

## **PERFORMANCE WORK STATEMENT**

**U.S. ARMY MEDICAL RESEARCH DIRECTORATE- GEORGIA (USAMRD-G)**  
**Research & Laboratory Services Support, Lugar Center**  
**Indefinite Delivery Indefinite Quantity (IDIQ)**

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## **PERFORMANCE WORK STATEMENT (PWS)**

**Title:** Research and Laboratory Services Support to the Lugar Center, Georgia 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 Department of Defense (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 neuro-trauma 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 research and clinical / veterinary surveillance 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 Development Command (USAMRDC), 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 National Center for Disease Control (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.

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.

### 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). Currently this contract has performance in Georgia and Bulgaria; possible expansion to other countries, e.g. Romania, Latvia, Ukraine, and Poland. The Contractor shall have and maintain a business license to perform in accordance with the host country laws and regulations.

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 biomedical research support, project management support, clinical research/surveillance support, and operational (management and ancillary) support. Task orders under this vehicle will direct programmatic requirements to support scientific research/surveillance efforts including: clinical surveillance and vector<sup>1</sup> sample collection; basic and applied biomedical research; clinical and One Health research. Task orders will also direct requirements for operational support to USAMRD-G including supplies and services to sustain project management and supervisory technical and resource management support. Additional operational and programmatic support will include: logistics (shipping and procurement), safety, recruitment, retention, training and project development / proposal submission support.

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

#### Scientific Research and Development (R&D) Support:

- Technical Lead in Infectious Disease Research and Project management Services
- Clinical Research Principal Investigator Services
- Microbiology Research (Bacteriology / Virology) Principle Investigator Services
- Molecular Biology Investigator Services
- Medical Entomology Research Investigator Services
- Animal Use Research / Surveillance
- Training of research / testing / surveillance procedures

#### Clinical Surveillance Support:

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<sup>1</sup> Vector refers to Arthropods, e.g. mosquitoes, flies, biting midges, ticks, mites, fleas, etc. that can/do transmit pathogens / infectious disease agents.

- Research and Laboratory Technical Services
- Human Use Research Services
- Training Clinical Investigators Services

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

Operational Support:

- Project and Research Operational Management Services
- Human Subjects Research Protection Review Support Services
- Animal Care and Use Protection Review Support Services
- Grantsmanship and agreement development Support Services
- Translation Services
- Transportation (Sample/Specimen/Equipment) Support Services
- Safety Support Services
- Administrative 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) through a Task Order Proposal Request (TOPR). 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.

### **3.1. Collaborative efforts in Bulgaria - Background**

**3.1.1.** 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.

**3.1.2.** 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.

**3.1.3.** 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.

#### **4. PERIOD OF PERFORMANCE**

The ordering period for this IDIQ contract is as follows:

12 March 2022 – 11 March 2026
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#### **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 primary work location is Richard G. Lugar Center for Public Health Research located at 4a Kakheti Highway, 0198, Tbilisi Georgia.

Individual Task Orders may require work locations in US European Command (USEUCOM) Area of Responsibility (AOR) based on objectives outlined in the Task Order PWS.

##### **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 facility 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, web-conference/meeting e.g. Microsoft TEAMS, telephone, 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-site for those days the Government or facility is closed due to safety conditions, inclement weather conditions, national emergencies, energy conservation or by direction of the Installation Commander Facility manager or equivalent for any other reason. During these periods of closure, the contractor employees that are not designated as essential in accordance with (IAW) this contract shall not report for work nor will they be compensated for those days.

## **5.2. National / Federal Holidays**

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

National/Federal holidays are an exception to the regular duty hours. Any of the holidays listed in Attachment 5 falling on a Saturday will be observed on the preceding Friday; holidays falling on a Sunday will be observed on the following Monday. The list of legal National/Federal holidays that services shall not be performed can be found in Attachment 3. The cumulative number of National/Federal holidays will not exceed 20 and are represented by a combination of US and host-nation holidays observed within a calendar year.

Holidays shall be updated according to the performance location at the base IDIQ level.

## **5.3. Post/Facility 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 regular Services / Support from 0900 to 1700 Host Nation local time, based on the country in which services are provided (e.g. in Georgia 0900 to 1700 GET [UTC +3]), unless otherwise coordinated with COR.

## **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 2) shall be submitted with the proposal as part of the Operational Support Plan (Deliverable 1)** 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.

