03-48 AMD01 AND Q&A1: 5 July 2013

AMD01:

The purpose of this amendment is to:

1. Clarify that this RFP is for Omnibus III contractors in the Full and Open lot.

All changes to RFP are made in red.

Q&A1:

Q1: Is this a re-compete of W911QY-11-D-0053-0001 or is it truly a new requirement?

A1: This is a new requirement.

Omnibus 3 RFP No.: O3-48
COMPREHENSIVE RESEARCH STUDIES FOR THE
DOD CENTER FOR DEPLOYMENT HEALTH RESEARCH AT NHRC

ADMINISTRATIVE

Release Date: 2 July 2013

This REQUEST FOR PROPOSALS is for the OMNIBUS III contractors in the Full and Open Lot. ~~or Small Business Lot.~~

PROPOSALS ARE DUE NO LATER THAN 2 August 2013 by 15:00 EST to mark.a.marchioli.civ@mail.mil, matthew.r.buchanan6.civ@mail.mil, michael.dalessandro6.civ@mail.mil, lisa.m.mardin.ctr@mail.mil, and issa.j.shawki.ctr@mail.mil. If you have any questions, please send it via e-mail to all five e-mails.

INSTRUCTIONS TO OFFERORS

PROPOSAL SUBMISSION

Proposals should only be sent via e-mail with a Technical PDF file, an Excel Cost/Price file and a Past Performance PDF file (if applicable). Instructions on proposal requirements for each section are listed below.

TECHNICAL AREA

Please provide a cover letter on company letterhead and attach the technical proposal with the content described below.

Administrative/Baseline Requirements

Baseline requirements are go/no-go requirements. Offeror's technical proposal shall state/demonstrate that they meet each of the baseline requirements below:

- **Personnel On-site Clearance capability**: State whether the company has personnel familiar with processing personnel for adjudication. This includes CAC card processing for on-site performance.
- **Business Associate Agreement (BAA)**: Indicate a willingness to sign a BAA representing compliance with 45 CFR parts 160 and 164, DoD Directive 6025.18, Privacy of Individually Identifiable Health Information in DoD Health Care Programs, DoD 6025.18-R, and the Health Insurance Portability and Accountability Act (HIPAA). Attachment 1 (BAA) should be signed and included with the offeror's proposal.
- **Data Sharing Agreement (DSS)**: Demonstrate understanding that the DSS is used to request and control the disclosure and/or use of Military Health System (MHS) data that are owned and/or managed by TRICARE Management Activity (TMA), to ensure compliance with applicable Privacy Act and HIPAA privacy and security requirements and agree to enter into agreement with TMA for a DUA upon award of this requirement to this offeror.
- **DHHS Federalwide Assurance (FWA)**: Include a copy of the FWA. If a copy is not available, then include a statement that the offeror has an FWA, its number and when it expires.

- **MPA DoD-Navy Addendum**: Include a copy of the DoD-Navy Addendum. Also state what the name of the protocol is or if it is good for all protocols (that is, it is an MPA). If the Service is different from that of the client's, then state that the offeror will submit to the cognizant client's Navy representative a request to use the such Addendum in lieu of the client's Navy Addendum and that all other client Navy-unique requirements will be met, upon award of this requirement to this offeror.
- **Acceptable Accounting System & Indirect Cost Rates**: A response on whether this will be a Cost-Plus-Fixed-Fee (CPFF) or a Firm-Fixed-Price (FFP) type task order with supporting rationale behind such. If a CPFF type is proposed, then discuss the acceptability of the offeror's accounting system and indirect cost rates. If a FFP type is proposed, then discuss how the final price is derived, including the use of indirect cost rates, and how the offeror's invoice will be based on actual salaries and estimated indirect cost rates rather than a fixed unit price for direct labor and that any direct travel or ODCs will be at cost.

Performance Requirements

Technical proposals will demonstrate the offeror's technical manpower and resources necessary to complete the task in the context of the subject matter area. This includes discussion of any proposed candidates, explanation of the company's personnel recruitment process, demonstration of successful recruiting in this market segment, and benefits to be offered employees specifically on this task order. Additionally, the offeror shall demonstrate a thorough understanding of the technical requirements in the context of relevant experiences, not to be confused with past performance information. For example, the offeror can describe how they formulated a vaccine for an infectious disease research task but do not have to go into providing contract number, contact information, etc. This is also where the offeror will discuss their OCI Mitigation Plan and NDAs, and demonstrate the understanding that the prime contractor company, subcontractors and personnel performing on this task order may have access to personnel sensitive information during their performance period (i.e., social security information and other personnel data covered by HIPAA). These positions may also have access to Government financial and budgeting information along with access to future Government statements of work that could give the incumbent's company or the company's competitor an unfair advantage or disadvantage and, therefore, an OCI Mitigation Plan with supporting Non-disclosure Agreements (NDAs) may be required. The OCI Mitigation Plan and NDAs shall state that "This document does not authorize access to another company's proprietary or company sensitive information." When the acquisition concerns a re-compete and there are incumbent employees, the offeror saying that they will hire the incumbent personnel and not providing required resumes will be considered non-responsive. The providing of resumes is demonstrative that the offeror can successfully recruit in this market segment if in the event a replacement candidate is necessary.

Performance Work Statement

Technical proposals shall include a Performance Work Statement (PWS), including a schedule for task completion and mention of any products or reports to be delivered as part of the task. An offeror's PWS that includes relevant added value acceptable to the client may be considered having more value to the Government than a PWS that just repeats the SOO Addendum. Those proposals lacking the minimum SOO Addendum elements may be considered having less value to the Government and unacceptable. Those proposals having the minimum may be considered having satisfactory value to the Government but still may be unawardable based on best value. The PWS shall include, at a minimum, the following: See the "Specific Requirements" and "Estimated Staffing" sections of the SOO Addendum.

COST/PRICE AREA

In the Cost/Price proposal, the Government will evaluate the offeror's proposed labor mix rates to determine if the level of effort is appropriate for the task order requirement. Pricing will also be evaluated to determine fairness and reasonableness.

The Excel pricing template for Omnibus III shall be utilized to provide a pricing breakdown. The template can be tailored to each task order if needed and an explanation of the cost build-up should be documented within the excel spreadsheet or as a separate PDF or Word file. If pricing information is found outside of the pricing file this may cause the proposal to be considered unacceptable.

(Microsoft Excel/Word 2007 or earlier version is acceptable)

PAST PERFORMANCE AREA

The Government will evaluate the contractor's past performance on task orders issued only under the OMNIBUS III contracts. The Contracting Officer will evaluate past performance on the basis of quality, schedule, management oversight, and/or cost control.

If a proposing contractor has worked on an Omnibus III task order for longer than 6 months, then their performance shall be documented in the areas of quality, schedule, management oversight, and/or cost control. If an offeror has no past performance, then no documentation is required and a neutral rating will be given.

EVALUATION METHOD

In accordance with Section H.26(g), task orders will be evaluated on Technical, Cost/Price and Past Performance (if applicable). An award will be made on a Best Value basis where technical is more important than price and price is more important than past performance (if applicable).

