Table of Contents

1. SOLICITATION INFORMATION

1.1 BACKGROUND

The United States Food and Drug Administration (FDA) has a mission to protect public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. In addition, FDA is responsible for facilitating innovations that make medicines more effective, safer, and more affordable. To accomplish these goals, FDA has stimulated advancement of regulatory science, which is defined as "the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA regulated products." FDA's vision is to facilitate the integration of new science into the process of evaluating the safety and efficacy of proposed and marketed products and to close the gap between scientific innovation and this process of drug review. To achieve this vision, we perform mission-critical research to develop and evaluate tools, standards, and approaches to assess the safety, efficacy, quality, and performance of drugs.

The FDA has the need for animal research as well as bioanalytical and other in vitro and ex vivo laboratory assay support. Depending on the project, the services required under this contract may include assessment of different drug and metabolite concentrations, biomarkers levels, in vitro assays or include novel experimental methodologies. These assessments may be needed for samples collected from animal or laboratory research performed within the contract or could be required as a standalone option to mission-critical research performed at FDA facilities. The results of studies and other performed work under this contract will be used to advance regulatory science. In most cases, the animal and laboratory work will not require GLP and/or GMP controls but the provider should have those capabilities.

Overall, the efforts would support a full range of services from animal study protocol development and execution, conducting supportive laboratory studies, and bioanalytical/biomarker/omics services, where required, as well as independent in vitro laboratory studies and ex vivo laboratory studies including but not limited to drug metabolism, transport and binding and drug-drug interaction studies.

It is the FDA's intent to award an indefinite delivery-indefinite quantity (IDIQ) contract, with a performance period of five (5) years. The Government anticipates awarding an IDIQ contract with a ceiling of $20,000,000.00. The minimum guarantee due to the contractor will be provided for via the first task order.

1.2 NOTICE OF COMBINED SYNOPSIS/SOLICITATION

This is a combined synopsis/solicitation for commercial items prepared in accordance with (IAW) the format in FAR Subpart 12.6, as supplemented with additional information included in this notice. This announcement constitutes the only solicitation; proposals are being requested and a written solicitation will not be issued. This is a request for proposal (RFP) for commercial items IAW the procedures of FAR Part 12 – Acquisition of Commercial Items, in conjunction with FAR Part 15 – Contracting by Negotiation. This acquisition is issued as a Request for Proposal (RFP)

1.3 NOTICE OF FAC

This solicitation document incorporates provisions and clauses in effect through Federal Acquisition Circular FAC 2023-01, effective December 30, 2022.

1.4 NOTICE OF NAICS/SET-ASIDE

The associated Product Service Code (PSC) is B529 (Special Studies/analysis – Scientific Data. The associated North American Industry Classification System (NAICS) code is 541715 (Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)). Offerors **must** have an active registration in SAM.gov (https://sam.gov/), with completed representations and certifications, by the close date of the solicitation. Proposals submitted by offerors not registered in SAM.gov will not be considered.

2. DESCRIPTION OF REQUIREMENTS/STATEMENT OF WORK

2.1 PURPOSE

The purpose of this IDIQ contract is to obtain Contractor services for non-clinical studies and laboratory support. Efforts would support a full range of services from animal study protocol development and execution, conducting supportive laboratory studies, and bioanalytical/biomarker/omics services, where required, as well as independent in vitro laboratory studies and ex vivo laboratory studies including but not limited to drug metabolism, transport and binding and drug-drug interaction studies.

2.2 SCOPE/OBJECTIVES

Independently and not as an agent of the Government, the Contractor shall furnish the necessary personnel, materials, services, and facilities to do all things necessary for the performance of this requirement.

The scope of activities FDA may require of the contractor shall include provision of animal and laboratory research sites and the provision of a full range of services to support contracted non-clinical studies as well as non-clinical in vivo and in vitro studies conducted at FDA sites and reporting of the results. All work shall be carried out in a timely fashion and in compliance with all FDA regulations and GLP, GMP and GCP guidelines when required by Task Order Request for Proposal (TORFP). The contractor should be able to provide laboratory studies including bioanalytical/biomarker/omics support that includes determination of drug concentration, anti-drug antibodies, and multiple pharmacodynamic biomarkers through various standard and potentially emerging technologies.

This Statement of Work (SOW) has been divided into 4 performance areas:

A) Overall Animal Research Operations Support and Execution in appropriate animal species
B) Bioanalytical/Biomarker/'Omics' Analysis and Laboratory Support resulting from performance area A or from independent work conducted at FDA facilities or through other FDA contracts
C) In vitro and ex vivo laboratory assay support for drug metabolism, drug transport, drug binding etc. from performance area A or from independent work conducted at FDA facilities or through other FDA contracts
D) GMP Manufacturing of API and Production final dosage form

To qualify for award, organizations must have in-house capabilities in performance areas A and in-house or sub-contracting capability for Performance Area B, Performance Area C and performance area D. Ability to provide access in-house or through subcontracts to specialized materials, assays or technologies is desired but not required. All work shall be carried out in a timely fashion. Unless otherwise specified, bioanalytical method validation shall be performed in compliance with FDA's Bioanalytical Method Validation Guidance. Sample analysis does not need to be performed under complete Good Laboratory Practice (GLP) guidelines.

2.3 PERFORMANCE AREAS

2.3.1. Performance Area A: Overall Animal Study Operations and Support

NOTE: FDA will issue TORFPs for individual animal studies under performance area A. Performance area A activities are outlined below and are to be considered general requirements that will be executed following issuance of individual performance area A Task Order awards. Each individual performance area A Task Order award will also define specific and additional requirements as appropriate for that Task Order Statement of Work.

Under this performance area, the contractor shall perform activities related to overall administration and implementation of animal study services including but not limited to the setup for project management, technical preparedness and support, communications and submission of deliverables and the ongoing archive of completed study data and reports. In addition, the contractor shall perform all activities associated with the conduct of animal studies as specified below. Specifically, for overall administration and implementation of the animal study, the contractor shall:

- Prepare responses to TORFPs issued under performance area A
- Provide a Principal Investigator (PI) and appropriate support staff who will be responsible for overall project management including the development, implementation and maintenance of a project management plan to ensure effective management of the contract infrastructure including clinical and support services, the tracking of progress, communication and preparation of deliverables and the archival activities.
- Prepare and deliver a Project Management Plan (PMP) within 30 days after a Task Order award. The PMP shall address and include, at a minimum, the following (if needed, alterations to this requirement will be made in specific Task Orders):
    - Standard operating procedures (SOPs) for the conduct of the animal study and for all other integrated and collaborating services;
    - Personnel listing including their roles and responsibilities;
    - Training program for site staff, data management staff and other support staff in the protocol procedures with every task order protocol to ensure reliability of evaluation, treatment and assessment procedures;
    - Data management procedures and systems planning that comply as specified with the contract terms and conditions including but not limited to development of database, data collection, data monitoring, data safety review;
    - Pharmacy management procedures for receiving, storing and dispensing agents; also, to be included a procedure for randomization and if appropriate stratification of eligible subjects (unless provided by the Government);
    - Procedures for blinding, including during pharmacy, study and data management activities, as appropriate;

  - Clinical and laboratory quality monitoring procedures, as appropriate;
  - Procedures for preventing, identifying, handling, reporting and resolving protocol deviations;
  - Quality control plans and procedures;
  - Establishment and demonstration for independence of oversight including quality assurance procedures;
  - Archival plans for securing completed study data per regulatory requirements;
  - Contingency planning; and
  - Close-out plan
- Conduct teleconferences and meetings for:
  - Standing and/or *ad hoc* teleconferences/webinars: as requested by the Contracting Officer Representative (COR), Contracting Officer (CO) or study team, participate in teleconferences or webinars to review progress and performance, discuss modifications to procedures, and/or discuss other issues related to project management or infrastructure of the overall contract or individual animal studies;
  - Site Visits: Host site visits as requested by COR, CO or FDA study team, as needed;
  - Prepare minutes of all site visits and teleconferences/webinars and submit to the COR, CO, or FDA study team for review and approval within 2 business days of the meetings.
- Archive the final dataset for each animal study conducted under each task order in Performance Area A in an agreed upon format (e.g., R, SAS, SPSS, ASCII) that is readily usable by FDA or FDA designee.

Specifically, for performing all activities associated with the conduct of animal studies, the general requirements are as described below.

Protocol Development and Finalization:

Finalize a full protocol based on protocol synopsis provided by the FDA study team and submit to FDA for scientific review and approval in compliance to the timelines specified within the Task Order. Submit the final protocol and other required documents to the Institutional Animal Care and Use Committee (IACUC) for review and approval.

Study Execution:

All animal studies to be conducted under this contract must be completed as per finalized protocol requirement. The time duration for a study from protocol writing to study completion can be variable based on specific needs and will be specified in respective Task Orders. The Government will be responsible for providing a detailed protocol outline or synopsis for each study.

A. Protocol Implementation: Compliance and Oversight

1. Activities required prior to study initiation
   a) Obtain local IACUC approval and approval of any other authority prescribe by the IACUC (e.g., Institutiional Biosafety Committee)
   b) Obtain any necessary Material Transfer Agreement (MTA) from contributor if required
   c) Prepare and deliver a study management plan

d) Conduct a study initiation meeting

2. Regulatory Compliance

a) Throughout the studies essential regulatory documents should be generated and stored in files/folders and be available for monitors and at the end of the studies all essential regulatory documents at the study unit should be placed in the master regulatory file for archiving. Regulatory documents may include but are not limited to: IACUC approved protocol, IACUC approval letter; IACUC membership list; PI and sub-investigators curriculum vitae, indemnification/insurance documents, shipment receipts, etc. During the conduct of the study, all new relevant information/data must be appended to the essential documents as it becomes available.
b) Ensure that the conduct of the clinical trials performed complies with all FDA and OLAW regulations and guidelines.
c) Ensure the confidentiality of all study records and information.

3. Study Initiation

The contractor's study team and support staff shall participate in a study initiation meeting at the Contractor's clinical research facility or through teleconference, as appropriate. Prepare and deliver a summary report of the initiation meeting to include but not be limited to the agenda and the list of participants.

