OMNIBUS IV
Military Medical Research and Development HT0011-21-R-0004

Attachment 1: STATEMENT OF OBJECTIVES 26 March 2021

C.1 TECHNICAL

C.1.1 BACKGROUND

Historically, the OMNIBUS contracting vehicles, which spanned over nine years (including OMNIBUS I, II and III), were productive vehicles (approximately $1 billion in contracts) for discovery and integration of innovative medical knowledge and material solutions to continually enhance Force health readiness, resilience, and rehabilitation. The OMNIBUS IV contracting vehicle is a continuation of the predecessor contracts and designed to enhance the related medical research and development programs of the Department of Defense (DoD). An added value of OMNIBUS IV is research and development migrating into medical practice via translation science support and services. Although the OMNIBUS IV is primarily an RDT&E contracting vehicle, funding sources at the task order (TO) level will be determined by scope and adherence to applicable law and federal regulations. If in scope and appropriately funded, OMNIBUS IV TOs may receive funding support from DHP RDT&E funds or other federal and non-federal sources to the extent permissible by the terms and conditions of the contract, law and federal regulations.

All work performed pursuant to OMNIBUS IV TOs shall comply with all applicable standards as well as Federal, State, and local laws and regulations, to include Agency-specific regulatory supplements, to be specified in each individual TO. OMNIBUS IV Base Awards will be made by Market Segment, but TO may span one or more Market Segments and Proficiency Areas.

C.2 SCOPE

C.2.1 PROGRAM AREAS

Program Areas broadly define health-related research and development areas and activities of interest to DoD and the Military Healthcare System (MHS). For the purposes of OMNIBUS IV, these Program Areas generally delineate categories used by the MHS R&D community to determine R&D investments. These Program Areas are generalized and distilled from the research topics of historical and anticipated MHS requirements. However, given the nature of R&D, these Program Areas cannot map perfectly to the OMNIBUS IV Market Segments and Proficiency Areas below. The Market Segments divide the very broad scope of OMNIBUS IV in to four well-defined but not mutually exclusive categories. The requirements of the Market Segments are further developed and explicated in Proficiency Areas. The Proficiency Areas indicate the main performance objectives, expertise, competence, etc. the government seeks. Task Order Proposal Requests will subsequently provide refined levels of detail sufficient to describe the requirements for solicitation. The program areas for OMNIBUS IV include but are not limited to the following:

1. Medical Simulation Technologies – Includes but is not limited to, systems, processes or methods supporting medical simulation to increase military medical personnel's knowledge, skills and abilities to deliver combat casualty care support to manage patient injury and illness and to conduct patient movement from point of injury through role of care four;

2. Infectious Diseases – Includes but is not limited to, medical readiness, vaccines, biology, prophylaxis/treatment drugs, diagnostics/prognostics, vector control, medical C4ISR, global and emerging disease countermeasures, and OCONUS field surveys (such as in Peru, Egypt, Cambodia, Italy, Singapore and Thailand);
3. Military Health, Performance and Recovery – Includes but is not limited to, injury prevention and reduction, psychological health and resilience, post-traumatic stress disorder, physiological health, physical and cognitive performance, human physiologic and cognitive factors associated with various military operations to include sea, aviation, space and other related environments, aviation safety, aeromedical standards, altitude effects, acceleration effects, fatigue assessments, environmental and occupational health, exposures, and environmental health and protection, nutrition and dietary supplements, conducting epidemiological studies investigating the longitudinal health of service members and their families, and developing and evaluating appropriate health surveillance and intervention strategies;
4. Joint Battlefield Healthcare – Includes but is not limited to, damage control resuscitation, traumatic neuro-trauma and brain injury, combat trauma therapies, health monitoring and diagnostic technology, in route care; forward surgical and intensive critical care; traumatic tissue injury; and combat dentistry;
5. Radiation Health Effects – Includes directed energy biomedical research, women proximity to nuclear power plants, post-exposure mitigation of radiation injury; protection and prevention of injury from ionizing radiation; understanding the mechanism of radiation injury; development of novel bio-dosimetry tools; and biomedical technology for radiation countermeasures.
6. Clinical & Rehabilitative Medicine – Includes but is not limited to, rehabilitation (including neuro-musculoskeletal, craniofacial health and restoration), regenerative medicine and transplants, hearing, vision and balance restoration, and pain management.
7. Chemical and Biological Readiness – Includes but is not limited to, medical chemical research such as pretreatments, therapeutics, diagnostics, and basic research; and medical biological research such as vaccines, therapeutics, diagnostics, and basic research;
8. Clinical Investigations, Graduate Health Science Education, and Military Health System Research - Programs responding to the needs of the Military Health System (MHS) and the dynamic nature of the health sciences through a focus on emerging research and training priorities established by the DoD and contribute to the high professional standing and accreditation of Graduate Health Science Education (GHSE) programs by fostering the conduct of research by both trainees and faculty. An aspect of MHS research includes Military Health System Research which encourages research that examines the cost, quality, variation, outcomes, and policy of care delivered within either the purchased or direct care systems designed to provide new knowledge about the structure, processes, and effects of health care at the Military treatment Facility (MTF), Market and Enterprise levels.
9. Genomics and Omics-based - Includes but is not limited to, clinical discovery, science, development, technologies, applications, translation, infrastructure and program and policy activities; digital biobank development and execution; sample collection; gene sequencing; secure data storage; clinical precision medicine; integration of omics, clinical, exposure, and military-specific data. Future discoveries and developments may drive additional contract needs to build DoD genomics program and to secure genetic information for operational security, biodefense, genetic defense, vaccine development, critical pharmacological independence, precision therapeutics, first-use identification, and future pandemic and epidemic agent identification.
10. Emerging Science and Technology – Includes but is not limited to new scientific areas or technology, possibly currently developing, with a strong potential for military medical application and are of interest to DoD and the MHS. This is a complement to Program Areas 1 through 9 and designed to maintain

