooling management.
c. Transparent materials for enhanced eye protection without reductions in visibility.
d. Improved lightweight integrated communications devices.
e. Engineering designs which incorporate enhancements to combat helmets including area of coverage, field of view, modular attachment points, speech recognition, compatibility with existing equipment and improved hearing capabilities.
f. Modeling and simulation tools for material/armor system designs
g. Modeling and simulation survivability design tools including bio-mechanics and injury prevention/diagnosis models.

A need also exists for:

h. Novel modular designs and integration concepts to identify the best technical approach to provide head protection to the individual combatant against multiple ballistic and non-ballistic threats. Such concepts should identify ballistic protection capabilities for each component and area of the head to be protected. Upon identification of critical design elements further efforts should establish the feasibility of systematically combining those modular components into a lightweight head borne system of approximately 3.5 pounds providing a high level of protection against the identified threats and high level of user comfort.
i. Unique and novel design approaches, which utilize the currently fielded equipment and developmental items as a base platform for incorporating modular components for improved ballistic/blast protection and would offer the user the ability to tailor the level of protection to the current threat by adding or removing modular integrated components (i.e. face shield, eye protection, neck protection).
j. Unique and novel design approaches for protective assemblies, which provide maximum area of coverage and ballistic resistance capabilities. These systems could weigh as much as 6 – 8 pounds and encompass the entire head. This type of approach will require attachment designs and bio-mechanic studies to determine the best means for carrying the system weight on the shoulders or other parts of the body and be capable of allowing the user to tailor the level of protection to the anticipated threat by adding or removing modular integrated components.
k. Ergonomic and human factor studies to identify key parameters for user acceptability. The identified design(s) include studies, laboratory data and human evaluations for heat stress retention, stability, ability to fire weapon systems, maneuverability and general form, fit and function of proposed design.
l. Modeling and simulation design and material evaluation tools which provide engineers and medical personnel the appropriate human interface information necessary to mitigate injuries from a variety of threats encountered on the modern battlefield.

m. Characterization and surveillance of, and mitigation of, Post-Traumatic Stress Disorder (PTSD) and Traumatic Brain Injury (TBI), primarily within military personnel. Within the surveillance domain, information on the type and prevalence of behavioral health problems and brain injury-related issues will be used to identify resource needs and potential mitigation strategies for prevention programs. The prevalence of deployment-related psychological symptoms in troops-in-transition who are returning to civilian life needs to be determined, and their health care utilization patterns need to be described. The extent to which PTSD and TBI data among military personnel are accurate and up to date will need to be determined. Medical data from theater will be required to characterize the pre-clinical deployment-related variables that covary with subsequent development of PTSD and TBI. Specific to TBI, neuropsychological baseline screening and follow-up assessment methods are needed to enhance the safety and performance of Warfighters. New diagnostic and assessment methods for PTSD and TBI are needed in order to more fully characterize specific populations at risk and requiring further clinical intervention.

n. There is a need to match evidence-based services to the needs of deployed personnel, and to allow the Navy Surgeon General and The Medical Officer of the Marine Corps to provide accurate psychological health information. Specifically, there is a critical need for surveillance to determine the prevalence of psychological health problems and TBI in expeditionary Sailors and Marines, particularly in high-risk populations such as infantry. The portfolio of programs proposed will document the prevalence of health problems and TBI in high-risk Naval populations, and the magnitude of resources needed by these populations.

o. Other topics pertaining to psychological health relevant to TBI are: develop a core body of knowledge in compassion fatigue; evaluate the need for telemedicine; educate professional on those affected by disease or addiction; develop course on how to use pharmacotherapy treatment and non-pharmacological intervention; standardize a Neurocognitive & Combat Stress Toolbox; develop a portable head-neck CT scan for use in patient transport; study ocular signs of TBI; develop the Navy Reserve's Psychological Health strategic plan; develop critical skills related to individual and family emotional regulation, problem solving, communication, and accessing support; develop assessment and treatment program for the families of Wounded Warriors; develop an outreach program for Marines; provide mental health case managers and oversight for each Wounded Warrior Battalion; train support staff at USMC HQ; enhance knowledge and skills on non-mental health caregivers to recognize combat related symptoms; train mental health providers on the techniques and interventions necessary to decrease combat operational stress; provide on-site training for OSCAR team members prior to deployment; investigate negative expectations about disclosing combat experiences; develop website for self-management intervention employing empirically derived cognitive-behavioral therapy; develop pre-deployment training for psychological first aid; etc.