- 5.5.1.** 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

- Non-personal 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, 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 Infectious Disease (ID) threats IAW priorities set by the US. Department of Defense, USEUCOM, and Global Emerging Infectious Surveillance (GEIS) program.

### **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 services for the development and/or refinement medical countermeasure (MCM; prophylactics, diagnostics or therapeutics) research, development, test and evaluation (RDT&E) /surveillance for infectious disease agents consistent with the USAMRD-G's strategic vision and mission.
- 6.2.2.** Submit proposals in accordance with USAMRD-G approved research / surveillance call for proposal solicitations (i.e. Broad Agency Announcement, Request For Proposal, Request for Prototype Proposals, ...), e.g. from Defense Health Program, Congressionally Directed Medical Research Program / Peer Reviewed Medical Research Program, GEIS, etc. Investigators shall staff proposals (surveillance and research project submissions) to USAMRD-G Portfolio Manager & Senior Scientist, so they can be reviewed/approved for submission. Following proposal approval by the funding agency and after USAMRD-G receives funds, Investigators shall conduct research as defined in the proposal. (E.g. execute surveillance or research, training, reporting, support establishment of collaborative agreements, obtain human or animal use committee approvals and execute response activities as related to emerging and endemic infectious diseases.)
- 6.2.3.** Maintain documentation (electronic or paper) of routine laboratory maintenance (e.g. certification/calibration) and accountability for designated laboratory equipment in compliance with USAMRD-G business processes.
- 6.2.4.** Respond to outbreaks and augment local public health diagnostic capabilities as needed/when requested by local public health authorities and approved by WRAIR Commander, when supporting approval via international agreement with U.S. Government and U.S. Department of Defense approved /staffed via government channels.
- 6.2.5.** Support Science Technology Engineering and Mathematics (STEM) initiatives IAW the unit's mission to support the U.S. State Department/Embassy Chief of Mission Integrated Country Team strategy for capability enhancement among local nationals.

### **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 to achieve the cost, schedule, and performance goals of its RDT&E / surveillance project 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. Governing regulations that shape the RDT&E / surveillance project activities i.e. Current Good Clinical Practices (cGCP) and human subjects protection are found in Code of Federal Regulations (CFR); see Section 15 for these references. References for military regulations and policies governing regulated research may be found at [https://mrmc.amedd.army.mil/index.cfm?pageid=research\\_protections\\_overview](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. Research and Surveillance Support Services**

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

#### **6.3.2. Quality Control**

The contractor review and comply with all documents for regulatory (FDA, Human or Animal Use, etc.) compliance and quality systems/SoPs at USAMRD-G. Contractor shall review study protocols ensuring plans encompass all required elements, data parameters, test objectives before submission through MRD-G/WRAIR channels for approvals. Contractor ensure data submissions are compliant with regulatory and programmatic requirements and ensure the protocols have proper review and approval prior to execution; perform audits as required to ensure proper procedures, techniques, and protocols are followed & that SOPs, 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 and comply with all USAMRD-G laboratory SOPs to ensure compliance with all applicable safety and occupational health policies, procedures, and regulations, to include the clinical research centers. Contractor shall provide feedback to USAMRD-G staff to support continuous improvement of said SOPs. Shall perform monitoring audits, in coordination with USAMRD-G staff, to ensure proper procedures, techniques, and protocols are followed SOPs, 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 logistics support, translation services, local transportation services, training, and quality control. The contractor shall provide an on-site scientific technical lead / 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 1)**

The contractor shall draft and submit an Operational Support Plan to address operations at USAMRD-G locations supporting biomedical research / clinical surveillance sites in Georgia and Bulgaria, with the provision for comparable activity in other USEUCOM locations, i.e. Romania, Latvia, Ukraine, and Poland. The Operational Support Plan is a composite of sub-plans and will cover, at a minimum but limited to, the daily functions such as:

- Contingency (**Deliverable 2**)
- Human Resources Support (inclusive of training plan)(**Deliverable 3**)
- Logistics Support – see Task Order(s) for details (**Deliverable 4**)
- Management support (**Deliverable 5**)
- Occupational Health and Safety
- 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 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 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, USAMDMC, 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 (annual refresher)
- Operations Security (OPSEC) training – Within 90 days of start date (annual refresher)
- Environmental Awareness Training
- Insurance Portability and Accountability Act (HIPAA) training (annual refresher)
- Information Assurance training (annual refresher)
- 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, clinical specimen, vectors, animal samples, infectious substances, supplies and equipment; shipment of biologics, supplies and equipment. 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 SOP.