4. Protocol Amendments

Prepare all protocol amendments and modifications, as needed.

a) Upon COR, CO or FDA study team approval, the contractor will submit the amended protocol to the IACUC for review and approval.
b) Upon IACUC approval, the amended protocol shall be archived in the master regulatory file.
c) The study management plan and other supporting documents will be modified to reflect the protocol amendments.
d) If necessary, the PI or designee will conduct a training session describing the protocol amendment and its impact on study procedures and assessments.

5. Protocol Oversight

Oversee all study activities conducted at the animal facility and all collaborating sites including research pharmacy, clinical laboratory, data management center, imaging center and subcontracting sites.

6. Data Management and Quality Control

a) Modify the database to support any protocol amendments that are implemented during the conduct of the study, as required.
b) Provide quality control to ensure initial data entry within 24 hours and to correct or issue a data query within 48 hours and inform promptly the study staff of any missing, incomplete and erroneous data.

7. Audit Compliance

The FDA at their discretion may undertake an audit of the contractor's facility including all collaborating sites. The contractor shall make available all facilities, records and files as related

to the contract. The contractor will submit a report describing the implementation of any corrective actions.

B. Study Agents and Clinical Specimens

1. Study Agents

a) Maintain inventory records of study agent(s) in accordance to the pharmacy SOPs.
b) Maintain documentation that the study agent(s) will be stored and quarantined under appropriate conditions in the research pharmacy per the sponsor and regulatory requirements.
c) Mechanism for the return and/or destruction of study material.

2. Study Specimens

a) Ensure collection, processing, labeling, temporary storage under appropriate conditions and management of all collected biological specimens.
b) Ensure shipping of biological specimens for testing and/or repository deposition, as specified in the protocol, in compliance with current domestic laws and regulations.

C. Study Analysis, Close-Out and Final Reporting

1. Close-Out and Analysis

Following completion of study procedures, the contractor shall (in discussion with the FDA study team):

a) Complete data editing/cleanup
b) Finalize and lock the database
c) Deliver the locked database in agreed upon format (e.g., R, SAS, SPSS, ASCII) and schedule as requested by the COR, CO, or FDA study team

2. Completion

In discussion with the FDA study team:

a) Prepare for archiving the final dataset and all associated study records. Study records are considered necessary to assess the final dataset with specific codes for all variables including all transformation that have been created (i.e., data dictionary), as needed.
b) Prepare and deliver draft and final study report, if needed and as specified in a Task Order.

D. Facilities, Equipment and Other Resources

The Contractor shall be responsible for the adequacy and availability of all facilities, equipment, and other resources necessary for the conduct of a clinical trial which may include, but is not limited to, the following.

Animal Research Facility:

a) The Office of Laboratory Animal Welfare (OLAW) Assurance
b) Adequate and secure computing resources for communication and data management (e.g., entry editing, quality control).
c) Adequate and secure electronic access to the data management center.

d) Emergency care and a definitive plan for management of life- threatening adverse events
e) Adequate equipment, staff and services for performing routine health evaluations, precisely timed phlebotomy, collection of urine and other bodily fluids for PK/PD trials and processing of PK and PD samples, as needed.
f) Staff with expertise in the conduct and support of animal studies.

Provide Laboratory Facility:

a) Adequate space for the processing and temporary storage of biological specimens.
b) On-site sample storage facilities at room temperature, 4, -20 and -70 degrees Celsius.
c) Laboratory support services with provisions of 24 hours/day processing/testing if required by the protocol.
d) Adequate and secure electronic access to the data management center.

Provide Pharmacy Facility:

a) Study staff with expertise in the preparation, distribution and storage of study agents for animal studies.
b) Adequate space for processing, storing and dispensing study agents under appropriate conditions.
c) Adequate and secure electronic access to the data management center.

Provide Data Management Center:

a) Adequate computing resources to support data collection activities.
b) Personnel knowledgeable about data management activities and operations including but not limited to data management planning and reporting, performance reporting, quality assurance and administrative support.
c) Data management capabilities necessary to support the conduct of the study.

Provide other facilities and equipment, as may be specified by the Task Order protocols.

E. Insurance

The Government will not provide third party liability insurance.

NOTE: The Government will not provide financial compensation to contractors for work-related injuries.

2.3.2. Performance Area B: Bioanalytical/Biomarker/'Omics' Analysis and Laboratory Support

NOTE: FDA will issue TORFPs for individual bioanalytical/biomarker and laboratory support work under performance area B or as a part of/in combination with performance area A. Performance area B activities are outlined below and are to be considered general requirements that will be executed following issuance of individual performance Task Order awards. Each individual (or combination) performance area Task Order award will also define specific and additional requirements as appropriate for that Task Order Statement of Work.

Under this performance area, the contractor shall perform activities related to development of laboratory work that may include sensitive bioanalytical methods and validation per current FDA

guidance followed by quantitative analyses of drug and/or metabolite concentrations, biomarkers in plasma/serum, urine, tissue homogenates, and other biological fluids found in animal species and humans, as applicable for small and large molecules for study samples. These analyses can include but are not limited to flow cytometry and cell-based assays, ligand binding assays, immunohistochemistry, liquid chromatography-tandem mass spectrometry and molecular assays and genomics. Contractor will be responsible for final bioanalytical reports and for shipping samples to designated facility if needed.

The general requirements for the different components under performance area B are as described below.

A. <u>Administrative</u>

- Prepare responses to TORFPs issued solely under performance area B (or, if applicable, in combination with performance area A and/or C)
- Provide a Principal Investigator (PI) or other managerial designate and appropriate support staff who will be responsible for overall project management including the development, implementation and maintenance of a project management plan to ensure effective management of the contract infrastructure including support services, the tracking of progress, communication and preparation of deliverables and the archival activities.
- Prepare and deliver a Project Management Plan (PMP) within 30 days after the base/initial Task Order award. The PMP shall address and include, at a minimum, the following (if needed, alterations to this requirement will be made in specific Task Orders):
    - Standard operating procedures (SOPs) for the conduct of bioanalytical/biomarker or laboratory support work as specified in the Task Order and for all other integrated and collaborating services;
    - Data management procedures and systems planning that complies as specified with the contract terms and conditions including but not limited to development of databases using specified common data element where applicable, data collection and data monitoring;
    - Laboratory quality monitoring procedures, as appropriate;
    - Procedures for preventing, identifying, handling, reporting and resolving protocol deviations;
    - Quality control plans and procedures;
    - Establishment and demonstration for independence of oversight including quality assurance procedures;
    - Archival plans for securing completed data per regulatory requirements;
    - Contingency planning; and
    - Close-out plan

- Conduct teleconferences and meetings for:
    - Standing and/or *ad hoc* teleconferences/webinars: as requested by the Contracting Officer Representative (COR), Contracting Officer (CO) or study team, participate in teleconferences or webinars to review progress and performance, discuss modifications to procedures, and/or discuss other issues related to project management or infrastructure of the overall contract or Task Order work;
    - Site Visits: Host site visits for the COR, CO and other FDA staff, as needed;
    - Prepare minutes of all site visits and teleconferences/webinars and submit to the COR, CO, or FDA study team for review and approval within 2 business days of the meetings.
- Archive the final locked dataset conducted under each task order in Performance Area B in an agreed upon format (e.g., R, SAS, SPSS, ASCII) that is readily usable by FDA or FDA designee.
    - Within 45 days of Task Order expiration, the contractor shall provide the COR, CO, or FDA study team with a proposed Transition Plan for an orderly and complete transition/relocation of the task order resources to a successor Contractor or to the Government. The plan shall include details on the relocation/disposition of: unused materials and supplies; manuals and directories developed by the contractor; and all other government property not listed. Upon written direction by the Government, the contractor shall transfer all Government property as directed, and fully cooperate with any successor contractor and the Government to ensure an efficient transfer.
- Audit(s): The FDA at their discretion may undertake an audit of the contractor's facility including all collaborating sites. The contractor shall make available all facilities, records and files as related to any activity under performance area B. The contractor will submit a report describing the implementation of any corrective actions.

B. <u>Study Agents and Biological Specimens</u>

<u>1. Study Agents</u>

a) Maintain inventory records of study agent(s) in accordance to the SOPs.

b) Maintain documentation that the study agent(s) will be stored and quarantined under appropriate conditions per the sponsor and regulatory requirements.

c) Mechanism for the return and/or destruction of study material.

<u>2. Biological Specimens</u>

a) Ensure collection, processing, labeling, temporary storage under appropriate conditions and management of all collected biological specimens.

b) Ensure shipping of biological specimens for testing and/or repository deposition, as specified in the protocol, in compliance with current Good Laboratory Practice (cGLP), cGCP and domestic laws and regulations as applicable.

c) Each agent will be considered potentially hazardous. Therefore, all necessary precautions must be taken to protect personnel and the environment against possible exposure to the agents being tested. The contractor shall perform all work associated with this contract in accordance with all applicable Federal, State and local regulations including transportation and disposal of hazardous waste.

C. Analysis, Close-Out and Final Reporting

1. Close-Out and Analysis

Following completion of Task Order work, the contractor shall (in discussion with the FDA study team):

a) Complete data editing/cleanup

b) Finalize and lock the database

c) Deliver the locked database in agreed upon format (e.g., R, SAS, SPSS, ASCII) and schedule as requested by the COR, CO, or FDA study team

2. Completion

In discussion with the FDA study team:

a) Prepare for archiving the final dataset and all associated records. Records are considered detailed documentation necessary to assess the final dataset with specific codes for all variables including all transformation that have been created (i.e., data dictionary), as needed.

b) Prepare and deliver draft and final report, as appropriate and as needed.

D. Facilities, Equipment and Other Resources

The Contractor shall be responsible for the adequacy and availability of all facilities, equipment, and other resources necessary for the conduct of bioanalytical work, which may include, but is not limited to, the following.

Provide Laboratory Facility:

a) Adequate space for the processing and storage of biological specimens.

b) Adequate facilities and equipment for conducting protocol-required tests and assays such as PK and specialty PD assays on blood, plasma, other body fluids and tissues found in both animal species and humans, as applicable and as needed.

c) On-site sample storage facilities at room temperature, 4, -20 and -70 degrees Celsius.

d) Clinical laboratory support services with provisions of 24 hours/day testing if required by the protocol.

