DRAFT PERFORMANCE WORK STATEMENT

Contents

PERFORMANCE WORK STATEMENT (PWS)

Title: Research and Laboratory Services Support to The Lugar Center, Republic of Georgia and Azerbaijan and the US European Command (USEUCOM) Area of Responsibility (AOR).

Requiring Activity Name: United States Army Medical Research Directorate – Georgia (USAMRD-G)

1. INTRODUCTION

The mission of the Walter Reed Army Institute of Research (WRAIR) is to conduct biomedical research that is responsive to Department of Defense and U.S. Army requirements and delivers life-saving products including knowledge, technology and medical materiel that sustain the combat effectiveness of the Warfighter.

The focus of WRAIR Leaders and scientists is the basic and applied medical research supporting U.S. military operations. However, despite the focus on the military, the institute has historically also addressed and solved a variety of non-military medical problems prevalent in the United States and the world over.

Headquartered in Silver Spring, Maryland, the Walter Reed Army Institute of Research is the largest biomedical research facility currently serving the Department of Defense. WRAIR research and development now reaches around the world from Maryland to Germany, Thailand, Kenya and Georgia.

WRAIR's vision is to be the premier DoD biomedical research organization, constantly relevant, integrating basic research and advanced technology that protects, projects, and sustains the Warfighter today, invents global medical solutions for the future, and keeps the Warfighter on point for the Nation. WRAIR hosts two Centers of Excellence for Military Psychiatry and Neuroscience Research and for Military Infectious Disease Research, each center ranging from blast induced neurotrauma to malaria vaccine development.

2. PURPOSE AND BACKGROUND

WRAIR's mission is to conduct biomedical research that is responsive to Department of Defense and U.S. Army requirements. This mission includes the delivery of lifesaving knowledge, technology, and medical materiel products that sustain Warfighter readiness and combat effectiveness. WRAIR's focus on research and surveillance for the Warfighter affects all aspects of its operations as military medical research priorities differ from those of the civilian sector. Specific infectious disease surveillance and research lines of effort include:

1. Antimicrobial resistance (AMR) and sexually transmitted infections (STIs)
2. Febrile and vector-borne infections (FVBI)
3. Enteric infections (EI)
4. Respiratory infections (RI)
5. Bacteriophage Research
6. One Health Research

In 2009, the Cooperative Biological Engagement Program (CBEP) engaged the United States Army Medical Research and Material Command (USAMRMC), following a request from the Government of Georgia to establish a long-term U.S. presence at the Richard G. Lugar Center for Public Health Research (Lugar Center), which will serve as the cornerstone of the Georgian National Disease Surveillance Program. In January 2011, WRAIR, through its command channels, was tasked by the Deputy Secretary of Defense as the Executive Agent, to establish a medical research unit at the Lugar Center in Tbilisi, Georgia. The U.S. Army Medical Research Directorate-Georgia (USAMRD-G) was established under the command and control of WRAIR. A formal memorandum of understanding (MOU) with the NCDC provides clear guidance on the relationship between the U.S. Army and the Georgian Public Health Service. Relevant partnerships and agreements with the Georgian Ministries of Defense; Labor, Health, and Social Affairs;

and Agriculture, promote partnerships in global health engagement, advance Chief of Mission Integrated Country Team strategy and support DoD OCONUS medical research and surveillance laboratory mission requirements.

3. SCOPE

Walter Reed Army Institute of Research (WRAIR) performs a biomedical research and infectious disease surveillance mission, in support Department of Defense (DoD) and Department of State (DoS) Interagency strategic objectives within the U.S. European Command (USEUCOM) area of responsibility (AOR). The U.S. Army Medical Research Directorate- Georgia (USAMRD-G), WRAIR's expeditionary medical research platform in Tbilisi, Georgia, supports the United States' international mission to build partnerships in global health engagement; advance medical diplomacy; build local national capabilities; strengthen research and strategic partnerships; and conduct presence activities to counter malign influence through a broad spectrum of research and surveillance activities. USAMRD-G's core scientific mission set is to deliver knowledge and materiel products to the Warfighter to sustain readiness and support lethality for U.S. and Allied forces.

The project aims to close knowledge gaps concerning infectious disease threats posed by viruses, parasites, and bacteria within Europe and adjacent regions as deemed necessary to meet DoD stakeholder requirements. This single award Indefinite Delivery Indefinite Quantity (IDIQ) contract vehicle shall support WRAIR's mission in Georgia and the USEUCOM AOR from USAMRD-G's primary laboratory space in the Richard G Lugar Center for Public Health in Tbilisi, Georgia and in other research sites developed to support stakeholder requirements and priorities (within the USEUCOM AOR). Specifically, the IDIQ award shall provide services to support: clinical research and product development;, program management and operational support; safety support; logistics support; and administrative support to the WRAIR mission at the Lugar Center, and other USEUCOM research sites as needed.

In order to support sustained research and biomedical surveillance efforts for USAMRD-G within the current dynamic strategic and resource constrained environment, WRAIR's research efforts must be responsive to emerging requirements. This performance work statement (PWS) for a non-personal services contract provides scientific support, clinical research support, and operational (management and ancillary) support. Task orders under this vehicle will direct programmatic requirements to support scientific efforts including: surveillance and sample collection; basic and exploratory research; translational research; clinical or product oriented research and development. Task orders will also direct requirements for operational support to USAMRD-G including supplies and services to sustain program management and supervisory functions, logistics, facilities service, safety, recruitment, retention, training, as well as operational IT support primarily in a .org environment.

These tasks may require, but not limited to, the expertise of the below

Scientific Support:

- Technical Lead in Infectious Disease Research and Program management
- Clinical Research Principal Investigator Services
- Microbiological Principle Investigator Services
- Virological Principle Investigator Services
- Entomology Principle Investigator

Clinical Research Support:

- Bioinformatics Support Services
- Quality Assurance/Quality Control Support Services
- Geography Information System (GIS) Technical Support services
- Research and Laboratory Technical Support Services
- Entomology Support Services
- Animal Use Research
- Human Resources

Operational Support:

- Program and Operational Management
- Human Subjects Research Protection
- Grantsmanship and business agreement development
- Translation Services
- Logistics, Biomedical Equipment and Supply Support Services
- Transportation Support Services
- Facilities Management Support
- Safety Support Services
- Training
- Administrative and Clerical Support Services
- Contingency

Performance requirements under this contract shall flow through the issuance of task orders individually negotiated and issued pursuant to the contract by the Contracting Officer (KO). The PWS for each required outcome will be detailed in each task order. More than one task order can be issued at any one time with overlapping periods of performance.

The contractor shall provide all personnel, equipment, supplies, facilities, transportation, tools, materials, supervision, management, and other items and non-personal services necessary to perform this requirement as defined in this Performance Work Statement (PWS), except for those items specified as government furnished property and services. The contractor shall perform to the standards in this contract.

Individual task orders will identify equipment, supplies, and materials that may be required to be purchased in support of the individual task order. Subcontractor support may be required to complete specific scopes of work in support of an individual task order (i.e. clinical research organizations, data management services, etc.).

Individual task orders will also identify any necessary travel support for non-military and non-government employees to participate in off-site strategic planning meetings, seminars, training, and symposia in support of a task order.

4. PERIOD OF PERFORMANCE

The periods of performance for this contract are as follows:

Base period	13 March 2022 – 12 March 2023
Option period 1	13 March 2023 – 12 March 2024
Option period 2	13 March 2024 – 12 March 2025
Option Period 3	13 March 2025 – 12 March 2026
Option Period 4	13 March 2026 – 12 March 2027

5. WORK SCHEDULE AND LOCATION

This PWS identifies services that are strictly non-personal in nature, as defined by FAR 37, and to ensure there is not an appearance of such, every task order shall have an identified task manager.

5.1. Work Location

The Lugar Center, Republic of Georgia and Azerbaijan and the US European Command (USEUCOM) Area of Responsibility (AOR).

5.1.1. Telecommuting

Telecommuting is situational and requires the approval of the contractor who will coordinate the telework schedule with the COR to ensure appropriate contractor coverage. Teleworking may be possible during government announced installation closures and delay.

5.1.2. Working During Emergency Situations

Individual contingency operation plans shall be activated immediately after determining that an emergency has occurred, shall be operational within twelve (12) hours of activation, and shall be sustainable until the emergency situation is resolved and normal conditions are restored or the contract is terminated, whichever comes first. In case of a life threatening emergency, the COR will immediately make contact with the Contractor Managers to ascertain the status of any Contractor personnel who were located in Government controlled space affected by the emergency. When any disruption of normal, daily operations occur, including base closures, the Contractor Manager shall promptly open an effective means of communication with the COR to verify:

a. Key points of contact (Government and Contractor)
b. Temporary work locations (alternate office spaces, telework, virtual offices, etc.)
c. Means of communication available under the circumstances (e.g. email, webmail, telephone, FAX, courier, etc.)
d. Essential duty personnel for emergency and contingency operations
e. Essential work products expected to continue production by priority

The Contractor Manager, in coordination with the COR, shall make use of the resources and tools available to continue contracted functions to the maximum extent possible under emergency circumstances. The Contractor shall obtain approval from the COR and Contracting Officer prior to incurring costs over and above those allowed for under the terms of this contract. Regardless of contract type, and of work location, Contractors performing work in support of authorized tasks within the scope of their contract shall charge those hours accurately in accordance with the terms of this contract.

Contractor shall not report to work on those days the Government or installation is closed due to safety conditions, inclement weather conditions, national emergencies, energy conservation or by direction of the Installation Commander for any other reason. During these periods of closure, the contractor employees that are not designated as essential IAW this contract shall not report for work nor will they be compensated for those days. Essential personnel tasks include the following:

5.2. Federal Holidays

5.2.1. The contractor shall / shall not perform services on days designated as a Federal Holiday by Federal Status, Executive Order, Presidential Proclamation or Installation Commander

Federal holidays are an exception to the regular duty hours. Any of the holidays listed below falling on a Saturday will be observed on the preceding Friday; holidays falling on a Sunday will be observed on the following Monday. The following is a list of legal federal holidays that services shall / shall not be performed.

The following are Federal Holidays:

▪ New Year's Day ▪ Birthday of Martin Luther King, Jr. ▪ Washington's Birthday	▪ Labor Day ▪ Columbus Day ▪ Veterans Day

▪ Memorial Day ▪ Independence Day	▪ Thanksgiving Day ▪ Christmas Day

5.3. Post Closure

All non-mission essential contract employees shall not report to work on days the Government or installation is closed due to local determinations relating to safety conditions, inclement weather conditions, national emergencies, energy conservation. During these periods of closure, the mission essential contractor personnel shall report for work.

5.4. Work Schedule

The contractor shall provide support from 0745 to 1630 Eastern Time.

5.5. Contingency Operations Plan

The Contractor shall prepare and submit a Contingency Operations Plan that shall be the plan in effect for all awarded task orders. **The draft Contingency Operations Plan (Deliverable 1) shall be submitted with the proposal as part of the Operational Support Plan (Deliverable 2)** and a final due ten (10) calendar days after the award of the task order. The plan shall be updated as needed, but no less than on a quarterly basis. The Contingency Operations Plan shall document Contractor plans and procedures to maintain WRAIR/USAMRD-G support during inclement weather, natural disasters, emergencies and on work outside of normal duty hours. The Contingency Operations Plan shall include the following:

- A description of the Contractor's emergency management procedures and policy and data backup/restoration plans
- A description of how the Contractor shall account for their employees during an emergency
- Planned temporary work locations or alternate facilities
- How the Contractor shall communicate with WRAIR during emergencies
- A list of primary and alternate Contractor points of contact, each with primary and alternate:
  - Telephone numbers
  - E-mail addresses
- Procedures for protecting Government furnished equipment (if any)
- Procedures for safeguarding sensitive Government information (if applicable)

6. PERFORMANCE REQUIREMENTS

6.1. Objectives

The USAMRD-G mission statement is to promote force health protection, global health security, Warfighter-readiness, recovery, and lethality through identification and mitigation of medical threats; collaborate with the Government of Georgia and local partners to combat endemic disease threats; and, to build strong partnerships for a self-sustaining medical research program to support U.S. and allied forces within U.S. European and neighboring commands. USAMRD-G will continue to align research and surveillance efforts to senior stakeholder priorities in the region including those of USEUCOM, USAEUR-AF, and Army Senior leader priorities that advance the delivery of products to support U.S. competition against peer and near peer adversaries within the Multi Domain Operations paradigm. Ongoing partnership between USAMRD-G and Georgian partners will ensure continued assessment of regional ID threats IAW senior stakeholder and Global Emerging Infectious Surveillance (GEIS) program priorities.

6.2. Common Program Objectives

The following program objectives and contractor support expectations apply to any current and future locations where USAMRD-G laboratories operate:

6.2.1. Provide support services for the GEIS, MRDC or USEUCOM strategic plans in accordance with the USAMRD-G Director's strategic vision, mission and established research plan.

6.2.2. Submit quality proposals annually or in accordance with DHP, CDMRP, MRDC or GEIS Program Office requests for funding proposals, work plans, and grant submissions. Investigators shall validate proposed surveillance and research projects and request required funding to execute proposed surveillance projects. Following proposal approval and receipt of funds, conduct surveillance or research, training, reporting, and response activities related to emerging and endemic infectious disease threats.

6.2.3. Support USEUCOM and USEUR-AF Command Health Related Theater Security Cooperation activities through responsive and timely surveillance, support for Military Exercises and timely translation of actionable findings.

6.2.4. Expand and improve pathogen discovery capability to include safety and quality assurance/quality control (QA/QC) standards and requirements.

6.2.5. Procure and distribute research project specific supplies and equipment.

6.2.6. Maintain accountability, maintenance, and certification/calibration records for durable equipment.

6.2.7. As required, establish, reconfigure, or modify existing laboratories in direct support of research under this effort.

6.2.8. Provide aid for meetings, workshops, and conferences associated with the key research and technology areas.

6.2.9. Ensure compliance of associated USAMRD-G activities with all necessary regulatory requirements.

6.2.10. Conduct research and surveillance of other emerging infectious diseases as directed by stakeholders and funders (e.g., Army, CDMRP, GEIS).

6.2.11. Respond to outbreaks and augment local public health diagnostic capabilities when requested by local public health authorities and approved by WRAIR Command and the COR.

6.2.12. Maintain a robust infectious disease surveillance and research program in vectors, reservoirs, and human subjects, throughout the USEUCOM AOR where USAMRD-G is establishing expeditionary capabilities in Georgia, Bulgaria, Poland, Latvia and any future locations.

6.2.13. Collaborate with military and civilian partners to expand military relevant funded research and surveillance activities supporting clinical trials, diagnostic, vaccine, and therapeutic development.

6.2.14. Develop and expand core capabilities to compete for intra- and extramural funding aligned to core mission priorities.

6.2.15. Develop and expand capability to identify requirements and draft preliminary business agreements and contracts.

6.2.16. Provide subject matter expertise on a broad range of pathogen research methods and technologies, medical materiel and knowledge product development and delivery, entomological sciences including the arthropod collection, morphological identification and advanced characterization.

6.2.17. Provide scientific and managerial expertise sufficient to manage, mentor, supervise, and support a team of international scientists. Consistently meet or exceed USG threshold expectations for the

aforementioned objectives in accordance with established cost, schedule, and performance parameters.

6.2.18. Provide clinical and bench scientists, laboratory technicians, human subjects and research regulatory support services, safety and biosafety expertise, resource management and cultural affairs expertise.

6.2.19. Provide timely, objective reporting with frequency (i.e., weekly and monthly) and level of detail delivered in accordance with COR guidance to communicate compliance with stakeholder driven cost, schedule, and performance targets for knowledge and materiel products. Reportables will be sufficient to meet routine stakeholder reporting requirements (e.g., GEIS monthly or quarterly reporting), or to assist in the delivery of programmatic metrics to leadership.

6.2.20. Provide capability to establish or support expeditionary medical research programs according to USG requirements in priority regions within the European AOR (e.g., Bulgaria, Romania, Ukraine, Latvia, Poland) or adjacent regions.

6.2.21. Provide weekly (or more frequently as requested) computer file back-ups to ensure preservation of intellectual property and file security against potential loss or mishap.