Some of the technical approaches for topics within this solicitation may be subject to export control restrictions under existing export control laws, and or required to be conducted as classified projects as outlined in the National Industrial Security Program Operating Manual (NISPOM) and its supplements. Contractors who would like to submit proposals pertaining to such technologies are encouraged to contact their local Defense Investigative Service (DIS)

Industrial Security representative or the Technical POC listed in the solicitation for guidance.

Communication with the Technical POC prior to submission of a formal proposal is essential.

Technical POC: Mr. James Mackiewicz, TEL: 508-233-5925, james.f.mackiewicz.civ@mail.mil

All concept papers, proposals and administrative inquiries should be submitted to:

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Kansas Street
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2. Modular Personnel Protection Equipment (MPPE) and Injury Diagnostic / Assessment Tools

Personnel protection for the individual combatant involves protection of the torso (to include the extremities, arms, groin and legs) against fragmentation munitions, blast, small arms and handgun projectiles. New materials, designs and technologies are required to meet these broad range of threats while also providing the appropriate ergonomics, comfort, weight and cooling necessary for the individual to be capable of wearing the body armor for extended periods of time. Torso/extremity protection for the individual combatant involves protection against fragmentation munitions, handgun projectiles, blunt trauma impact and behind armor effects including injuries caused by kinetic energy and blast waves. New materials, designs including modeling and simulation design tools, survivability models, treatments and diagnosis technologies are required to meet this broad range of threats while also providing in-depth consideration to the appropriate ergonomics, comfort, maneuverability, mission requirements, thermal/vapor management and other cognitive functions necessary for the combatant to fully execute his/her operational duties without extensive physical impairments.

The goal of this task is to develop a personnel protective system and modeling tools which can be tailored to defeat specific threats including fragmentation/blast munitions, hand-gun and small arms projectiles. The modular system will have the capability to achieve various levels of personnel protection to meet specific threats and to provide protection to specific and critical areas of the Soldier. The modular system will be designed to protect areas of the body not currently protected by the Interceptor Outer Tactical Vest (OTV) and Small Arms Protective Plates (SAPI). The primary challenge becomes one of designing an efficient and synergistic system that offers various level of protection while being operationally effective and meets form, fit and heat stress reduction requirements so that sustainability is increased.

New diagnostic and assessment tools/methods that medically evaluate the effectiveness of armor and the individual combatant are needed in order to more fully characterize specific warrior threats and populations at risk requiring further clinical intervention. In order to support this requirement new diagnostic and assessment methods and tools for behind armor and penetrating

wounds are required. In addition, research data needs to be collected in a systematic manner for the various services, compiled and analyzed in order to develop a baseline for a requirements document. The injury data is a key element in developing treatment and diagnosis tools and new protection/survivability models so that troops maybe better protected in future engagements and injuries treated at the front lines. Marine Corps personnel, both Navy Active and Reserve personnel are deploying in unprecedented numbers to the CENTCOM AOR as Individual Augmentee personnel in support of Army missions. This large movement of Navy personnel to extreme environments in a non-traditional combat role presents unique medical readiness requirements.

Scientific and Technological Areas of Interest:

A comparison of current capabilities versus future battlefield requirements dictates interest in the following major areas of scientific knowledge and technological capabilities.