contract scope for new discoveries or emerging technologies presenting major opportunities for 5-10 year targeted investment with potential for transformative impact within the MHS. Investment in emerging S&T will be rare and can occur only after rigorous examination of the new area, its potential impact within the MHS, and its priority within the military medical R&D program.

C.2.2 MARKET SEGMENTS

The OMNIBUS IV requirement is comprised of four Market Segments: (1) Research and Development; (2) Research and Development Support Services; (3) Regulatory Processes; and (4) Translational Science Support and Services. Each one of these four Market Segments has a set of applicable Proficiency Areas. The proficiency areas seek core missions and competencies in expert professionals with demonstrable qualifications and access to state-of-the-art facilities to find medical solutions, services, and support for the Department of Defense. Competency involves understanding of and adherence to applicable laws, federal regulations, and DoD Process, Rules, Regulations, and Standards. The Market Segments and their Proficiency Areas are as follows:

C.2.2.1 **Research & Development (R&D).** Medical Research and Development leads innovative military medical care to meet the highest priority needs across the Department of Defense. The DoD medical force seeks to ensure efficient and effective discovery and delivery of medical solutions that enhance warfighter health and readiness. Funded research aligns directly to prioritized requirements and capability gaps to ensure successful research efforts transition into medical materiel products or into clinical practice as knowledge products. The goal is to establish and maintain collaborative medical partnerships across the medical field in industry and academia.

The proficiency area seeks core missions and competencies in world-class professionals and state-of-the-art facilities to find medical solutions for the Department and Defense while adhering with full aptitude all Federal, State, and DoD Process, Rules, Regulations, and Standards. Organizations providing demonstrative qualifications in this Market Segment may/can be representing itself as a University Affiliated Research Center (UARC), a Contract Research Organization (CRO), a company operating under a CRO-based business model, a Contract Drug Development Manufacturer Organization (CDMO), or other entity capable of self-directed research, Independent R&D (IRAD), Contracted R&D (CRAD).

Performance by the contractor is in support of government research programs, projects, and protocols. Performance includes expertise in developing analysis of alternatives to develop the most effective and efficient deliverable. TOs addressing this Market Segment shall be sensitive to conflict of interest issues. Proficiency areas in this Market Segment include but are not limited to the following:

1. Collaborations in DoD Medical Research, to include, but not limited to: Successful transitioned efforts from industry, commercial, or university/scholar collaborations, including assistance agreements such as grants, contracts, or Cooperative R&D Agreements (CRADAs), in direct support of the Congressional Directed Medical Research Program (CDMRP), the Peer Reviewed Medical Research Program (PRMRP), Joint Program Committees (JPCs), and other Medical Funding Programs especially in areas outlined in C.2.1 Program Areas. Special emphasis for successes in all classified settings (i.e. world-wide field efforts, military OCONUS deployed locations and training environments).