### Management Reports and Plans

#### 6.4.7. Management Plan (Deliverable 5).

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 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.

#### 6.4.8. Monthly Status Report.

The contractor shall provide a monthly report detailing all work at the Task Order level, 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 (Principle Investigator's (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:

- SOP / study specific protocol (SSP) / and risk assessment development/ maintenance
- Knowledge product development and translation (e.g., abstracts, SPOT reports, manuscripts)
- Study specific documentation (e.g., research protocols, amendments, continuing review documents, federal wide assurance completion, and other documents as required by regulatory oversight bodies)
- Biological specimen inventory targets (but must be 100% compliant by directed suspense date); includes inventory of perishable consumables and associated expiration date(s)
- Funding obligation rates by project/line of effort (is project specific funding on glide path with established spend plan)

- f. Study sample, specimen, or participant enrollment numbers IAW stakeholder expectations (i.e., is the study meeting projected enrollment targets, and, if not, what remediation efforts are underway to meet projected targets 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, and 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.

#### **6.4.9. Quality Control Plan (Deliverable 6).**

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.

#### **6.4.10. Service Contract Reporting Application (SCRA) (Deliverable 7).**

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.\***

#### **6.4.11. 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 8**). 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	Operational Support Plan	Draft at time of proposal. Final 10 days after contract award/ Updated Quarterly
5.5	Deliverable 2	Contingency Plan	Draft at time of proposal. Final 30 days after contract award/ Updated Annually
6.4.5.	Deliverable 3	Human Resources Support Plan	Draft at time of proposal. Final 30 days after contract award/ Updated Annually
6.3.6.	Deliverable 4	Logistics Support Plan	Draft at time of proposal. Final 30 days after contract award/ Updated Annually
6.4.7.	Deliverable 5	Management Plan	Draft at time of proposal.

			Final 15 days after contract award
6.4.9.	Deliverable 6	<b>Quality Control Plan</b>	Draft at time of proposal. NLT 15 days after contract award
6.4.4.	Deliverable 7	<b>Service Contract Reporting Application</b> The contractor shall complete and deliver the CMRA.	By October 31 or on the last day of contract performance – whichever is first
6.4.11.	Deliverable 8	<b>CPARS Concurrence/Non-concurrence</b> The contractor shall provide concurrence or non-concurrence with the CPARS assessment.	60 calendar days after Government evaluation
9.2.	Deliverable 9	<b>Summarized Final Report</b>	To be submitted along with Transition-Out Plan/Update as needed
10.2	Deliverable 10	<b>Trip Report</b>	NLT 30 days following trip completion
11	Deliverable 11	<b>Inventory detailing Government Furnished Equipment/Material or Contractor-Acquired-Government Owned Property (CAP)</b> To be attached to the Monthly Progress Report	Per Task Order- 15 <sup>th</sup> day of each month for the preceding month
13.1.2	Deliverable 12	<b>Occupational Health and Safety Plan</b>	30 days after award and updated annually thereafter.
15.11.12.	Deliverable 13	<b>Threat Awareness Reporting Program</b> The contractor shall ensure all personnel traveling in support of this PWS receive Threat Awareness Reporting Program (TARP) training.	60 days (or as soon as practicable) before contractor travel outside Georgia.
15.12.	Deliverable 14	<b>Information Security Program Training</b> The contractor shall ensure all personnel receive ISP training.	NLT 30 calendar days after contractor personnel begin performance under this contract and annually thereafter
15.15	Deliverable 15	<b>Health Insurance Portability and Accountability Act (HIPAA) and Collaborative Institutional Training Initiative (CITI) Program Training</b> The contractor and all employees working on this contract and associated with clinical research/surveillance must complete the annual HIPAA training	Within 30 days after contract award, before they can participate in clinical research/surveillance protocols and then annually thereafter for the remainder of the contract.
Attachment 13 and 14	Deliverable 16	Participation Agreement	NLT 15 calendar days after contractor personnel begin performance at the Task Order level.
15.11.7 / 15.11.8	Deliverable 17	<b>OPSEC and DOD IA Awareness training.</b> The contractor and all employees working on this contract	NLT 15 calendar days after contractor personnel begin performance under this contract and annually

			thereafter.
15.11.4	Deliverable 18	<b>iWATCH training completion</b>	NLT 60 calendar days after contractor award and 30 calendar days of new employee commencing performance.
15.19	Deliverable 19	<b>OSHA 300A</b> The contractor shall complete and deliver the OSHA 300A.	Quarterly provide a report of all mishaps, regardless of class or reportability. Annually, provide a 300A (summary) report.