Provide Information Technology System:

a) Securely submitting, compiling, storing, collating, analyzing, tracking and retrieving data, structures, results, specimens, reagents, biological agents, drug product produced and released, documents generated in product development, and data received from other compound screening activities performed by third parties. This database will contain confidential/ proprietary information that shall not be used for data-mining purposes by the contractor or any potential subcontractors.

b) Ensuring secure electronic communications, including email, word processing and transmission of data files, between the contractor, FDA staff, subcontractors and consultants.

c) Organizing, maintaining, and transferring information on protocols and test results and provide electronic copies of all reports to the COR, CO, or FDA study team. All electronic deliverables shall comply with Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d).

d) Maintaining the confidentiality of data received from FDA or third parties and data generated within the scope of the contract. [Note: The Government reserves the right to have complete access to those files relevant to FDA studies in databases, provide access to third parties, and to transfer all rights and custody to a successor contractor.]

Provide other facilities and equipment, as may be specified by the Task Order protocols.

2.3.3. Performance Area C: In-Vitro and Ex-Vivo Laboratory assay support for drug metabolism, drug transport, drug blinding etc.

NOTE: FDA will issue TORFPs for individual bioanalytical/biomarker and laboratory support work under performance area B or as a part of/in combination with performance area A. Performance area B activities are outlined below and are to be considered general requirements that will be executed following issuance of individual performance Task Order awards. Each individual (or combination) performance area Task Order award will also define specific and additional requirements as appropriate for that Task Order Statement of Work.

Under this performance area, the contractor shall perform activities related to development of laboratory work that may include sensitive bioanalytical methods and validation per current FDA guidance followed by quantitative analyses of drug and/or metabolite concentrations, biomarkers in plasma/serum, urine, tissue homogenates, and other biological fluids found in animal species and humans, as applicable for small and large molecules for study samples. Contractor will be responsible for final bioanalytical reports and for shipping samples to designated facility if needed. Assay and analysis of in vitro and in vivo samples may also include but not be limited to FDA standard measurements for drug-drug interaction and receptor binding. Contractor will be responsible for final reports for all assays and for shipping sampled to subcontracted or alternate site.

The general requirements for the different components under performance Area C are as described below.

A. Administrative

- Prepare responses to TORFPs issued solely under performance Area C (or, if applicable, in combination with performance area A and/or B)
- Provide a Principal Investigator (PI) or other managerial designate and appropriate support staff who will be responsible for overall project management including the development, implementation and maintenance of a project management plan to ensure effective management of the contract infrastructure including support services, the tracking of progress, communication and preparation of deliverables and the archival activities.
- Prepare and deliver a Project Management Plan (PMP) within 30 days after the base/initial Task Order award. The PMP shall address and include, at a minimum, the following (if needed, alterations to this requirement will be made in specific Task Orders):
    - Standard operating procedures (SOPs) for the conduct of bioanalytical/biomarker or laboratory work as specified in the Task Order and for all other integrated and collaborating services;
    - Data management procedures and systems planning that complies as specified with the contract terms and conditions including but not limited to development of databases using specified common data elements where applicable, data collection and data monitoring;
    - Laboratory quality monitoring procedures, as appropriate;
    - Procedures for preventing, identifying, handling, reporting and resolving protocol deviations;
    - Quality control plans and procedures;
    - Establishment and demonstration for independence of oversight including quality assurance procedures;
    - Archival plans for securing completed data per regulatory requirements;
    - Contingency planning for operational delays and interruptions; and
    - Close-out plan
- Conduct teleconferences and meetings for:
    - Standing and/or *ad hoc* teleconferences/webinars: as requested by the Contracting Officer Representative (COR), Contracting Officer (CO) or study team, participate in teleconferences or webinars to review progress and performance, discuss modifications to procedures, and/or discuss other issues related to project management or infrastructure of the overall contract or Task Order work;

- Site Visits: Host site visits for the COR, CO and other FDA staff, as needed;
- Prepare minutes of all site visits and teleconferences/webinars and submit to the COR, CO, or FDA study team for review and approval within 2 business days of the meetings.
    - Archive the final locked dataset conducted under each task order in Performance Area B in an agreed upon format (e.g., R, SAS, SPSS, ASCII) that is readily usable by FDA or FDA designee.
    - Within 45 days of Task Order expiration, the contractor shall provide the COR, CO, or FDA study team with a proposed Transition Plan for an orderly and complete transition/relocation of the task order resources to a successor Contractor or to the Government. The plan shall include details on the relocation/disposition of: unused materials and supplies; manuals and directories developed by the contractor; and all other government property not listed. Upon written direction by the Government, the contractor shall transfer all Government property as directed, and fully cooperate with any successor contractor and the Government to ensure an efficient transfer.

- Audit(s): The FDA at their discretion may undertake an audit of the contractor's facility including all collaborating sites. The contractor shall make available all facilities, records and files as related to any activity under performance area B. The contractor will submit a report describing the implementation of any corrective actions.

B. <u>Study Agents and Biological Specimens</u>

- <u>Study Agents</u>
    - Maintain inventory records of study agent(s) in accordance to the SOPs.
    - Maintain documentation that the study agent(s) will be stored and quarantined under appropriate conditions per the sponsor and regulatory requirements.
    - Mechanism for the return and/or destruction of study material.
- <u>Biological Specimens</u>
    - Ensure collection, processing, labeling, temporary storage under appropriate conditions and management of all collected biological specimens.
    - Ensure shipping of biological specimens for testing and/or repository deposition, as specified in the protocol, in compliance with current Good Laboratory Practice (GLP), and domestic laws and regulations as applicable.
    - Each agent will be considered potentially hazardous. Therefore, all necessary precautions must be taken to protect personnel and the environment against possible exposure to the agents being tested. The contractor shall perform all work associated with this contract in accordance with all applicable Federal, State and local regulations including transportation and disposal of hazardous waste.

C. Sample Analysis, Close-Out and Final Reporting

1. Close-Out and Analysis - Following completion of Task Order work, the contractor shall (in discussion with the FDA study team):

- Prepare and deliver draft and final report, as appropriate and as needed.
- Prepare for archiving the final dataset and all associated records. Records are considered detailed documentation necessary to assess the final dataset with specific codes for all variables including all transformation that have been created (i.e., data dictionary), as needed.
- Complete data editing/cleanup
- Finalize and lock the database
- Deliver the locked database in agreed upon format (e.g., R, SAS, SPSS, ASCII) and schedule as requested by the COR, CO, or FDA study team

2. Completion - In discussion with the FDA study team:

- Prepare for archiving the final dataset and all associated records. Records are considered detailed documentation necessary to assess the final dataset with specific codes for all variables including all transformation that have been created (i.e., data dictionary), as needed.
    - Within 45 days of Task Order expiration, the contractor shall provide the COR, CO, or FDA study team with a proposed Transition Plan for an orderly and complete transition/relocation of the task order resources to a successor Contractor or to the Government. The plan shall include details on the relocation/disposition of: unused materials and supplies; manuals and directories developed by the contractor; and all other government property not listed. Upon written direction by the Government, the contractor shall transfer all Government property as directed, and fully cooperate with any successor contractor and the Government to ensure an efficient transfer.
- Prepare and deliver draft and final report, as appropriate and as needed.
- Audit(s): The FDA at their discretion may undertake an audit of the contractor's facility including all collaborating sites. The contractor shall make available all facilities, records and files as related to any activity under performance Area C. The contractor will submit a report describing the implementation of any corrective actions.

E. Facilities, Equipment and Other Resources

The Contractor shall be responsible for the adequacy and availability of all facilities, equipment, and other resources necessary for the conduct of bioanalytical work, which may include, but is not limited to, the following.

1. Provide Research Laboratory Facility:

    e) Adequate space for the processing and storage of chemicals, drugs and biological specimens.

    f) Adequate facilities and equipment for conducting protocol-required tests and assays.

    g) On-site sample storage facilities at room temperature, 4, -20 and down to -80 degrees Celsius.

    h) Laboratory support services with provisions of 24 hours/day testing if required by the protocol.

    i) Licenses and capabilities to work with scheduled compounds

2. Provide Information Technology System:

    e) Securely submitting, compiling, storing, collating, analyzing, tracking and retrieving data, structures, results, specimens, reagents, biological agents, drug product produced and released, documents generated in product development, and data received from other compound screening activities performed by third parties. This database will contain confidential/ proprietary information that shall not be used for data-mining purposes by the contractor or any potential subcontractors.

    f) Ensuring secure electronic communications, including email, word processing and transmission of data files, between the contractor, FDA staff, subcontractors and consultants.

    g) Organizing, maintaining, and transferring information on protocols and test results and provide electronic copies of all reports to the COR, CO, or FDA study team. All electronic deliverables shall comply with Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d).

    h) Maintaining the confidentiality of data received from FDA or third parties and data generated within the scope of the contract. [Note: The Government reserves the right to have complete access to those files relevant to FDA studies in databases, provide access to third parties, and to transfer all rights and custody to a successor contractor.]

Provide other facilities and equipment, as may be specified by the Task Order protocols.

2.3.4. Performance Area D: GMP manufacturing of API and Production final dosage form

NOTE: FDA will issue TORFPs for individual GMP manufacturing work under performance area D. Each individual (or combination) performance area Task Order award will also define specific and additional requirements as appropriate for that Task Order Statement of Work.

Under this performance area, the contractor shall perform activities under GMP conditions to manufacture API requested by FDA. Contractor would be responsible for characterization and final release of the API under FDA directions. Contractor should have ability and GMP facility for production of the final dosage form. Contractor will follow FDA guidelines in the manufacture, certification and release of the final dosage form. Contractor would also be responsible for all development of analytical, testing, release and stability testing methods needed for the production and release of the API and the dosage form.

The general requirements for the different components under performance Area D are as described below.