6.2.22. Georgia Specific Program Objectives

6.2.22.1. Support Science Technology Engineering and Mathematics (STEM) initiatives IAW the unit's mission to support Integrated Country Team strategy for capability enhancement among local nationals.

6.2.23. Bulgaria Specific Program Objectives

6.2.23.1. USAMRD-G is resourced to conduct infectious disease research and surveillance with its primary in country partners the Bulgarian National Center of Infectious and Parasitic Diseases (NCIPD) and the Bulgarian Military Medical Academy (MMA). The development of collaborative studies with NCIPD and MMA in Sofia both have substantial potential to bolster regional FVBI, AMR, ARI, and Enteric pathogen research and surveillance efforts in clinical and operational conditions.

6.2.23.2. The NCIPD is a national laboratory within the Bulgarian Ministry of Health. NCIPD's aim is to develop the scientific foundations for the fight against ID pathogens and the methods to implement this fight and is the only non-university reference laboratory in Bulgaria to conduct surveillance of ID agents (bacterial, viral, and parasitic infections). The NCIPD serves as National Reference Laboratory, conducts microbiology training exercises, and offers scientific advice at the national level. Since 2007, the NCIPD is also designated as a World Health Organization (WHO) Collaborating Center of the United Nations on epidemiological surveillance of communicable diseases and antibiotic resistance with the task of responding in these areas and training personnel in Southeast European and Asian countries within the former Soviet constellation.

6.2.23.3. MMA of Sofia is a large complex for medical treatment, as well as education in Bulgaria, located in Sofia, Bulgaria. It MMA has several branches and smaller clinics in other cities in the country. It was established in 1891 as a military hospital and was transformed into a Senior Military Medical Institute (SMMI) in 1960. The current structure dates from 1989, when the SMMI was unified with the main government hospital, the Navy hospital in Varna, and the Aero-medical research institute in Sofia. Doctors and specialists from the MMA are employed in army units.

6.2.23.4. Bulgaria Program Work Location

The address of primary Bulgaria in-country collaborator is:
The Bulgarian National Center of Infectious and Parasitic Diseases (NCIPD)
Blvd. Yanko, Sakazov 26
Sofia, Bulgaria, 1504

6.3. Performance Requirements

The Contractor shall furnish the necessary personnel, equipment, supplies and support, to complete the performance of the work outlined below at a standard enabling the WRAIR other USAMRMC subordinate commands, to achieve the cost, schedule, and performance goals of its research and development activities (inclusive of preparations for post Milestone-C requirements of the acquisition process), and to the level of quality necessary to comply with programmatic requirements, DoD and Army regulations, ISO (International Organization for Standardization) standards, and FDA (Federal Drug Administration) and EPA (Environmental Protection Agency) regulations (to include both human subject protection and animal care and use regulations); including submissions to federal regulatory agencies.

Federal regulations governing Current Good Clinical Practices (cGCP) are found in, Code of Federal Regulations (CFR), 21 CFR 11, 50, 54, 56, 312, and 314 and important guidelines are in the FDA Information Sheets. Additional regulations for human subjects' protection are found in 45 CFR 46. Those governing cGLP are found in 21 CFR 11 and 58. The International Convention on Harmonization Guidelines for Good Clinical Practice is the standard governing the conduct of research trials. References for military regulations and policies governing regulated research may be found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.overview. Specific task requirements will be further defined on a task order basis.

6.3.1. Resarch and Suvellance Support Services

The contractor shall insure all services will be conducted in accordance with all regulatory affairs entities (e.g. institutional review boards [IRBs]s, WRAIR SOPs, standards, policies, and procedures (references), including maintaining proper certification to ship samples IAW the International Air Transport Association (IATA) www.iata.org.

6.3.2. Quaility Control

The contractor shall review all documents for regulatory compliance, readability, and alignment with stakeholder priorities and guidance documents (e.g., GEIS road maps). Contractor shall be responsible for the review of study protocols to ensure test plans encompass all required test elements, data parameters, test objectives, and laboratory notebooks and records. Contractor shall determine the accuracy of data submissions and compliance with regulatory and programmatic requirements and ensure the test protocols have proper review and approval prior to execution; perform monitoring audits to ensure proper procedures, techniques, and protocols are followed standard operating procedures, study specific procedures, case report forms, study staff personnel training records, and laboratory notebooks and records are kept and properly stored as is needed.

6.3.3. Safety

The contractor shall review all USAMRD-G laboratory SOPs for compliance with all applicable safety and occupational health policies, procedures, and regulations, to include the clinical research centers. Contractor shall determine the accuracy of safety-related documents and compliance with regulatory requirements; perform monitoring audits to ensure proper procedures, techniques, and protocols are followed standard operating procedures, laboratory staff personnel training records, and records are kept and properly stored as is needed.

6.4. Specific Tasks / Requirements

The following functional areas identify the range of services that are anticipated in this award. **The task orders shall specify the requirements:**

6.4.1. Operational Support

The Contractor shall manage the day to day operations and oversee requirements of USAMRD-G in clinical research, information technology services, logistics support, safety services, translation services, local transportation services, training, administration, and quality control. The contractor shall provide an on-site program manager to perform and/or oversee these functions. Additionally the contractor shall perform the required human resource support services to recruit, retain, and train contractor personnel, as well as programmatic support services to advise, manage, and direct a contractor force.

The contractor shall provide administrative, communications, facilities support, work transportation conducive to meet mission requirements, , and financial reporting support to include the capability to conduct business effectively and efficiently at OCONUS locations and to leverage dollars from the widest range of Government, Non-Governmental Organizations (NGO) and private sources.

The Contractor shall develop and adhere to its Operational Support Plan for the required services that cohesively integrates the functions of this requirement.

6.4.1.1. Operational Support Plan (Deliverable 2)

The contractor shall draft and submit a Operational Support Plan to address at a minium but limited to the daily functions such as:

- Human Resources Support (inclusive of training plan)
- Logistics Support
- Occupational Health and Safety
- Contingency
- Resource Management support
- Cultural liaison support

The Contractor shall develop separate sub-plans for each of the items listed above, which shall be incorporated into the operation support plan. The Operation Support Plan combined with the Management Plan will be used to develop the standard operating procedure (SOP) for use in contract performance.

Additional plans, which may be required, shall be addressed in individual task orders and consolidated in the SOP.

6.4.2. Programmatic Support Services

The Contractor shall provide programmatic support services, which may be used at all organizational levels, to help managers achieve maximum effectiveness or economy in their operations. Services may include, but are not limited to: (1) Obtaining outside points of view to avoid too limited judgment on critical issues; (2) Obtaining advice regarding developments in industry, university, or foundation research; (3) Obtaining the opinions, special knowledge, or skills of noted experts; (4) Enhancing the understanding of, and develop alternative solutions to, complex issues; (5) Researching and reviewing existing standards and developing new policies and procedures; (6) Developing policy strategies, implementing plans, and assisting in policy implementation; (7) Providing expert advice to senior leaders; (8) Providing administrative direction to contractor personnel.

6.4.3. Travel Plan Coordination

At the task order level, the Contractor shall arrange for travel of personnel (Contractor, Non-Military,

Non-Governmental personnel (i.e. collaborator)) when the task order requires and identifies specific travel requirements. Travel may be CONUS, OCONUS, or local. The Contractor shall provide for all necessary travel documents and approvals, immunization support, and safety plans that may be required for some destinations. The Contractor will provide a comprehensive travel estimate to be approved by the COR prior commencing travel arrangements. The estimate must be provided to the COR 90 days before travel or COR directs travel inside that window, then within 3 days of Government directing travel. The Contractor must provide an invoice for travel expenses and copies of receipts. All travel shall be in accordance with the Joint Travel Regulation (JTR).

6.4.4. Translation Services

The Contractor shall provide translation services to and from English to singularly Georgian, Russian, German, Bulgarian, Estonian, Latvian, Polish languages, and other languages when the task order requires and identifies specific translation needs for written documents, audio conferences, and/or face to face meetings. The Contractor shall be prepared to provide translation services, in the language(s) and timelines specified in individual task orders, to facilitate communications.

6.4.5. Personnel Support Services

The Contractor shall prepare and adhere to a Human Resources Support Plan (HRSP) as a basis of all task orders. **The draft HRSP will initially be submitted with the Offeror's proposal (Deliverable 3)** and shall be updated NLT 30 days after award. The HRSP shall document how the Contractor shall meet and comply with the human resources requirements established in the IDIQ performance work statement. At a minimum, the HRSP shall include a self-inspection plan, an internal staffing plan, a training plan, and an outline of the procedures that the Contractor shall use to provide the required human resources support, maintain quality, timeliness, responsiveness, customer satisfaction, and any other performance requirements set forth in this solicitation.

The Contractor shall provide personnel support services in accordance with its HRSP. The Contractor shall recruit personnel in accordance with host nation laws and regulations. The Contractor is required to provide the full spectrum of necessary human resources support services to include, but not limited to, payment of wages, execution of any agreed upon incentive or benefits programs, performance evaluation plans, terminations of employment, training, etc. The Contractor shall provide timely and accurate payment of personnel wages in the host nation currency. Upon acceptance, the HRSP shall form the basis of a Human Resources Standard Operating Procedure (SOP) for all task orders.

6.4.5.1. Training Requirements

The Contractor shall develop, maintain and operate in accordance with its training program. The Contractor shall insure all Contractor personnel complete all training required by WRAIR, USAMRMC, and Army. The Contractor shall document training completion per individual and per clinical research in accordance with FDA requirements. Training requirements shall be identified on each task order. The Contractor shall provide evidence of their training program and evidence of individual training completion upon request.

Such training provided by the USAMRD-G includes, but is not limited to:

- Anti-Terrorism Force Protection training – Within 90 days of start date
- Operations Security (OPSEC) training – Within 90 days of start date
- Environmental Awareness Training
- Insurance Portability and Accountability Act (HIPAA) training
- Information Assurance training
- Local Safety Brief
- International Air Transport Association (IATA) training
- Fire Prevention/Emergency Response (annually)

Hazardous material response training depending on individual job specialty, additional training may be required. Lab personnel shall have additional training specific to work in the lab (lab safety, blood borne pathogens, chemical safety etc.) but those are specific based on the task. The following identifies the minimum required training:

- The Personal Protective Equipment (PPE) required
- General safety requirements particular to the operation
- Risk mitigation techniques and controls
- Special safety requirements
- Lessons learned from previous operations
- Procedures for reporting and responding to accidents
- Identification of all known and perceived hazards

Although not anticipated, specialty training may be required that cannot be provided by the USAMRD-G. In this case, it would be identified at the task order level and the contractor would be required to obtain and document completion.

6.4.6. Logistic Support

The contractor shall provide logistics support to the USAMRD-G in obtaining: Materials, biologics, supplies and equipment; biomedical maintenance and repair; facilities management; shipment of biologics, supplies and equipment; operation and maintenance of transportation assets for the movement of biologics, supplies, equipment, and personnel essential to the mission in a cost effective and timely manner. The task orders shall identify specific requirements.

The Contractor shall prepare and adhere to its Logistics Support Plan (LSP) which shall be in effect for every awarded task order. **The draft LSP will initially be submitted with the Offeror's proposal (Deliverable 4)** and shall be updated NLT 30 days after award. The LSP shall document how the Contractor shall meet and comply with the logistics requirements established in the IDIQ. At a minimum, the LSP shall include: A plan for inventory and materiel support, biomedical maintenance support, and transportation support, a self-inspection plan, an internal staffing plan, and an outline of the procedures that the Contractor shall use to provide the required logistics support, maintain quality, timeliness, responsiveness, customer satisfaction, and any other performance requirements set forth in this solicitation. Upon acceptance of the draft LSP, it shall form the basis of a Logistics Standard Operating Procedure (SOP).

6.4.6.1. Ordering and Receiving Support

When specified as a task order requirement, the Contractor shall provide ordering and receiving services in accordance with Army Regulations and in consonance with WRAIR Logistics policies and procedures. Equipment shall be accounted for in accordance with Army Property Accountability Systems and Regulations. Inventories of consumables shall be accounted for in accordance with Army Regulations.

6.4.6.2. Biomedical Maintenance and Repair

When specified as a task order requirement, the Contractor shall repair, maintain, and document the maintenance history of biomedical equipment. Biomedical support shall be conducted in accordance with Army Regulations to include: Maintenance history, work orders documentation, repair parts ordering, equipment downtime reporting, and documenting economic value of equipment. The Contractor shall provide a history equipment maintenance and replacement recommendation to the COR. Approval for supply and equipment purchases shall be requested in writing. A written approval from the COR for consumables with an aggregate price greater than the micro-purchase threshold defined in FAR Part 2 is required. Written approval of equipment requests, with a unit price greater

than the micro-purchase threshold defined in FAR Part 2, must be obtained from the Contracting Officer prior to purchase.

6.4.6.3. Shipment of Biologics, Supplies, and Equipment

When specified as a task order requirement, the contractor shall provide shipment of biologics, supplies and equipment, locally or worldwide, in accordance with International Air Shipment rules, Host Country laws and regulations, and Army policies and procedures. The Contractor shall use appropriate, cGMP-compliant refrigerated shipping carriers for drug product shipments (FedEx, World Courier, or similar, as agreed to by the COR), and appropriate shipping methods for all other materials, equipment, and hard copy documents. The COR must approve the selected shipping method and any exceptions to these requirements.

6.4.6.4. Optional Task

The Contractor shall provide facilities maintenance and management tasks to ensure occupant safety, structural safety, the facility's accreditation is maintained, and mission requirements are met. The Contractor shall maintain the facilities/buildings and all associated Real Property Installed Equipment (RPIE) by providing labor and material to support Emergency Maintenance, Preventative Maintenance Programs, Operations of Facilities/Buildings and Utilities, support for outages of the utility systems, and Service Orders at the Lugar Center in accordance with both Georgian laws, codes and regulations and US installation Federal codes, laws, and regulations. Facility operations differs from preventive maintenance in that activities are included that go beyond the preventive maintenance tasks and are required for the operation of the facility. Facilities operations involve monitoring, analysis, judgment, and performing adjustments to maintain requirements.

Facility Operations: Mechanical Room maintenance. All space designated as mechanical, electrical, plenum, basement, balconies and wall hang-up units, underground vault, interstitial, attic, roof/roof top or otherwise related to the housing of mechanical, electrical RPIE components shall be maintained in a clean, safe and professional appearance. The contractor shall be responsible for custodial services in these spaces.

6.4.6.4.1. **Facility Operations: Facility Inspection Rounds.**

The contractor shall be responsible to conduct rounds of the facility/buildings. An annual Infrared/Thermal Imaging scan and associated analysis of all electrical components and building envelop will be performed. This activity is to observe all spaces and record any previously unknown facility deficiencies. Attention will be given to run-to failure equipment and heating and cooling equipment not requiring daily preventive maintenance.

6.4.6.4.2. **Facility Operations: Building Operation System.**

The contractor shall be trained and proficient in the use of the facility building operating system that controls the HVAC, lighting, room pressure, fire alarms, public address system, and other features. The contractor shall keep the system current will all system updates released by the manufacturer. The contractor shall retain a backup copy of the facility settings off site, in the event of a system failure, the setting can be reloaded.

6.4.6.4.3. **Facility Operations: Work Reception.**

The provided examples generally indicate the criticality or complexity of issues that would fall under each priority, but the list is not intended to be a complete list of all work that might be

required under a given priority. Questions regarding work classification shall be addressed to the Logistics Director/Facility Manager. Response times shall be as defined in the task order.

6.4.6.4.4. **Defense Medical Logistics Standard Support (DMLSS).**

The contractor shall ensure the (DMLSS) database is updated and current to include all data inputs for work requests, preventative maintenance, and new work. This shall include all labor and materials as well as updating the equipment database. Currently no DMLSS database system in place. The contractor will ensure required data is provided to WRAIR Logistics each month to update DMLSS data. The contractor shall ensure that all electronic and/or hard copy drawings of the facility and its utilities are current.

6.4.6.4.5. **Exterior Building Inspection.**

A semiannual exterior building inspection shall be performed, with a PM task entered and documented in DMLSS, during which the Contractor shall survey and document the condition of the complete building exterior envelope (painting, concrete panels, concrete slabs and foundation, parking, storm drainage, lightning protection, exterior windows and framing, signage, roof and roof support, woodwork, etc.). In addition to documenting the required repairs in the DMLSS system, the Contractor shall submit a report to the Logistics Manager upon completion of the survey.