### 7.1. Inspection and Acceptance

The COR delegated oversight of specific technical, functional and oversight responsibilities 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.

### 7.2. COR Information

The COR will be identified by a separate letter for the base IDIQ and at the Task Order level. 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 at the Task Order Level. 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 un-compiled 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 un-compiled 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 IDIQ Labor Category 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/TEMPORARY 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 will be identified at the Task Order Level.

#### **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. See attachment 6 for additional information and 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 (ISO-PREP)
  - d) Area of responsibility briefing completed within three months of travel.

**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>

## **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 at the Task Order Level. 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. Within two business days of employee no longer supporting the contract and/or on contract expiration, the contractor shall, return these items to the COR or their designee.

**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 National/Federal holidays 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 Non-Disclosure Agreement on behalf of the company at the Task Order Level; ensure that all staff assigned to or performing on each task/delivery order execute and adhere to the terms of the Participation Non-Disclosure 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.** Contractor may add subcontractors to their team after notification and written approval from the KO.

## 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. 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](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 (Deliverable 12)** and shall be updated NLT 30 days after award and annually thereafter. The contractor's Safety program shall include Conducting Training, Documenting, and Monitoring for Compliance, and shall be in consonance with USAMRDC 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 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](http://www.army.mil/usapa/epubs/340_Series_Collection_1.html)

- b) Army Regulation 25-2, Information Assurance.
- c) 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>
- d) Department of Defense (DOD) 6025.18 Regulation, DOD Health Information Privacy Regulation, 24 January 2003.
- e) DOD Instruction 3210.7, Research Integrity and Misconduct, 14 May 2004.
- f) Army Regulation (AR) 70-25: Use of Volunteers as Subjects of Research, Headquarters, Department of the Army, dated 25 January 1990 – currently under revision
- g) Clinical Laboratory Improvement Amendments, 2013. [https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA\\_Regulations\\_and\\_Federal\\_Register\\_Documents.html](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>
- h) 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.
- i) College of American Pathologists Inspection Checklists. <http://www.cap.org>
- j) Clinical Laboratory Standards Institute. Standards and Guides for Laboratories:  
<http://clsi.org/standards>
- k) 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>
- l) 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>
- m) ICH Guideline for Good Clinical Practice, Consolidated Practice (E6)  
<http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html>
- n) Title 21, CFR Part 11 Electronic Records: Electronic Signature.  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11>
- o) Title 21, CFR Part 50 Protection of Human Subjects  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50&showFR=1>
- p) Title 21 CFR Part 54 Financial Disclosure by Clinical Investigators  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54>
- q) Title 21 CFR Part 56, Institutional Review Boards  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56>

- r) Title 21 CFR Part 812, Investigational Device Exemptions, April 1, 2014  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=812>
- s) Title 45 CFR 46, Protection of Human Subjects, April 1, 2014,  
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#>
- t) 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](https://www.osha.gov/pls/oshaweb/owastand.display_standard_group?p_toc_level=1&p_part_number=1910)
- u) 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>
- v) 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>
- w) Dangerous Goods Regulations of the International Air Transport Association.  
<http://www.iata.org/Pages/default.aspx>
- x) 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. Medical and Laboratory Compliance**

### **13.2.1. *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](http://www.army.mil/usapa/epubs/340_Series_Collection_1.html)

### **13.2.2. *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>

### **13.2.3. *DOD Health Information Privacy***

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

### **13.2.4. *Research Integrity and Misconduct***

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

### **13.2.5. *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

### **13.2.6. *Clinical Laboratory Improvement***

Clinical Laboratory Improvement Amendments, 2013. [https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA\\_Regulations\\_and\\_Federal\\_Register\\_Documents.html](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>

**13.2.7. 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.

**13.2.8. Pathology Inspection**

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

**13.2.9. Laboratory Standards**

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

**13.2.10. 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>

**13.2.11. 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>

**13.2.12. 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>

**13.2.13. Clinical Practice**

Title 21, CFR Part 11 Electronic Records: Electronic Signature.