A. <u>Administrative</u>

- Prepare responses to TORFPs issued solely under performance Area D
- Provide a manufacturing supervisor (MS) or other managerial designate and appropriate support staff who will be responsible for overall project management including the development, implementation and maintenance of a project management plan to ensure effective management of the contract infrastructure including support services, the tracking of progress, communication and preparation of deliverables and the archival activities.
- Prepare and deliver a Project Management Plan (PMP) within 30 days after the base/initial Task Order award. The PMP shall address and include, at a minimum, the following (if needed, alterations to this requirement will be made in specific Task Orders):
    - All SOPs and GMP will followed;
    - API and product management procedures and systems planning that complies as specified with the contract terms and conditions;
    - Laboratory quality monitoring procedures, as appropriate;
    - Procedures for preventing, identifying, handling, reporting and resolving manufacturing issues;
    - Quality control plans and procedures;
    - Establishment and demonstration for independence of oversight including quality assurance procedures;
    - Archival plans for securing completed data per regulatory requirements;
    - Contingency planning for operational delays and interruptions; and
    - Close-out plan

- Conduct teleconferences and meetings for:
    - Pre-TORFP meetings if needed: to review the task order requirements, timelines, milestones and deliverables; discuss task order plans and approaches and identify any anticipated difficulties in completing the task order requirements;
    - Standing and/or *ad hoc* teleconferences/webinars: as requested by the Contracting Officer Representative (COR), Contracting Officer (CO) or study team, participate in teleconferences or webinars to review progress and performance, discuss modifications to procedures, and/or discuss other issues related to project management or infrastructure of the overall contract or Task Order work;
    - Site Visits: Host site visits for the COR, CO and other FDA staff, as needed;
    - Prepare minutes of all site visits and teleconferences/webinars and submit to the COR, CO, or FDA study team for review and approval within 2 business days of the meetings.
        - Within 45 days of Task Order expiration, the contractor shall provide the COR, CO, or FDA study team with a proposed Transition Plan for an orderly and complete transition/relocation of the task order resources to a successor Contractor or to the Government. The plan shall include details on the relocation/disposition of: unused materials and supplies; manuals; batch records and directories developed by the contractor; and all other government property not listed. Upon written direction by the Government, the contractor shall transfer all Government property as directed, and fully cooperate with any successor contractor and the Government to ensure an efficient transfer.
- Audit(s): The FDA at their discretion may undertake an audit of the contractor's facility including all collaborating sites. The contractor shall make available all facilities, records and files as related to any activity under performance area D. The contractor will submit a report describing the implementation of any corrective actions.

B. API and Dosage forms

- Maintain inventory records of API and manufactured dosage forms in accordance to the SOPs and GMP regulations.
- Maintain documentation that the study agent(s) will be stored and quarantined under appropriate conditions per the sponsor and regulatory requirements.
- Mechanism for the return and/or destruction of study material.
- Precautions must be taken to protect personnel and the environment against possible exposure to the agents being tested. The contractor shall perform all work associated with this contract in accordance with all applicable Federal, State and local regulations including transportation and disposal of hazardous waste.

C. Sample Analysis, Close-Out and Final Reporting

Following completion of Task Order work, the contractor shall (in discussion with the FDA study team):

- Prepare and deliver draft and final report, as appropriate and as needed.
- Prepare for delivery and archiving all manufacturing, analysis, stability and release related records.

3. CONTRACT TYPE AND MINIMUM/MAXIMUM AMOUNTS

3.1 CONTRACT TYPE

It is anticipated that a single-award Indefinite Delivery-Indefinite Quantity (IDIQ) type Contract, per FAR 16.5, will be awarded as a result of this solicitation. Authorized contract types under this IDIQ contract are: Labor-Hour (LH), Time-and-Materials (T&M), Firm-Fixed-Price (FFP) or a combination thereof.

3.2 MINIMUM AND MAXIMUM CONTRACT VALUE

IDIQ Minimum: The minimum guarantee for this IDIQ contract is $2,500.00, which will be obligated through a separate Task Order following the IDIQ award.

IDIQ Maximum: The maximum aggregate dollar value of all task orders awarded over the 5-year ordering period of this IDIQ shall not exceed the IDIQ ceiling amount of $20,000,000.00.

See FAR Clause 52.216-19 for individual order limitations.

4. PRICING AND ORDERING OF SERVICES

4.1 OVERVIEW OF PRICING SCHEDULE

Offerors shall propose labor categories and labor rates as a completed version of Attachment 1 – Pricing Schedule, to be included in the "Volume II – Business Proposal" submission (see Section 10.3.3).

The Contractor's pricing schedules for labor categories shall contain fully burdened hourly rates. The fully burdened hourly rates for each labor category shall include wages, indirect costs, fringe benefits, overhead, general and administrative, and profit. Hourly rates shall apply to services at both Government and non-Government sites.

By mutual agreement of the parties, additional labor categories may be added to this IDIQ contract to support the tasks of this contract.

Key personnel are subject to HHSAR clause 352.237.75. Key Personnel may be identified in any resulting Call Orders issued. These Key Personnel positions shall be considered essential to the work to be performed thereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer required by this RFQ. The contract may be modified from time to time during the contract to either add or delete personnel, as appropriate.

The Contractor shall provide a detailed explanation of the circumstances necessitating the proposed substitutions, complete resumes for the proposed substitutes, and any additional information requested by the Contracting Officer. Proposed substitutes shall have comparable qualifications to those of the persons being replaced. The Contracting Officer will notify the Contractor within fifteen (15) calendar days after receipt of all required information of the decision on substitutions.

4.2 PRICING TERMS

The Contractor shall comply with FAR 52.232-7, Payments Under Time-and-Materials and Labor-Hour Contracts (AUG 2012), with regard to the ceiling price for each labor-hour or time-and-materials type task order.

The total amount specified in Firm-Fixed Price (FFP) task orders shall be fixed for the task order period of performance and shall not be subject to adjustment; except, as a result of a direct action or inaction by the Government which delays the Contractor from completing the task order within the time specified in the order. The Contractor shall comply with FAR Clause 52.232-1 Payments (APR 1984) in regard to the firm-fixed-prices for individual task orders.

4.3 ORDERING

A request for task order proposal (RFTOP) will be issued via email for individual task orders. Task orders against the IDIQ contract will be issued via email and will be in accordance with FAR 16.505 and FAR clause 52.216-18.

4.3.1. Ordering Procedures

Any Contracting Officer of the Food and Drug Administration (FDA) is authorized and may place orders under this IDIQ contract. Each individual task order will describe the specific performance requirements. When a need for services within the scope of this IDIQ contract arises, the process for issuing task orders is as follows:

1. The FDA CO will issue a RFTOP via email. The RFTOP will include the following information:
    a. SOW
    b. Period of performance
    c. Anticipated contract type
    d. Reporting requirements and deliverables
    e. Key Personnel
    f. Any special terms and conditions specifically applicable to the task order
2. The Contractor will typically have a minimum of ten (10) business days, unless otherwise specified, to provide a proposal in response to the RFTOP. The proposal shall include:
    a. Brief description of the technical approach to the task order requirements
    b. Price buildup (including labor categories, hours for each labor category, extended pricing, total task order pricing, and concurrence with the anticipated contract type)
    c. Resumes of any key personnel identified in the RFTOP
3. The FDA will evaluate the task order proposal for technical acceptability and price reasonableness. If the FDA has questions or concerns, the Contracting Officer will contact the Contractor and may request a revised proposal.

4. If the task order proposal is determined acceptable, the Contracting Officer will issue a task order. All task orders will, at a minimum, include the following:
    a. Task Order number
    b. Date of Task Order
    c. Funding for the Task Order
    d. Task order SOW and specific deliverables and due dates
    e. Task order pricing
    f. Period of performance of the task order
    g. Any terms, conditions, and instructions specific to the task order

Any work that the Contractor undertakes prior to receiving a fully executed task order that has been signed by the Contracting Officer (or the Contractor has received prior authorization to proceed from the Contracting Officer) shall be at the Contractor's risk.

4.3.2. Pricing of Orders

a. Proposals submitted in response to a RFTOP **must** be in accordance with the Ordering Period rates in the IDIQ Price Schedule based on the performance start date of the task order, and that rate must be used for the duration of the task order performance period. The Contractor may propose lower rates in response to a RFTOP.
b. RFTOPs may include option periods in accordance with FAR clause 52.217-9. However, option periods must utilize the Ordering Period rates listed in the IDIQ Price Schedule, based on the performance start date of the option period.
c. Labor-Hour (LH) and Time-and-Materials (T&M) type task orders will include a ceiling price.
d. If a task order's stated period of performance must be extended as a result of Government delay, the Contractor may request that the most current labor rates be used to price the work effort during the extended period for LH and/or T&M task orders.

These Ordering Pricing terms and conditions apply to all task orders issued against this IDIQ contract.

4.3.3. Emergency Orders

In emergency situations or other times when it is not practical to prepare a written work plan prior to the commencement of work, the Contracting Officer may verbally authorize performance to commence immediately, so long as the work to be performed in the emergency situation is within the scope of this contract. In those instances, a written work plan shall be submitted within 10 days following the authorization to commence work. When work is authorized to commence prior to the submission and negotiation of a work plan, the Contracting Officer will indicate, at time of authorizing work, a dollar ceiling that may not be exceeded except at the Contractor's own risk.

5. DELIVERABLES AND ACCEPTANCE

5.1 DELIVERABLES

Specific deliverables and a schedule of deliverables will be identified in each task order.

A. **Be advised that the FDA does not accept documents which contain the use of "macros."**

Document submissions required throughout the period of performance of this IDIQ contract including

any task orders under this IDIQ shall not have macro-enabled functionality, and any document delivered having that functionality will be deemed delinquent, if not corrected prior to the due date.

B. All non-electronically submitted deliverables required under this contract shall be packaged, marked and shipped in accordance with the requirements and specifications contained herein this contract. At a minimum, all deliverables shall be marked with the Contract Number and Contractor Name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

C. Reports not submitted electronically shall be delivered F.O.B. Destination, as set forth in FAR Clause 52.247-35, F.o.b. Destination, Within Consignee's Premises, and as specified in the delivery schedule in the task order.