6.4.6.4.6. **Interior Building Inspection.**

A semiannual interior building inspection shall be performed to document the condition of all interior elements of the building (painting, floors, walls, ceilings, windows and doors, stairwell, signage, handrails, etc.), with a PM task entered and documented in DMLSS. In addition to documenting the required repairs in the DMLSS system, the Contractor shall submit a report to the Facility Manager upon completion of the survey. The interior building inspection report shall include a proposed painting schedule.

6.4.6.4.7. **Monthly Report.**

A monthly report shall be provided to the Logistics Manager, consolidating the reports and also providing analysis and trends on equipment wear and tear, utility usage, and those items which require replacement or are expected to require replacement before the end of the next reporting period (i.e., items in a failed or failing condition)

6.4.6.4.8. **Alarm History Report.**
The Contractor shall provide the Government an Alarm History Report upon request so the Government is able to produce forensics on conditions in the facility or upon failure of systems.

6.4.6.4.9. **Environmental Maintenance.**

The Contractor must maintain environmental conditions in animal holding areas IAW the parameters provided by Government based on the type studies being conducted.

6.4.6.4.10. **Emergency Disaster Support.**

The Contractor shall establish, implement, and maintain an Emergency Disaster Support plan to be followed immediately following serious inclement weather, flood, earthquakes, tornadoes, etc. for building inspection. The contractor shall provide the initial structural assessment of the facilities, i.e. roof inspection, unless the building is structurally unsound.

6.4.6.4.11. **Firewall and Ceiling Penetration Support.**

At sites that currently have a firewall and ceiling penetration program, the Contractor will assume responsibility for the maintenance and execution of the program. Duties may include but not be limited to training other contractors on the requirements, administering and maintaining records of written tests, authorizing firestop/ceiling penetration permits, verifying the use of acceptable firestop material and proper application, verifying proper containment procedures were followed, and maintaining records of authorized firestop/ceiling penetrations. At sites without an existing firewall and ceiling penetration program, the contractor is responsible for creating and administering the program. Examples of firewall and ceiling penetration programs are available from the Government.

6.4.6.4.12. **Meeting Attendance.**

Attendance by the maintenance superintendent may be required at pre- construction and work plan or design coordination meetings in order to coordinate work to be performed by other contractors in facilities/buildings that are maintained under this task order.

6.4.6.4.13. **Verification of Work Request Response/Completion Times.**

The Contractor will have the requester (or in the absence of the requester another person with knowledge of the service requirement) verify by printed name and signature on the work request, that the work was performed and the time and date the work was completed.

6.5. Management Reports and Plans

6.5.1. Management Plan (Deliverable 4).

The Contractor shall provide a draft Management Plan that includes detailed staffing plans and the Offeror's approach to controlling, coordinating, and directing performance, as well as organizing and managing resources in order to achieve technical/scientific requirements. The Management Plan shall detail the Offeror's approach to selecting, directing, and managing subcontractors. The Management Plan shall describe howthe Offeror will communicate with subcontractors and ensure that performance is at the level required to ensure timely and effective contract execution. The Management plan shall detail how the Offeror will comply with requirements to obtain pre-approval of subcontractors and clearly identify the primary role of the subcontractor(s). The Management Plan shall explain the Offeror's approach to recruiting, selecting, hiring, and managing employees having an exclusive OCONUS duty location. **The Management Plan shall initially be submitted with the Offeror's proposal** and will be updated within 15 days after contract award.

6.5.2. Monthly Status Report (Deliverable 6).

The contractor shall provide a monthly report detailing all work, including the subcontractor's work, and where there is critical or significant data related to the provided support. The report shall include a detailed list of all hours worked and workload accomplished, to include but not limited to, a list of equipment serviced and writing assignments in support of all tasks.
Reporting requirements include but are not limited to the PI's, Associate Principle Investigators, technicians and specialist staff will meet 90% of established performance standard milestones in any given month in the areas of:

a. SOP/ study specific protocol/ and risk assessment development
b. Knowledge product development and translation (e.g., abstracts, SPOT reports, manuscripts)
c. Study specific documentation (e.g., research protocols, amendments, continuing review documents, federal wide assurance completion, and other documents as required by regulatory oversight bodies)
d. Biological specimen inventory targets (but must be 100% compliant by directed suspense date)

e. Funding obligation rates by line of effort (is protocol specific funding on glidepath with established spend plan)
f. Study sample, specimen, or participant enrollment numbers IAW stakeholder expectations (is the study meeting projected enrollment targets, if not- what remediation efforts are ongoing to meet with stakeholder and notification of enrollment as a percentage of projected milestone.

Monthly reporting will be used to evaluate contract cost, schedule and performance and will be used to communicate contractor performance in contract reporting systems (PIIE).

The contractor shall submit the report (including raw individual reports from research line of effort leads) with a transmittal letter that highlights major events in the reporting period. The report will be sorted by the task order number and scientific line of effort (e.g., Enterics, ARI, MDRO, STI, AFI, Vector, Phage). The report shall include details outlining the expenditures and billings to date, projected expenditures and billings, progress, status, and any problems/issues encountered. The contractor shall require and incorporate input from subcontractors as specified above and where there are critical or significant tasks related to the prime contract. Critical or significant tasks shall be defined by mutual agreement between the Government and contractor. The format for the report shall be agreed upon by the Government and contractor. Additional reporting requirements will be identified at the task order level.

6.5.3. Quality Control Plan (Deliverable 7).
The contractor shall provide a draft Quality Control Plan (QCP) no later than (NLT) 15 days after contract award. The contractor shall prepare and adhere to a QCP describing how the contractor intends to manage the contract to achieve the established standards set forth in the Performance Standards Summary Matrix and the contractor's QCP. At a minimum, the QCP must include a self-inspection plan, an internal staffing plan, and an outline of the procedures that the Contractor will use to maintain quality, timeliness, responsiveness, customer satisfaction, and any other requirements set forth in this solicitation. The QCP shall initially be submitted with the Offeror's proposal and will be updated after contract award.

6.5.4. Service Contract Reporting Application (SCRA) (Deliverable 8).
The contractor shall report ALL contractor labor hours (including subcontractor labor hours) required for performance of services provided under this contract for the via a secure data collection site. The contractor is required to completely fill in all required data fields using the following web address: https://www.sam.gov starting at the end of FY20, ECMRA has been decommissioned effective June 19, 2020.

Reporting inputs will be for the labor executed during the period of performance during each Government fiscal year (FY), which runs October 1 through September 30. While inputs may be reported any time during the FY, all data shall be reported no later than October 31 of each calendar year, beginning with 2013. Contractors may direct questions to the help desk at: https://www.sam.gov starting at the end of FY20, ECMRA has been decommissioned effective June 19, 2020.

The contractor shall register under the "All Other Defense Components" module. The WRAIR Unit Identification Code (UIC) is W03KAA.

*The Office of the Secretary of Defense has issued a Memorandum dated 16 October 2019 which removes the requirement for contractors to report manpower data into the eCMRA system at https://www.ecmra.mil, beginning 1 Oct 2019. It is anticipated, however, that contractors shall be required to report similar manpower data to https://www.sam.gov beginning sometime within the next year. Currently, there is no reporting requirement or transition plan but the contractor shall perform the documentation/tracking required demonstrating an understanding **that manpower data reporting shall be required for the performance of this contract.***

6.5.5. Contractor Performance Assessment Reporting System (CPARS).
A CPAR assesses a contractor's performance and provides a record, both positive and negative, on a given contractor during a specific period of time. Each assessment is based on objective facts and

supported by program and contract management data, such as cost performance reports, customer comments, quality reviews, technical interchange meetings, financial solvency assessments, construction/production management reviews, contractor operations reviews, functional performance evaluations, and earned contract incentives. Performance evaluations are transmitted into the Past Performance Information Retrieval System (PPIRS) which is used by government agencies to assess contractor past performance for future acquisitions.

The contractor shall appoint a Contractor Representative (CR) and provide this information to the Contracting Officer (KO) within 10 calendar days of award. The contractor POC shall have the authority to comment on the CPAR assessment on behalf of their company and within the timeframes established.

A CPARS assessment must be completed within 120 calendar days after the evaluation. Evaluations are sent to PPIRS within 14 calendar days after the government Assessing Official (AO) has submitted the rating. If the CR has not concurred/non- concurred with the rating, PPIRS will show the government evaluation as "Contractor Comment Pending Review". The CR has a total of 60 calendar days to concur/non- concur with the assessment. After 60 days, the CR can either concur/non-concur **(Deliverable 9)**. The CR has the authority to: access the Government evaluation; review/comment/concur or non-concur with the assessment within 60 calendar days after notification of the government's assessment. The CR has the right to request a meeting (in writing) with the government within 7 calendar days of notification of an assessment. Once the government and the CR complete the evaluation; an automatic update will be sent to PPIRS and visible for Source Selection. If the CR fails to respond within 60 days, the assessment will be finalized. Training for CPARS can be found on the CPARS website: https://www.cpars.gov/index.htm.

To access CPARS, the contractor must have a Public Key Infrastructure (PKI). It is suggested an ECA certificate of Medium Assurance should be purchased. This should be a Department of Defense identity certificate, not an e-mail certificate.

7. DELIVERABLES

The contractor shall complete and submit deliverables in accordance with the “Deliverables Table” below. Unless specified in the PWS within the description of the deliverable, all deliverables will be made to the COR electronically.

DELIVERABLES TABLE

PWS Ref.	Number	Title/Description	Due
5.5.	Deliverable 1	Contingency Plan	10 days after contract award/ Updated Quarterly
6.4.1.1.	Deliverable 2	Operational Support Plan	
6.3.5.	Deliverable 2	Human Resources Support Plan	30 days after contract award/ Updated Annually
6.3.6.	Deliverable 3	Logistics Support Plan	30 days after contract award/ Updated Annually
6.4.1.	Deliverable 4	Management Plan	15 days after contract award
6.4.2.	Deliverable 5	**Monthly Status Report**	5th day of each month
6.4.3.	Deliverable 6	**Quality Control Plan**	NLT 15 days after contract award
6.4.4.	Deliverable 7	**Service Contract Reporting Application** The contractor shall complete and deliver the CMRA.	By October 31 or on the last day of contract performance – whichever

			is first
6.4.5.	Deliverable 8	**CPAR Concurrence/Non-concurrence** The contractor shall provide concurrence or non-concurrence with the CPARS assessment.	60 calendar days after Government evaluation
9.2.	Deliverable 9	**Summarized Final Report**	To be submitted along with Transition-Out Plan/Update as needed
11.2	Deliverable 10	**Trip Report**	NLT 30 days following trip completion
12	Deliverable 11	**Inventory detailing Government Furnished Equipment/Material or Contractor-Acquired-Government Owned Property (CAP)** To be attached to the Monthly Progress Report	Per Task Order- 15th day of each month for the preceding month

7.1. Technical Reports and Documents

Technical reports and documents delivered by the contractor in the performance of this contract shall be considered Technical Data and documents delivered by the contractor in the performance of this contract shall be considered Technical Data as defined in the applicable DFAR clause 252.227-7013, Rights in Technical Data-Noncommercial Items. All documentation shall reflect the latest version of the work product or activity, unless specifically directed otherwise by the Government. All documentation shall be prepared in accordance with (IAW) standard industry practices, ensuring electronically produced documents which reflect logical flow of material, tables of contents indexes and page numbering. Where applicable, the contractor's attention is called to the availability of commercial, industry, federal, and military guides, instructions, and standards for many of the topics addressed in this PWS and under this contract.

7.2. Inspection and Acceptance

The COR delegated oversight of specific technical, functional and oversight responsiblities is responsible for inspection and acceptance of all services, incoming shipments, documents, and services.

Certification by the Government of satisfactory services provided is contingent upon the Contractor performing in accordance with the performance standards contained in the Performance Work Statement and all terms and conditions of this order, including all modifications.

7.3. COR Information

The COR will be identified by a separate letter. The COR monitors all technical aspects of the contract and assists in contract administration. The COR is authorized to perform the following functions:

- Assure that the Contractor performs the technical requirements of the contract
- Perform inspections necessary in accordance with the PWS and the Quality Assurance Surveillance Plan (QASP)
- Maintain written and oral communications with the Contractor concerning technical aspects of the contract
- Issue written interpretations of technical requirements, including Government drawings, designs, specifications
- Monitor Contractor's performance and notify both the Contracting Officer and Contractor of any deficiencies
- Coordinate availability of Government Furnished Property and Equipment (GFE), and

- Provide site entry of Contractor personnel
- Enter monthly reports of contractor performance in the PIEE/WAWF database to characterize contractor performance within cost, schedule and performance domains.

A letter of designation issued to the COR, a copy of which is sent to the Contractor, states the responsibilities and limitations of the COR, especially with regard to changes in cost or price, estimates or changes in delivery dates. The COR is not authorized to change any of the terms and conditions of the resulting order.

8. PERFORMANCE REQUIREMENTS SUMMARY MATRIX

The Government intends to utilize a Quality Assurance Surveillance Plan (QASP) to monitor the quality of the Contractor's performance in relation to performance objectives. The Government will finalize the QASP immediately following award, and the COR will provide a copy of the final QASP to the contractor. The QASP is a living document and may be updated by the Government as necessary.

The Government will use the following performance requirements to measure the performance of the contractor. The contractor shall meet the Performance Objective(s) and Acceptable Quality Level(s) within the "Performance Requirements Summary Matrix" (PRS Matrix).

Performance Requirements Summary Matrix

A Performance Requirements Summary Matrix may or may not be included at the Task Order level to further define acceptable quality specific to the task order.

9. TRANSITION SUPPORT

When applicable, the Contractor shall provide transition support services for transitioning work from a Government entity or from an active contract to a follow-on contract/order or to a Government entity. A draft Transition Plan shall be submitted with the proposal for a 60-day transition period and will be updated within 15 DACA. Transition Plans may be required at the task order level. When required, Contractor shall ensure a transition approach for both a phase-in and phase-out transition of the task order. The Contractor shall include formal coordination with Government and successor staff. The Contractor shall conduct planning, coordination, and implementation of a successful transition in accordance with the approved Transition Plan for each awarded task order and for the IDIQ award, as appropriate.

9.1. Incoming Transition Plan

In accordance with the individual task orders under this contract, the Government may direct the Contractor to separately price items for a draft plan for incoming transition. When ordered, the Contractor shall coordinate with the Government in planning and implementing a complete transition to the Contractor's support model. The Contractor shall collaborate with the Government to develop and deliver a Transition Plan. The Incoming Transition Plan shall include, but is not limited to:

a. Coordination with Government representatives,
b. Review, evaluation and transition of current support services,
c. Transition of historic data to new Contractor system,
d. Government-approved training and certification process,
e. Transfer of hardware warranties and software licenses,
f. Transfer of all System/Tool documentation to include, at a minimum: user manuals, system administration manuals, training materials, disaster recovery manual, requirements traceability matrix, configuration control documents and all other documents required to operate, maintain and administer systems and tools,
g. Transfer of compiled and uncompiled source code, to include all versions, maintenance updates and patches,

h. Orientation phase and program to introduce Government personnel, programs, and users to the Contractor's team, tools, methodologies, and business processes,
i. Distribution of Contractor purchased Government owned assets, including facilities, equipment, furniture, phone lines, computer equipment, etc.,
j. Transfer of Government Furnished Equipment (GFE) and Government Furnished Information (GFI), and GFE inventory management assistance,
k. Applicable WRAIR briefing and personnel in-processing procedures,
l. Coordinate with the Government to account for government keys, ID/access cards, and security codes.