2. Transitioning of Programs though Funding Continuum, to include, but not limited to: Accomplishments in utilizing RDT&E Funds 6.1 through 6.7 especially in applied research efforts and transitioning through advanced development. Expect expertise in use of applicable Operations and Maintenance (O&M) funds for proof of concept efforts, feasibility studies, test cases, studies and analysis, education and training, and other uses in accordance with federal laws and regulations.

3. Maintenance of Quality, Safety, Security, and Surety Standards, to include, but not limited to: Leaders in industry for biosurety including Biological Safety, Physical and Personnel Security, Personnel Reliability, Agent Accountability, Biological Safety Level (BSL), Animal Biological Safety Requirements, Biological Select Agents and Toxins (BSAT), and/or other safety standards. This also includes laboratories operating under Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) regulations.

4. Success in Research Deliverables and Outcomes applying all federal (e.g. HHS and FDA) and DoD Rules and Regulations, to include, but not limited to: Achievements in efforts transitioned from research to development to testing to product dissemination and implementation accounting for all necessary compliance especially research involving humans, animal use guidelines, maintenance of a Federal Wide Assurance, navigating FDA drug and adjuvant discovery and delivery, formulation development and drug product acquisition, managing clinical trials, medical device development, implementation, and fielding and product testing protocols.

C.2.2.2 **R&D Support Services.** This is for work where the Contractor provides support for research activities rather than direct management and performance of the actual research.

Organizations providing demonstrative qualifications in this Market Segment may be performing, but not limited to, tasks such as administration, staff support, subject matter expertise consult, non-inherently government function management and oversight support to R&D leadership; drafting congressional responses regarding medical research programs; program management support; scientific/technical strategic planning; portfolio management; or execution management at the level of headquarters. TO addressing this Market Segment shall be sensitive to conflict of interest issues.

TOs addressing these support/services shall be sensitive to conflict of interest issues. Proficiency areas in R&D Support Services include but are not limited to the following:

1. Administrative Support Services, to include, but not limited to: Administrative/Clerical Support, Acquisition Support, Visual Information Support, Library Services Support, Military and Civilian Human Resources Support, Program and Financial Analysis Support, Program Management Analysis Support and Technology Transfer Support.
2. Information Technology Support Services, to include, but not limited to: Information Assurance Engineering Support, Computer Technical Support, System Administration Support, Telecommunications Engineer Support, IT Application Support, Help Desk Support, Communications/Local Area Network (LAN) Specialist, Database Administration Support, IM/IT Project Management Support and IM/IT Technical Writing Support.
3. Scientific and Technical Support Services, to include, but not limited to: Scientific Support, Laboratory Technical Support, Veterinary Services Support (Clinical, Technical, Animal Husbandry, Farm Management), Veterinary Pathology Support, Computer Programming, Biostatistics Support,

Public Health Specialist, Data Collection Management and Analysis Support, Program and Project Management Support, to include, but not limited to Program and Project Evaluation, Capability-based Assessments, Research Marketing Reports, to include, but not limited to Alternatives of Analysis, Analytical Methods, to include, but not limited to return on investment studies, Quality Control and Quality Assurance Support, Biosurety Support, Design, Construction and Maintenance of Research Equipment and Systems Support, and Technical Writing Support.

4. Facilities Support Services, to include, but not limited to: Engineering Technical Support and Facilities Quality Assurance Support.
5. Medical Services Support for clinical and research protocols to include but not limited to: Physicians, Psychologists, Physiologists, Biochemists, Toxicologists, Licensed Nurses and Clinical Research Associates, and Research Assistants.
6. Supplies and Equipment, to include, but not limited to: lifecycle support incidental to the research projects. Lifecycle support requirements are requirements for availability, scalability, maintainability, supportability, and other requirements as appropriate for the specific initiative.
7. Logistical Support Services, to include, but not limited to: training, medical readiness, management and operation, maintain/operate infrastructure and biomedical support.
8. TO Administrative, Technical, and Other Support, to include, but not limited to: Meeting and Informational Products Support, Clinical Trial and Clinical Research Volunteer Support (Volunteer Compensation and Volunteer Sustenance).

C.2.2.3 **Regulatory Processes.** This Market Segment encompasses support and expertise in comprehensive regulations protecting the welfare and rights of human and animals in medical research. All medical research must be in compliance with all relevant federal, DoD, and Service regulations. This Market Segment provides strategies to foster and oversee the compliance and ethics of all research, tests, and studies involving human and animal use across the Department of Defense. It further supports funding and industry cooperation principles that leads short and long-term strategic planning, provides operational direction and guidance, and ensures policy compliance for ongoing medical research from development through transition.

