

**03-50 AMD01: 22 July 2013**

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The purpose of this amendment is to change the period of performance from 12 to 36 months and to extend the due date of proposals. See changes in red below.

**Omnibus 3 RFP No.: O3-50  
Interdigitated Surveillance and Academic Collaboration (ISAAC)**

**ADMINISTRATIVE**

Release Date: 11 July 2013

This REQUEST FOR PROPOSALS is for the OMNIBUS III contractors, in the Small Business Lot.

PROPOSALS ARE DUE NO LATER THAN (~~13 11~~ August 2013 @ 15:00 EST) to [mark.a.marchioli.civ@mail.mil](mailto:mark.a.marchioli.civ@mail.mil), [matthew.r.buchanan6.civ@mail.mil](mailto:matthew.r.buchanan6.civ@mail.mil) and [michael.dalessandro6.civ@mail.mil](mailto:michael.dalessandro6.civ@mail.mil), [lisa.m.mardin.ctr@mail.mil](mailto:lisa.m.mardin.ctr@mail.mil), and [issa.j.shawki.ctr@mail.mil](mailto: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:

- **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.
- **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.
- **DoD-Service Addendum, any military Service:** Include a copy of the DoD-Service 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 Service representative a request to use the such Addendum in lieu of the client's Service Addendum and that all other client Service-unique requirements will be met, upon award of this requirement to this offeror.
- **Small Business Size Qualification (500 employees):** The offeror shall state whether it is a small business concern or not at the time of the proposal due date when bidding a small business set aside. If it was a small business at the time of the basic contract award but is not at the time of the proposal due date, then refer to the basic contract for instructions.

- **FAR Subpart 52.219-14 Compliance (prime 50% direct personnel cost):** The offeror shall state in their proposal that they will comply, if in the event of a small business award. If the small business anticipates using a subcontractor, then the name of the potential subcontractor and the percentage for that contractor shall be disclosed. 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. This compliance will only be required of the direct labor to coordinate the efforts of the task order. It does not include any direct labor of subcontractors having a particular expertise, not commonly available.
- **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.

### **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 information contained in 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 1/2/3 TO RFP No.:**

**Competitive Classification:** *SMALL BUSINESS 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: Project Manager (requirements may be met by providing more than one resume)*

**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. The PWS provided by the offeror shall provide added value to the SOO Addendum provided by the Government. The RFP Instructions has the required proposal format for a RFP response.*

*\* There is an indeterminate amount of diseases throughout the world and the amount of surveillance/research to combat the spread of disease and the amount of research needed to develop vaccines is unknown. FFP may be acceptable if labor CLIN is billed based on cost rather than a fixed unit price.*

*\*\* [Schedule for incremental funding: TBD]*

*\*\*\* 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.*

### **Interdigitated Surveillance and Academic Collaboration (ISAAC)**

#### **STATEMENT OF OBJECTIVES**

This acquisition will provide: (1) The comprehension and management action associated with coherently interdigitating the surveillance resources throughout the world (similarly to that of a systems integrator); and (2) The coordination of resources such as academia conducting research in response to surveillance outcomes. The estimated staffing includes: equivalent of one Project Manager (which may be distributed among more than one company employee), and includes any admin support within the 1 FTE. This acquisition is being structured as such in order to allow for flexibility and speed when responding to disease outbreak dynamics such as was seen with the H1N1, H1N9 influenza strains. With the heightened concerns regarding the outbreak of H7N9 influenza in China, and the MERS-CoV infections that has now spread to nine countries in the Middle East and Europe, the DoD needs to ensure that there is an infrastructure to handle these agents should they impact the DoD forces and eventually the US populous.

## Administrative Requirements

- a. **Inspection/Acceptance/Points of Contact (DoDAAC):** (W23MWP)
- b. **Inspection/Acceptance/LPO DoDAAC:** W23MWP
- c. **Contracting Officer's Representative (DoDAAC):** (W23MWP)
- d. **Period of Performance:** Performance shall be for ~~36~~ 12 months+, approximately from date of task order award to end of FY14.
- 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: There are a myriad of coordination activities requiring corporate knowledge be retained. Should this corporate knowledge be lost prematurely, it may significantly impair the DoD's capability to respond to global crisis concerning infectious diseases.
- 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 GEIS Division of the Armed Forces Health Surveillance Center in Maryland. This task order  does not  does represent a mix of on-site and off-site contractor personnel. 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. 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: Contractor personnel must comply with all the onsite security requirements of the host command when on base.
  - (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: [Provide the name of the data source under TMA cognizance.]