9.2. Outgoing Transition Plan

In accordance with the individual task orders under this contract, the Government may direct the Contractor to separately price item for a draft plan for transitioning work and/or leased facilities from an active contract or task order to a follow-on contract. (Note that the transition may be to a Government entity, another Contractor or to the incumbent contractor under a new contract vehicle). In accordance with the Government approved plan, the Contractor shall assist the Government in planning and implementing a complete transition from this contract to the follow- on provider. This Outgoing Transition Plan shall be on a task order level and delivered prior to the end of the task order base period and updated prior to the end of each task option period as directed by the Government in each task order. The Outgoing Transition Plan shall include, but is not limited to:

a. Coordination with Government representatives,
b. Review, evaluation and transition of current support services,
c. Transition of historic data to new Contractor system,
d. Government-approved training and certification process,
e. Transfer of hardware warranties and software licenses (if applicable),
f. Transfer of all necessary business and/or technical documentation,
g. Transfer of compiled and uncompiled source code, to include all versions, maintenance updates and patches (if applicable),
h. Orientation phase and program to introduce Government personnel, programs, and users to the Contractor's team, tools, methodologies, and business processes,
i. Disposition of Contractor purchased Government owned assets, including facilities, equipment, furniture, phone lines, computer equipment, etc.,
j. Transfer of Government Furnished Equipment (GFE) and Government Furnished Information (GFI), and GFE inventory management assistance.
k. Applicable WRAIR debriefing and personnel out-processing procedures.
l. Turn-in of all government keys, ID/access cards, and security codes.
Summarized final report **(Deliverable 9)**

10. KEY PERSONNEL

Substitutions of proposed Key Personnel shall not be allowed for a period of six months after award, except under extreme circumstances. Any substitution or replacement Key Personnel shall have qualification equal to or greater than the individuals proposed. For temporary and/or permanent replacement of Key Personnel, the Contractor shall provide a resume for each individual to the COR. Resumes shall be provided at least two weeks (or as mutually agreed upon) prior to making any personnel changes. The Government reserves the right to pre-approve any replacement or substitution of Key Personnel. Contractor personnel must submit necessary information to be issued a clearance prior to reporting for performance. Key Personnel will be identified at the task order level.

The contractor shall provide Key Personnel in accordance with the minimum requirements listed within the Key Personnel table.

Substitutions of proposed Key Personnel shall not be allowed for a period of six months after award, except under extreme circumstances. Any substitution or replacement Key Personnel shall have the necessary experience and knowledge required to perform the duties defined herein. For temporary and/or permanent replacement of Key

Personnel, the Contractor shall provide a resume for each individual to the COR. Resumes shall be provided at least two weeks (or as mutually agreed upon) prior to making any personnel changes. The contractor agrees that during the contract performance period substitution for Key Personnel shall not be permitted unless such substitution is necessitated by sudden illness, death, or change in employment conditions (e.g. termination, change in position, etc.). In any of these events, the contractor shall promptly notify the KO in writing and provide the information required below.

All requests for substitutions must provide a detailed explanation of the circumstances necessitating the proposed substitution(s), a complete resume for the proposed substitute(s), and any other information requested by the KO needed to approve or disapprove the proposed substitution(s). Any proposed substitute or replacement key personnel shall have qualifications comparable to the individual being replaced, taking into account the requirements of the PWS. The KO or his authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

If any of the listed Key Personnel are subcontractor personnel, the contractor shall flow down the substance of this instruction in any subcontract which is awarded in support of this contract.

The Government reserves the right to pre-approve any replacement or substitution of Key Personnel. Contractor personnel must submit necessary information to be issued a clearance prior to reporting for performance. Substitution or replacement personnel shall be replaced with 30 days.

Contractor personnel that are evaluated in a source selection process and that may be required to be used in the performance of a contract by the Key Personnel listed in the PWS. When key personnel are used as an evaluation factor in best value procurement, an offer can be rejected if it does not have a firm commitment from the persons that are listed in the proposal.

TRAVEL/TEMPOARY DUTY (TDY)-

The COR is the CONUS travel order approval authority as designated in writing by the KO. All CONUS travel requirements (including plans, agenda, itinerary, or dates) shall be pre-approved by the COR and is on a strictly cost reimbursable basis. The Contractor shall be authorized travel expenses consistent with the substantive provisions of the JTR and the limitation of funds specified in this contract. Costs for travel shall be billed in accordance with the regulatory implementation of Public Law 99-234 and FAR 31.205-46 Travel Costs, subject to local policy and procedures.

10.1. Travel Arrangements

Arrangements for and costs of all travel, transportation, meals, lodging, and incidentals are the responsibility of the Contractor. The Contractor shall remain current on applicable regulations, policies, and procedures that may impact processes for travel and modify their processes accordingly. No later than 30 calendar days prior to scheduled CONUS travel date, the Contractor will prepare the estimate in an official memorandum format. The estimate shall include airline ticket costs, car rental, per diem, registration fees and any other allowable costs associated with the travel request. All travel and transportation shall utilize commercial sources and carriers provided the method used for the appropriate geographical area that results in reasonable charges to the government. The Government will not pay for economy plus, business class or first-class travel. The COR will provide the Contractor a signed approval of Government Contractor Official Travel Letter of Identification before the Contractor is authorized to travel either CONUS or OCONUS. Estimated travel is indicated below:

Period	From	To	Round Trip (Y/N)	# of Trips	# of People	# of Days
Base						

10.2. Travel Claim Procedures, Approval, and Reimbursement

Travel shall be reimbursed after the KO has determined fair and reasonable cost reimbursement IAW the JTR and FAR Part 31.205-46. The Contractor shall submit an estimate for travel to COR no later than 30 calendar days prior to the first day of travel; in order for the Contractor to obtain economical travel arrangement and cost. The contractor shall provide a Trip Report **(Deliverable 10)** following each trip.

The COR will verify the travel receipts are valid and match the travel requirements identified in the PWS. The Contractor shall provide a trip report to include costs associated with the travel to the COR within ten (10) calendar days after the completion of travel trip. All travel costs shall be billed within 30 days after travel is complete unless an approval for later billing is approved by COR or KO. All travel cost reimbursement requests must detail all authorized expenses associated with the travel and all receipts including ticket stubs (booked airline, hotel receipts, etc.) shall be provided to substantiate claims for costs of all expense items in excess of $75.00.

10.3. DOD Contractor Foreign Travel / OCONUS

Approval of Foreign Travel. Foreign travel under this contract is defined as any travel outside of the continental United States and its territories and possessions. The cost of foreign travel is allowable only when specific written approval of the Contracting Officer is obtained prior to the commencement of the travel. This is a requirement for all DoD contractors traveling on official DoD business.

10.3.1. The following requirements will be accomplished by the contractor(s) prior to foreign travel on approval of the Contracting Officer. Allow 90 days for completion of training requirements and approval of the application process. Detailed information can be found on the U.S. Army Medical Research and Development Command (USAMRDC) website: https://mrdc.amedd.army.mil/index.cfm/resources/mrdc_resources/oconus. Select all the links under "Contractor Travel Requirements" and comply with the instructions. Consult the DoD Foreign Clearance Guide https://www.fcg.pentagon.mil

10.3.2. Mandatory training and minimum requirements must be met and a copy provided to the contracting officer 15 days prior to scheduled departure.

10.3.3. Costs incurred by contractor personnel on official company business, whether foreign travel and/or domestic/local travel, are allowable subject to the limitations in the Federal Acquisition Regulation (FAR clause 52.216 - 7 Allowable Cost and Payment); incorporated into this contract

10.3.4. MANDATORY TRAINING – OFFICIAL GOVERNMENT TRAVEL

a) Anti-Terrorism Level 1 (valid for one year)
b) SERE 100 (valid for two years)
c) PRO - File
d) Human Rights, SOUTHCOM travel only (valid for one year)
e) US Forces Korea, Korea travel only (valid for one year
f) Area of responsibility briefing completed within three months of travel.
g) PACOM travel; verification that PACOM's Travel Tracker/Individual Antiterrorism Plan (TT/IATP) has been completed
h) AFRICOM travel; verification that AFRICOM'S Theater Information Management System (TIMS) or Statement of Preparedness Document (when TIMS is not available), has been completed.
i) USFK Form 700-19A-R-E
j) US-ROK SOFA IAW FAR 25.8 and USFK Regulation 700-19.

10.3.5. TRAINING LINKS

Anti-Terrorism Level 1-https://atlevel1.dtic.mil/at/.
SERE 100 -https://jko.ifcom.mil
PRO-File –https://prmsglobal.prms.af.mil/prmsconv/profile/survey/survey.aspx
Human Rights -https://www.americasnet.org.

US Forces Korea -https://www.usfk.mil

11. GOVERNMENT FURNISHED PROPERTY

The Contractor shall identify, in their proposal for each task order, any Government Furnished Equipment/Information or Contractor-acquired-Government Owned property (CAP), necessary to perform each order to the extent such property requirements are known at the time of proposal. Detailed Bills of Materials shall be submitted along with each proposal; noting part numbers, prices, and need dates for all required GFE. Automated and IT equipment shall not be purchased as CAP. All equipment (non-consumables) purchases require the express approval from the Contracting Officer prior to purchase.

Government Furnished Property includes: WRAIR network laptops and docking stations, and mobile devices for support personnel onsite and laptops and mobile devices for support personnel offsite. Government provided Laptops will be profiled for WRAIR network access, will be CAC enabled, and will have VPN access.

Equipment issued at time of contract award will be annotated in a separate document.

Government Furnished Information/System Access includes: WRAIR Network access to the shared drives as required; and the SharePoint collaboration site. The Government will provide any and all current local templates, SOPs, and policies.

In accordance with FAR 45.102 and DFARS PGI 245.103-70, the Contracting Officer shall ensure that each of the requirements of FAR 45.102 are addressed and documented in the contracting file.

The Contractor shall maintain a detailed inventory accounting system for Government Furnished Equipment/Material or Contractor-Acquired-Government Owned Property (CAP). **(Deliverable 11)** The inventory accounting system must specify, as a minimum: product description (make, model), Government tag number, date of receipt, name of recipient, location of receipt, current location, purchase cost (if CAP), and contract/order number under which the equipment is being used. The Contractor shall attach an update inventory report to each Monthly Progress Report (Deliverable XX) by the 15th of each month for the preceding month. The Contractor's inventory listing must be available for Government review within one business day of COR request.

11.1. Return of Government Furnished Equipment

The contractor shall return CACs, WRAIR Picture ID Card, keys, and key fobs for employees no longer supporting the contract and/or on contract expiration. Specifically, the contractor shall, within two business days of employee no longer supporting the contract and/or on contract expiration, return:

a) CACs to WRAIR Security office;
b) WAIR Picture ID Card to WRAIR Security office;
c) Keys to the WRAIR key custodian; and
d) Key Fobs to the WRAIR key custodian.

If the contractor does not returned items a-d within 2 business days, the COR will provide a Contract Deficiency Report (CDR) to the KO.

12. CONTRACT MANAGEMENT

12.1. Government Management

The Contracting Officer's Representative (COR) for this contract will be appointed by the Contracting Officer (KO). The COR will serve as the primary point of contact for all activities and issues that occur under this contract. Only the KO has the authority to enact changes to this award.

12.2. Contractor Management

The contractor shall provide a corporate contract manager who shall be responsible for the performance of the work. The name of this person and an alternate, who shall act for the contractor when the manager is absent, shall be designated in writing to the contracting officer. The contract manager, or alternate, shall have full authority to act for the contractor on all contract matters relating to daily operation of this contract. The contract manager or alternate shall be available between 1000 and 1700 GET (Georgia Standard Time), Monday through Friday except Federal holidays Contractor or when the government facility is closed for administrative reasons.

For each individual task/delivery order issued under this contract, the Contractor shall: Sign and submit the designated Participation Agreement (Section J) on behalf of the company; ensure that all staff assigned to or performing on each task/delivery order execute and adhere to the terms of the Participation Agreement, including all subcontractors and consultants; protect the procurement sensitive information of the Government and the proprietary information of other contractors. Assignment of staff who have not executed this statement or failure to adhere to this statement may constitute default on the part of the.

12.3. Contractor Organization

The contractor shall establish clear organizational lines of authority and responsibility to ensure effective management of the resources assigned to the requirement. The contractor shall ensure that all contractor personnel are advised of their chain of command and who they should contact if they have questions.

12.4. Contractor Vacant Positions

The contractor shall fill vacant positions within thirty (30) business days. If contractor positions are vacant for more than thirty (30) days, the COR will provide a Contract Deficiency Report (CDR) to the KO.

12.5. Subcontract management

12.5.1. The contractor is responsible for any subcontract management necessary to integrate services performed on this contract.

12.5.2. The contractor is responsible and accountable for subcontractor performance on this contract.

12.5.3. The contractor is responsible to manage task distribution to ensure there are no OCI considerations.

12.5.4. Contractor may add subcontractors to their team after notification and written approval from the KO.

12.5.5. Privy of contract is with the contractor and the subcontractor.

12.6. Foreign Nationals

Total performance of this award shall be conducted outside of the contiguous U.S. and its territories. It is expected that the Contractor shall recruit from both internationally and within the host country as appropriate to obtain the required skill sets. The Contractor shall have and maintain a business license to perform in accordance with the host country laws and regulations. Contractor employees under this contract shall be compensated in host country currency and in accordance with host country laws.

All contractor personnel shall be capable of communicating, orally and in writing, in English. The level of English requirement is established per each labor category and in accordance with Common European Framework of Reference for Languages: Learning, Teaching, Assessment (http://www.coe.int/t/dg4/linguistic/Source/Framework_EN.pdf).

13. COMPLIANCE DOCUMENTS

13.1. General Compliance

13.1.1. *Federal Law*

The services provided under this contract must be conducted in accordance with all Federal law, Department of Defense (DOD), Department of the Army (DA) and Medical Research and Development Command (USAMRDC) laws and command laws, regulations, policies, and procedures that govern the conduct of regulated research.

Federal regulations governing regulations for human subject's protection are found in 45 CFR 46. The International Convention on Harmonization Guidelines for Good Clinical Practice is the standard governing the conduct of research trials. References for military regulations and policies governing regulated research may be found at https://MRDC.amedd.army.mil/rodorphrpo.asp.

13.1.2. Occupational *Safety and Health Administration*

The Contractor shall prepare and adhere to an Occupational Health and Safety plan which, for brevity, shall be called a Safety Program that shall provide the basis of Safety Support for every awarded task order. **The draft Occupational Health and Safety Plan shall initially be submitted with the Offeror's proposal** and shall be updated NLT 30 days after award. The contractor's Safety program shall include Conducting Training, Documenting, and Monitoring for Compliance, and shall be in consonance with USAMRMC Command Safety Priorities. Contractor shall comply with Occupational Safety and Health Administration (OSHA) http://www.osha.gov/ and all pertinent provisions of the publication 29 CFR 1910, and any other installation, state, or federal safety related regulations. These include but are not limited to the AR 385-10, MEDCOM 385-2, MRMC 385-1, and the WRAIR. The Safety Plan shall document how the Contractor shall meet and comply with the safety requirements in an OCONUS medical laboratory environment as established in this performance work statement. At a minimum, the Safety Plan shall include a self-inspection plan, an internal safety staffing plan, and an outline of the procedures that the Contractor shall use to provide the required safety support, timeliness, responsiveness, customer satisfaction while mitigating health and safety risks, and any other performance requirements set forth in this solicitation. Upon acceptance, the Safety Plan shall form the basis of a Safety Standard Operating Procedure (SOP).