Technology is needed for:

a. New and improved polymers for fiber reinforced plastics and resins which can provide increased ballistic protection and lighter weight.
b. New fibers and materials for energy absorption and moisture vapor permeability/cooling management.
c. Improved ceramic materials capable of providing weight reductions and improved frangibility.
d. Improved lightweight integrated and flexible extremity protection.
e. Engineering designs which incorporate enhancements to personnel protection including area of coverage (soft and hard armors), modular attachment points, flexibility, compatibility with existing equipment and tailorability to increasing threat levels.
f. Novel modular designs and integration concepts to identify the best technical approach to provide body/extremity protection to the individual combatant against multiple ballistic and non-ballistic threats. Such concepts should identify ballistic protection capabilities for each component and area of the body to be protected. Upon identification of critical design elements further efforts should establish the feasibility of systematically combining those modular components into a lightweight personnel protection system of approximately 15-pounds providing a high level of protection against the identified threats and high level of user comfort.
g. Unique and novel design approaches, which utilize the currently fielded Interceptor Body Armor as a base platform for incorporating modular components for improved ballistic/blast protection and would offer the user the ability to tailor the level of protection to the current threat by adding or removing modular integrated components (i.e. hard plates, soft panels, neck protection and extremity protection).
h. Unique and novel design approaches for protective assemblies, which provide maximum area of coverage and ballistic resistance capabilities. These systems could weigh as much as 12 - 20 pounds and encompass most of the body. This type of approach will require attachment designs and bio-mechanic studies to determine the best means for carrying the system weight on the shoulders or other parts of the body and be capable of allowing the user to tailor the level of protection to the anticipated threat by adding or removing

modular integrated components.

i. Ergonomic and human factor studies to identify key parameters for user acceptability. The identified design(s) include studies, laboratory data and human evaluations for heat stress retention, stability, ability to fire weapon systems, maneuverability and general form, fit and function of proposed design.

j. Modeling and simulation design and material evaluation tools which provide engineers and medical personnel the appropriate human interface information necessary to mitigate injuries from a variety of threats encountered on the modern battlefield.

k. There is a need for research programs with specific goals and end-points for health related issues relevant to military personnel and veterans. These research programs are generally concerned with topics relating to, but not limited to, healthcare delivery, detection, diagnosis, treatment and control or eradication of specified chronic diseases, conditions, or syndromes, or to other initiatives relevant to health needs.

l. A primary goal of the DoD's Operational Medicine Research Program is to develop strategies to assure and protect the health of military personnel. Research is directed toward improved surveillance systems for early identification of health outcomes that affect military performance and preparedness. Research results will improve understanding of disease and non- battle injury risks to deployed military service members and development of successful intervention strategies to protect against materiel and environmental hazards that affect health and performance. Current areas of emphasis may include: (1) Environmental physiology and metabolic interventions such as thermal physiology and injury prevention, nonfreezing cold injury protection, sustainment in mountainous terrain, metabolic regulators to optimize performance in adverse environments, nutritional optimization of soldier mental status, optimization of physical performance and musculoskeletal injury prevention. (2) Biodynamics and injury sciences research such as blunt trauma models, soldier performance and injury-based criteria and crash injury protection; laser eye injury protection and treatment. (3) Epidemiological studies that determine incidence rates of acute and infectious disease and injury in military service members and are aimed at identification of environmental, bacteriological, immunological, microbiological or physiological factors associated with increased risk of acute or chronic disease or injury.

m. Development of a methodology and model to simulate the target detection, recognition, identification and acquisition process under various lighting and operational conditions.

n. Tools and capabilities that allow simulation of the full spectrum of missions ranging from peacekeeping to combat.

o. Development of light weight, low powered prototypical devices that improve the mobility of individual dismounted (non-vehicular riding) Soldiers in complex terrain and enhances their ability to carry heavy loads with reduced stress on the body and less fatigue.

p. Investigate the effects of acute and chronic head borne weight on Soldier performance, fatigue and the incidence of injuries.

q. Develop physics based analytical models and virtual prototyping tools of human locomotion and combat environment individual movement techniques to provide design guidance for individual equipment.

r. Determine the biomechanical effects of placing loads of varying mass, volume and location on the extremities during typical Naval tasks.