Omnibus 3 TO RFP No.: O3-48 (N63116-64)
7/2/2013

Competitive Classification: *UNRESTRICTED LOT – The expectation is that this will be a ☐ Firm-Fixed-Price ☒ Cost-Plus-Fixed-Fee task order under Omnibus ☐ 1 ☐ 2 ☒ 3 as defined by the basic contract and, in the case of a CPFF task order, because of the absence of precise specifications, difficulties in estimating costs with accuracy, and the relatively long duration*. In the case of a FFP task order, this task order ☐ will not ☐ will** be incrementally funded. This effort ☐ is not ☒ is considered a new requirement and therefore the right of first refusal*** concerning incumbent employees with the successful offeror ☒ is not ☐ is relevant to this task order. Resumes ☐ need not ☐ should be ☒ shall be provided for the following positions: All positions.*

Additional instructions for the offeror: *The offeror is expected to provide a Performance Work Statement (PWS) within its proposal, which will become part of the task order by reference, if successful. The proposal should be of sufficient detail to allow the evaluator(s) to determine an adjectival rating. Creation of the PWS by the offeror is an opportunity for the offeror to exercise innovation and creativity.*

To facilitate the offeror with development of its proposal and a representative PWS, an Addendum is provided that offers some information based on the expectations of the client. <u>The PWS provided by the offeror shall provide added value to the SOO Addendum provided by the Government.</u> The RFP Instructions has the required proposal format for a RFP response.

** Performance of this requirement is dependent upon the data collected from surveys that are to be completed by military, veteran, and dependent populations. There is an unpredictability of the number of survey participants from which data is to be collected.*
*** N/A*
**** If in the event a new offeror is awarded a re-competed task order, the incumbent contractor shall communicate to the new offeror the availability of incumbent personnel prior to the end of the current task order. If the incumbent employee is available for the new offeror to pick up, then the incumbent contractor shall communicate to the new offeror the name, phone, and e-mail for that employee.*

COMPREHENSIVE RESEARCH STUDIES FOR THE DOD CENTER FOR DEPLOYMENT HEALTH RESEARCH AT NHRC

STATEMENT OF OBJECTIVES

This acquisition will provide comprehensive umbrella coverage of all research studies relevant to the entire continuum of deployment health issues and under the cognizance of the DoD Center for Deployment Health Research, located at the Naval Health Research Center (NHRC). This may include coverage of projects performed on other contracts or performed by other contractors. If in the event of a conflict, the Government client will mediate and resolve.

Administrative Requirements

a. **Inspection/Acceptance/Points of Contact** (DoDAAC): N63116
b. **Inspection/Acceptance/LPO DoDAAC**: N63116

c. **Contracting Officer's Representative** (DoDAAC): N63116
d. **Period of Performance**: Performance shall be for 36 months from date of task order award.
e. **Severability**: This task is considered to be ☐ severable or ☒ non-severable (entire). For a non-severable requirement, this task order is considered non-severable because of the amount of research and performance required over an extended period of time such that any interruption in continuance of the particular performance would prohibit a meaningful deliverable to the Government client. Specifically: Contractor is to assist in the preparation and publishing of results of the long-term research conducted through technical reports for military use and/or peer-reviewed journals for use by the appropriate medical community, as well as present research findings at scientific meetings from the data collected during this period of performance. Without the completion of the analysis and subsequent technical reporting of the results, no meaningful deliverable will be delivered to the Government client and continuity of the logic and process will be lost.
f. **Security Clearance**: Performance of this task order ☒ does not require access and does not authorize access to classified information or ☐ does require access and does authorize access to classified information up to and including the SECRET level and will have a DD254. For task orders that do have a security clearance requirement, Offerors are expected to demonstrate in the proposal possession of an active facility security clearance at the company level, including the name, phone number, and e-mail address of the company's Facility Security Officer; and the name, phone number, and e-mail address of their cognizant DSS agent. Before extending an offer to the proposed candidates and processing personnel on this requirement for adjudication, first receive acknowledgement from the client on acceptance of their resumes and information from the client's security representative concerning instructions for processing personnel clearances or government background checks.
g. **Government Furnished Facilities (on-site) and Government Furnished Information**:
    (i) This task order ☐ does not or ☒ does require on-site contractor personnel to be located at NHRC, San Diego, CA. This task order ☐ does not ☒ does represent a mix of on-site and off-site contractor personnel. The great majority of contractor personnel shall be located on-site. Contractor personnel and its subcontractors must comply and meet the requirements under Directive-Type memorandum (DTM 08-003, Homeland Security Presidential Directive-12 (HSPD-12) and Federal Information Standards prior to issuance of Personal Identity Verification (PIV) credential or Common Access Card. The applicable SF form can be sent either by the contractor or the client's security office, depending upon the direction of the client's security office, prior to contractor personnel arriving at agency to begin work. For NHRC task orders, the SF and FD 258 shall be sent by way of FEDEX (or comparable carrier) to Naval Health Research Center (Attention: Security Manager), 140 Sylvester Road, San Diego, CA 92106 (phone 619-767-4256). This task order ☐ does not ☒ does require proposed contractor personnel to have a favorable adjudication of the results of the background investigation. Those personnel performing on-site shall be processed in accordance with on-site base/command procedures (e.g., CAC cards, personnel physicals, etc.), particularly: Common Access Cards (CAC). Contractor personnel must comply with all the onsite security requirements of the host command.
    (ii) Health Insurance Portability and Accountability Act (HIPAA) of 1996 related guidance and requirements in accordance with BUMEDINST 7050.1B – Agreements with non-DoD entities: DoD commands are a Covered Entity as defined by the aforementioned BUMED instruction. However, in performance of its mission, the DoD command may and does contract out to non-DoD entities such that these non-DoD entities may have

access to information covered under the HIPAA of 1996. When doing so, the DoD command must execute documentation in accordance with this instruction as it pertains to non-DoD entities by executing with the non-DoD entity a Business Associate Agreement (BAA, not to be confused with a Broad Agency Announcement). This task order ☐ does not ☒ does require a BAA and if so then the BAA is attached. This task order ☐ does not ☒ does require a Data Use Agreement or Data Sharing Agreement; Comment: Contractor is required to enter into a Data Sharing Agreement (DSA) and ensure compliance with applicable regulations when accessing Protected Health Information (PHI) within database(s) managed by the TRICARE Management Activity (TMA).

h. **Government Furnished Equipment / Property**: There is no GFE/P identified at this time that is unique to this task order. It should be noted that all contractor procured equipment under this task order (either for FFP or CPFF) is considered as a deliverable end item and ownership title is retained by the Government unless otherwise defined within the contractor's proposal and approved by the client (FAR Subpart 45.4 applies).

i. **Personal Services**: This task order ☒ does not or ☐ does include personal services. This task order ☒ does not or ☐ does include Health Care Workers. This task order ☒ does not or ☐ does include clinical positions. Contract medical and dental services (such as those provided by clinicians) may be personal or non-personal in nature. In a Personal Services Contract (PSC), the contract health care workers appear to be Government employees and may have Government personnel exercise direct supervision and control over them such that an employer/employee relationship exist. Clinical positions are eligible for PSCs. However, these PSC contractor personnel cannot perform inherently Government functions such as supervision of Government or military personnel. For those clinicians performing under a PSC, they are covered under the Federal Tort Claims Act. Otherwise, clinicians performing as health care workers not under a PSC must be covered by indemnification and medical liability insurance provided by the contractor and as prescribed by FAR 52.237-7. Any Health Care Workers providing clinician services shall be certificated / registered in accordance with client-site requirements.