13.1.3. *DoD Compliance Documents*

A complete list of Department of Defense compliance documents providing specifications, standards, or guidelines can be found at http://www.dtic.mil/whs/directives/corres/dir.html

a) Army Regulation 340-21, Army Privacy Program.
http://www.army.mil/usapa/epubs/340_Series_Collection_1.html

b) Army Regulation 25-1, Information Technology.
http://armyhpubs.army.mil/epubs/25_Series_Collection_1.html

c) Army Regulation 25-2, Information Assurance.

d) Department of Defense (DoD) Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, dated November 2011.
http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf

e) Department of Defense (DOD) 6025.18 Regulation, DOD Health Information Privacy Regulation, 24 January 2003.

f) DOD Instruction 3210.7, Research Integrity and Misconduct, 14 May 2004.

g) Department of Defense (DOD) Instruction 8500.01 Cybersecurity

h) Department of Defense (DOD) Instruction 8510.01 Risk Management Framework (RMF) For DOD Information Technology (IT Department of Defense (DoD) Instructions 5400.11-R, Privacy Program
http://www.dtic.mil/whs/directives/corres/pdf/540011p.pdf

i) Army Regulation (AR) 70-25: Use of Volunteers as Subjects of Research, Headquarters, Department of the Army, dated 25 January 1990 – currently under revision

j) Clinical Laboratory Improvement Amendments, 2013. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Regulations_and_Federal_Register_Documents.html. Specific guidance: http://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5

k) Clinical Laboratory Improvement Program (CLIP) Manual, May 29, 2014. http://www.dtic.mil/whs/directives/corres/pdf/64402m.pdf (this document is codified Title 42 Part 493 under Memorandum of Agreement between the US Department of Defense and Health and Human Services.

l) College of American Pathologists Inspection Checklists. http://www.cap.org

m) Clinical Laboratory Standards Institute. Standards and Guides for Laboratories: http://clsi.org/standards

n) Title 42 Part 493 Laboratory Requirements, 1 October 2011 https://www.gpo.gov/fdsys/granule/CFR-2011-title42-vol5/CFR-2011-title42-vol5-part493/content-detail.html

o) National Institutes of Allergy and Infectious Diseases, DAIDS Guidelines for Good Clinical Laboratory Practice Standards, https://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/gclp.pdf

p) ICH Guideline for Good Clinical Practice, Consolidated Practice (E6) http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html

q) Title 21, CFR Part 11 Electronic Records: Electronic Signature. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11

r) Title 21, CFR Part 50 Protection of Human Subjects https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50&showFR=1

s) Title 21 CFR Part 54 Financial Disclosure by Clinical Investigators https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54

t) Title 21 CFR Part 56, Institutional Review Boards https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56

u) Title 21 CFR Part 812, Investigational Device Exemptions, April 1, 2014 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=812

v) Title 45 CFR 46, Protection of Human Subjects, April 1, 2014, http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#

w) Title 29 Part 1910.1030 Bloodborne Pathogens; 1910.1200, Hazard Communication; 1910.132 Personal Protective Equipment https://www.osha.gov/pls/oshaweb/owastand.display_standard_group?p_toc_level=1&p_part_number=1910

x) Title 42 CFR 72.3 Transportation of Materials Containing Certain Etiologic Agents; Minimum Packaging Requirements. https://www.gpo.gov/fdsys/granule/CFR-2007-title42-vol1/CFR-2007-title42-vol1-sec72-3

y) Title 49 CFR Part 173.199 Category B Infectious Substances https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol2/pdf/CFR-2015-title49-vol2-sec173-199.pdf

z) Dangerous Goods Regulations of the International Air Transport Association. http://www.iata.org/Pages/default.aspx

aa) Title 5, U.S.C section 5A, Records Maintained on Individuals https://www.gpo.gov/fdsys/granule/USCODE-2010-title5/USCODE-2010-title5-partI-chap5-subchapII-sec552a/content-detail.html

13.2. Human Research Protections

13.2.1. Research Involving Human Subjects

The Contractor shall oversee the execution of the research to ensure compliance with this clause. The Contractor shall comply fully with 32 CFR Part 219 and DoD Directive 3216.02, applicable DoD component policies, 10 USC. 980, and, when applicable, FDA policies and regulations.

The Contractor shall not commence performance of research involving human subjects that is covered under 32 CFR Part 219 or that meets exemption criteria under 32 CFR 219.101(b), or expend funding on such effort, until and unless the conditions of either the following paragraph (c)(1) or (c)(2) have been met:

a) The Contractor furnishes to the ORP, with a copy to the KO, an assurance of compliance and IRB approval and receives notification from the KO that the ORP has approved the assurance as appropriate for the research under the Statement of Work and also that the ORP has reviewed the protocol and accepted the IRB approval for compliance with the DoD component policies. The Contractor may furnish evidence of an existing assurance of compliance for acceptance by the ORP, if an appropriate assurance has been approved in connection with previous research. The Contractor shall notify the KO immediately of any suspensions or terminations of the assurance.

b) (2) The Contractor furnishes to the ORP, with a copy to the KO, a determination that the human research proposed meets exemption criteria in 32 CFR 219.101(b) and receives written notification from the KO that the exemption is determined acceptable. The determination shall include citation of the exemption category under 32 CFR 219.101(b) and a rationale statement. In the event of a disagreement regarding the Contractor's furnished exemption determination, the ORP retains final judgment on what research activities or classes of research are covered or are exempt under the contract.

c) The Contractor shall adhere to all applicable DoD regulations pertaining to Human Subjects Protection and Ethical Standards. Specifically, 32 Code of Federal Regulations (CFR) 219, National Defense, Protection of Human Subjects; Department of Defense (DoD) Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, dated November 2011; Army Regulation (AR) 70-25 (under revision): Use of

Volunteers as Subjects of Research, Headquarters, Department of the Army, dated 25 January 1990. Applicable US CFR regulations are: Title 21, CFR Part 50 Protection of Human Subjects, Title 21 CFR Part 56, Institutional Review Boards; Title 21 CFR Part 812, Investigational Device Exemptions, April 1, 2014; Title 32 CFR Part 219, Protection of Human Subjects; Title 45 CFR 46, Protection of Human Subjects, April 1, 2014

13.2.2. Research Involving Human Anatomical Substances, Human Subjects, Or Human Cadavers

All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Development Command (USAMRDC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is not required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes. Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application as a stand-alone study. Submission to HRPO of protocols involving more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

A clinical trial is defined as a prospective accrual of patients (human subjects) in whom an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction.

13.2.3. Medical Malpractice and Indemnification

The contractor and contract Physician Health Care Provider (HCP) shall abide by all Government standards, regulations, rules, and procedures including requirements for any licensure, credentialing and quality assurance requirements. Such regulations include, but are not limited to, general safety, fire prevention, waste disposal, infection control, Joint Commission (JC), and patient safety initiatives.

For the contracts awarded as non-personal service contracts, the Government will not be liable for malpractice allegations against contract Physician HCP's based upon performance of this contract. The contractor shall be required to carry malpractice insurance for its contract Physician HCPs, at a level stated in the solicitation and included in any resulting contract for subject acquisition in tailored FAR Clause 52.237-7. If an apparent successful Offeror, the contractor shall provide evidence of insurability concerning medical liability insurance prior to task order award. Upon task order award, the contractor shall provide evidence of insurance demonstrating the required coverage prior to commencement of performance. In accordance with FAR Clause 52.237-7, the contractor will indemnify the Government for any liability producing act or omission by the contractor, its contract HCPs and agents occurring during contract

performance. If the contractor uses subcontractors in the performance of this contract, the contractor is required to ensure that its subcontracts for provisions of healthcare services contain the requirements of FAR 52.237-7, including the maintenance of medical liability insurance.

If any suit or action is filed or any claim is made against the contract Physician HCP which occurred as a result of work performed by the Physician HCP under this contract, the Physician HCP shall immediately notify the contractor, the KO and the chief of the appropriate services and promptly furnish them copies of all pertinent documents received.

The contractor or contract Physician HCPs shall not bill the patient, any insurer, or any other person, for services rendered under this contract. The contractor or contract Physician HCPs shall not request or accept compensation of any kind for patients treated, procedures performed, or any other actions performed. The contractor or contract Physician HCPs shall not, while performing services under this contract, advice, recommend, or suggest to persons eligible to receive medical care at Government expense that such persons should receive care from the contractor or contract Physician HCPs or from any third party at any place other than as designated under this contract.

The contractor shall not use patient care rendered pursuant to this contract or any subsequently awarded task order as part of a study, research grant, or publication without the prior written consent of the KO.

The contractor shall comply with each of the following:

a) Title 32, Part 219 Protection of Human Subjects also known as the Common Rule (PDF, 2011) Electronic Code of Federal Regulations 32 CFR 219 (2011)

b) Title 48, Part 252.235-7004 Part 207.172 , Federal Acquisition Regulations Part 207.172 applies to human research

c) United States Code Section 980 of Title 10 (PDF, 2001), *Limitation on Use of Humans as Experimental Subjects*

d) DoD Instruction 3216.02 , Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research (2011)

e) DoD Instruction 5134.01 , Under Secretary of Defense for Acquisition, Technology, and Logistics (2005)

f) DoD Instruction 6200.02 , Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs (2008)

g) DoD Instruction 6000.08 , Funding and Administration of Clinical Investigation Programs (2007)

h) DoD Directive 2310.01E , Department of Defense Detainee Program (2006)

i) DoD Directive 5400.11 and 5400.11R , Department of Defense Privacy Program (2007)

j) DoD Instruction 6025.18 , Privacy of Individually Identifiable Health Information in DoD Health Care Programs (2009)

k) DoD 6025.18-R , Health Information Privacy Regulation (2003)

l) AR 70-25 , Use of Volunteers as Subjects of Research (1990)

m) AR 40-7 , Use of U.S. Food and Drug Administration-Regulated Investigational Products in Humans Including Schedule I Controlled Substances (2009)

13.3. Research Involving Animals

All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the U.S. Army Medical Research and Development Command (USAMRDC) Office of Research Protections (ORP) Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled, "Research Involving Animals." Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.

13.4. Information Technology Compliance

13.4.1. Army Regulation 25-1, Information Technology

Compliance information regarding Army Information Technology may be found at: http://armyhpubs.army.mil/epubs/25_Series_Collection_1.html

13.4.2. Army Regulation 25-2, Information Assurance

Compliance information regarding Army Information Assurance may be found at: https://ia.signal.army.mil/docs/AR25-2.pdf

13.4.3. Cyber-security

13.4.3.1. Federal Law

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA)
- The Federal Information Security Management Act (FISMA)
- The E-Government Act of 2002

13.4.3.2. Office of Management and Budget (OMB)

- The following publications are located at https://www.whitehouse.gov/omb/agency/default
- Circular A-130
- Guidance M-05-24, Implementation of Homeland Security Presidential Directive (HSPD) 12-Policy for a Common Identification Standard for Federal Employees and Vendors

13.4.3.3. National Institute of Standards and Technology (NIST)

- The following publications are located at http://www.nist.gov/publication-portal.cfm
- NIST Special Publication (SP) 800-37 – Guide for Applying the Risk Management Framework (RMF) to Federal Information Systems
- NIST SP 800-53 – Security and Privacy Controls for Federal Information Systems and Organizations

13.4.3.4. Federal Information Processing Standards (FIPS)

- The following publications are located at http://www.nist.gov/itl/fipscurrent.cfm
- FIPS Publication (FIPS PUB) 140-2, Security Requirements for Cryptographic Modules
- FIPS PUB 199 – Standards for Security Categorization of Federal Information and Information Systems
- FIPS PUB 201-2, Personal Identity Verification of Federal Employees and Vendors

13.4.3.5. Department of Defense (DoD)

- The following publications are located at http://www.dtic.mil/whs/directives/
- DoD Instruction 5200.2, DoD Personnel Security Program (PSP)
- DoD Instruction 8500.1, Cybersecurity

- DoD Instruction 8520.02, Public Key Infrastructure (PKI) and Public Key (PK) Enabling
- DoD Instruction 8510.01, Risk Management Framework Process (RMF)
- DoD Instruction 8551.1, Ports, Protocols, and Services Management (PPSM)
- DoD Instruction 8580.02, Security of Individually Identifiable Health Information in DoD Health Care Programs
- DoD Instruction 6025.18, Privacy of Individually Identifiable Health Information in DoD Health Care Programs
- DoD Directive 5400.11, DoD Privacy Program
- DoD Manual 5400.11-R, Department of Defense Privacy Program

13.4.4. Risk Management Framework

Department of Defense (DOD) Instruction 8510.01 Risk Management Framework (RMF) For DOD Information Technology (IT Department of Defense (DoD) Instructions 5400.11-R, Privacy Program http://www.dtic.mil/whs/directives/corres/pdf/540011p.pdf

13.5. Cybersecurity Management

13.5.1. Cybersecurity Requirements

13.5.1.1. System Security Requirements (Deliverable XX)

The vendor shall submit to Government, included in the quote, the blue section of the Medical Device Cybersecurity Assessment provided by government.

13.5.1.2. Key System Attributes

Failure to meet any key attribute is considered a breach of contract. The vendor device or system shall pass a pre-validation screening **(Deliverable XX)**, administered within six (6) months of contract award that will be conducted by Government, and must meet criteria listed below:

- No unmitigated Category I (CAT I), findings as described in the appropriate Defense Information System Agency (DISA) Security Technical Implementation Guides (STIGs) located on http://iase.disa.mil/stigs/Pages/index.aspx
- No unmitigated Category II (CAT II), findings as described in the appropriate Defense Information System Agency (DISA) Security Technical Implementation Guides (STIGs) located on http://iase.disa.mil/stigs/Pages/index.aspx
- No unmitigated critical or high Category I (CAT I) findings from Nessus vulnerability scans
- No unmitigated Category II (CAT II) findings from Nessus vulnerability scans.
- The vendor shall mitigate all CAT I and CAT II findings discovered during the Assistance & Accreditation (A&A) process according to a schedule published by Government. The vendor shall appoint a vendor point of contact responsible for the cybersecurity of the vendor device or system throughout the lifecycle of the system. The vendor shall provide Subject Matter Experts (SMEs) to support all assessments of contracted products and materials, and meet required deliverable timelines. The vendor shall obtain a recommendation of Authority to Operate (ATO) as determined by a Government appointed third party validator within twelve (12) months of contract award. Government will defer delivery of, and payment for the system for twelve (12) months, or until the ATO is granted **(Deliverable XX)**. The vendor shall, after the award of an ATO to vendor's device or system, ensure that the vendor's device or system maintains its ATO for as long as the equipment is operated by Government.

13.5.1.3. Post Award Cybersecurity Requirements

The vendor shall establish appropriate administrative and technical safeguards to ensure the confidentiality, integrity, and availability of Government data under their control. The vendor shall provide anticipated costs and timelines required to address any inability to meet any of the security requirements.

13.5.1.4. Assessment and Accreditation (A&A) (**Deliverable XX**)

The vendor shall submit all RMF required documentation, as specified by Government Reps for review and approval, no later than four (4) months after request by the Government. The vendor shall obtain approval from the Government, any vendor developed policies, plans, and procedures prior to implementation. The vendor shall provide any additional documentation required by Government for completion of the A&A process within thirty (30) business days of request by Government. The vendor shall provide technical scans within one (1) month of the A&A kickoff meeting. The vendor shall provide updated technical scans on a monthly basis, on the 10th day of each month until an ATO is granted awarded.

13.5.1.5. Continuous Risk Management **(Deliverable XX)**

The vendor shall maintain a duplicate of the fielded device or system in a vendor supplied lab environment at vendor location for as long as the system is operated by the Government. The vendor shall maintain the duplicate system or device in operational condition with the latest security patches installed. The vendor shall maintain the authorized security configuration and notify the government within **forty eight (48) hours** of any major changes. **(Deliverable XX)** The vendor shall ensure the vendor's device or system is in compliance with the Department of Defense (DoD) Information Assurance Vulnerability Management (IAVM) program upon each deployment. The vendor shall ensure any new deployment (including rebuilds) deploy with a fully patched, accredited version maintained in a lab environment. The vendor shall make the duplicate device or system available for periodic security reviews, within **forty five (45)** business days of notification by Government.

The vendor shall perform **monthly vulnerability scans** using the most recent and updated version of approved DoD scan tools.

Vendor shall maintain system and update to comply with updated STIGS as made available by the Government within **three (3) months** of notification by the Government. **(Deliverable XX)** The vendor shall provide vulnerability scan and SCAP scan results to Government on a **monthly basis**. Vendor shall provide raw scan results and administrative reports no later than the **10th calendar day** of each month. **(Deliverable XX)** The vendor shall close all discovered vulnerabilities within **three (3) months** of discovery. **(Deliverable XX)** The vendor shall submit to Government detailed explanations for the inability to close discovered vulnerabilities. The vendor shall submit to Government for approval of any mitigation that addresses any open vulnerabilities. The vendor shall review all required policies, plans, and procedures documentation on an annual basis and submit changes to Government for approval. The vendor shall use Government approved methods and procedures for remote access administration of system or device.