A need also exists for:

s. Flame and thermal protection for the individual involves protection of the body, head and extremities against a variety of fire hazards that occur in combat situations and operations other than war. Lightweight and flexible materials are required to protect against these threat and hazards to reduce burn injuries. Science and Technology Areas of Interest: A comparison of current capabilities versus battlefield requirements dictates interest in the following major areas of scientific knowledge and technological capabilities.

t. New high performing fibers for clothing applications (woven, nonwoven, knit, and batting fabric structures) which provide flame and thermal resistance without melt drip characteristics.

u. Improvements to existing fibers (e.g. incorporate novel flame retardant chemicals, flames suppressors or char formers into conventional low cost fibers).

v. Advanced concepts to integrate multiple protection capabilities into materials and clothing systems. Such concepts should integrate flame and thermal protection with other protective capabilities such as environmental protection, signature management, and electrostatic dissipation without significantly increasing weight.

w. Novel developmental flame resistant treatments, coatings, and films that are moisture vapor permeable, lightweight, and chemically compatible with a wide variety of substrate materials.

x. Test methodology and supporting instrumentation to characterize and evaluate the melt burn potential of thermoplastic fiber-based fabric in layered configurations at either the bench scale or full instrumented manikin system.

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Communication with the Technical POC prior to submission of a formal proposal is essential.

Technical POC: Mr. James Mackiewicz, TEL: 508-233-5925,
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All concept papers, proposals and administrative inquiries should be submitted to:

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J. ADVANCED TECHNOLOGY

1. Information Operations

Information Operations to include Computer Network Operations and Electronic Warfare has had a dramatic impact on the battlefield in recent years; permitting commanders and Warfighters to leverage technology as a means to improve awareness and decision making during operations planning and execution. This area of the battle space is largely technology driven and tied directly to the commercial communications industry. Changes in commercial industry standards and technologies require constant vigilance on behalf of the government for development of advanced Information Operations equipment and software.

Efforts are underway to leverage software development and hardware integration to address any emerging threats in the following areas:

- Computer Network Operations
- Electronic Warfare

Scientific and Technical Areas of Interest

Concept papers and proposals are requested in the following areas and are not necessarily limited to the specific area of interest indicated:

a. Computer Network Operations as defined by the Department of Defense.
b. Electronic Warfare in a Tactical Application.
c. Electronic Warfare as defined by the Department of Defense.
d. Targeting within Information Operations.
e. Integration into UAV and other Aerial Platforms.
f. Use in Ground Platforms.
g. Use as Handheld/Man packable Form Fit and Function.
h. Testing of above mentioned technologies.

Additionally, technology candidates must exhibit the following:

i. Technical Readiness level 1—7.

Performance under this Area of Interest may require the Contractor to meet specific security requirements IAW a DD 254, Contract Security Classification Specification, and have individuals cleared up to the TOP SECRET/SCI level at the start of the task. Contractor personnel involved in any contract awarded under this BAA may be required to execute an SF-312, Non-Disclosure Agreement, as a condition of employment.

Communication with the technical POC prior to the submission of a formal proposal is essential.

TECHNICAL POC: MAJ Heather Bellusci: heather.bellusci@us.army.mil.

All concept papers should be submitted on CD ROM to PM Special Programs, Attn: MAJ Heather Bellusci, 10401 Totten Road, Bldg 399 3rd Floor, Fort Belvoir, VA 22060

All concept papers, proposals and administrative inquiries should be submitted to:

Naval Health Research Center
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K. NAVAL MEDICAL RESEARCH UNIT (NAMRU) DAYTON, WRIGHT-PATTERSON AFB, OH

Research and development is conducted to support fleet operational readiness, protect the war fighter and provide the Department of the Navy, the Bureau of Medicine and Surgery and other customers with timely solutions to current and anticipated operational problems through an integrated approach to innovative human health effects toxicological research and aero medical research. New materials and weapon systems are evaluated for potential adverse health effects and preventive/curative strategies are proposed. NAMRU Dayton professionals anticipate data needs and propose research projects to fill data gaps.