j. **Indemnification of the Government by the Contractor and Requirement for Medical Liability Insurance**: This task order ☒ does not or ☐ does require indemnification and medical liability insurance. If indemnification and medical liability insurance is required, then the offeror shall provide documentation in their proposal supporting the amounts recommended as acceptable coverage, including individual occurrence and aggregate limits. This insurance can cover the entire task order or the following positions: N/A

k. **Management Requirements**: Monthly status reports will be accompanied by its matching invoice and DD250 for client approval/signature before submitting each invoice into the WAWF. Signed DD250 shall be uploaded into WAWF as an attachment to the monthly invoice (cost voucher for CPFF; combo for FFP for services and supplies; or 2-in-1 for FFP services only). An e-mail from the cognizant client can serve as a substitute for a signed DD250. In such case, the e-mail shall be uploaded into WAWF with the invoice. This process still applies for those contractors have DCAA/DCMA-approved direct payment authorization.

l. **Human Research**: There ☐ is not ☒ is human research involved with the client's effort. If there is human research involved with the client's effort, is there a copy of the IRB protocol in the contract file? ☒ Yes ☐ No. This task order ☐ does not or ☒ does require human-subjects research assurance certification by the contractor performer. If this task order is for research and involves human subjects, then the Human Research Protection Official (HRPO) ☐ has ☒ has not reviewed this document to ensure that appropriated information is included in the solicitation and subsequent award. The contact information for the HRPO is: LCDR Kellie

McMullen, (619) 553-0645, kellie.mcmullen@med.navy.mil. This task order is for ☒ intramural (DoD) ☐ extramural (non-DoD) research. Research herein involving human subjects ☐ has ☒ has not been separated into an option that would not be exercised until all documentation is provided. Research with human subjects may not begin until the contractor obtains either a DoD granted Institutional Assurance or a Federal Wide Assurance (FWA) issued by the Department of Health and Human Services (DHHS) combined with a DoD-Navy Addendum to their FWA. Additionally, all research must be approved by an Institutional Review Board (IRB) named in the Assurance application before the research commences. A copy of the approved DoD Assurance or the DoD-Navy FWA Addendum, along with all IRB approval documentation, shall be provided to the technical point of contact assigned to the specific delivery order, and to the IRB of the Navy institution being supported, before any human subjects research begins. All DoD supported research must also comply with the Health Information Portability and Accountability Act (HIPAA) Privacy Rule, and related DoD instructions. Any task order that does require research on human subjects requires that the DoD component be responsible for contractor oversight of compliance with 32 CFR Part 219, Protection of Human Subjects; and that the Government personnel responsible for such oversight is the client's Human Research Protection Official as defined by DFAR 252.235-7004, Protection of Human Subjects. All research need to be determined to be compliant with federal and Department of Defense regulations for protecting human subjects. All studies similarly need to be compliant with the requirements of the Health Information Portability and Accountability Act (HIPAA) Privacy Rule. Further, evolving human subject protection regulations need to be investigated and training plans developed to educate researchers as to their human subject responsibilities. Contractor shall support Institutional Review Board (IRB) functions and HIPAA Privacy Office functions by reviewing all command studies, including those in the areas of medical resource planning, enhancing performance during shipboard and ground operations, investigating and monitoring disease incidence among military personnel, development of computer systems for monitoring the physiologic status of individual patients, clinical research studies, survey administration efforts, and evaluating physiological effects of various agents found in military operational environments. Such support shall include analyzing research protocols to determine compliance with relevant human subject protection regulations and drafting administrative correspondence detailing review proceedings and findings. Support shall also include development of educational materials, monitoring of research, and database development for tracking of research protocols. If human-subjects research assurance certification is required, then the offeror shall provide a copy of the FWA and DoD-Navy Addendum in their proposal. For those task orders supporting several protocols, a Multiple Protocol Assurance (MPA) version of the DoD-Navy Addendum is required. "Service" shall mean the service of the client, for example, Air Force or Navy. Comment: A DHHS Federalwide Assurance and MPA DoD-Navy Addendum are required.

m. **Animal Use:** There ☒ is not ☐ is animal use involved with the client's effort. If there is animal use involved with the client's effort, is there a copy of the IACUC protocol in the contract file? ☐ Yes ☐ No. This task order ☒ does not or ☐ does require animal use assurance and accreditation by the contractor performer. Any task order that does require the use of animals in research shall be compliant with all applicable federal and DoD regulations, specifically including 7 U.S.C. 2131 *et. Seq.* and 9 CFR 1-4, "Animal Welfare Act"; DoDI 3216.01, "Use of Animals in DoD Programs"; and specific DoD component management plans. Evolving animal use and care regulations need to be investigated and training plans developed to educate researchers regarding their animal use and care responsibilities. Contractor shall support Institutional Animal Care and Use Committee (IACUC) functions and comply with any procedures

required for IACUC approval, including research protocol submission, Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accreditation, Department of Health and Human Services (DHHS) Office of Laboratory Animal Welfare (OLAW) assurance, and USDA site inspections. Comment: N/A

n. **Organizational Conflicts of Interest (OCI)**: There ☐ is not or ☒ is an identified potential or perceived OCI within this task order. If there is an identified potential or perceived OCI, then the technical proposal shall include as an attachment an OCI Mitigation Plan for review/approval by the client / Contracting Officer. Acceptance of this task order by the contractor shall not create an OCI condition, either for legacy work being performed or future work to be bid or performed. The OCI Mitigation Plan shall include Non-disclosure Agreements signed by the personnel performing on this task order and counter-signed by their management. The OCI Mitigation Plan and NDAs shall state: "This document does not authorize access to another company's proprietary or sensitive information." Comment: Contractor personnel performing on this contract may have access to personnel sensitive information (i.e., social security information and other info covered under HIPAA), Government budgetary information and research program design.

o. **NAICS Code for Omnibus 1/3 Task Orders**: 541712 – Research and Development in the Physical, Engineering, and Life Sciences (except biotechnology), 500 employees. Organizations (including parent organizations) having a 12-month average number of employees greater than this value prior to posting of the TO RFP do not qualify as a small concern.
NAICS Code for Omnibus 2 Task Orders: 541990 – All Other Professional, Scientific, and Technical Services ($7.0M). Organizations having an average annual gross revenue over the last three complete accounting years greater than $7.0M do not qualify as a small business concern.

p. **Market Research**: This requirement ☐ is not or ☐ is over the Simplified Acquisition Threshold. In the case of the latter, a Market Research doc was developed (for Government use only).

q. **Other Contract Requirements**:
   (i) This SOO has been reviewed and contains no services that are inherently Government functions.
   (ii) Performance of this SOO may include access or exposure to private information subject to compliance to FAR Subparts 52.224-1 and 52.224-2.
   (iii) Performance of this SOO may include dissemination of information / publishing subject to compliance with client requirements.
   (iv) This SOO may include data that is subject to data right restrictions by the client.
   (v) One FTE = 1920 hours (2080 hours – 80 holidays – 80 hours PTO); PTO amount may vary from company to company.
   (vi) For all NHRC task orders, a TAD form must be completed by the contractor and submitted to the Principal Investigator/Project Officer for review. After such review and if there are sufficient provisions already in the task order, the COR will notify the contractor that travel is approved. If there are not sufficient provisions in the task order, then the COR will ask the Contracting Officer for approval. This process must be adhered to before contractor personnel go on travel.
   (vii) Comply with Contractor Manpower Reporting requirements.