Organizations providing demonstrative qualifications in this proficiency area may/can be representing itself as a Contract Research Organization (CRO) or a company operating under a CRO-based business model. Other examples may include, but are not limited to, a company versed in compliance with regulations associated with animal use, human subjects, Personally Identifiable Information (PII), Protected Health Information (PHI), or Institutional Review Board (IRB) protocols. Organizations having Department of Health and Human Services (DHHS) expertise in this Market Segment be desirable in support of DoD projects/programs.

This is for work where the performance by the contractor is in support of government research and protocols. TOs addressing this Market Segment shall be sensitive to conflict of interest issues. Proficiency areas in the Regulatory Processes Market Segment include but are not limited to the following:

1. Animal Use Programs and Vivaria, to include, but not limited to: DoD Instruction (DoDI) 3216.01 Use of Animals in DoD Conducted and Supported Research and Training, Animal Welfare Act, Institutional Animal Care and Use Committee (IACUC) review requirements, Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International accreditation

requirements, HHS Office of Laboratory Animal Welfare (OLAW) assurance requirements, and USDA site inspection requirements.

2. Research Involving Human Subjects, to include, but not limited to: DoDI 3216.02 Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and –Supported Research, Federal-Wide Assurance (FWA) terms, DoD Human Research Protection Program (HRPP) requirements, Institutional Review Board (IRB) requirements, Federal human research protections requirements (32 CFR 219; 45 CFR 46 Subparts B, C, D, &E), 21 CFR 50, 56, 10 U.S.C. 980.

3. DoD Use of Investigational Products, to include, but not limited to: 10 USC 1107, DoDI 6200.02 Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs.

4. CFR Title 21, (FDA): Investigational New Drug Application (IND) (21 CFR 312), to include, but not limited to: Investigational Device Exemptions (IDE) (21 CFR 812); other FDA applications, approvals and processes.

5. Federal and DoD Privacy, to include, but not limited to: Personally Identifiable Information (PII), Protected Health Information (PHI), Survey Office Policy and Regulations, Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs

6. Technology Transfer, to include, but not limited to: DoDI 5535.8, DoD Technology Transfer Program, Cooperative Research and Development Agreements (CRADAs), Education Partnership Agreements (EPAs), Commercial Test Agreements (CTAs), Data Use Agreements (DUA), Patent License Agreements, Knowledge Translation Agreements.

C.2.2.4 **Translational Science Support and Services.** Translation is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public – from diagnostics and therapeutics to medical procedures and behavioral changes. Translation services are activities that support translation. Translational science is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process. In this context, translation is migrating science and enhanced technology (including equipment) for use in MTFs, deployed environments or non-DoD hospitals, where applicable to the research effort and specified in the TO. Translation service and support can include lifecycle support requirements associated with translation activity. Lifecycle support requirements are requirements for availability, scalability, maintainability, supportability, and other requirements as appropriate for the specific initiative. OMNIBUS IV does not support post-translation or product sustainment and does not currently fund the equipping of fielded units, which is a Title 10 authority aligned to Services.

This is for work where the performance by the contractor is performing and/or supporting government translational science and service activities. TOs addressing this Market Segment shall be sensitive to conflict of interest issues. Proficiency areas in Translational Science Support and Services include but are not limited to the following:

1. Pre-Transition Support, to include, but not limited to: Needs and Gaps Assessment, Evidence Maturity Assessment (Readiness for Translation), Strategic Analysis, Transition Plans and Agreements, and analysis of alternative solutions.

2. Transition Support, to include, but not limited to: Initial Outfitting & Transition Support and Services, Project Management Services, Equipment Planning Services, Transition Planning and Relocation Services, Final Turnover and Close-out Services, Installation, Testing and Training Services applicable to transitioning emerging science or technology (equipment) into an operational environment, and lifecycle support services.
3. Evidence-based Solution Development, to include, but not limited to: Clinical Practice Guidelines, Clinical Decision Support Tools, Policy, Creative or Scientific Writing Services, Language Translation Services, or Material Adaptation for special populations, Audio-visual, Print, Computer-aided, Computer-based, Web-based formats or Applications, Design, Copying, and Distribution.
4. Dissemination Strategies, Processes, and Evidence-based Practices, to include, but not limited to: Market Research, Environmental Scans, Consumer Behavior, Health Communication, Messaging, Marketing and Product Promotion, customizing Support Materials or Infographics, and Measuring Dissemination Reach and Impact.
5. Implementation Strategies, Processes, and Evidence-based Practices, to include, but not limited to: Implementation and De-implementation; Public Health Education; Adult Learning Theory; Training; Change Management; Organizational Readiness Assessment; and Measuring Implementation Impact, Behavior Change, and Adoption Practices.
6. Evaluation Strategies, Plans, and Execution, to include, but not limited to: Evaluation Methods and Compliance, Paperwork Reduction Act, Solution Evaluation, Process Evaluation, Program Evaluation, Quantitative and Qualitative Analysis, including Meta-analysis or Cost-benefit Analysis, and standardized Lessons Learned feedback to inform future requirements.