1. Toxicological Impact of Sodium Tungstate and other Heavy Metals Exposure

This program aims to determine the health effects of tungsten (W) following exposure by relevant routes including intranasal, ingestion and embedded fragments. The project includes the toxicity and health effects data are most often used in support of DoD and other governmental panels and their operational uses.

Scientific and Technological Areas of Interest:

A comparison of current capabilities versus future battlefield requirements dictates interest in the following major areas of scientific knowledge and technological capabilities. Concept papers and proposals are requested in the following areas and are not necessarily limited to the specific area of interest indicated:

a. Uptake and pharmacokinetics of inhaled tungstate entry into the brain
b. Evaluation of the toxicological impact of exposure on the endocrine and immune system organs in vivo and in vitro models.

Communication with the Technical POC prior to submission of a formal proposal is essential.

Technical POC: Edward D. Gorham, PhD, (619) 524-9876, edward.gorham@med.navy.mil

All concept papers, proposals and administrative inquiries should be submitted to:

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ATTN: Dr. Edward D. Gorham

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San Diego, CA 92106-3521
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2. Characterization of Biological Impacts of Exposure to Middle East Sand-derived Particulate Matter for Risk Analysis, Assessment and Management of US Military Personnel

This program investigates the health risks from exposure to particulate matter (PM) prevalent in Middle Eastern areas of operation. This information facilitates DoD and Navy requirement for specialized toxicity and health effects data.

a. Identification of the components of the particulate matter (PM) that may contribute to respiratory complaints among deployed personnel and assess if smoking contributes to the conditions
b. Develop appropriate inhalation exposure system that mimics personnel exposure conditions and examine if cigarette smoking exacerbates the effects of inhaled PM
c. Examine if soluble or insoluble extracts or microbial factors contribute to the potential systemic toxicity of PM and in turn provides the development of disease or morbid conditions

Scientific and Technological Areas of Interest:

A comparison of current capabilities versus future battlefield requirements dictates interest in the following major areas of scientific knowledge and technological capabilities. Concept papers and proposals are requested in the following areas and are not necessarily limited to the specific area of interest indicated:

a. Uptake and pharmacokinetics of inhaled tungstate entry into the brain
b. Evaluation of the toxicological impact of exposure on the endocrine and immune system organs in vivo and in vitro models.

Communication with the Technical POC prior to submission of a formal proposal is essential.

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3. Developing Technology for Identification of Non-Culturable Microorganisms in Middle East Sand Environments to Mitigate Exposure Risk to Our Military Personnel

Developing techniques to detect environmental microbial pathogens may allow for identification of materials, which pose threats to the environment and will significantly improve efforts to identify pathogenic microorganisms in a given environmental location, resulting in potential decreased risk of exposure and subsequent infection to our war fighters

Scientific and Technological Areas of Interest:

A comparison of current capabilities versus future battlefield requirements dictates interest in the following major areas of scientific knowledge and technological capabilities. Concept papers and proposals are requested in the following areas and are not necessarily limited to the specific area of interest indicated: Develop an approach to improve identification of metabolically active microbial community in environmental locations which are not cultivatable under routine laboratory conditions

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4. Health effects of Jet Fuels, 1, 4-Dioxane and other Solvents

This program investigates the potential toxicity from exposure to jet fuels, 1, 4-Dioxane and other solvents of military relevant chemicals used in the operational field.

Scientific and Technological Areas of Interest:

A comparison of current capabilities versus future battlefield requirements dictates interest in the following major areas of scientific knowledge and technological capabilities. Concept papers and proposals are requested in the following areas and are not necessarily limited to the specific area of interest indicated:

a. Identification of the toxicity that includes gene/protein expression, dermal toxicity, chromosomal aberration, lung response and functional observational battery of new synthetic jet fuel (SPK) following acute and 90-day inhalation exposure in rat models and compares this response with JP-8.
b. Identify and set occupational exposure limits of SPK for personnel
c. Examine the risk associated with noise and JP-8 co-exposure and resulting hearing loss is being through a series of studies in vivo
d. Examine 1,4-dioxane exposure threshold through inhalation and thus provide health impact of this chemical

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5. Biomarker discovery and Mechanistic toxicology

This program conducts research to support risk assessment and injury prevention for emerging chemical contaminants.