ADDENDUM

COMPREHENSIVE RESEARCH STUDIES FOR THE DOD CENTER FOR DEPLOYMENT HEALTH RESEARCH

GLOBAL REQUIREMENT

The Naval Health Research Center (NHRC) was designated as the United States Department of Defense (DoD) Center for Deployment Health Research, 30 September 1999, by the Assistant Secretary of Defense for Health Affairs (ASD(HA)). To assist in this mission, NHRC established the Deployment Health Research Department (Code 164). The mission of Department 164 includes conducting epidemiological studies on the health of service members and their families. An experienced department staff and flexible framework provide the ability to quickly adapt and confront novel health concerns of military, veteran, and DoD beneficiary populations and, where applicable, the general public. Department 164 has varied expertise in biostatistics, epidemiology, medicine, psychology, reproductive health, complex data management, large mail and telephone surveys, and occupational health. Departmental personnel work in close collaboration with the ability to contribute across projects to ensure integration of all projects within the Department. Currently, Department 164 has several major research studies in progress including its core program, the Millennium Cohort Study, the largest prospective health project in military history, which evaluates the long-term health effects of military service and deployments among >200,000 US military personnel for up to 67 years. Department 164 also has several other core programs including the Millennium Cohort Family Study, the Birth and Infant Health Registry, and the Recruit Assessment Program, as well as other deployment- and vaccine-related studies. Together, these complex epidemiologic studies and databases have over 1.4 million personnel and dependents. This acquisition will provide research support services for conducting epidemiological studies to investigate the longitudinal health outcomes of military personnel and their families, including services for participant enrollments, data capture and management, longitudinal study design, and data analyses and presentation. Department 164 has several key sponsors including DoD and non-DoD agencies (e.g., the Department of Veterans Affairs) that provide diverse funding streams and, therefore, a vehicle is needed to accept various funding types such as R&D, O&M, DHP, etc. It should be noted that, despite the varied nature of Department 164 funding, all funds applied to this acquisition will share the same appropriated purpose – deployment health research.

SPECIFIC REQUIREMENTS

This acquisition will provide comprehensive umbrella coverage of all research and development relevant to the entire continuum of deployment health issues under the cognizance of the DoD Center for Deployment Health Research. Contractor will conduct and coordinate epidemiological studies to investigate the (a) longitudinal health outcomes of military personnel and their families and (b) the impact of military experiences including deployments. Research includes studies of symptoms, hospitalization, reproductive outcomes, mortality, vaccinations, and other health-related outcomes among DoD beneficiary populations, both military and civilian. Research activities will have a great emphasis on statistical analysis, data handling and storage; the creation and maintenance of large DoD health databases; and survey-based methodologies. The contractor will have demonstrative experience in the conduct of large, coordinated epidemiologic research in the field of military deployment health research. The research requires linkage with and knowledge of DoD data sources including military and medical records which entail the pre-existence of a TMA/OSD agreement. In contrast with previous

similar requirements for NHRC Code 164, this requirement is designed to provide a more comprehensive research scope with an emphasis on the expansion and advancement of longitudinal health studies leveraged off the data compilation and analysis completed under the previous task orders. This may include coverage of projects performed on other contracts. If in the event of a conflict, the Government client will mediate and resolve.

ESTIMATED STAFFING

The period of performance shall be for 36 months. Estimated level of effort per 12 month period of performance to accomplish the aforementioned requirement includes:

Task Order Labor Category	Minimum Qualifications – Contract Labor Category*	FTEs (hours)
Sr. Medical Epidemiologist	Doctor	2 (3,840)
Chief of Operations	Project Manager	1 (1,920)
Program Manager	Project Manager	1 (1,920)
Sr. Budget Analyst	G&A Specialist	1.25 (2,400)
Regulatory Affairs Specialist	Scientist	1 (1,920)
Sr. Epidemiologist	Senior Scientist	8 (15,360)
Research Psychologist	Senior Scientist	1 (1,920)
Data Analyst	Scientist	12** (23,040)
Sr. Biostatistician	Scientist or Senior Scientist	2.25 (4,320)
Clinical Research Coordinator	Scientist	8 (15,360)
Assistant Study Coordinator	Scientist	3 (5,760)
Research Assistant	Lab Assistant	3 (5,760)
Research/Student Intern	Intern	4.5 (8,640)
Programmer	Architect	3 (5,760)
Software Developer	Architect	1 (1,920)
Marketing Expert	Scientist	0.5 (960)
Media Writer	Scientist	0.25 (480)
	YEAR 1 TOTAL:	52.75 (101,280)
	YEAR 2 TOTAL:	53.75 (103,200)
	YEAR 3 TOTAL:	53.75 (103,200)
	TASK ORDER TOTAL:	160.25 (307,680)

*Resumes provided shall demonstrate sufficiently enough to the evaluator that the person proposed has the knowledge and experience relevant to accomplish the aforementioned tasks. If there is any conflict between eligibility criteria/tasking below and the basic contract labor category description, then the eligibility criteria below would prevail.

**Requirement expands to 13 FTEs/24,960 hours in years 2-3 of the period of performance.

Activities (tasks) to accomplish this task order involve the following:

1. Task 1: DoD Healthcare Utilization Data.

    a. Augment the evaluation and analysis of Department of Defense healthcare utilization data among military, veteran, and dependent populations.
    b. Clean and edit the increasingly large and complex databases through summarization, mathematical longitudinal modeling and interpretation, utilizing complex algorithms and computer programs.
    c. Ensure that data collected are cleaned, linked to demographic data and warehoused securely.
    d. Keep up-to-date contact data for multiple contact survey studies.
    e. Conduct statistical analyses including longitudinal modeling, and address issues such as missing data and response biases.
    f. Write manuscripts contributing to the peer-reviewed literature.
    g. Develop materials for presentations, and present these findings at peer-review professional and military meetings.

2. Task 2: DoD Healthcare Utilization Data (Exposure and Disease Specific).

    a. Augment the evaluation and analysis of Department of Defense healthcare utilization data among military, veteran and dependent populations from current military Operations and related deployment health surveys with exposure-specific and disease-specific analyses.
    b. Provide expertise and data use agreements to access datasets to support the research portfolio.
    c. Work in a multidisciplinary team to collect, clean, analyze and present data including working with both internal and external stakeholders and collaborators.
    d. Prepare and publish results of the research conducted through technical reports for military use and/or peer-reviewed journals for use by the appropriate medical community.
    e. Present research findings at scientific and military meetings during this performance period.