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11>

**13.2.14. 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>

**13.2.15. 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>

**13.2.16. Institutional Review Boards**

Title 21 CFR Part 56, Institutional Review Boards

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56>

**13.2.17. 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>

**13.2.18. 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](http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title32/32cfr219_main_02.tpl)

**13.2.19. Protection of Human Subjects**

Title 45 CFR 46, Protection of Human Subjects, April 1, 2014,

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#>

**13.2.20. 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](https://www.osha.gov/pls/oshaweb/owastand.display_standard_group?p_toc_level=1&p_part_number=1910)

**13.2.21. 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>

**13.2.22. 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>

**13.2.23. 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>

**13.2.24. 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](http://www.apd.army.mil/pdffiles/r600_110.pdf)
- e) Code of Federal Regulations (CFR), <https://ecfr.gov>.
  - i. Electronic Records; Electronic Signatures, 21 CFR 11; applies to Current Good Clinical Practice and Current Good Laboratory Practice
  - ii. Protection of Human Subjects; 21 CFR 50
  - iii. 21 CFR 54 Financial Disclosure by Clinical Investigators
  - iv. 21 CFR 56 Institutional Review Boards
  - v. 21 CFR 58 Good Laboratory Practice for Nonclinical Laboratory Studies
  - vi. 21 CFR 312 Investigational New Drug Application
  - vii. 21 CFR 314 Applications for FDA Approval to Market a New Drug
  - viii. Protection of Human Subjects: 45 CFR 46
- f) International Conference on Harmonization, (<https://ichgcp.net>), i.e. Guidelines for Good Clinical Practice which is the international standard governing the conduct of clinical trials

**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 Contracting*. 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 Non-Disclosure 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 Non-Disclosure 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.

#### **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. Anti-Terrorism and Operational Security**

##### **15.10.1. *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>.

##### **15.10.2. *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.

**15.10.3. *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.

**15.10.4. *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 60 calendar days of contract award and within 30 calendar days of new employees commencing performance, with the results reported to the COR NLT 60 calendar days after contract award (Deliverable 18).

**15.10.5. *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.

**15.10.6. *For Contracts That Require an OPSEC SOP.***

The contractor shall develop an OPSEC 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.

**15.10.7. *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 (**Deliverable 17**).

**15.10.8. 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 (**Deliverable 17**). 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.

**15.10.9. 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.

**15.10.10. 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.

**15.10.11. 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 13**)

**15.11. 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 14**). Training can be found at - <https://www.lms.army.mil/>

**15.12. System Security Plan and Associated Plans of Action. N/A**

**15.13. 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. N/A**

**15.14. 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 15**)

#### **15.15. 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)).

#### **15.16. 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/>)

#### **15.17. 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:

- 15.17.1.** 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"

**15.17.2.** 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.

**15.17.3.** 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).

## **15.18. 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 (Deliverable 19) 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, USAMRDC 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 and COVID-19 vaccination along with annual influenza vaccination are encouraged for all employees.

## **16. ATTACHMENTS**

**Attachment 1 – Acronyms List**

**Attachment 2 – Organizational Conflict of Interest**

**Attachment 3 – Division Organization Chart**

**Attachment 4 – National / Federal Holidays**

**Attachment 5 - DOD Contractor Foreign Travel / OCONUS**

## 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
RDT & E	Research, Development, Test and Evaluation

SOP	Standi 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
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)

- 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.