D. Unless otherwise specified, deliveries shall be made to the COR on Mondays through Fridays (excluding Federal Holidays and Executive Order), between the hours of 8:00 a.m. and 5:00 p.m., Eastern Time, only. Supplies or services scheduled for delivery on a Federal holiday shall be made the following day.

5.2 INSPECTION AND ACCEPTANCE

A. Satisfactory performance of this contract shall be deemed to occur upon performance of the work and upon delivery and acceptance by the Task Order Contracting Officer's Representative (TO COR). The TO COR will perform inspection and acceptance of materials and services to be provided in each task order. For the purpose of this section, the Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer.

B. If a deliverable is found by the COR to be sub-standard, it may require that alterations be made until the deliverable meets the standard expectations at which point it is considered delivered. In some task orders, the deliverable must be 100% accepted by the delivery date. The deliverables and delivery dates will be specified in the task order.

C. A Quality Assurance Surveillance Plan (QASP) may be included in individual task orders.

D. Acceptance may be presumed within 10 days of receipt, unless otherwise indicated in writing by the COR. Unless otherwise specified in individual task orders, inspection and acceptance will be performed at the Place of Performance in Section 6.2.

6. CONTRACT ADMINISTRATION DATA

6.1 PERIOD OF PERFORMANCE

The anticipated period of performance for this contract consists of five (5), 12-month ordering periods, as follows:

Ordering Period 1: March 2, 2023 – March 1, 2024
Ordering Period 2: March 2, 2024 – March 1, 2025
Ordering Period 3: March 2, 2025 – March 1, 2026
Ordering Period 4: March 2, 2026 – March 1, 2027
Ordering Period 5: March 2, 2027 – March 1, 2028

The period of performance for task orders will be specified in individual orders. Two (2) constraints apply to the period of performance for task orders:

1. Individual task orders may not exceed five (5) years (inclusive of option periods)
2. The period of performance end date of the last option period on individual task orders may not extend more than 60 months beyond the IDIQ Ordering Period end date

6.2 PLACE OF PERFORMANCE

The place of performance will be identified in individual task orders but is expected to occur primarily at the Contractor's facility, with the Contractor providing courier services to multiple FDA facilities. FDA facilities are predominantly located in the Washington, DC metropolitan area, with concentrations in the FDA's Maryland locations, including Bethesda, College Park, Laurel, Rockville and Silver Spring.

Specific working arrangements, such as work approved for performance at alternate contractor locations, will be described in individual task orders.

6.3 HOURS OF OPERATION

Unless otherwise specified in the individual task order, Contractor staff must be available during normal FDA business hours, from 8:00 am – 5:00 pm Eastern Time (ET), Monday through Friday, except on Government Closures.

The Contractor may be required to deliver documents and records materials outside of normal FDA business hours. If working outside of normal business hours, the Contractor will have the flexibility to use management tools (i.e., swing shifts) to successfully meet individual task order requirements. Any overtime incurred must be approved in advance, in accordance with FAR 52.232- 7 Payments under Time and Materials and Labor Hour Contracts (Aug 2012). Normal FDA business hours are defined as being from 8:00 am – 5:00 pm ET, Monday through Friday, with deliveries on some weekends and holidays.

6.4 OBSERVANCE OF GOVERNMENT CLOSURES

The Contractor may not bill the Government for any hours that Contractor employees did not work due to any Government closure under this contract or any task orders under this contract that include labor-hour or time-and-materials contract types. In the event Contractor personnel work during a holiday observed by the Contractor other than those below, no form of holiday or premium compensation will be reimbursed as either a direct or indirect cost. However, this does not preclude reimbursement for authorized overtime work.

Recognized Federal Holidays: Contractor coverage is expected during all Federal workdays. Except for designated around-the-clock or emergency operations and after-hour courier services, Contractor personnel shall not perform on-site under this contract on Federal holidays or any other day designated as a Federal holiday for the Washington, DC area. No services or deliveries shall be performed at Federal sites on Federal holidays unless specifically requested by the Contracting Officer.

January – New Year's Day	September – Labor Day
January – Martin Luther King, Jr. Day	October – Columbus Day
February – President's Day	November – Veterans Day
May – Memorial Day	November – Thanksgiving Day

June – Juneteenth
July – Independence Day
December – Christmas Day

Inclement Weather and other Government Closures: The Contractor is not required to provide on-site service on days when the Federal Government is closed due to inclement weather, government closures or other emergencies. The COR will notify the Contractor of Government Closures due to inclement weather, government closure or emergencies (man-made or otherwise).

In the event the Federal Government is closed by order of the President of the United States or the U.S. Office of Personnel Management (OPM) for any reason, the agency is closed, or the Center or FDA building is closed for administrative or safety reasons, the Contractor shall follow directives issued by responsible officials concerning reporting for work.

If adverse weather conditions develop after the Federal Government has opened for normal business, upon notification of early release from OPM, the COR and/or CO will notify the Contractor of Facility closings and specify the time for a final document pickup.

Additional specific inclement weather plans may be specified at the task order level.

6.5 CONTRACTING OFFICER (CO)

Contracting Officer's Authority: The Contracting Officer is the only individual who has the authority to enter into, administer, or terminate this contract and is the **only person authorized** to approve changes to any of the requirements under this contract. It is the Contractor's responsibility to contact the CO immediately if there is even the appearance of any technical direction that is, or may be, outside the scope of the contract. In the event the Contractor effects any changes to this contract or contracts at the direction of any person other than the CO, the changes will be considered to have been made without authority and no adjustment will be made in the contract price to cover any increase in costs incurred as a result thereof. The CO will be the only individual authorized to accept nonconforming work, waive any requirement of the contract/task order and modify any term or condition of the contract/task order. The Contracting Officer is the only individual who can legally obligate Government funds. No costs chargeable to the proposed contract can be incurred before receipt of a fully executed contract or specific authorization from the Contracting Officer.

Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The following person is the Contracting Officer for this contract:

Ian Weiss
Office of Acquisitions and Grants Services
4041 Powder Mill Road
Beltsville, MD 20705
Email: ian.weiss@fda.hhs.gov
Phone: 301-796-5782

6.6 CONTRACT SPECIALIST (CS)

The Contract Specialist supports the Contracting Officer. The following person is the Contract Specialist:

Nikola Zuber
Office of Acquisitions and Grants Services
4041 Powder Mill Road
Beltsville, MD 20705
Email: Nikola.Zuber@fda.hhs.gov
Phone: 301-796-9671

6.7 CONTRACTING OFFICER'S REPRESENTATIVES (CORS)

6.7.1. Contracting Officer's Representative's Authority:

The Contracting Officer (CO) may designate other Government personnel, known as the Contracting Officer's Representative (COR) to act as his or her authorized representative for contract administration functions which do not involve changes to the scope, price, schedule, or terms and conditions of the contract. The designation will be in writing, signed by the Contracting Officer, and will set forth the authorities and limitations of the representative(s) under the contract. Such designation will not contain authority to sign contractual documents, order contract changes, modify contract terms, or create any commitment or liability on the part of the Government different from that set forth in the contract. CORs do not have authority to act as agent of the Government under the contract or task order. The Government may unilaterally change its COR designation.

6.7.2. IDIQ Contracting Officer's Representative (IDIQ COR):

The IDIQ COR, to be designated at time of contract award, will represent the Government for the purpose of the IDIQ. The IDIQ COR will be responsible for the following:

- Tracking compliance with Limitations on Subcontracting clause across task orders
- Tracking and monitoring contract ceiling
- Tracking and monitoring staff allocation across task orders
- Reviewing changes to staffing matrix
- Secondary point of contact for issues that need to be escalated
- Reviewing Task Order SOWs for scope compliance
- Completing annual CPARs evaluations

The following person has been identified as the IDIQ COR:

TBD at time of contract award

6.7.3. Task Order Contracting Officer's Representative (TO COR):

For each individual task order, a Task Order (TO) COR will be assigned. The TO COR will serve as the Contractor's first point of contact for any technical questions and is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and compliance with all substantive project objectives; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; (5) assisting in the resolution of

technical problems encountered during performance; and (6) providing technical direction; and, (7) reviewing and approving invoices/vouchers.

6.8 TASK ORDER PROJECT MANAGERS (TO PMS):

Task Order project managers may assist the CORs, but will not have the authority to provide technical direction as described in Section 6.9; however, they may be responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and compliance with all substantive project objectives; (2) performing technical evaluation as required; (3) performing technical inspections and acceptances then reporting to the COR of the acceptance as required by this performance; and (4) reviewing of invoices/vouchers.

6.9 TECHNICAL DIRECTION

Performance of the work under this contract shall be subject to the technical direction of the COR. The term "technical direction" is defined to include, without limitation, the following:

- Directions to the Contractor which redirect the contract effort, shift work emphasis between work areas or tasks, require pursuit of certain lines of inquiry, fill in details or otherwise serve to accomplish the contractual statement of work.
- Provision of information to the Contractor which assists in the interpretation of drawings, specifications, or technical portions of the work description.
- Review and, where required by the contract, approval of technical reports, drawings, specifications, and technical information to be delivered by the Contractor to the Government under the contract.

Technical direction must be within the general Scope of Work stated in the contract. The COR does not have the authority to and may not issue any technical direction which:

- Constitutes an assignment of additional work outside the general Scope of Work of the contract.
- Constitutes a change as defined in the applicable contract clause FAR 52.212-4.
- Change any of the expressed terms, conditions, or specifications of the contract.

All technical direction will be issued in writing by the COR or will be confirmed by him/her in writing within five (5) business days after issuance.

If, in the opinion of the Contractor, any instructions or direction issued by the COR is within one of the categories described above, the Contractor shall not proceed but shall notify the Contracting Officer in writing within 5 working days after the receipt of any such instructions or direction and shall request the Contracting Officer to modify the task order, accordingly. Upon receiving such notification from the Contractor, the Contracting Officer will issue an appropriate contract modification or advise the Contractor in writing that, in his/her opinion, the technical direction is within the scope of this contract. The Contractor shall proceed immediately with the instructions or directions and shall be subject to the "Disputes" clause within FAR 52.212-4(d), Contract Terms and Conditions – Commercial Items.