3. Task 3: Health Surveillance of Marines (Recruit Assessment Program).

    a. Augment the evaluation and analysis of results from the baseline health data of more than 10,000 Marines undergoing recruit training in San Diego on an annual basis.
    b. Maintain complete health surveillance data on these Marines comprising over 150,000 individual records.
    c. Collect and analyze additional questionnaire-based follow-up data, using standardized scannable, self-completed, paper-and-pencil health questionnaires.
    d. Ensure that surveys are administered by study personnel to new accessions attending basic training at MCRD, San Diego.
    e. Surveys shall be collected by Naval Health Research Center (NHRC) contractors, processed by the contractor, and entered into a current Recruit Assessment Program (RAP) database. Establish and validation of QA processes for data integrity and security.
    f. Establish and subsequently utilize linkages of survey data with other military and medical record databases to augment data analyses of important health questions.
    g. Prepare and publish results of the research conducted through technical reports for the military use and/or peer-reviewed journals for use by the appropriate medical community.

4. Task 4: Millennium Cohort and Family Studies.

    a. Support the Millennium Cohort Study operations by continuing to follow US military personnel prospectively by using postal surveys and web-based/internet surveys.
    b. Establish, maintain and manage an interactive website with state-of-the-art security features.
    c. Conduct very large mailings that include introductory and reminder postcards, Memorial and Veterans Day postcards, and questionnaire packets.
    d. Maintain and update web servers which enable mailing surveys and other study materials to >200,000 participants.
    e. Securely maintain email addresses for study subjects, and use these email addresses to send invitational emails, Memorial and Veterans Day emails, as well as other study relevant electronic communications.
    f. Employ consultants as needed to successfully accomplish the work of this study.
    g. Follow cohort members previously surveyed, and continue to recruit participation for a new panel of cohort members as funding allows.
    h. Design and maintain the survey instruments, and continue to gather self-reported data on demographic characteristics, medical conditions and symptoms, alcohol and smoking behaviors, diet and exercise, as well as new information on deployment-related exposures.
    i. Utilize standardized, validated instruments to capture self-assessed physical and mental well-being (SF-36V), mental health diagnoses (Patient Health Questionnaire), and post-traumatic stress disorder (PCL-17).
    j. Use established cost-effective initiatives to encourage participant website use – these include, but are not limited to, caps, coins, and gift cards.
    k. Establish methods to design, produce, mail and track participant receipt of such initiatives.
    l. Develop strategies to maintain participant retention in the study, including a newsletter as well as other mailers.
    m. Clean and analyze the data using complex algorithms and computer programs, and develop and utilize linkages with military and medical records to augment the analysis of the data examining important health and service outcomes.
    n. Obtain objective health and behavioral measures from additional data sources through established data use agreements including access to the MDR (Medical Data Repository), military records, and other data for the study of long-term health outcomes.
    o. Provide periodic assessments of the scientific data.
    p. Prepare and publish results of the research conducted through technical reports for the military use and/or peer-reviewed journals for use by the appropriate medical community.
    q. Additionally, support the work of enrollment, data collection, cohort follow-up, data analyses, and dissemination of findings for the Family Study (currently >10,000 spouses). Databases, cleaning, linkages and analyses described in this section will similarly be employed for the Family Study.
    r. Create and revise survey instruments and develop marketing strategies to enhance response and retention efforts.
    s. Create a new database for the study, enter/clean data, perform complex data analyses, and publish study results.

5. Task 5: DoD Birth and Infant Health Registry and Vaccine Studies Examining Birth Outcomes.

    DoD Birth and Infant Health Registry

a. Collect and analyze data from infants born to military beneficiaries that have been captured in the Department of Defense Birth and Infant Health Registry. The Registry includes data on associated medical conditions, geographic location, and demographics of the military sponsor. Birth defects and other critical health outcomes are identified by International Classification of Diseases, Version 9 (ICD9) coding of inpatient and outpatient encounters. When linked to other standard military databases, important information can be captured on vaccination, occupational, and environmental exposures that may be associated with birth defects.
b. Collaborate with leading experts on this project on exposure-specific and diagnosis-specific analyses.
c. In addition, prepare and publish results of the research conducted through technical reports for military use and/or peer-reviewed journals for use by the appropriate medical community, as well as present research findings at scientific meetings during this performance period.

Vaccine Studies Examining Birth Outcomes

a. Create surveys, newsletters and other materials as needed for annual contact with mothers enrolled in the National Smallpox Vaccine in Pregnancy Registry. Annual contact includes acquiring current contact information, mailing required items, processing returned materials, and contacting enrollees by phone.
b. Post-Marketing Vaccine Safety and Effectiveness Studies:
    i. Study the impact of military relevant vaccinations received by military personnel to ensure safety and to meet Food and Drug Administration (FDA) post-marketing requirements. Vaccine exposures may be as prescribed, or inadvertent such as receipt of the anthrax or smallpox vaccine in pregnancy. This work includes creating vaccine registries to identify, invite, and enroll eligible subjects. Success depends on the ability to work effectively with external DoD entities such as the Office of Assistant Secretary of Defense for Health Affairs, the US Military Vaccine Agency, as well as other federal agencies, including the Centers for Disease Control and Prevention and the Food and Drug Administration, and vaccine manufacturers. Tasks include subject tracking, survey creation and administration, data management and analyses, and the writing of monthly, quarterly, and annual reports, as well as adverse event reports as needed.
c. DoD-funded projects:
    i. Assess the short-term and long-term reproductive health effects of receipt of specific vaccines among pregnant women and their live born infants. Essential tasks include securing permission to access data from DoD databases, develop code to identify pregnancies with appropriately timed vaccine exposures, identify any live born infants born to exposed women, develop code to assign outcomes, and conduct analyses. Requires the ability to work with external funding agencies and meet any reporting requirements established by these agencies.

6. Task 6: Impact of Vaccinations on Health Outcomes.

    a. Study the impact of vaccinations received among military beneficiaries, as well as specific health outcomes including both adverse and protective effects of the vaccinations.
    b. Additionally, examine the effect of a combination of vaccinations on health outcomes.
    c. This work includes creating and working with large military databases (may exceed >1 million persons). Be facile with their creation and analyses, including date interpretation and writing.

7. Task 7: Other Research Protocols.

    a. Support a variety of other research protocols on deployment and military health by assisting with the execution of these studies from design to completion. These tasks will include, but not limited to study design; regulatory; study execution including enrollment and retention; data base development and management; complex statistical analyses; and data reporting.

Staffing Eligibility / Qualifications
(beginning on following page)