13.5.1.6. Intrusion Detection and Prevention, Antivirus, and Antimalware

The vendor shall ensure that the vendor device or system is capable of supporting the use of DISA approved intrusion detection and prevention, antivirus, and antimalware applications. The vendor shall provide technical specifications that clearly demonstrate whether the proposed solution can integrate and support, either fully or partially the operation without performance degradation of the medical system/device. In cases where the operation of security applications are not technically achievable, the vendor shall provide detailed justification and a Plan of Actions and Milestones (POA&M) describing steps towards compliance with this requirement. The vendor shall ensure that the vendor device or

system is configured in such a way that allows the updating of malware definition signatures on a scheduled basis. Scanning shall encompass the entire system (file system, operating system, real-time processes), by default. In cases where scanning of the entire system may negatively affect its operation, the vendor shall provide a detailed list of exclusions with justifications.

13.6. Medical and Laboratory Compliance

13.6.1. *Army Regulation 340-21, Army Privacy Program*

Compliance information regarding Army Privacy program may be found at: http://www.army.mil/usapa/epubs/340_Series_Collection_1.html

13.6.2. *Protection of Human Subjects*

Compliance information regarding Department of Defense (DoD) Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, dated November 2011, may be found at: http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf

13.6.3. *DOD Health Information Privacy*

Department of Defense (DOD) 6025.18 Regulation, DOD Health Information Privacy Regulation, 24 January 2003.

13.6.4. *Research Integrity and Misconduct*

DOD Instruction 3210.7, Research Integrity and Misconduct, 14 May 2004.

13.6.5. *Volunteers as Subjects of Research*

Army Regulation (AR) 70-25: Use of Volunteers as Subjects of Research, Headquarters, Department of the Army, dated 25 January 1990 – currently under revision

13.6.6. *Clinical Laboratory Improvement*

Clinical Laboratory Improvement Amendments, 2013. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Regulations_and_Federal_Register_Documents.html. Specific guidance: http://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5

13.6.7. *Clinical Laboratory Improvement Program*

Clinical Laboratory Improvement Program (CLIP) Manual, May 29, 2014. http://www.dtic.mil/whs/directives/corres/pdf/64402m.pdf (this document is codified Title 42 Part 493 under Memorandum of Agreement between the US Department of Defense and Health and Human Services.

13.6.8. *Pathology Inspection*

College of American Pathologists Inspection Checklists. http://www.cap.org

13.6.9. *Laboratory Standards*

Clinical Laboratory Standards Institute. Standards and Guides for Laboratories: http://clsi.org/standards

13.6.10. *Laboratory Requirements*

Title 42 Part 493 Laboratory Requirements, 1 October 2011 https://www.gpo.gov/fdsys/granule/CFR-2011-title42-vol5/CFR-2011-title42-vol5-part493/content-detail.html

13.6.11. *Clinical Laboratory Practice Standards*

National Institutes of Allergy and Infectious Diseases, DAIDS Guidelines for Good Clinical Laboratory Practice Standards, https://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/gclp.pdf

13.6.12. ***Clinical Practice***
ICH Guideline for Good Clinical Practice, Consolidated Practice (E6)
http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html

13.6.13. ***Clinical Practice***
Title 21, CFR Part 11 Electronic Records: Electronic Signature.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11

13.6.14. ***Clinical Practice***
Title 21, CFR Part 50 Protection of Human Subjects
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50&showFR=1

13.6.15. ***Financial Disclosure by Clinical Investigators***
Title 21 CFR Part 54 Financial Disclosure by Clinical Investigators
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54

13.6.16. ***Institutional Review Boards***
Title 21 CFR Part 56, Institutional Review Boards
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56

13.6.17. ***Investigational Device Exemptions***
Title 21 CFR Part 812, Investigational Device Exemptions, April 1, 2014
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=812

13.6.18. ***National Defense, Protection of Human Subjects***
Title 32 CFR Part 219, National Defense, Protection of Human Subjects,
http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title32/32cfr219_main_02.tpl

13.6.19. ***Protection of Human Subjects***
Title 45 CFR 46, Protection of Human Subjects, April 1, 2014,
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#

13.6.20. ***Bloodborne Pathogens***
Title 29 Part 1910.1030 Bloodborne Pathogens; 1910.1200, Hazard Communication; 1910.132 Personal Protective Equipment
https://www.osha.gov/pls/oshaweb/owastand.display_standard_group?p_toc_level=1&p_part_number=1910

13.6.21. ***Transportation of Materials Containing Certain Etiologic Agents***
Title 42 CFR 72.3 Transportation of Materials Containing Certain Etiologic Agents; Minimum Packaging Requirements. https://www.gpo.gov/fdsys/granule/CFR-2007-title42-vol1/CFR-2007-title42-vol1-sec72-3

13.6.22. ***Category B Infectious Substances***
Title 49 CFR Part 173.199 Category B Infectious Substances https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol2/pdf/CFR-2015-title49-vol2-sec173-199.pdf

13.6.23. ***Dangerous Goods Regulations of the International Air Transport Association***
Dangerous Goods Regulations of the International Air Transport Association.
http://www.iata.org/Pages/default.aspx

13.6.24. ***Records Maintained on Individuals***
Title 5, U.S.C section 5A, Records Maintained on Individuals
https://www.gpo.gov/fdsys/granule/USCODE-2010-title5/USCODE-2010-title5-partI-chap5-subchapII-sec552a/content-detail.html

14. REFERENCE DOCUMENTS

a) Department of Defense Directive 6485.01, Human Immunodeficiency Virus, June 7, 2013. http://www.dtic.mil/whs/directives/corres/pdf/648501p.pdf

b) Department of Defense Instruction 6440.02, Clinical Laboratory Improvement Program (CLIP) Manual, May 29, 2014. http://www.dtic.mil/whs/directives/corres/pdf/644002p.pdf

c) Department of Defense Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standard in D00D-Supported Research. http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf

d) Army Regulation 600-110, Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus, 22 April 2014. http://www.apd.army.mil/pdffiles/r600_110.pdf

e) Army Regulation 40-501, Standards of Medical Fitness

f) US Medical Entrance Processing Command Regulation 40-1, Medical Processing and Examinations http://www.mepcom.army.mil/ASP/pubnform.asp?topic=Regulations&sort=pubNo

g) US Medical Entrance Processing Command Regulation 40-8, Department of Defense (DOD) Human Immunodeficiency Virus (HIV) Testing Program and Drug and Alcohol Testing (DAT) Program http://www.mepcom.army.mil/ASP/pubnform.asp?topic=Regulations&sort=pubNo

15. OTHER TERMS, CONDITIONS, AND PROVISIONS

15.1. Non-Personal Services

This PWS identifies services that are strictly non-personal in nature, as defined by Federal Acquisition Regulation (FAR) Part 37, *Service Contractin*g. To ensure there is no appearance of any personal services, the Government shall neither supervise contractor personnel nor control the method by which the contractor performs the required tasks. Under no circumstances shall the Government assign tasks or prepare work schedules for individual contractor personnel. It shall be the responsibility of the contractor to manage its personnel and to guard against any actions that give the perception of personal services. If the contractor believes that any actions constitute, or are perceived to constitute personal services, it shall be the contractor's responsibility to notify the Contractor Officer (KO) immediately.

15.2. Severable / Non-Severable Services

This award identifies services that are severable in nature.

15.3. Inherently Governmental Functions

This requirement has been reviewed and contains no services that are inherently governmental functions.

15.4. Acquisition Functions Closely Associated with Inherently Governmental Functions

This shall be assessed on each task order.

15.5. Organizational Conflict of Interest

Walter Reed Army Institute of Research (WRAIR) has categorized its requirements into two broad categories, as defined below, for purposes of identifying, avoiding or mitigating against OCIs in accordance with FAR Subpart 9.5. These categories apply to all enterprise laboratories (Armed Forces Research Institute of Medical Sciences (AFRIMS), United States Medical Research Unit – Kenya (USAMRU-K), and United States Medical Research Unit – Georgia (USAMRD-G). These categories are defined as follows:

Global Support: Where services which, by their very nature, give the Contractor access to non-public procurement sensitive data about the contract requirements, other contractors' proprietary information, or put the contractor in a position to influence the award decision on a contract in which they are participating. These services are identified as those having a direct impact to the operations of the greater WRAIR enterprise.

Services would be characterized as having access to Command Wide procurement sensitive information, or work that could likely have an influence over follow-on awards or contracts within subordinate directorates/Commands.

Mitigation strategies may include: avoidance (non-participation), firewalls between existing personnel and new requirement.

Isolated Support: Services which have focused impact on a specific Branch/ Department/ Program of WRAIR rather than the WRAIR enterprise.

Services can be characterized as having little or no access to procurement sensitive information other than the immediate requirement and little chances of follow-on work that can be influenced by the immediate requirement.

Mitigation Strategies: Contractor can provide a mitigation plan or acceptable self-certification that no OCI exists.

Contractor participation in more than one of these areas may give rise to an unfair competitive advantage resulting from access to advance acquisition planning, source selection sensitive or proprietary information. Furthermore, Contractor participation in more than one area may give rise to a real or apparent loss of Contractor impartiality and objectivity where its advisory or planning assistance in one area potentially affects its present or future participation in another area.

The purpose of this categorization is to accomplish the following three objectives: (1) to inform prospective Offerors that WRAIR presumes that award of a contract or order in the subject category will give rise to real or apparent OCI's with respect to requirements in the other category and or may give rise to an OCI in the same category; (2) to assist current Contractors and prospective Offerors in developing their own business strategies regarding participation in WRAIR requirements and in identifying and, where possible, avoiding or mitigating against OCIs; and (3) to ensure that all current Contractors and prospective Offerors are afforded the maximum practicable opportunity to compete for all WRAIR requirements consistent with the restrictions required under FAR Subpart 9.5 and sound business practices.

For purposes of identifying and/or mitigating against OCIs, WRAIR will examine all its services requirements and acquisitions regardless of the cognizant contracting activity (e.g., USAMRAA, GSA, other agency Multiple Award Schedules, etc.) or the type of contract vehicle used (e.g., FSS order, Fair Opportunity competitive order under Multiple Award ID/IQ Contracts, competitively negotiated awards under FAR Part 15, etc.).

Each WRAIR services solicitation will therefore be designated as falling within one of the above defined categories. The applicable OCI category will be set forth in each award.

This requirement is categorized as **ISOLATED SUPPORT.**

Organizational and consulting conflicts of interest may arise by performing advisory or consulting support services. Organizational conflicts of interest include providing services or performing advisory or consulting work for private companies that participate or will participate in future services or contract activities (solicitations and award). See FAR subpart 9.5.

The Contractor shall ensure that the Participation Agreement, either A and / or B as identified on each award, is signed by all staff assigned to or performing on each award before performing any work, including all

subcontractors and consultants. The Participation Agreement shall be cosigned by a corporate official (contractor Task Manager or higher). The Contractor shall also ensure that all staff understand and adhere to the terms of the non-disclosure statement, protecting the procurement sensitive information of the Government and the proprietary information of other contractors. Assignment of staff who has not executed this statement or failure to adhere to this statement shall constitute default on the part of the Contractor and the COR will immediately initiate a CDR.

15.6. Invoices

The contractor shall submit invoices monthly to Wide Area Work Flow (WAWF) with sufficient documentation to provide certification of invoice.

The contractor is responsible for properly preparing and forwarding to the appropriate Government official, the invoice and receiving report for payment. The contractor shall attach back up information to receiving reports for direct labor and Other Direct Costs (ODCs). Direct labor backup information shall reflect the person's name, job title and quantity of hours worked for each pay period at a minimum. Backup information for ODCs shall list all elements of costs, such as travel breakout backup, including itinerary, dates of travel, name of employees traveling plus per diem costs shall accompany the receiving report. All ODCs exceeding $3,000 requires that the contractor conduct appropriate competition and obtain approval from the COR prior to purchase. Equipment purchases are not authorized under this contract. The Wide Area Workflow – Receipt and Acceptance application is the required method of submission.

Where applicable, contractor will include additional ODC invoice details as required per protocol for any volunteer payments in support of this PWS.

Insert Cost type process with DCAA approval
If Cost, vendor shall submit draft invoice to COR NLT 5 days prior to submission in WAWF for COR review….. add more here

15.7. Dissemination of Information/Publishing

There shall be no dissemination or publication, except within and between the Contractor and any Sub Contractors or specified Integrated Product/Process Team (IPT) members who have a need to know, of information developed under this order or contained in the reports to be furnished pursuant to this order without prior written approval of the COR or the Contracting Officer.

DFARS 252.204-7012 Safeguarding Covered Defense Information and Cyber Incident Reporting. The contractor shall implement National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171, "Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations."

15.8. Contractor Identification

When contractor personnel perform the services required in this contract on a Government installation they are required to possess and wear an identification badge that displays his or her name and the name of the Company. The contractor shall ensure that contractor personnel identify themselves as contractors when attending meetings, answering Government telephones, providing any type of written correspondence, or working in situations where their actions could be construed as official Government acts.

While performing in a contractor capacity, contractor personnel shall refrain from using their retired or reserve component military rank or title in all written or verbal communications.

15.9. Attendance at Meetings

Contractor personnel may be required to attend meetings or otherwise communicate with Government and/or other contract or assistance agreement representatives to meet the requirements of this order. Contractor personnel shall make their contractor status known during introductions.

15.10. Data Rights

The Government will retain rights to all data generated in the course of developing, deploying, training, using and supporting WRAIR or other federal agencies that utilize this contract. The contractor shall adhere to the guidelines described in the Contract Data Requirements List (CDRL), DD form 1423 for reports. (Exhibits A & B).

15.11. Anti-Terrorism and Operational Security

15.11.1. *AT Level I Training.*

All contractor employees, including subcontractor employees, requiring access to Army installations, facilities, and controlled access areas shall complete ***AT Level I awareness training*** within *30* calendar days after contract start date or effective date of incorporation of this requirement into the contract, whichever is applicable.

DFARS 204.7202 Contractor personnel who, as a condition of contract performance, require routine physical access to a Federally-controlled facility or military installation are required to complete Level I antiterrorism awareness training within 30 days of access and annually thereafter.

Include the clause at DFARS 252.204-7004 DoD Antiterrorism Awareness Training for Contractors, in solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial items, when contractor personnel require routine physical access to a Federally-controlled facility or military installation.

The contractor shall submit certificates of completion for each affected contractor employee and subcontractor employee to the COR or to the contracting officer, if a COR is not assigned, within *30* calendar days after completion of training by all employees and subcontractor personnel. AT Level I awareness training is available at the following website: http://jko.jten.mil.

15.11.2. *Installation Access.*

Contractor and all associated subcontractor employees shall provide all information required for background checks to meet installation access requirements to be accomplished by the installation Provost Marshal Office, Director of Emergency Services, or Security Office.

Contractor workforce must comply with all personal identity verification requirements (CFR clause 52.204-9, Personal Identity Verification of Contract Personnel) as directed by DoD, HQDA and/or local policy. In addition to the changes otherwise authorized by the changes clause of this contract, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in contractor security matters or processes.

a) For contractors requiring CAC. Before CAC issuance, the contractor employee requires, at a minimum, a favorably adjudicated National Agency Check with Inquiries (NACI) or an equivalent or higher investigation in accordance with Army Directive 2014-05. The contractor employee will be issued a CAC only if duties involve one of the following: (1) both physical access to a DoD facility and access, via logon, to DoD networks on-site or remotely; (2) remote access, via logon, to a DoD network using DoD-approved remote access procedures; or (3) physical access to multiple DoD facilities or multiple non-DoD federally controlled facilities on behalf of the DoD on a recurring basis for a period of 6 months or more. At the discretion of the sponsoring activity, an initial CAC may be issued based on a favorable review of the FBI fingerprint check and a successfully scheduled NACI at the Office of Personnel Management.

b) For contractors that do not require CAC, but require access to a DoD facility or installation. Contractor and all associated subcontractor employees shall comply with adjudication standards and procedures using the National Crime Information Center Interstate Identification Index (NCIC-III) and Terrorist Screening Database (Army Directive 2014-05/AR 190-13); applicable installation, facility and area commander installation and facility access and local security policies and procedures (provided by Government representative); or, at OCONUS locations, in accordance with status-of-forces agreements and other theater regulations.

15.11.3. ***AT Awareness Training for Contractor Personnel Traveling Overseas.***

This standard language requires U.S.-based contractor employees and associated subcontractor employees to make available and to receive Government-provided area of responsibility (AOR)–specific AT awareness training as directed by AR 525-13. Specific AOR training content is directed by the combatant commander, with the unit ATO being the local point of contact.