6.10 INVOICING PROCEDURES

Specific invoicing instructions may be provided in each individual task order. See attachment 3 – FDA IPP Invoicing Instructions.

6.11 GOVERNMENT FURNISHED PROPERTY

Specific Government furnished property will be identified in each individual task order.

The Contractor shall return all Government furnished property to the COR no later than the expiration date of this contract or any task order.

In addition to the requirements of FAR clause 52.245-1, Government Property (Jan 2017) incorporated in this contract, the Contractor shall comply with the provisions of HHS Publication, "HHS Contracting Guide for Control of Government Property," which is incorporated into this contract by reference. This document can be accessed at:
https://oamp.od.nih.gov/sites/default/files/appendix_q_hhs_contracting_guide.pdf

6.11.1. Government Furnished Equipment (GFE)

FDA may provide laptops, tower computers, printers, scanners, copier, data cable line, and basic PC desktop images and Center Software Top-Offs for FIRF in individual task orders. Upon receipt of FDA badges, FDA will provide Contractor FDA network access to staff under this contract. FDA will provide access to any server-based environment necessary to accomplish the stated work.

The Contractor shall work with the FDA Help Desk Support to relocate/install all GFE to ensure no breaks in current work performance.

Upon the expiration of the one-year manufacturer's warranty for the Government Furnished Equipment (GFE), the Contractor shall be responsible for maintaining all GFE equipment in accordance with current commercial operating standards until replaced or returned to the FDA.

The Contractor shall be responsible for providing any supplies necessary to operate the GFE (other than maintenance/repair supplies).

6.11.2. FDA Information Technology (IT) Help Desk Support

Help Desk Support will be provided by the FDA for only FDA functions inclusive of support for all Government Furnished Property (GFP) and software. FDA's Help Desk is responsible for distributing new and replacement laptops as they are needed and configuring laptops with standard and Center specific software. FDA Help Desk Support will be provided through remote access, drop-in support, or when the Contractor transports the equipment to the nearest FDA IT servicing location. Drop-in support services include: transition-in services and support for major technology changes that cannot efficiently be accomplished remotely. Upon request by FDA Help Desk Support, the Contractor shall be responsible for transporting the items in need of repair to and from the designated FDA facility for repair. In addition, the FDA's Help Desk provides best effort support – defined as basic troubleshooting - for peripheral equipment connected to FDA owned computers. FDA does not grant the Contractor administrative rights for Government- owned computers. If required, the Contractor shall submit a request for administrative rights using the Form 3530 and submit to FDA for approval.

6.11.3. Government Furnished Information

Government Furnished Information will be accessible through the FDA network and paper copies, as needed. The Contractor shall inform and require staff to comply with Government regulations that prohibit the use of any Government property for personal use.

The FDA will not supply the Contractor with phones. The FDA will provide the data drops (if not pre-existing or extras are needed) and network infrastructure (e.g. DS3 circuit, network switch, network router) for connection to the FDA network, via the Verizon direct connection between the Contractor's facility and the FDA WO Campus. The applicability of Appendix 6A or 6B will depend on the Contractor's existing network closet.

6.11.4. Contractor Equipment Requirements

The FDA Master Approved Technology (MAT) list contains a list of software applications and equipment approved by the Office of Information Management (OIM). The approved technologies are determined to be compatible with FDA's Technical environment. The MAT list is posted on FDA's intranet and will be available after contract award). In addition, FDA posts a list of technologies not approved by OIM on the intranet.

All Contractor peripheral equipment connected to FDA computers or laptops must be on the MAT List. If Contractor equipment and software is not on the MAT List, it must be approved via the formal FDA technical approval process prior to connection to FDA's network.

The Contractor shall be responsible for identifying needed technologies that are not provided by the FDA. FDA has instituted the Information Technology Information Management (ITIM) approval process in order to track technologies across the Agency. The introduction of a new technology or a different version of an already approved technology requires the submission and approval of an ITIM request. The Contractor may be responsible for supporting the ITIM process including writing and submitting ITIM requests and tracking them from inception through completion. FDA Center IT Investment Review Boards may need to be included in a coordinated review process.

6.11.5. Government Furnished Data

The Government shall retain all rights and privileges, including those of patent and copy, to all Government-furnished data and materials. The Contractor shall neither retain not reproduce for private or commercial use any data or other materials furnished under this contract. The Contractor agrees not to assert any rights at common law or in equity or establish any claim to statutory copyright in such data. These rights are not exclusive and are beyond any other rights and remedies to which the Government is otherwise entitled elsewhere in this contract.

6.12 POST-AWARD EVALUATION OF CONTRACTOR PERFORMANCE

A. **Contractor Performance Evaluation:** Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations will be prepared annually to coincide with the anniversary date of the IDIQ period of performance start date. At the discretion of the CO, additional interim performance evaluations may be prepared as necessary.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted 14 days to review the document and to submit additional information or a rebutting statement. If the Contractor is in agreement with the performance evaluation outcome, the evaluation becomes final. Should the Contractor be in disagreement with the

performance evaluation outcome, rebuttal comments must be submitted via CPARS within 14 days from date the evaluation was issued by FDA. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

B. **Electronic Access to Contractor Performance Evaluation:**

FDA will utilize the Contractor Performance Assessment Reporting System (CPARS) in order to execute annual and final contractor performance evaluations. CPARS is a secure Internet website located at http://www.cpars.csd.disa.mil/cparsmain.htm. FDA will register the contractor in CPARS upon receipt of the name and email address of the individual who will be responsible for serving as the Contractor's CPARS contacts. Once FDA registers the contractor in CPARS, the Contractor will receive an automated CPARS email message which contains User ID and instructions for creating a password. Copies of the evaluations, contractor responses, and review comments, if any, will be retained in CPARS and as part of the contract file, and may be used to support future award decisions.

Contractors may obtain CPARS training material and register for on-line training at http://www.cpars.csd.disa.mil/allapps/cpcbtdlf.htm. There is no fee for registration or use of the CPARS.

7. FDA-SPECIFIC CONTRACT REQUIREMENTS

7.1 NON-PERSONAL SERVICES AND INHERENTLY GOVERNMENTAL FUNCTIONS

Pursuant to FAR 37.1, no personal services shall be performed under this contract. No Contractor employee will be directly supervised by the Government. All individual employee assignments, and daily work direction, shall be given by the applicable employee supervisor. If the Contractor believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

The Government and the Contractor understand and agree that the services delivered by the Contractor to the Government are non-personal services. The parties also recognize and agree that no employer-employee relationship will exist between the Government and the Contractor. The Contractor and the Contractor's employees are not employees of the federal Government and are not eligible for entitlement and benefits given federal employees.

Contractor personnel under this contract shall not:

- Be placed in a position where there is an appearance that they are employed by a Federal Officer, or are under the supervision, direction, or evaluation of a Federal Officer.
- Be placed in a position of command, supervision, administration or control over personnel or personnel of other Government contractors, or become a part of the Government organization.
- Be used in administration or supervision of procurement activities.

Pursuant to FAR 7.5, the Contractor shall not perform any inherently governmental actions under this contract. No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this

contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. In all communications with other Government contractors in connection with this contract, the Contractor employee shall state that they have no authority to in any way change the contract and that if the other contractor believes this communication to be a direction to change their contract, they should notify the Contracting Officer for that contract and not carry out the direction until a clarification has been issued by the Contracting Officer.

The Contractor shall ensure that all of its employees working on this contract are informed of the substance of this article. Nothing in this article shall limit the Government's rights in any way under the other provisions of the contract, including those related to the Government's right to inspect and accept the services to be performed under this contract. The substance of this article shall be included in all subcontracts at any tier.

7.2 IDENTIFICATION OF CONTRACTOR EMPLOYEES

During the period of this contract, the rights of ingress and egress to and from any Government office for Contractor representatives will be made available, as required. All Contractor employees whose duties under this contract require their presence at any Government facility shall be clearly identifiable by a distinctive badge furnished by the Government. All prescribed information shall immediately be delivered to the FDA Personnel Security Branch for cancellation or disposition upon the termination of the employment of any Contractor personnel. All on-site Contractor personnel shall abide by security regulations applicable to that site.

7.3 CONTRACTOR PERSONNEL SECURITY CLEARANCE STANDARDS AND RESIDENCY REQUIREMENTS (OCT 2017)

1. BACKGROUND - The Office of the Assistant Secretary for Management and Budget, Department of Health and Human Services (DHHS), requires that Contractor employees (including subcontractors) who will be working in DHHS-owned or leased space and/or who will have access to DHHS equipment, and non-public privileged, proprietary, or trade secret information, must undergo a background investigation that results in a favorable determination.

Contractor employees who will work in DHHS-owned or leased space for less than thirty (30) days are considered visitors and are exempted from background investigation requirements; and therefore, will not be issued a Personal Identity Verification (PIV) Card. These contractor employees go through visitor screening each day and must be escorted at all time while in DHHS- owned or leased space.

2. GENERAL - The Contractor must submit the following items to the Contracting Officer's Representative (COR), within five (5) business days of commencement of work under this contract:

- A roster of contractor employee names, identifying Key Personnel and Tier designation(s);
- Confirmation all individual employee security information has been submitted properly; and
- "Contractor's Commitment to Protect Non-public Information Agreement" forms signed by each employee named in the roster.

Pursuant to HSPD-12, the Contractor must advise its prospective employees about the security and background requirements stated herein.

For any individual who does not obtain a favorable background investigation he/she must cease work on the contract immediately.

If a Contractor employee changes job responsibilities under this contract, the Contractor must notify the COR, and the Government will make a determination whether an additional security clearance is required.

In the event there are any proposed personnel changes in the Contractor's staffing roster previously submitted to the COR, the Contractor must submit an updated roster to the COR, along with a brief explanation for the change. In turn, the COR will initiate the procedures stated herein to ensure any new contractor employees obtain a PIV card in a timely manner – prior to that individual commencing work under the contract.