- 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, possibly at the subcontractor level. This task order  does not or  does include clinical positions, possibly at the subcontractor level. 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, not at the prime contractor level, but at the subcontractor level when the provisions in Section "i" above apply. 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: Any subcontractor positions when the provisions of Section "i" above apply. Documentation of such is not required during the prime contractor's proposal submission. However, such provisions should be included in any subcontractor agreement between prime contractor and subcontractor.
- 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: (1) Name of person: (2) phone: (3) e-mail: (4) name of command: . 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 (Service) 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 (Service) 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 (Service) 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 (Service) Addendum in their proposal. For those task orders supporting several protocols, a Multiple Protocol Assurance (MPA) version of the DoD-Service Addendum is required. "Service" shall mean the service of the client, for example, Air Force or Navy. Comment: DHHS FWA and DoD-Addendum required for the prime contractor. Any subcontractor performing where human research is involved will also require such assurances. For international subcontractors, see DHHS and DoD regulations.

- 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, but not at the prime contractor level. 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: Any subcontractor extramurally performing where animal research is involved shall have the proper assurances. Documentation is not required during the prime contractor's proposal submission. Any subcontractor intramurally performing where animal research is involved shall abide by the cognizant client's assurances.

- 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: The prime contractor shall remain ethical when considering subcontracting versus performing in house, such that the objectives/desires of the client are best served.
- 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) Comply with Contractor Manpower Reporting requirements.

## **ADDENDUM**

### **Interdigitated Surveillance and Academic Collaboration (ISAAC)**

#### **GLOBAL REQUIREMENT**

This acquisition will provide: (1) The comprehension and management action associated with coherently interdigitating the surveillance resources throughout the world (similarly to that of a systems integrator); and (2) The coordination of resources such as academia conducting research in response to surveillance outcomes. This acquisition is being structured as such in order to allow for flexibility and speed when responding to disease outbreak dynamics such as was seen with the H1N1, H1N9 Influenza strains. With the heightened concerns regarding the outbreak of H7N9 influenza in China, and the MERS-CoV infections that has now spread to nine countries in the Middle East and Europe, the DoD needs to ensure that there is an infrastructure to handle these agents should they impact the DoD forces and eventually the US populous.

The aim of the Global Emerging Infections Surveillance and Response System (GEIS) Division at the Armed Forces Health Surveillance Center (AFHSC) is to contribute to the protection of all Department of Defense (DoD) healthcare beneficiaries and the global community through an integrated worldwide emerging infectious disease surveillance system. GEIS was created in 1997 in response to Presidential Decision Directive NSTC-7 to provide a mechanism within the DoD to centralize coordination of surveillance efforts conducted through DoD overseas medical research and development laboratories. Efforts ultimately support and strengthen surveillance among deployed US military personnel and aid in diagnosis and treatment at military treatment facilities. Additionally, all host country partner activities are directed toward improvement of each country's diagnostic and reporting requirements in accordance with World Health Organization's International Health Regulations (2005) core capacities.

GEIS provides direction, funding and oversight to a network of over 35 partners based in all regions of the world. These partners conduct disease surveillance and rapid outbreak response, encourage research and innovation, and build capacity. These partners include but are not limited to: academic institutions (such as the University of Florida, SUNY Upstate Medical School, University of South Florida, USUHS, UCSF, UC-Berkeley and others in the USA, The Imperial College, LSHTM and Oxford University in the UK), Non-government Organizations (NGOs) (such as the Foundation Merieux and the Institute Pasteur), and others in the performance of our mission. Executing research projects, providing critical reagents and supplies, organizing conferences and travel, and building capacity are all interdigitated in the overall program.