Task Order Labor Category		Contract Labor Category	Number of Personnel
Research Psychologist		Senior Scientist	1
	1. Must have a minimum of a Doctorate degree in psychology or health related field.		
	2. Must possess and maintain certification to conduct human research such as HIPAA and CITI training.		
	3. Must have extensive professional knowledge of psychology as evidenced by experience conducting and publishing psychological research.		
	4. Must have technical expertise in HIPAA and IRB regulatory processes, and preferred working knowledge of federal grant and contracting procedures.		
	5. Prefer an understanding of military public health issues and family health research as evidenced by experience writing and publishing in this area.		
	6. Must be proficient in written and verbal communication and interpersonal skills; prefer experience with grant/proposal writing for acquisition of research funding from academic, governmental and DoD sources.		
	7. Must have proven experience in managing complex research studies.		
	8. Must have ability to provide oversight and management for DoD human research studies; ensure adequate staffing, funding and adherence to all regulations and policies within the DoD. Assists in the conduct of studies such as setting meetings and deadlines, ensuring IRB requirements are met, and delivering of results to stakeholders.		
	9. Must be proficient with computers and facile with computer software for word processing, graphic productions, and database management. Expertise and experience in the following programs are specifically required: MS Word, Excel/Access, PowerPoint. Knowledge of SAS statistical software and analyses.		
	10. Prefer experience working within the Federal Government system as military, civilian or government contractor. Experience in providing individual and group-level teaching and mentorship within a departmental setting.		
	11. Must be able to communicate orally and in writing using universal English.		
Clinical Research Coordinator		Scientist	8
	1. Must have at least 3-5 years related experience in a research setting.		
	2. Must possess and maintain certification to conduct human research such as HIPAA and CITI training.		
	3. Must have proven experience in managing complex research studies involving large datasets including all aspects of study from enrollment to data collection and security.		
	4. Must have ability to provide coordination, oversight and management, meet regulatory requirements for DoD human research studies. Coordinates studies such as setting meetings and deadlines, ensuring IRB requirements are met, and delivering of results to stakeholders.		
	5. Must be proficient in written and verbal communication and interpersonal skills.		
	6. Preferred experience working within the Federal Government system such as military, civilian or government contractor.		
	7. Must be able to communicate orally and in writing using universal English.		
Data Analyst		Scientist	12 (expanding to 13 in Years 2-3)
	1. Must have a minimum of a Bachelor's degree, preferred MPH, MA, or MS degree in Public Health, Statistics, or a related field.		

	2. Must possess and maintain certification to conduct human research such as HIPAA and CITI training.		
	3. Must be proficient with computers and facile with computer software for word processing, graphic productions, database management, and mathematical and statistical analysis. Expertise and experience in the following programs are specifically required: MS Word, Excel, PowerPoint and SAS statistical software.		
	4. Must have proven experience in basic design and statistical methodology for performing longitudinal research, as indicated by prior work history or graduate work.		
	5. Must have ability and knowledge to manage complex military databases such as the MDR and DMDC with our DHRD databases which exceed 1 million records. Must be able to write code for data merging and be proficient in data cleaning and verification processes.		
	6. Must have ability to work as a team member on large research projects. Must be able to present research results to sponsors and attend professional conferences.		
	7. Must be able to communicate orally and in writing using universal English.		
Research Assistant		Lab Assistant	3
	1. Prefer a minimum of a Bachelor's degree in a Health or related field.		
	2. Must possess and maintain certification to conduct human research such as HIPAA and CITI training.		
	3. Must be proficient with computers and facile with computer software for word processing, graphic productions, database management, and mathematical and statistical analysis. Expertise and experience in the following programs are specifically required: MS Word, Excel, and PowerPoint.		
	4. Must have proven experience in assisting with the conduct of human research studies.		
	5. Must have ability to work as a team member on large research projects. Proven experience working on large complex research studies including all aspects of study from enrollment to data collection and security.		
	6. Must have good understanding of research methodologies, from design to data collection.		
	7. Prefer experience working within the Federal Government system as military, civilian or government contractor.		
	8. Must be able to communicate orally and in writing using universal English.		
Research/Student Intern		Intern	4.5
	1. Prefer a minimum of a Bachelor's Degree.		
	2. Must possess and maintain certification to conduct human research such as HIPAA and CITI training.		
	3. Must be proficient with computers and facile with computer software for word processing, graphic production, and database management. Prefer knowledge of statistical analysis. Expertise and experience in the following programs are specifically required: MS Word, Excel and PowerPoint.		
	4. Must have ability to work as a team member on large research projects.		
	5. Must have basic knowledge of statistics and epidemiology; prefer some knowledge of SAS.		
	6. Must be able to communicate orally and in writing using universal English.		
Marketing Expert		Scientist	0.5
	1. Must have at least 10 years experience in marketing research and prefer prior experience working with DoD and military-related health studies that require marketing to service members and their families.		
	2. Must know how to identify and define marketing opportunities in the recruitment of study subjects for large health research studies.		

	3. Must know how to identify problems; generate, refine, and evaluate marketing actions.		
	4. Must be able to work with survey methodologist and medical researchers to design all aspects of marketing materials for several large DoD health studies.		
	5. Must provide examples of previous work, and be able to work as a team member on large research projects.		
	6. Must be detailed-oriented with excellent organizational and follow-through skills.		
	7. Must have knowledge of HTML, Adobe Photoshop, Adobe Illustrator, Adobe Flash, Adobe Dreamweaver, Excel and Microsoft Office including Word.		
Sr. Medical Epidemiologist		Doctor	2
	1. Must have a MD or DO with a proven history of epidemiological research, preferably with background of conducting research within the DoD and familiarity with the MDR.		
	2. Ability to participate in and lead studies conducted within the Department of Deployment Health Research. This includes overseeing research assistants and other members of the study team. Conducting complex data analyses, and interpreting and summarizing study results.		
	3. Ability to develop research proposals primarily using survey medical data.		
	4. Will be expected to write and publish research results in peer reviewed journals and brief sponsor on a regular basis on the status of the ongoing research within the department.		
	5. Will be expected to write research grants and proposals and seek out funding sources.		
	6. Will be expected to work within a team environment and mentor junior research staff.		
Chief of Operations		Project Manager	1
	1. Must be able to evaluate and develop improved processes for administrative, financial, technical and scientific oversight for all levels of the department.		
	2. Must be able to assess strengths and weaknesses of departmental resources and design and implement improved support mechanisms to increase and improve performances for federally supported programs and research.		
	3. Must be able to interact with personnel at all internal and external levels to facilitate information flow and operations, including Investigators, Coordinators, Managers, Administrators, IRB, and Sponsors. Acts as liaison between the DHRD, NHRC, and Sponsors.		
	4. Must be able to initiate change management processes to improve the organizational response to the work product, utilizing organizational development techniques to yield highly successful results while also providing professional growth opportunities for staff and enhanced employee morale, and establish promotion pathways.		
	5. Documents responsibilities and competencies for program staff, students and consultants; coordinates there recruiting, interviewing, and hiring.		
	6. Provides staff leadership to multi disciplinary teams, as well as manages work of outside expert consultants. Provides direction for staff supervision, mentoring and productivity of scientific work. Develops teambuilding skills in senior leadership.		
Program Manager		Project Manager	1
	1. Responsible for providing administrative and management oversight in order to maximize the effective use of program resources.		
	2. Program Manager will be expected to coordinate program functions and activities, provide administrative support to Program Directors.		
	3. Must be able to assist in generation and management of budgets, draft and coordinate proposal submissions and grant applications.		
	4. Must be able to assist in defining and determining personnel, supply, travel, equipment and contract requirements.		
	5. Must be able to supervise lower level program members and is responsible for their hiring.		