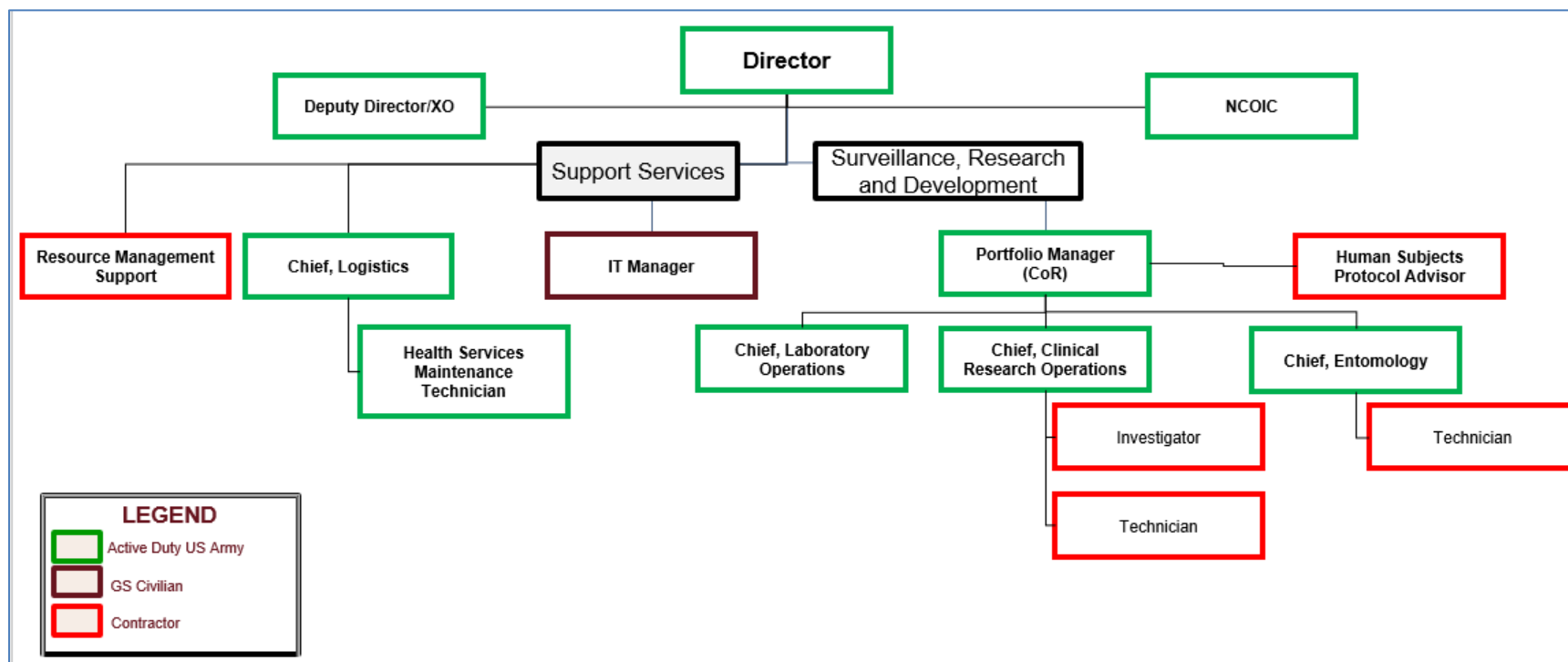
\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Printed Name of Organization

#### ATTACHMENT 4: DIVISION ORGANIZATIONAL CHART



**Attachment 5 – National / Federal Holidays for calendar year 2022 are listed below, by country:  
United States of America**

**United States of America**

January 17	M.L. King, Jr. Birthday
February 21	Presidents' Day
May 30	Memorial Day
June 20	Juneteenth Day
July 4	Independence Day
September 5	Labor Day
October 10	Columbus Day
November 11	Veteran's Day
November 24	Thanksgiving Day
December 26	Christmas Day (Observed)
December 31	New Year's Day (Observed)

January 7	Christmas (Orthodox)
January 19	Epiphany (Orthodox)
March 3	Mother's Day
March 8	International Women's Day
April 9	Memorial Day
April 22	Good Friday (Orthodox) <sup>2</sup>
Apr 25	Easter Monday <sup>2</sup>
May 26	Independence Day
October 14	Svetitskhovloba
November 23	St. George's Day

The following Georgian holidays are also observed, but they either fall on a weekend or exceed the 20 holidays allowed (between US and Georgian Holidays); no additional leave credit is given for them:

January 1	New Year's Day
January 2	New Year's Day Holiday
April 9	Memorial Day
August 28	Assumption of the Virgin (Mariamoba)

Actual day observed varies by calendar year.

### **Bulgaria**

January 3	New Year's Day
March 3	National Day
April 22	Good Friday
April 25	Orthodox Easter Monday
May 2	Labor Day (observed)
May 6	St. George's Day and Day of Valor of the Bulgarian Army
May 24	Saints Cyril & Methodius Day
September 5*	Unification Day
September 6	Unification Day
September 22	Independence Day
December 26*	Day after Christmas
December 27	Christmas Eve (Observed)
December 28	Christmas Day (Observed)

The following Bulgarian holidays in 2022 fall on Saturdays and Sundays:

New Year's Day (January 1, Saturday)  
 Orthodox Easter (April 23-24, Saturday - Sunday)  
 Labor Day (May 1 - Sunday)  
 Christmas Eve (Dec. 24, Saturday)  
 Christmas Day (December 25, Sunday).

\* Holidays coincides with US holidays.