C.3 ADMINISTRATIVE

C.3.1 PLACE OF PERFORMANCE

The Government anticipates performance of this contracting vehicle to be worldwide. The Government may require services in deployed locations, which will be specified at the TO level. The contractor shall be responsible for the safety and security of its employees. TOs may require contractor personnel to perform in close proximity to Government personnel. Place of performance, applicable base support and travel requirements will be specified at the TO level.

C.3.2 TYPES OF REPORTS AND DELIVERABLES

Required reports and Contract Data Requirements Lists (CDRLs) will be specified and established at the TO level, respectively. Example reports include but are not limited to the following:

C.3.2.1 Project Management Plan Support. Project Management Plan (PMP) includes the Installation Plan and Timeline Support. Timeline includes the Integrated Master Schedule.

C.3.2.2 Installation Plan and Timeline Support. This Plan addresses what parts need to be compliant in order to achieve the Authority to Operate (ATO) milestone.

C.3.2.3 Integrated Master Schedule (IMS). The IMs summarizes the tasks to support the installation, deployment, certification, authorization, operation, and maintenance of translated technology.

C.3.2.4 In-Process Review (IPR). The IPR review addresses the status of technical and programmatic progress and provides focused emphasis on the status of TOs, risk management activities, unresolved issues, action items, status of funds execution and any known problems measured against objectives, goals, and a schedule.

C.3.2.5 User Outreach Plan (OP) Support. Outreach support includes development of informational materials about the technology for DoD Users, development of Frequently Asked Questions (FAQs) for technology and the gathering of educational materials for the use of the technology by DoD technical staff.

C.3.2.6 Usage Report. The usage report informs on systems access, data sharing agreements, usage of technology, and the performance and delivery of technology. This report includes User Workload Migration Status and User List Maintenance.

C.3.2.7 User Workload Migration Status Report. A report on the status of user workload migrations, including but not limited to, workloads in queue, workloads in migration, workloads migrated, and workloads expected to enter the queue, issues and mitigations.

C.3.2.8 User List Maintenance Report. This a list of prior and current users, and user organizations, including point of contact (POC) information.

C.3.2.9 Technical Status Reports. Technical status reports are used review and evaluate the overall progress along with any existing or potential problem areas and recommendations for remedy.

C.3.2.10 Travel Expense Reports. The report includes the cost of insurance and travel.

C.3.2.11 Related Deliverables. The Contractor shall provide related deliverables necessary to assess, acquire, configure, install, interface, and integrate the appropriate hardware and software to satisfy desired system capabilities and functions. The Contractor shall integrate all solutions and interface with existing DoD systems. The solution shall include hardware, software, documentation, training, warranty and maintenance services. The Contractor shall report this information to the Government COR in accordance with the TO CDRL.

C.3.2.12 R&D Impact Report. This report is designed to report high level TO information for DHA tracking and reporting purposes.

C.3.2.13 Acquisition Management Intelligence (AMI) Report. The AMI report is a simplified version of the Earned Value Management (EVM) Report. It is a graphical representation of the integration of performance (milestones/deliverables), cost, and schedule that is tied to the Contractor's monthly invoice. It feeds into the monthly COR Report, the quarterly QAS Report and the annual CPARS Report.

C.3.2.14 Final Research Report. This report consists all final data and information necessary to close the effort to include conclusions and recommendations.

C.3.3 GOVERNMENT FURNISHED PROPERTY/EQUIPMENT/INFORMATION

Defined at the TO level.

C.3.4 CONTRACTOR PROCURED EQUIPMENT/INFORMATION/PROPERTY (INCLUDING INTELLECTUAL PROPERTY)

Defined at the TO level.

C.3.5 DELIVERABLES

Deliverables shall be defined at the TO level.