15.11.4. ***iWATCH Training. This standard language is for contractor employees with an area of performance within an Army-controlled installation, facility, or area.***

The contractor and all associated subcontractors shall brief all employees on the local iWATCH program (training standards provided by the requiring activity ATO). This locally developed training will be used to inform employees of the types of behavior to watch for and instruct employees to report suspicious activity to the COR. This training shall be completed within XX calendar days of contract award and within YY calendar days of new employees commencing performance, with the results reported to the COR NLT XX calendar days after contract award.

15.11.5. ***Army Training Certification Tracking System (ATCTS) registration for contractor employees who require access to Government information systems.***

All contractor employees with access to a Government info system must be registered in the ATCTS at commencement of services and must successfully complete the DoD Information Assurance Awareness prior to access to the information system and annually thereafter.

15.11.6. ***For Contracts That Require an OPSEC Standing Operating program.***

The contractor shall develop an OPSEC Standing Operating Procedure (SOP)/Plan within 90 calendar days of contract award, to be reviewed and approved by the responsible Government OPSEC officer. This plan will include a process to identify critical information, where it is located, who is responsible for it, how to protect it, and why it needs to be protected. The contractor shall implement OPSEC measures as ordered by the commander. In addition, the contractor shall have an identified certified Level II OPSEC coordinator per AR 530-1.

15.11.7. ***For Contracts That Require OPSEC Training.***

Per AR 530-1, *Operations Security*, the contractor employees must complete *Level I OPSEC Awareness training*. New employees must be trained within 30 calendar days of their reporting for duty and annually thereafter.

15.11.8. ***For IA/IT training.***

All contractor employees and associated subcontractor employees must complete the DoD IA awareness training before issuance of network access and annually thereafter. All contractor employees working IA/IT functions must comply with DoD and Army training requirements in DoDD 8570.01, DoD 8570.01-M, and AR 25-2 within six months of appointment to IA/IT functions.

15.11.9. ***For Information Assurance (IA)/Information Technology (IT) Certification.***

Per DoD 8570.01-M , DFARS 252.239.7001, and AR 25-2, the contractor employees supporting IA/IT functions shall be appropriately certified upon contract award. The baseline certification as stipulated in DoD 8570.01-M must be completed upon contract award.

15.11.10. ***For Contractors Authorized to Accompany the Force.***

DFARS Clause 252.225-7040, *Contractor Personnel Authorized to Accompany U.S. Armed Forces Deployed Outside the United States*, shall be used in solicitations and contracts that authorize contractor personnel to accompany U.S. Armed Forces deployed outside the U.S. in contingency operations; humanitarian or peacekeeping operations; or other military operations or exercises, when designated by the combatant commander. The clause discusses the following AT/OPSEC-related topics: required compliance with laws and regulations, pre-deployment requirements, required training (per combatant command guidance), and personnel data required.

15.11.11. ***For Contract Requiring Performance or Delivery in a Foreign Country.***
DFARS Clause 252.225-7043, *Antiterrorism/Force Protection for Defense Contractors Outside the US*, shall be used in solicitations and contracts that require performance or delivery in a foreign country. This clause applies to both contingencies and non-contingency support. The key AT requirement is for non-local national contractor personnel to comply with theater clearance requirements and allows the combatant commander to exercise oversight to ensure the contractor's compliance with combatant commander and subordinate task force commander policies and directives.

15.11.12. ***For Contracts That Require Handling or Access to Classified Information.***
Contractor shall comply with FAR 52.204-2, Security Requirements. This clause involves access to information classified "Confidential," "Secret," or "Top Secret" and requires contractors to comply with (1) the Security Agreement (DD Form 441), including the National Industrial Security Program Operating Manual (DoD 5220.22-M); (2) any revisions to DoD 5220.22-M, notice of which has been furnished to the contractor.

15.11.13. ***Threat Awareness Reporting Program (TARP).***
All contractor employees, regardless of whether or not they possess a security clearance, must complete TARP training on an annual basis per USAMRDC command directive, as outlined in USAMRDC Memorandum for Record, Command Guidance for TARP Training Compliance, dated 06 January 2016. The training can be conducted face-to-face in a classroom setting or on-line. The supported military organization will coordinate all face-to-face training. Personnel may access the on-line training via the ALMS website under the course name, U.S. Army Threat Awareness and Reporting Program (TARP) Course. This training shall be completed within 60 calendar days after the contract award or after new employees commence performance, and annually thereafter. (**Deliverable XX**)

15.12. Information Security Program Training

The Information Security Program (ISP) Training Certification meets an Army mandatory annual training requirement for this subject. This Certification is the consolidation of the training topics previously provided in the Security Training - Initial Security Orientation and Security Training - Annual Security Refresher Training courses. The contractor shall ensure all service providers receive ISP training not later than 30 calendar days after contractor personnel begin performance under this contract and annually thereafter (**Deliverable XX**). Training can be found at - https://www.lms.army.mil/

15.13. System Security Plan and Associated Plans of Action

15.13.1. The Contractor shall, upon request, provide the government with access to the system security plan(s) (or extracts thereof) and any associated plans of action for each of the Contractor's tier one level subcontractor(s), vendor(s), and/or supplier(s), and the subcontractor's tier one level subcontractor(s), vendor(s), and/or supplier(s), who process, store, or transmit covered defense information associated with the execution and performance of this contract. System Security Plan and Associated Plans of Action for a Contractor's Internal Unclassified Information System [Insert Contract Data Requirements List (CDRL) Data Item Number Block 1 of DD Forum 1423-1]. **(Deliverable XX)**

CDRL for System Security Plan and Associated Plans of Action for a Contractor's Internal Unclassified Information System is found in Defense Pricing and Contracting Memo, Guidance for Assessing

Compliance and Enhancing Protections Required by DFARS Clause 252.204-7012, dated November 6, 2018 (https://www.acg.osd.mil/dpap/pdi/cyber/index.html).

15.14. Identification, Tracking, and Restricted Flow Down of all Covered Defense Information, and for Requesting the Contractor's Record of Tier 1 Level Subcontractors, Vendors, and/or Suppliers who Receive or Develop Covered Defense Information

15.14.1. Identify all covered defense information associated with the execution and performance of this contract.

At the post-award conference the Contractor and the Government/Program Office shall identify and affirm marking requirements for all covered defense information, as prescribed by DoDM 5200.01 Vol 4, Controlled Unclassified Information, and DoDI 5230.24, Distribution Statements on Technical Documents, to be provided to the Contractor, and/or to be developed by the contractor, associated with the execution and performance of this contract.

15.14.2. Track all covered defense information associated with the execution and performance of this contract.

The Contractor shall document, maintain, and provide to the Government, a record of tier 1 level subcontractors, vendors, and/or suppliers who will receive or develop covered defense information – as defined in DFARS Clause 252.204-7012 and associated with the execution and performance of this contract. Contractor's Record of Tier 1 Level Suppliers Receiving/Developing Covered Defense Information [Insert Contract Data Requirements List (CDRL)* Data Item Number Block 1 of DD Forum 1423-1] (**Deliverable XX**).

The Contractor shall restrict unnecessary sharing and/or flow down of covered defense information – as defined in DFARS Clause 252.204-7012 and associated with the execution and performance of this contract – in accordance with marking and dissemination requirements specified in the contract and based on a 'need-to-know' to execute and perform the requirements of this contract. This shall be addressed and documented at the post-award conference.

15.14.3. The Contractor shall flow down the requirements in 16.15.1 and 16.15.2 to their Tier 1 level subcontractors, vendors, and/or suppliers.

CDRL for Contractor's Record of Tier 1 Level Suppliers Receiving/Developing Covered Defense Information, is found in Defense Pricing and Contracting Memo, Guidance for Assessing Compliance and Enhancing Protections Required by DFARS Clause 252.204-7012, dated November 6, 2018, (https://www.acg.osd.mil/dpap/pdi/cyber/index.html).

15.15. Compliance with Relevant DoD, Service, and Institutional Policy Regulations.

The Contractor shall comply with HIPAA and all relevant DoD/USG regulations for collection, storage, and transfer of sensitive data and PHI. In addition, the Contractor will comply with all requirements for communication of findings and publication in the scientific peer reviewed literature (e.g. Public Affairs clearance and Operational Security clearance for dissemination). Finally, all contractor employees must complete a yearly HIPAA training that is on Joint Knowledge Online (JKO). **(Deliverable XX)**

15.16. Personally Identifiable Information (PII) and Protected Health Information (PHI)

The contractor shall comply with the DHA Procedures, and Information (PGI) 224 – Protection of Privacy and Freedom of Information, revised 17 May 2015. The contractor may access PII in the course of task response to

the requirements of this contract, as such the contractor shall comply with the document entitled "Personally Identifiable Information (PII), Protected Health Information (PHI) and Federal Information Requirements".

The Contractor shall establish appropriate administrative, technical, and physical safeguards to protect any and all Government data. The Contractor shall also ensure the confidentiality, integrity, and availability of Government data in compliance with all applicable laws and regulations, including data breach reporting and response requirements, in accordance with DFAR Subpart 224.1 (Protection of Individual Privacy), which incorporates by reference DoDD 5400.11, "DoD Privacy Program," May 8, 2007, and DoD 5400.11-R, "DoD Privacy Program," May 14, 2007. The contractor shall also comply with federal laws relating to freedom of information and records management. The Contractor shall comply with all requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-191), as implemented by the HIPAA Privacy and Security Rules codified at 45 CFR Parts 160 and 164, and as further implemented within the Military Health System (MHS) by DoD 6025.18-R, "DoD Health Information Privacy Regulation," January 24, 2003, and DoD 8580.02-R, "DoD Health Information Security Regulation, July 12, 2007.

IT services that collect, maintain, use, or disseminate personally identifiable information must be managed in a manner that protects privacy, in accordance with section 552a of Title 5, U.S.C. (Reference (aa)), DoD 5400.11 (Reference (ab)) and DoD 5400.11-R (Reference (ac)). DoDI 5400.16 (Reference (ad)) established the guidance for development, review, and approval of Privacy Impact Assessments, in accordance with chapter 36 of Title 44, U.S.C. (Reference (ae)).

15.17. Public Key Infrastructure Authentication and Encryption

Contractors shall follow the DoD standards, policies, and procedures related to the use of Public Key Infrastructure (PKI) certificates and biometrics for positive authentication including authentication to DoD private web servers or applications. Where interoperable PKI is required for the exchange of unclassified information, including the encryption of e-mail containing sensitive information, between DoD and its Contractors, industry partners shall obtain all necessary certificates if they are not eligible for a DoD Common Access Card. (refer to: http://iase.disa.mil/pki/eca/ and http://www.cac.mil/)

15.18. Network Security

Contractor personnel requiring access to DoD networks to perform work under this contract must have a NACI or an open, pending investigation prior to commencement of work. If the Contractor has a pending investigation, the contractor must present a copy of this investigation to the WRAIR Security Manager at the time of in-processing for review and must contain no unfavorable information. The Contractor must maintain this level of security for the life of the contract. Citizenship will be verified by presenting an original birth certificate or a valid US Passport or the original Naturalization certificate to the WRAIR Personnel Security Manager at the time of in-processing for all contractor personnel assigned to the contract.

Contractor personnel shall use only Government-provided computer equipment; and shall follow all applicable statutes, regulations and policies governing DoD, MEDCOM, USAMRDC, and WRAIR cyber security and information system assets. Personnel must provide proof of applicable training and certifications to include annual Cyber Awareness training. This training must be documented in the Army Training and Certification Tracking System (ATCTS) unless otherwise authorized by applicable policies. DoD Information System, IT service, and IT product acquisition or development must also adhere to applicable policies as described below:

15.18.1. It is DoD policy that Cybersecurity requirements shall be identified and included in the design, acquisition, installation, operation, upgrade, or replacement of all DoD information systems. This includes systems and processes developed within the Defense Acquisition System; systems and processes developed at private expense; outsourced business processes supported by private sector information systems; and outsourced information technologies. Information technology services provided under this contract must comply with statutory and regulatory IA policy. The source documents for this policy are (available in the WRAIR regulatory repository for review):

a. The National Security Act of 1947
b. Title 40/Clinger-Cohen Act
c. Executive Order 12333, "United States Intelligence Activities,"

d. National Security Presidential Directive-54/Homeland Security Presidential Directive-23
e. Subchapter III of chapter 35 of Title 44, United States Code (also known as the "Federal Information Security Management Act (FISMA) of 2002")
f. National Security Telecommunications and Information Systems Security Policy No. 11, "Revised Fact Sheet National Information Assurance Acquisition Policy" and associated "Frequently Asked Questions"
g. National Institute of Standards and Technology (NIST) Special Publication (SP) 800-39
h. Federal Information Processing Standards
i. DoD Instruction 8500.01, "Cybersecurity," March 13, 2014
j. DoD Instruction 8500.2, "Information Assurance Implementation"
k. DoD Instruction 8580.1, "Information Assurance in the Defense Acquisition System"
l. DoD Instruction 5000.02, "Operation of the Defense Acquisition System,"
m. DoD Directive 8570.01, "Information Assurance Training, Certification, and Workforce Management"
n. Chairman of the Joint Chief of Staff Instruction 6510.01E, "Information Assurance (IA) and Computer Network Defense (CND)"
o. Defense Acquisition Guidebook – Chapter 7 Acquiring Information Technology and National Security Systems, Section 7.5 Information Assurance
p. DoD Instruction 8510.01, "Risk Management Framework (RMF) for DoD Information Technologies"

15.18.2. Each proposal under this contract, will be screened for compliance with applicable Cybersecurity statutes, policies, and procedures. Specific requirements will be stated in the performance work statement/statement of objectives. This special contract provision shall be updated by reference for any changes to source documents. Any new laws or policies applicable to Cybersecurity subsequent to issuance of this contract will be incorporated into the basic contract unilaterally without equitable adjustment to the basic contract. Any equitable adjustment shall be assessed by individual contracts that may be affected by the change as applicable.

15.18.3. Non-US citizens are **not being adjudicated** for WRAIR trustworthiness determinations at this time. Non-US Citizens are not allowed access to DoD IT systems unless approved by an authority designated in Appendix 6, DoD 5200.2-R. Only US citizens shall be granted access and assigned to sensitive duties. Exceptions to these requirements shall be permitted only for compelling national security reasons (DoD 5200.2-R. C2.1.1, AP6.6.1).

15.19. Workplace Safety

The contractor employee must be able to maintain a safe workplace and comply with occupational health and safety rules and regulations. Contractor employees are required to attend safety training(s) relative to his/her position and report any infractions of safety procedures to the COR immediately.

The Contractor will be required to ensure compliance with Occupational Health physicals or vaccinations in support of the PWS. These shall be documented and charged as an ODC.

The contractor shall maintain an OSHA 300a log for all reportables (greater than first aid, lost time, lost days, transfer). The contractor shall provide a quarterly report of all mishaps, regardless of class or reportability. Annually, the contractor shall provide a 300A (summary) report to the COR and KO.

Some projects may require immunization with licensed or experimental vaccines for the protection of potentially exposed personnel. When appropriate and as identified in each task order, USAMRMC will offer the experimental vaccines at no cost to the Contractor and provide enrollment into the appropriate safety protocol for the recipient. If a licensed vaccine is available, the Contractor must provide the vaccination through its internal occupational safety program. The Contractor must assure that employees only receive vaccines on a voluntary basis; however, for some projects with specific agents, unvaccinated employees will not be allowed to

participate. The needs for vaccination will be discussed between the COR, the Contractor, and the Contractor's safety specialist. Hepatitis B vaccination and annual influenza vaccination are encouraged for all employees.