Scientific and Technological Areas of Interest:

A comparison of current capabilities versus future battlefield requirements dictates interest in the following major areas of scientific knowledge and technological capabilities. Concept papers and proposals are requested in the following areas and are not necessarily limited to the specific area of interest indicated:

a. Investigation and development of exposure biomarkers through mechanism-based assay
b. Broadening in vitro screening through cutting edge technologies that includes genomic toxicology, human genome research, environmental toxicology, bone marrow, etc.
c. determining preventive method strategy through intervention
d. Investigate the mechanism of neurodegeneration in response to manganese exposure as the level of this metal in the dust is high in the Middle East
e. Investigate the efficacy of hyperbaric oxygen treatment for induced neurological damage and sequelae following carbon monoxide poisoning in the rodent model.
f. Identify the toxicological effects of military relevant exposure materials of concern to the Navy by using microarray analysis

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6. Aero Medical Research

Research and development is conducted in the areas of spatial orientation, human performance, aeromedical standards, and general aviation medicine.
Programs

Scientific and Technological Areas of Interest:

A comparison of current capabilities versus future battlefield requirements dictates interest in the following major areas of scientific knowledge and technological capabilities. Concept papers and proposals are requested in the following areas and are not necessarily limited to the specific area of interest indicated:

a. Vestibular Systems: Over the course of conducting vestibular research, the laboratory has acquired a unique collection of man-rated acceleration research devices. These devices are used by the laboratory, as well as by visiting scientists from around the world, to maintain a technology base in research areas of interest to naval aviation, the DoD, and NASA. Applied efforts focus on the transition of products from the laboratory's fundamental research base, among them clinical drug trials, novel techniques to reduce SD mishaps, and ground-breaking medications for ameliorating the symptoms of motion sciences
b. Biomedical, Cognitive and Aviation Selection Research: NAMRL's research efforts in aerospace medicine address human biological systems and phenomena including sensory processes, adaptation syndromes, therapeutic drug efforts, atmospheric physiology, including hypoxia, and various preventative medicine issues relevant to aerospace and other operational environments. In addition, NAMRL performs cognitive, psychomotor, and psycho physiological research aimed at improving aviation selection standards and performance in other communities, in support of a broad range of missions related to of Sea Power 21 and Sea Warrior.

Communication with the Technical POC prior to submission of a formal proposal is essential.

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L. NAVAL MEDICAL RESEARCH UNIT (NAMRU) SAN ANTONIO, SAN ANTONIO, TX

NAMRU San Antonio is a medical research organization that reports to the Navy's Surgeon General. Departments include Directed Energy Biomedical Research, Dental and Biomedical Research, and Combat Casualty Care Research.

NAMRU San Antonio's direct energy biomedical research thrusts include RF, microwave, optical radiation (laser), and injected current bioeffects. NAMRU San Antonio's mission is to conduct directed-energy (DE) biomedical-effects research with the goal of understanding and managing the risks associated with human exposure to radio frequency (RF), microwave, optical (i.e., laser), and low-frequency injected current directed-energy sources. Research products support programs that protect the health and safety of Navy and Marine Corps personnel in training and combat operating environments.

Scientific and Technological Areas of Interest:

A comparison of current capabilities versus future battlefield requirements dictates interest in the following major areas of scientific knowledge and technological capabilities. Concept papers and proposals are requested in the following areas and are not necessarily limited to the specific area of interest indicated:

a. Health and safety of Naval forces in directed energy operating environments
b. Threat Countermeasures in hostile directed energy operating environments (Battlefield uses of Directed Energy weapons
c. Etiology and treatment of Directed Energy casualties
d. Directed Energy diagnostic technology development programs

Communication with the Technical POC prior to submission of a formal proposal is essential.