Note: If the proposed personnel change is for a position designated Key Personnel under the contract, a complete justification – along with a resume or curriculum vitae – must be submitted to the Contracting Officer and COR for review and approval. If approved, the Contracting Officer will execute a Contract Modification prior to that individual commencing work under the contract.

BACKGROUND INVESTIGATIONS - With the exception of costs associated with fingerprinting Contractor employees outside of the FDA Personnel Security Office, the Government will conduct all required background investigations at no cost to the Contractor. The cost of fingerprinting Contractor employees at any location other than the FDA Personnel Security Office will be borne by the Contractor. Employees who hold or have previously held a Government security clearance must advise the FDA Personnel Security Staff of the details of such clearance.

Note: Background investigations will be conducted by the Office of Personnel Management (OPM)

3. CONTRACT RISK DESIGNATION(S) - Contractor employees who will be in DHHS-owned or leased space for thirty (30) days or more must be able to obtain and shall obtain a PIV card pursuant to Homeland Security Presidential Directive-12 (HSPD-12) in order to access to DHHS-owned or leased property without an escort. (See Section 6 for details on the PIV Card process) However, in the event that work must commence before a security screening can be completed, contractor employees will be considered visitors, as described above, and allowed onto DHHS-owned or leased property, but must be escorted at all times.

All Contractor employees who undergo a background investigation are required to log onto the Office of Personnel Management's (OPM's) Electronic Questionnaire for Investigation Processing system (e-Qip) system. The FDA Personnel Security Specialist will provide access to the e-Qip as well as guidance as to which forms will be required. The forms required vary with the position risk designations for the contract.

All standard forms submitted to the FDA will be forwarded to the Office of Personnel Management (OPM) to initiate background investigations. The assigned FDA Personnel Security Specialist will resolve with the contractor employee any issues arising out of inaccurate or incomplete forms.

The Risk Designation will be Tier 1 unless otherwise specified at the individual task order level.

There are three (3) potential position risk designations, which are:

- Non-Sensitive Low Risk (Tier 1) - Positions which involve the lowest degree of adverse impact on the efficiency of the Agency. The forms set forth by the FDA Personnel Security Specialist are required for Non-Sensitive Low Risk Positions.
- Sensitive Moderate Risk (Tier 2) or Sensitive High Risk (Tier 4) - Public Trust Positions - Positions in which the incumbent's actions or inaction could diminish public confidence in the integrity, efficiency, or effectiveness of assigned Government activities, whether or not actual damage occurs.

In order to access the e-QIP system, Contractor employees must provide the appropriate FDA Personnel Security Specialist with the following information: (a) full name; (b) position title; (c) social security number; (d) date of birth; (e) place of birth; (f) email address; and (g) phone number. This information will be provided on the e-Qip form that will be electronically sent to the employee. The FDA Personnel Security Specialist will use this information to enter each Contractor employee into the e-QIP system. Once this is done, each Contractor employee will receive an email that contains a web link to access the e-QIP system, as well as instructions and additional forms needed to initiate the background investigation.

A Contractor's failure to comply with the e-QIP processing guidelines will result in that Contractor's employees being denied access to FDA property until all security processing has been completed. Furthermore, any such noncompliance may detrimentally impact Contractor performance, Contractor performance evaluations, rights and remedies available at law and equity retained by the Government.

4. PERSONAL IDENTITY VERIFICATION (PIV) CARDS - All PIV Cards (and any other type of Government-issued Access Card) shall remain the property of the Federal Government. At any time, if a Contractor employee is terminated or otherwise ceases work under the contract, or no longer requires a PIV Card for contract performance purposes, the Contractor must collect the individual's PIV card and immediately notify FDA Personnel Security Staff in writing, with copies to the respective COR and Contracting Officer. The Contractor must immediately return the PIV Card(s) to the COR.

Because PIV Cards, like other Government-issued Access Cards are Government property, Contractors and Contractor Employees are hereby placed on notice that any abuse, destruction, defacement, unauthorized transfer or withholding (i.e., failure to return to the Government) may be punishable to the greatest extent at law.

Unauthorized possession of a PIV Card, or any other type of Government-issued Access Card, and/or willfully allowing any other person to have or to use your Access Card, is prohibited and can be criminally prosecuted under 18 U.S.C. §§ 499 and 70I, which prohibit photographing or otherwise reproducing or possessing HHS identification cards in an unauthorized manner, under penalty of fine, imprisonment, or both. Wrongdoers may also be held financially responsible for any/all civil and equitable remedies – to include, but not limited to, damages for any pecuniary loss suffered by the Government as a result of any of the above-listed actions or failure to act.

5. PIV CARD PROCESS - The COR will sponsor Contractor employees on the Form HHS 745 and HHS Smart Card Management System (SCMS) for the purpose of obtaining an FDA PIV Card. In order to obtain a PIV card, a Contractor employee must receive a favorable FBI fingerprint return and complete

required security forms. The FDA Personnel Security Specialist will provide the Contractor employee(s) direction for scheduling fingerprinting appointments at the FDA location or other approved location.

During a fingerprint appointment, each contractor employee must present two (2) forms of identification in order to receive his or her PIV Card. One form of identification must be a government-issued photo identification document. Acceptable forms of identification are listed in Chart A, provided below. An individual who receives an unfavorable report may appeal that finding by submitting a written request to the FDA Personnel Security Specialist.

Required background investigations may include, but are not limited to:

- Review of prior Government/military personnel records;
- Review of FBI records and fingerprint files;
- Searches of credit bureaus;
- Personal interviews; and
- Written inquiries covering the subject's background.

6. RESIDENCY REQUIREMENTS FOR FOREIGN NATIONALS - Under the requirements for Homeland Security Presidential Directive-12 (HSPD-12), OPM can complete a background investigation only for persons who have resided in the U.S. for a total of at least three (3) of the past five (5). The residency requirements apply only to foreign nationals. **If any prospective foreign national contractor/subcontractor employee does not meet the residency requirements, he/she cannot qualify for a PIV Card under HSPD-12.**

7. NON-PUBLIC DATA PROTECTION - The Contractor must protect the privacy of all information reported by or about Contractor employees and protect against unauthorized disclosure.

***Upon a favorable fingerprint return, the Contractor will be notified to return to the Badging and Credentialing Office for their building pass.**

*Food and Drug Administration
Badging and Credentialing Office
8:00 a.m. – 11:00 a.m. and 1:00 p.m. – 3:00 p.m., Eastern Time
10903 New Hampshire Avenue
Building 32, Room 1205
Silver Spring, MD 20993
No appointment necessary
Telephone: (301) 796-4000

Chart A

LIST A Documents that Establish Both Identity and Employment Authorization	OR	LIST B Documents that Establish Identity	AND	LIST C Documents that Establish Employment Authorization
1. U.S. Passport or U.S. Passport Card		1. Driver's license or ID card issued by a State or outlying possession of the United States provided it contains a photograph or information such as name, date of birth, gender, height, eye color, and address		1. A Social Security Account Number card, unless the card includes one of the following restrictions: (1) NOT VALID FOR EMPLOYMENT (2) VALID FOR WORK ONLY WITH INS AUTHORIZATION (3) VALID FOR WORK ONLY WITH DHS AUTHORIZATION
2. Permanent Resident Card or Alien Registration Receipt Card (Form I-551)		2. ID card issued by federal, state or local government agencies or entities, provided it contains a photograph or information such as name, date of birth, gender, height, eye color, and address		2. Certification of report of birth issued by the Department of State (Forms DS-1350, FS-545, FS-240)
3. Foreign passport that contains a temporary I-551 stamp or temporary I-551 printed notation on a machine-readable immigrant visa		3. School ID card with a photograph		3. Original or certified copy of birth certificate issued by a State, county, municipal authority, or territory of the United States bearing an official seal
4. Employment Authorization Document that contains a photograph (Form I-766)		4. Voter's registration card		4. Native American tribal document
5. For a nonimmigrant alien authorized to work for a specific employer because of his or her status: a. Foreign passport; and b. Form I-94 or Form I-94A that has the following: (1) The same name as the passport; and (2) An endorsement of the alien's nonimmigrant status as long as that period of endorsement has not yet expired and the proposed employment is not in conflict with any restrictions or limitations identified on the form.		5. U.S. Military card or draft record		5. U.S. Citizen ID Card (Form I-197)
		6. Military dependent's ID card		6. Identification Card for Use of Resident Citizen in the United States (Form I-179)
		7. U.S. Coast Guard Merchant Mariner Card		7. Employment authorization document issued by the Department of Homeland Security
		8. Native American tribal document		
		9. Driver's license issued by a Canadian government authority		
		For persons under age 18 who are unable to present a document listed above:		
6. Passport from the Federated States of Micronesia (FSM) or the Republic of the Marshall Islands (RMI) with Form I-94 or Form I-94A indicating nonimmigrant admission under the Compact of Free Association Between the United States and the FSM or RMI		10. School record or report card		
		11. Clinic, doctor, or hospital record		
		12. Day-care or nursery school record		

7.4 SECURITY REQUIREMENTS FOR PROCUREMENTS REQUIRING INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY

The following requirements will be specifically tailored to each individual task order:

A. Baseline Security Requirements

1) **Applicability.** The requirements herein apply whether the entire contract or order (hereafter "contract"), or portion thereof, includes either or both of the following:
   a. Access (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) employee will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.
   b. Operate a Federal System Containing Information: A Contractor (and/or any subcontractor) will operate a federal system and information technology containing data that supports the HHS mission. In addition to the Federal Acquisition Regulation (FAR)

Subpart 2.1 definition of "information technology" (IT), the term as used in this section includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources.