#### **SPECIFIC REQUIREMENTS**

The expectation is that the ISAAC contractor performer will orchestrate strategic studies and advanced concepts and requirements domain in the specific area of infectious diseases. This may include operational test and evaluation as it pertains to medical and medical-related material, equipment, and information technology products and their uses. Such activity shall contribute to building the DoD Medicine knowledge management capabilities that positively impact the AFHSC by enabling innovation, performance improvement, and powerful decision making. In such a role, the ISAAC contractor performer will orchestrate integration functions to ensure information systems are correctly designed, populated, and integrated into the broader healthcare delivery system or subsystems they are intended to support. From a mission perspective, these actions serve as an integral player in the Force Management, Development, Integration, Sustainment, and Modernization processes of building the

medical arm or tomorrow’s Armed Forces, as they pertain to infectious disease surveillance and research. The vision is to have an integrated and effective Military Medical system equipped, manned, and properly aligned to support a Transformed, Modular Armed Forces at war on today’s and future battlefields. Under such a mission and vision, the ISAAC contractor performer, through its established network of subcontractors, consultants, and affiliates, develops concepts, organizations, materiel, and doctrine for Force Health Protection (FHP) to the Armed Forces across the operational continuum; provides independent operational tests, evaluations, and experiments in support of the Military Medical materiel and systems acquisition process; is the customer advocate and corporate catalyst for integration and synchronization of Military Medical information management/information technology support systems; builds knowledge management capabilities that enable the workforce to positively impact the Military Medical mission through innovation, performance improvement, and powerful decision making; relates to the DoD medical evacuation system ensuring effective integration into the Joint Force Health Protection System; provides data-driven studies, analyses, and evaluations to the AFHSC in support of current and future Force Health Protection Operations; fosters and promotes excellence in operational and military academic medicine; and enhances military clinical education through development, publication, and maintenance of the Textbooks of Military Medicine.

Activities/deliverables to accomplish the aforementioned requirement to completion include:

1. Establish and maintain liaison and/or subcontracting working relationships with various entities, both CONUS, OCONUS, and FOREIGN, that best serves the objectives of the client, similar to as a systems integrator would perform. Outcomes/deliverables may include technical reports, lab results, assays, etc.
2. Deliver technical and progress reports to the client periodically on the above relationships and their outcomes. Periodicity shall be flexible and timely accommodates both the requirements of the client and the outcomes being reported.
3. Add value to the above that is beneficial to the client.

Note: Offerors shall be capable of cash flow significant enough to facilitate processing of ODCs. There are no advanced payments or progress payments. The prime contractor should be able to design a payment plan with their vendor to minimize the impact ODCs will have on the prime’s cash flow. As soon as the ODC vendor is identified in writing, the prime shall enact agreements as soon as possible. Also, the amount that the prime is charging on top of or burdening the ODC costs will be a significant evaluation factor considered by the client. If possible, the prime should identify a separate cost center to minimize prime’s burden rate.

**ESTIMATED STAFFING**

The estimated staffing includes: equivalent of one Project Manager (which may be distributed among more than one company employee to perform either PM, G&A, or admin functions).

The period of performance shall be for ~~36~~ 12 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)
Project Manager (does not have to reside within one person)	Project Manager, Admin, as applicable	1 (1920)
ANNUAL TOTAL:		1

	TASK ORDER TOTAL:	1
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\*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.

#### Staffing Eligibility / Qualifications

Project Manager (may be met over more than one resume)

1. Experience and proficiency in conducting discussions and building/maintaining relations with other entities. This includes working knowledge of initiating/negotiating/administering contracts, subcontracts, and agreements with other entities in support of the client. Ability to travel with minimal notice is required.
2. Experience/working knowledge of technical substance concerning infectious diseases and the research, clinical trials, etc. associated with such and with vaccines.
3. Experience/working knowledge of the protection regulations associated with Intellectual Property, from a Project Manager's perspective (not an attorney's perspective).

#### 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 by the COR or the Contracting Officer 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 \$20K (before contractor burdens). Travel to DoD Medical research laboratory facilities, and laboratory field sites (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.)
CONUS, OCONUS, or FOREIGN	4	1	3

Other Direct Costs (ODC): There are ODCs required to perform this SOO (NTE \$7.9M before contractor burdens) 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. All ODCs will need to be approved by the COR or the Contracting Officer in writing (e.g., email) if within scope and budget. Otherwise, a modification to the task order will be required. The prime contractor shall allow for some flexibility of the ODCs based on the medical surveillance dynamics that occur within during the period of performance. For example, in any given year, there is a new "disease du jour" that overrides previous priorities and therefore the client needs the ability to shift assets on the run to keep pace with their leadership demands. The ODCs anticipated over the period of performance are as follows (but subject to change): Subcontract awards to various academic institutions and organizations throughout the world, in addition to domestic entities; various consultant services, computer related services, preservation, packaging, package costs, special test equipment, and any special US taxes.

#### 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.