	6. Must be able to assist with the preparation of requests for grant actions and proposals. Provides support for pre-award proposal submission and post-award financial management of grants, contracts and cooperative agreements.		
	7. Must be able to assist in personnel management: monitor personnel projections and rebudget or advise PI as necessary, submit position requisitions and coordinate recruitment, promotion and evaluation and termination activities, oversee timesheet approval and payroll reconciliation, ensure correct combo codes are available for employees to charge their labor.		
Sr. Budget Analyst		G&A Specialist	1.25
	1. Must be able to perform technical analysis to determine present and future financial performance.		
	2. Must be able to gather, analyze, prepare and summarize recommendations for financial plans, acquisition activity, trending future requirements, operating forecasts, etc.		
	3. Develops budget estimates for a multitude of research studies. May contribute to the writing of funding proposals.		
	4. Prepares timely and periodic management reports to facilitate decision-making within the Department.		
	5. Will be responsible for developing, interpreting and implementing financial concepts for financial planning and control.		
	6. Must have Bachelor's degree in business or research related field.		
	7. Government contract experience preferred. Grant writing experience preferred. Research regulatory documentation experience preferred.		
Regulatory Affairs Specialist		Scientist	1
	1. Will provide routine and non routine regulatory support for large epidemiologic research projects for the DHRD.		
	2. Must be able to provide administrative oversight and support, supervise and/or mentor junior staff, and exercise appropriate judgment in the resolution of problems while working in a team environment.		
	3. Must be able to prepare, submit and respond to all regulatory related items including new protocols, continuing review reports, and memo’s. Maintains a regulatory system to track protocol dates, approvals, reports and correspondence.		
	4. Must be able to facilitate information flow between the Department members, Principal Investigators, collaborators, IRB Chair and staff, sponsors, other NHRC Departments.		
	5. Must be able to manage and assist with the review and preparation of grants, contracts, sub awards, data sharing agreements and other research activities to ensure compliance with relevant federal and local regulations and policies of research involving human subjects and data protection.		
	6. Serves as the HIPAA Compliance Officer for the DHRD with respect to Human Use Protocols. Assists management with compliance, regulatory, and research training activities for principal investigators and research personnel.		
	7. Must be able to actively participate and assist research staff with audits and monitors from sponsors, FDA, and other governmental and/or military agencies.		
Sr. Epidemiologist		Senior Scientist	8
	1. Masters in Public Health or related field required. Prefer PhD or MD with training and degree in Epidemiology.		
	2. Must have a sophisticated understanding of and the ability to interpret quantitative methods.		
	3. Minimum 3 years of Epidemiological research experience required.		
	4. Experience working with large epidemiological datasets.		

	5. Must be experienced in longitudinal study design and methodology.		
	6. Routinely research and provide updates of emerging research in the field of deployment health research.		
	7. Must have a proven research record indicated by at least 5-10 articles published in peer review journals as first author.		
	8. Must have a strong background in using SAS for statistical analyses.		
Sr. Biostatistician		Scientist or Sr. Scientist	2.25
	1. Provide statistical support for evaluation/research studies, including study design, sample size estimation, participant randomization, statistical analyses, and interpretation of data.		
	2. Provide statistical analysis plans, including the definition of derived data sets, and the design of statistical tables, figures, and data listings for evaluation and research summary reports.		
	3. Perform routine and complex statistical analysis, ensuring statistical integrity and efficiency using SAS. Must be familiar with longitudinal study designs.		
	4. Provide support to the Director in activities to publish and share findings with other professionals, at conferences and other health forums.		
	5. Provide support to the Department Head in identifying and interpreting trends and patterns in complex data sets used by the DHRD, and have a strong background in using SAS.		
	6. Provide mentorship on statistical methods to junior research staff.		
Assistant Study Coordinator		Scientist	3
	1. Assists with all aspects of the coordination of military research studies.		
	2. Collects, organizes and manages data for research projects. Assists with the preparation of data for technical reports, summaries and protocols.		
	3. Assists with maintaining databases for research projects. Retrieves information from databases and multiple data sources.		
	4. Scans and verifies survey data. Tracks progress for team distribution.		
	5. Communicates regularly with the Principal Investigator and project team members in order to facilitate the research assistants' progress in executing study goals/tasks.		
	6. May enroll subjects in research studies including administering informed consent.		
	7. May assist with IRB document submissions. May facilitate communication between NHRC IRB office and Principal Investigator to ensure that protocols are submitted in the correct manner and timely responses are generated.		
Programmer		Architect	3
	1. Evaluates and analyzes existing systems and determines needs for and develops new systems for the conduct of large survey studies including web and paper designs.		
	2. Devises logical procedures, prepares flowcharts, performs coding, tests, and debugs programs.		
	3. Provides input for documentation of new or existing programs.		
	4. Determines system specifications, input/output processes and working parameters for hardware/software compatibility.		
	5. Develops policies, procedures, expansion strategies and product evaluations.		
	6. Assists users with using software and resolves any problems.		
Software Developer		Architect	1
	1. Must have experience maintaining large longitudinal databases.		
	2. Designs, modifies, develops, writes and implements software for specific database tasks.		
	3. Implements data models and database designs, data access and table maintenance codes.		
	4. Supervises or oversees the work of programming and web development.		
	5. Provides assistance and training to system users.		

	6. Develops and designs methods and procedures for collecting, organizing, interpreting and classifying information for input into databases.		
	7. Works with researchers in the design and development of new applications to solve specific research questions.		
Media Writer		Scientist	0.25
	1. Must have at least 5 years experience in summarizing and drafting research findings for general dissemination in the media. Prefer familiarity with DoD and military related health studies.		
	2. Must know how to identify and reach out to points of contact in the DoD (Washington DC) to establish networks for study findings disseminations.		
	3. Must be able to work with survey methodologist, marketing expert, and medical researchers to draft and disseminate findings from large health studies.		
	4. Must provide examples of previous work, and be able to work as a team member on large research projects.		
	5. Must be detailed-oriented with excellent organizational and follow-through skills and ability to meet established timelines.		
	6. Must have knowledge of Microsoft Office including Word.		

TRAVEL AND OTHER DIRECT COSTS

Travel destinations are not definitive at this time and will be defined on an as needed basis in writing (e.g., email) by the technical point of contact. All travel will need to be approved the technical point of contact and COR in writing (e.g., email) if within scope and budget. Otherwise, a modification to the task order will be required. For proposal purposes, the offeror shall use a figure of NTE $100K average per 12 months (before contractor burdens). Travel to medical treatment facilities, research collaborator sites, and professional conferences (including travel outside the continental United States (OCONUS) are the most typical travel destinations, which may include but are not limited to:

Destination	# of trips	# of people	# of days (approx.)
Washington, DC	3	3	4
Ft. Detrick, MD	3	3	4
Orlando, FL	1	3	3
London, UK	1	2	6
Sydney, Australia	1	2	5

Other Direct Costs (ODC): There may be ODCs required to perform this SOO and will be defined on an as needed basis in writing (e.g., e-mail) by the technical point of contact for this task order. For proposal purposes, ODCs are estimated at NTE $8.2M per 36 months period of performance; due to the research survey cycle occurring during the first year, Year 1 ODCs are estimated at $6.8M while Years 2 and 3 are estimated at $668K and $645K, respectively. All ODCs will need to be approved the technical point of contact and COR in writing (e.g., email) if within scope and budget. Otherwise, a modification to the task order will be required. The ODCs anticipated over the period of performance are as follows (but subject to change): general office supplies, post office box rental, training and registration, recruitment services, survey participant incentives/gift cards (for over 200,000 individuals), printing and mailing support, consultants (including survey methodologist consultant, advisory board and related meetings), server maintenance, statistical software and miscellaneous CUP supplies.