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M. NAVAL SUBMARINE MEDICAL RESEARCH LAB (NSMRL), GROTON, CT

The United States Submarine Service has a long and proud tradition of developing and operating with leading edge technologies. The Naval Submarine Medical Research Laboratory (NSMRL) is a major contributor to integrating these technologies into submarine crew operations.

Established in World War II to conduct mission critical studies in night vision, sonar sound discrimination, and personnel selection, NSMRL continues to serve the fleet by taking the lead in undersea human factors, sensory sciences, and operational medicine.

Scientific and Technological Areas of Interest:

A comparison of current capabilities versus future battlefield requirements dictates interest in the following major areas of scientific knowledge and technological capabilities. Concept papers and proposals are requested in the following areas and are not necessarily limited to the specific area of interest indicated:

a. Diving and Environmental Simulation
b. Submarine Medicine and Survival Systems
c. Hearing Conservation
d. Human Performance Programs

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N. VITAMIN D, SAN DIEGO, CA

Research and development studies are conducted in the area of operational importance of vitamin D such as in prevention of complications of traumatic brain injury, neurological disorders, diabetes, autoimmune and respiratory disease, and cancer.

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O. CLINICAL DECISION SUPPORT AND HEALTHCARE INTEROPERABILITY TECHNOLOGIES

1. Healthcare Interoperability

Few healthcare systems are able to take advantage of the full potential of the current state of the art in computer science and health informatics. Integration and interoperability technologies / standards need to be developed and implemented before the qualitative and economic implications of health care information exchange can be realized either within a single organization or between potential healthcare partners.

Scientific and Technological Areas of Interest:

a. Specifications and infrastructure for standardizing inter-organizational behavior and data exchange processes.
b. Vendor agnostic, open source technologies and reference architectures to leverage available health information exchange standards to include both document-based and message based delivery systems.
c. Tools and standards to address the policy/legal/financial barriers to adoption.
d. Technologies and environments for collaboratively developing and testing security solutions in a multi-domain, distributed environment.
e. Processes and services to widely implement, extensively use, and critically assess the value of interoperable healthcare data and patient outcomes.
f. Development of terminologies, ontologies, and supporting products and services.
g. Methods to make terminology translation services available through registries, service discovery servers, etc.
h. Tools to facilitate classification, mapping and cross-indexing vocabularies.
i. Studies investigating the use terminology registries with in a clinical systems and evaluating clinical outcomes.

2. Clinical Decision Support

There is currently little infrastructure support for the automated evaluation of basic clinical data as it is being generated or exchanged. The lack of real-time analysis and notification inserts unnecessary latency into the healthcare delivery process and negatively impacts the quality of care received. Tools and technologies providing automated analytic and workflow management services that can be utilized by other systems and applications are desperately needed.

Scientific and Technological Areas of Interest:

a. Formal representations of clinical domain knowledge and CDS interventions in standardized formats (both human and machine-interpretable).
b. Specifications and infrastructure for coordinating content creation and domain knowledge efforts to demonstrate the feasibility, scalability, and value of a collaborative approach to CDS.
c. Vendor agnostic technologies and architectures to leverage semantically constrained data, rules, guidelines, etc within the runtime environment.
d. Processes and services to widely implemented, extensively use, and critically measure clinical value and patient outcomes.

e. Tools and standards to address the policy/legal/financial barriers to adoption.
f. Multiple inference and workflow technologies to address specific use cases ranging from population based data analysis to complex event processing of streaming medical device data.
g. Technologies and environments for collaboratively developing system requirements and reference implementations of clinical decision support capabilities.
h. Studies investigating the use of clinical decision support and evaluating clinical outcomes.

Some of the technical approaches for topics within this solicitation may be subject to export control restrictions under existing export control laws, and or required to be conducted as classified projects as outlined in the National Industrial Security Program Operating Manual (NISPOM) and its supplements. Contractors who would like to submit proposals pertaining to such technologies are encouraged to contact their local Defense Investigative Service (DIS) Industrial Security representative or the Technical POC listed in the solicitation for guidance.

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