16. ATTACHMENTS

Attachment 1 – Acronyms List
Attachment 2 – Organizational Conflict of Interest
Attachment 3 – Participation Agreement

ATTACHMENT 1 – ACRONYMS LIST

Acronym	Definition
AFARS	Army Federal Acquisition Regulation Supplement
AFRIMS	Armed Forces Research Institute of Medical Sciences
AKO	Army Knowledge Online
AOR	Area Of Responsibility
AT OPSEC	Antiterrorism and Operational Security
ATCTS	Army Training Certification Tracking System
CAC	Common Access Card
CFR	Code of Federal Regulations
CONUS	Continental United States
COR	Contracting Officer Representative
DFARS	Defense Federal Acquisition Regulation Supplement
DoD	Department of Defense
EIT	Electronic and Information Technology
FAR	Federal Acquisition Regulation
FBI	Federal Bureau of Investigation
FPCON	Force Protection Condition
FSC	Federal Supply Code
FSS	Federal Supply Schedule
GFE	Government Furnished Equipment
GFI	Government Furnished Information
GSA	General Services Administration
IA	Information Assurance
ID	Identification
ID/IQ	Indefinite Delivery / Indefinite Quantity
IPT	Integrated Product/Process Team
IT	Information Technology
NAC	National Agency Check
NACI	National Agency Check with Inquiries
NCIC-III	National Crime Information Center Interstate Identification Index
NLT	No Later Than
OCI	Organizational Conflict of Interest
OCONUS	Outside Continental United States
OPSEC	Operational Security
PMO	Project Management Office
PRS	Performance Requirements Summary
PWS	Performance Work Statement
QASP	Quality Assurance and Surveillance Plan
QCP	Quality Control Plan
SOP	Standing Operating Procedure

TARP	Threat Awareness and Reporting Program
U.S.C.	United States Code
UIC	Unit Identification Code
US	United States
USAMRAA	United States Army Medical Research Acquisitions Activity
USAMRD-G	United States Medical Research Directorate – Georgia
USAMRD-A	United States Medical Research Directorate – Africa
WAWF	Wide Area Work Flow
WRAIR	Walter Reed Army Institute of Research

ATTACHMENT 2: ORGANIZATIONAL CONFLICT OF INTEREST

Walter Reed Army Institute of Research (WRAIR) Acquisition Operational Support

Walter Reed Army Institute of Research (WRAIR) has categorized its requirements into two broad categories, as defined below, for purposes of identifying, avoiding or mitigating against OCIs in accordance with FAR Subpart 9.5. These categories apply to all enterprise laboratories (Armed Forces Research Institute of Medical Sciences (AFRIMS), United States Medical Research Directorate – Kenya (USAMRD-K), and United States Medical Research Directorate – Georgia (USAMRD-G). These categories are defined as follows:

> Global Support: Where services which, by their very nature, give the Contractor access to non-public procurement sensitive data about the contract requirements, other contractors' proprietary information, or put the contractor in a position to influence the award decision on a contract in which they are participating. This services are identified as those having a direct impact to the operations of the greater WRAIR enterprise.
>
> Services would be characterized as having access to Command Wide procurement sensitive information, or work that could likely have an influence over follow-on awards or contracts within subordinate directorates/Commands.
>
> Mitigation strategies may include: avoidance (non-participation), firewalls between existing personnel and new requirement.
>
> Isolated Support: Services which have focused impact on a specific Branch/ Department/ Program of WRAIR rather than the WRAIR enterprise.
>
> Services can be characterized as having little or no access to procurement sensitive information other than the immediate requirement and little chances of follow-on work that can be influenced by the immediate requirement.
>
> Mitigation Strategies: Contractor can provide a mitigation plan or acceptable self-certification that no OCI exists.

Contractor participation in more than one of these areas may give rise to an unfair competitive advantage resulting from access to advance acquisition planning, source selection sensitive or proprietary information. Furthermore, Contractor participation in more than one area may give rise to a real or apparent loss of Contractor impartiality and objectivity where its advisory or planning assistance in one area potentially affects its present or future participation in another area. An unfair competitive advantage exists where a contractor competing for award of any Federal contract possesses –

> (1) Proprietary information that was obtained from a Government official without proper authorization; or
> (2) Source selection information (as defined in FAR 2.101) that is relevant to the contract but is not available to all competitors, and such information would assist that contractor in obtaining the contract.

The purpose of this categorization is to accomplish the following three objectives: (1) to inform prospective Offerors that WRAIR presumes that award of a contract or order in the subject category will give rise to real or apparent OCI's with respect to requirements in the other category and or may give rise to an CCI in the same category; (2) to assist current Contractors and prospective Offerors in developing their own business strategies regarding participation in WRAIR requirements and in identifying and, where possible, avoiding or mitigating against OCIs; and (3) to ensure that all current Contractors and prospective Offerors are afforded the maximum practicable opportunity to compete for all WRAIR requirements consistent with the restrictions required under FAR Subpart 9.5 and sound business practices.

For purposes of identifying and/or mitigating against OCIs, WRAIR will examine all its services requirements and acquisitions regardless of the cognizant contracting activity (e.g., USAMRAA, GSA, other agency Multiple Award Schedules, etc.) or the type of contract vehicle used (e.g., FSS order, Fair Opportunity competitive order under Multiple Award ID/IQ Contracts, competitively negotiated awards under FAR Part 15, etc.).

Each WRAIR services solicitation will therefore be designated as falling within one of the above defined categories. The applicable OCI category will be set forth in each task order. Contractors may submit a proposal for task orders in either of the OCI categories.

WRAIR will administer this clause for purposes of award eligibility for each solicitation as follows:

The offeror shall provide a listing of all contracts performed for the WRAIR and any enterprise laboratories (USAMRD-G, USAMRD-A, and AFRIMS) as well as with other MRDC laboratories (i.e. U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), U.S. Army Medical Materiel Development Activity (USAMMDA), the Telemedicine and Advanced Technology Research Center (TATRC) or MRDC) in the last three (3) years. A single-category Offeror/Contractor wishing to submit an offer in the other category, or any Offeror/Contractor which now provides or previously has provided support in both categories, ***must include the following as part of its offer***:

- Perform a comparative analysis of the potential new work against *all* current and previous work performed in support of WRAIR in *any category*. The comparative analysis must be included in the proposal for the new work, and must include a statement certifying whether the Contractor believes that its performance of the proposed new work would create a real or apparent OCI. If the Contractor believes that no real or perceived OCI will result from an award of the proposed work, no additional action by the Contractor is required, unless the Contracting Officer specifically requests an OCI mitigation Plan.

- If the Offeror/Contractor believes that a real or apparent OCI may exist as a result of an award, the Contractor shall also submit an OCI Mitigation Plan with its proposal.

Inclusion of the comparative analysis and OCI Mitigation Plan will not be counted against any offer page limitations otherwise stated in the solicitation.

The following subsections prescribe certain limitations on contracting as the means of avoiding, neutralizing or mitigating organizational conflicts of interest.

It is the contractor's responsibility to notify the Contracting Officer of any potential OCI. In the event that an OCI exists the contractor shall propose a Mitigation Plan that shall be reviewed and accepted by the Contracting Officer prior to continuance of the work that presents an OCI. Should the proposed Mitigation Plan not be accepted by the Contracting Officer, the Government may terminate this contract, disqualify the Contractor from subsequent related contractual efforts, and pursue any remedies as may be permitted by the law or this contract.

Contractors shall sign a Non-Disclosure Agreement at the start of their performance on the contract.

If, under this contract, the contractor will provide systems engineering and technical direction for a system, but does not have overall contractual responsibility for its development, integration, assembly, checkout or production, the contractor shall not be awarded a subsequent contract to supply the system or any of its major components, or to act as consultant to a supplier of any system, subsystem, or major component utilized for or in connection with any item or other matter that is (directly or indirectly) the subject of the systems engineering and technical direction. The term of this prohibition shall endure for the entire period of this contract and for two (2) years thereafter.

If, under this contract, the contractor will prepare and furnish complete specifications covering non-developmental items, to be used in a competitive acquisition, the contractor shall not be permitted to furnish these items, either as a prime or subcontractor. The term of this prohibition shall endure for the entire period of this contract performance and for either two (2) years thereafter or the duration of the initial production contract whichever is longer. This rule

shall not apply to contractors who furnish specifications or data at Government request or to situations in which contractors act as Government representatives to help Government agencies prepare, refine or coordinate specifications, provided this assistance is supervised and controlled by Government representatives.

If, under this contract, the contractor will prepare or assist in preparing a work statement to be used in competitively acquiring a system or services, the contractor shall not supply the system, its major components, or the service unless the contractor is the sole source, the contractor has participated in the development and design work, or more than one contractor has been involved in preparing the work statement. The term of this prohibition shall endure for the length of this contract.

If, under this contract, the contractor will provide technical evaluation of products or advisory and assistance services, the contractor shall not provide such services if the services relate to the contractor's own or a competitor's products or services unless proper safeguards are established to ensure objectivity.

If, under this contract, the contractor gains access to proprietary or source selection information of other companies in performing advisory assistance services for the Government, the contractor agrees to protect this information from unauthorized use or disclosure and to refrain from using the information for any purpose other than that for which it was furnished. A separate agreement shall be entered into between the contractor and the company whose proprietary information is the subject of this restriction. A copy of this agreement shall be provided to the Contracting Officer.

The Contracting Officer has significant discretion as to the acceptability of any mitigation plan offered.

Offerors are encouraged to present their best strategy for mitigation of any potential OCI under this requirement. Offerors shall submit a mitigation plan at the Contract level and update it as often as necessary throughout the life of the Contract.

The Contracting Officer (and when applicable the appropriate program office, acquisition manager, and legal counsel) will review the comparative analysis and, if provided, the Mitigation Plan, in accordance with the requirements of FAR Subpart 9.5 (Organizational Conflict of Interest) to determine whether award to that Offeror would be consistent with those requirements. If it is unilaterally determined by the Contracting Officer that no OCI would arise or that the OCI Mitigation Plan adequately protects the interests of the government in the event of award to that Offeror, the Offeror will be determined, for purposes of this clause, to be eligible for award. If the Contracting Officer reasonably determines that a Contractor has not provided either a comparative analysis or Mitigation Plan, or both, or that the analyses or plan provided is inadequate, sanctions including elimination from the award process, or termination of the related contract effort already awarded, as well as other appropriate sanctions will be considered.

If the Offeror/Contractor knows of no OCI in accepting work under this contract, it shall certify its OCI status and submit the certification at the end of this clause with its proposal and any later award, if awarded the contract. The Contractor shall also obtain a similar certification of OCI status from all subcontractors, teaming partners or consultants prior to tasking any such party under this contract. The Contractor shall appropriately modify and include this clause, including this paragraph, in all consulting agreements and subcontracts of any tier to preserve the rights of the Government.

For breach of any of the above restrictions or for nondisclosure or misrepresentation of any relevant facts required to be disclosed concerning this contract, the Government may terminate this contract, disqualify the Contractor from subsequent related contractual efforts, and pursue any remedies as may be permitted by law or this contract.

Prior to a contract modification involving a change to the Statement of Work, or an increase in the level of effort or extension of the term of the contract, the Contractor shall submit any applicable organizational conflict of interest disclosure or an update of the previously submitted disclosure or representation.

The Offeror/Contractor should review the considerations below in determining whether or not a conflict of interest exists.

- Does the Offeror or any intended subcontractors, teaming partners, proposed employees, or affiliates have Unequal Access to Information? Would award to the Offeror result in the Offeror having the opportunity to access nonpublic information that may give the Offeror a competitive advantage in a later competition for a government contract? Specifically, will the Offeror/Contractor have access to any of the following information:

    - Budget(s), or Budget Information?
    - Acquisition Sensitive Information related to the procurement process to include, but not limited to Acquisition Plans, Requirements, Statements of Work, or Evaluation Criteria?

- Does the Offeror or any intended subcontractors, teaming partners, proposed employees, or affiliates have "*impaired objectivity*" because the Offeror's ability to render impartial judgments may be compromised because of its conflicting role(s) on this effort and other government contracts?

- Do "*biased ground rules*" exist? Most commonly, this would include a situation where the Offeror has, as a government Contractor, written specifications or a statement of work for this effort, which could skew competition in favor of itself?

- Is the Offeror aware of any other information relating to this proposed contract/order, which could reasonably be construed as creating an OCI?

- Does the Offeror or any intended subcontractors, teaming partners, proposed employees, or affiliates have access to third party proprietary information including but not limited to third party Intellectual Property, financial data, or future plans?

The Offeror/Contractor hereby certifies to the best of its knowledge its OCI status below:

(Offeror: Choose one of the following two statements. Indicate which one applies by placing an X in the box to the left of the statement.)

□ No real or perceived OCI, as defined in FAR 2.1 and discussed in FAR 9.5, will result from an award of the proposed work (there are no 'Yes' responses to the questions above).

□ A real or apparent OCI may exist as a result of an award and therefore an appropriate OCI Mitigation Plan is attached (Offeror shall include an appropriate OCI Mitigation Plan, as required by this clause, with its quote to the Contracting Officer).

Upon award the Contractor agrees that it will provide timely OCI training to all employees and subcontractor employees working on this effort, which will include emphasis on how work performed by Contractor employees (either prime Contractor, subcontractor, or other teaming partners) under one WRAIR OCI category can exclude the Contractor as well as its teaming partners from performing related tasks under a different OCI category of work.

_____ (Signature) _____ (Date)

_____ (Printed Name) _____ (Title)

ATTACHMENT 3: COVERED EMPLOYEE PARTICIPATION AGREEMENT

As a participant in the _____, you are a "covered employee" (contractor employee or subcontractor self-employed individual performing an acquisition function that is closely associated with inherently governmental functions) under FAR 3.11 and FAR 52.203-16. You are required to protect the confidentiality of information and avoid personal conflicts of interest.

This agreement must be read, understood, and agreed to before you begin any activities.

1. Confidentiality of Information.

Certain information you prepare or receive in the course of your participation will be non-public information that must be safeguarded. Non-public information means any Government or third-party information that:

a. Is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552) or otherwise protected from disclosure by statute, Executive Order or regulation; or
b. Has not been disseminated to the general public and the Government has not yet determined whether the information can or will be made available to the public.

Non-public information would include proposal information, pricing, review materials, evaluation information, review group discussions, program and project related information, personally identifiable information and proprietary information of third parties, including but not limited to information regarding properties, formulae, structures, manufacturing processes, and test results.

You are required to sign a non-disclosure agreement that prohibits you from disclosing non-public or proprietary information. **Any questions on confidentiality of information should be directed to your employer/contractor.**

_____ (initial) *I agree to maintain a high degree of physical security over non-public information at all times. When the non-public information is no longer needed for my participation, I will either return it as requested or immediately destroy it.*

_____ (initial) *I will use non-public information strictly for purposes of my participation in the activity designated above and will not use it for personal gain. I will not discuss or otherwise disclose non-public information to anyone who is not authorized to receive it.*

2. Personal Conflict of Interest

It is essential that all actions be conducted impartially so there is no public doubt about the propriety and fairness of government programs and operations. You would have a personal conflict of interest in a situation where a financial interest, personal activity, or relationship could impair your ability to act impartially and in the best interest of the Government. Among the sources of personal conflicts of interest are:

- Financial interests of you, of close family members, or of other members of your household.
- Other employment or financial relationships (including seeking or negotiating for prospective employment or business); and
- Gifts, including travel

Financial interests may arise from:

- Compensation, including wages, salaries, commissions, professional fees, or fees for business referrals;
- Consulting relationships (including commercial and professional consulting and service arrangements, scientific and technical advisory board memberships, or serving as an expert witness in litigation);
- Services provided in exchange for honorariums or travel expense reimbursements;
- Research funding or other forms of research support;
- Investment in the form of stock or bond ownership or partnership interest (excluding diversified mutual fund investments);
- Real estate investments;

- Patents, copyrights, and other intellectual property interests; or
- Business ownership and investment interests.

Any questions on conflicts of interest should be directed to your employer/contractor.

_____ (initial) *I have disclosed, all financial interests, personal activities, or relationships that could impair my ability to act impartially and in the best interest of the Government in participating in the above described activity. I will not participate until the conflict has been resolved.*

_____ (initial) *I agree that should I become aware of a personal conflict of interest or an appearance of a conflict of interest during my participation, I will immediately report the conflict to my employer/contractor and remove myself from further participation until the conflict has been resolved.*

_____ (initial) *I agree not to use my participation for purposes that are, or give the appearance of being, motivated by the desire for private gain.*

By initialing above and signing below, I acknowledge my responsibilities and obligations in regard to maintaining confidentiality of information and avoiding conflicts of interest while participating in the above-described activity. I understand that there may be disciplinary actions, civil and criminal penalties for violation of my obligations.

_____ _____
Signature Date

_____
Printed Name

_____
Printed Name of Organization