Attachment 1

Department of Defense
Standard Contract Clause for Business Associates

Introduction

In accordance with DoD 6025.18-R "Department of Defense Health Information Privacy Regulation," January 24, 2003, the Contractor meets the definition of Business Associate. Therefore, a Business Associate Agreement is required to comply with both the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security regulations. This clause serves as that agreement whereby the Contractor agrees to abide by all applicable HIPAA Privacy and Security requirements regarding health information as defined in this clause, and in DoD 6025.18-R and DoD 8580.02-R, as amended. Additional requirements will be addressed when implemented.

(a) **Definitions**. As used in this clause generally refer to the Code of Federal Regulations (CFR) definition unless a more specific provision exists in DoD 6025.18-R or DoD 8580.02-R.

Individual has the same meaning as the term "individual" in 45 CFR 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

Privacy Rule means the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

Protected Health Information has the same meaning as the term "protected health information" in 45 CFR 160.103, limited to the information created or received by the Contractor from or on behalf of the Government pursuant to the Contract.

Electronic Protected Health Information has the same meaning as the term "electronic protected health information" in 45 CFR 160.103.

Required by Law has the same meaning as the term "required by law" in 45 CFR 164.103.

Secretary means the Secretary of the Department of Health and Human Services or his/her designee.

Security Rule means the Health Insurance Reform: Security Standards at 45 CFR part 160, 162 and part 164, subpart C.

Terms used, but not otherwise defined, in this Clause shall have the same meaning as those terms in 45 CFR 160.103, 160.502, 164.103, 164.304, and 164.501.

(b) The Contractor shall not use or further disclose Protected Health Information other than as permitted or required by the Contract or as Required by Law.

(c) The Contractor shall use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Contract.

(d) The Contractor agrees to use administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits in the execution of this Contract.

(e) The Contractor shall, at their own expense, take action to mitigate, to the extent practicable, any harmful effect that is known to the Contractor of a use or disclosure of Protected Health Information by the Contractor in violation of the requirements of this Clause. These mitigation actions will include as a minimum those listed in the TMA Breach Notification Standard Operating Procedure (SOP), which is available at: http://www.tricare.mil/tmaprivacy/breach.cfm

(f) The Contractor shall report to the Government any security incident involving protected health information of which it becomes aware.

(g) The Contractor shall report to the Government any use or disclosure of the Protected Health Information not provided for by this Contract of which the Contractor becomes aware.

(h) The Contractor shall ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by the Contractor, on behalf of the Government, agrees to the same restrictions and conditions that apply through this Contract to the Contractor with respect to such information.

(i) The Contractor shall ensure that any agent, including a subcontractor, to whom it provides electronic Protected Health Information, agrees to implement reasonable and appropriate safeguards to protect it.

(j) The Contractor shall provide access, at the request of the Government, and in the time and manner reasonably designated by the Government to Protected Health Information in a Designated Record Set, to the Government or, as directed by the Government, to an Individual in order to meet the requirements under 45 CFR 164.524.

(k) The Contractor shall make any amendment(s) to Protected Health

Information in a Designated Record Set that the Government directs or agrees to pursuant to 45 CFR 164.526 at the request of the Government, and in the time and manner reasonably designated by the Government.

(l) The Contractor shall make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by the Contractor, on behalf of the Government, available to the Government, or at the request of the Government to the Secretary, in a time and manner reasonably designated by the Government or the Secretary, for purposes of the Secretary determining the Government's compliance with the Privacy Rule.

(m) The Contractor shall document such disclosures of Protected Health Information and information related to such disclosures as would be required for the Government to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

(n) The Contractor shall provide to the Government or an Individual, in time and manner reasonably designated by the Government, information collected in accordance with this Clause of the Contract, to permit the Government to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

General Use and Disclosure Provisions

Except as otherwise limited in this Clause, the Contractor may use or disclose Protected Health Information on behalf of, or to provide services to, the Government for treatment, payment, or healthcare operations purposes, in accordance with the specific use and disclosure provisions below, if such use or disclosure of Protected Health Information would not violate the HIPAA Privacy Rule, the HIPAA Security Rule, DoD 6025.18-R or DoD 8580.02-R if done by the Government.

Specific Use and Disclosure Provisions

(a) Except as otherwise limited in this Clause, the Contractor may use Protected Health Information for the proper management and administration of the Contractor or to carry out the legal responsibilities of the Contractor.

(b) Except as otherwise limited in this Clause, the Contractor may disclose Protected Health Information for the proper management and administration of the Contractor, provided that disclosures are required by law, or the Contractor obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Contractor of any instances of which it is aware in which the confidentiality of the information has been breached.

(c) Except as otherwise limited in this Clause, the Contractor may use Protected Health Information to provide Data Aggregation services to the Government as permitted by 45 CFR 164.504(e)(2)(i)(B).

(d) Contractor may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR 164.502(j)(1).

Obligations of the Government

Provisions for the Government to Inform the Contractor of Privacy Practices and Restrictions

(a) The Government shall provide the Contractor with the notice of privacy practices that the Government produces in accordance with 45 CFR 164.520.

(b) The Government shall provide the Contractor with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect the Contractor's permitted or required uses and disclosures.

(c) The Government shall notify the Contractor of any restriction to the use or disclosure of Protected Health Information that the Government has agreed to in accordance with 45 CFR 164.522.

Permissible Requests by the Government

The Government shall not request the Contractor to use or disclose

Protected Health Information in any manner that would not be permissible under the HIPAA Privacy Rule, the HIPAA Security Rule, or any applicable Government regulations (including without limitation, DoD 6025.18-R and DoD 8580.02-R) if done by the Government, except for providing Data Aggregation

services to the Government and for management and administrative activities of the Contractor as otherwise permitted by this clause.

Termination

(a) Termination. A breach by the Contractor of this clause, may subject the Contractor to termination under any applicable default or termination provision of this Contract.

(b) Effect of Termination.

(1) If this contract has records management requirements, the records subject to the Clause should be handled in accordance with the records management requirements. If this contract does not have records management requirements, the records should be handled in accordance with paragraphs (2) and (3) below

(2) If this contract does not have records management requirements, except as provided in paragraph (3) of this section, upon termination of this Contract, for any reason, the Contractor shall return or destroy all Protected Health Information received from the Government, or created or received by the Contractor on behalf of the Government. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of the Contractor. The Contractor shall retain no copies of the Protected Health Information.

(3) If this contract does not have records management provisions and the Contractor determines that returning or destroying the Protected Health Information is infeasible, the Contractor shall provide to the Government notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Government and the Contractor that return or destruction of Protected Health Information is infeasible, the Contractor shall extend the protections of this Contract to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as the Contractor maintains such Protected Health Information.

Miscellaneous

(a) Regulatory References. A reference in this Clause to a section in DoD 6025.18-R, DoD 8580.02-R, Privacy Rule or Security Rule means the section currently in effect or as amended, and for which compliance is required.

(b) Survival. The respective rights and obligations of Business Associate under the “Effect of Termination” provision of this Clause shall survive the termination of this Contract.

(c) Interpretation. Any ambiguity in this Clause shall be resolved in favor of a meaning that permits the Government to comply with DoD 6025.18-R, DoD 8580.02-R, the HIPAA Privacy Rule or the HIPAA Security Rule.

_____

Company Name

_____

Authorized Signature Date