2) **Safeguarding Information and Information Systems.** In accordance with the Federal Information Processing Standards Publication (FIPS)199, *Standards for Security Categorization of Federal Information and Information Systems*, the Contractor (and/or any subcontractor) shall:
   a. Protect government information and information systems in order to ensure:
      - **Confidentiality**, which means preserving authorized restrictions on access and disclosure, based on the security terms found in this contract, including means for protecting personal privacy and proprietary information;
      - **Integrity**, which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and
      - **Availability**, which means ensuring timely and reliable access to and use of information.
   b. Provide security for any Contractor systems, and information contained therein, connected to an FDA network or operated by the Contractor on behalf of FDA regardless of location. In addition, if new or unanticipated threats or hazards are discovered by either the agency or contractor, or if existing safeguards have ceased to function, the discoverer shall immediately, **within one (1) hour or less**, bring the situation to the attention of the other party. This includes notifying the FDA Systems Management Center (SMC) within one (1) hour of discovery/detection in the event of an information security incident.
   c. Adopt and implement the policies, procedures, controls, and standards required by the HHS/FDA Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Contractor is responsible under this contract or to which the Contractor may otherwise have access under this contract. Obtain the FDA Information Security Program security requirements, outlined in the FDA Information Security and Privacy Policy (IS2P), by contacting the CO/COR or emailing your ISSO.
   d. Comply with the Privacy Act requirements and tailor FAR clauses as needed.

3) **Information Security Categorization**. In accordance with FIPS 199 and National Institute of Standards and Technology (NIST) Special Publication (SP) 800-60, *Volume II: Appendices to Guide for Mapping Types of Information and Information Systems to Security Categorie*s, Appendix C, and based on information provided by the ISSO or other security representative, the risk level for each Security Objective and the Overall Risk Level, which is the highest watermark of the three factors (Confidentiality, Integrity, and Availability) of the information or information system are the following:

Confidentiality:	[ ] Low [ ] Moderate [ ] High
Integrity:	[ ] Low [ ] Moderate [ ] High
Availability:	[ ] Low [ ] Moderate [ ] High

Overall Risk Level: [ ] Low [ ] Moderate [ ] High

Based on information provided by the Privacy Office, system/data owner, or other privacy representative, it has been determined that task orders may involve:

[X] No PII [ ] Yes PII

Specific security requirements will be specified in individual task orders

Personally Identifiable Information (PII). Per the OMB Circular A-130, "PII is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual." Examples of PII include, but are not limited to the following: Social Security number, date and place of birth, mother's maiden name, biometric records, etc.

PII Confidentiality Impact Level may potentially be : [ ] Low [ ] Moderate [X] High

Specific PII Impact Level will be specified in individual task orders

4) **Controlled Unclassified Information (CUI).** CUI is defined as "information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information." The Contractor (and/or any subcontractor) must comply with *Executive Order 13556, Controlled Unclassified Information, (implemented at 3 CFR,* part 2002*)* when handling CUI. 32 C.F.R. 2002.4(aa). As implemented the term "*handling"* refers to "…any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re- using, and disposing of the information." 81 Fed. Reg. 63323. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, shall be:
   a. marked appropriately;
   b. disclosed to authorized personnel on a Need-To-Know basis;
   c. protected in accordance with NIST SP 800-53, *Security and Privacy Controls for Federal Information Systems and Organizations* applicable baseline if handled by a Contractor system operated on behalf of the agency, or NIST SP 800-171, *Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations* if handled by internal Contractor system; and
   d. returned to FDA control, destroyed when no longer needed, or held until otherwise directed.
   Destruction of information and/or data shall be accomplished in accordance with NIST SP 800-88*, Guidelines for Media Sanitization* and the FDA IS2P Appendix T: *Sanitization of Computer-Related Storage Media*.

5) **Protection of Sensitive Information**. For security purposes, information is *or* may be sensitive because it requires security to protect its confidentiality, integrity, and/or availability. The Contractor (and/or any subcontractor) shall protect all government information that is or may be sensitive in accordance with OMB Memorandum M-06-16, *Protection of Sensitive Agency Information* by securing it with a FIPS 140-2 validated solution.

6) **Confidentiality and Nondisclosure of Information.** Any information provided to the contractor (and/or any subcontractor) by FDA or collected by the contractor on behalf of FDA shall be used only for the purpose of carrying out the provisions of this contract and shall not be disclosed or made known in any manner to any persons except as may be

necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and shall ensure that all work performed by its employees and subcontractors shall be under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any FDA records may be made available or disclosed shall be notified in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein.

The confidentiality, integrity, and availability of such information shall be protected in accordance with HHS and *FDA* policies. Unauthorized disclosure of information will be subject to the HHS/*FDA* sanction policies and/or governed by the following laws and regulations:

a. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);
b. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and
c. 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

7) **Internet Protocol Version 6 (IPv6).** All procurements using Internet Protocol shall comply with OMB Memorandum M-05-22, *Transition Planning for Internet Protocol Version 6 (IPv6)*.

8) **Government Websites.** All new and existing public-facing government websites must be securely configured with Hypertext Transfer Protocol Secure (HTTPS) using the most recent version of Transport Layer Security (TLS). In addition, HTTPS shall enable HTTP Strict Transport Security (HSTS) to instruct compliant browsers to assume HTTPS at all times to reduce the number of insecure redirects and protect against attacks that attempt to downgrade connections to plain HTTP. For internal-facing websites, the HTTPS is not required, but it is highly recommended.

9) **Contract Documentation**. The Contractor shall use FDA-provided templates, policies, forms and other agency documents to comply with contract deliverables as appropriate.

10) **Standard for Encryption.** The Contractor (and/or any subcontractor) shall:
    a. Comply with the *HHS Standard for Encryption of Computing Devices and Information* to prevent unauthorized access to government information.
    b. Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI], proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with FIPS 140-2 validated encryption solution.
    c. All devices (i.e.: desktops, laptops, mobile devices, etc.) that store, transmit, or process non-public FDA information should utilize FDA-provided or FDA information security authorized devices that meet HHS and FDA-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).
    d. Verify that the encryption solutions in use are compliant with FIPS 140-2. The Contractor shall provide a written copy of the validation documentation to the COR.
    e. Use the Key Management system on the HHS Personal Identification Verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys. Encryption keys

(PIV card) shall be provided to the COR upon request and at the conclusion of the contract. Upon completion of contract, contractor ensures that COR is able to access and read any encrypted data.

11) **Contractor Non-Disclosure Agreement (NDA)**. Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract shall complete the FDA non-disclosure agreement (3398 Form), as applicable. A copy of each signed and witnessed NDA shall be submitted to the CO and/or COR prior to performing any work under this acquisition.

12) **Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA)** – The Contractor shall assist the procuring activity representative, program office and the FDA SOP or designee with conducting a PTA for the information system and/or information handled under this contract to determine whether or not a full PIA needs to be completed.
   a. If the results of the PTA show that a full PIA is needed, the Contractor shall assist procuring activity representative, program office and the FDA SOP or designee with completing a PIA for the system or information after completion of the PTA and in accordance with HHS and FDA policy and OMB M-03-22, *Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002*. The PTA/PIA must be completed and approved prior to active use and/or collection or processing of PII and is a prerequisite to agency issuance of an authorization to operate (ATO).
   b. The Contractor shall assist the procuring activity representative, program office and the FDA SOP or designee in reviewing and updating the PIA at least every ***three years*** throughout the Enterprise Performance Life Cycle (EPLC) /information lifecycle, or when determined by the agency that a review is required based on a major change to the system, or when new types of PII are collected that introduces new or increased privacy risks, whichever comes first.

B. Training

1) **Mandatory Training for All Contractor Staff.** All Contractor (and/or any subcontractor) employees assigned to work on this contract shall complete the applicable FDA Contractor Information Security Awareness, Privacy, and Records Management training (provided upon contract award) before performing any work under this contract. Thereafter, the employees shall complete FDA Information Security Awareness, Privacy, and Records Management training at least ***annually***, during the life of this contract. All provided training shall be compliant with HHS and FDA training policies.
2) **Role-based Training.** All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the program manager) must complete role-based training ***annually*** commensurate with their role and responsibilities in accordance with HHS and FDA policy and *FDA Role-Based Training (RBT) of Personnel with Significant Security Responsibilities Standard Operating Procedures (SOP).*
3) **Training Records.** The Contractor (and/or any subcontractor) shall maintain training records for all its employees working under this contract in accordance with HHS and FDA policy. A copy of the training records shall be provided to the CO and/or COR within ***30 days*** after contract award and ***annually*** thereafter or upon request.

C. Rules of Behavior

1) The Contractor (and/or any subcontractor) shall ensure that all employees performing on the contract comply with the *HHS Information Technology General Rules of Behavior*.
2) All Contractor employees performing on the contract must read and adhere to the Rules of Behavior (ROB) before accessing HHS and FDA data or other information, systems, and/or networks that store/process government information, initially at the beginning of the contract and at least ***annually*** thereafter, which may be done as part of annual FDA Information Security Awareness Training. If the training is provided by the contractor, the signed ROB must be provided as a separate deliverable to the CO and/or COR per defined timelines.

D. Incident Response

The Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/FDA SMC /Incident Response Team (IRT) teams **within 24 hours,** whether the response is positive or negative.

FISMA defines an incident as "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies." The HHS *Policy for IT Security and Privacy Incident Reporting and Response* further defines incidents as events involving cybersecurity and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.

A privacy breach is a type of incident and is defined by FISMA as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose. The HHS *Policy for IT Security and Privacy Incident Reporting and Response* further defines a breach as "a suspected or confirmed incident involving PII."

In the event of a suspected or confirmed incident or breach, the Contractor (and/or any subcontractor) shall:

1) Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract to avoid a secondary sensitive information incident with FIPS 140-2 validated encryption.
2) NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, the Contractor shall send FDA approved notifications to affected individuals as directed by FDA's SOP.
3) Report all suspected and confirmed information security and privacy incidents and breaches to the FDA Systems Management Center, COR, CO, and other stakeholders, including incidents involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than **one (1) hour of discovery/detection**, and consistent with the applicable FDA and HHS policy and procedures, NIST standards and guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contract information, impact classifications/threat vector, and the type of information

compromised. In addition, the Contractor shall:

a. cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;
b. not include any sensitive information in the subject or body of any reporting e-mail; and
c. encrypt sensitive information in attachments to email, media, etc.

4) Comply with OMB M-17-12, *Preparing for and Responding to a Breach of Personally Identifiable Information* and HHS and FDA incident response policies when handling PII breaches.
5) Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to contractor facilities during a breach/incident investigation demand.

E. Position Sensitivity Designations

All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR). The following position sensitivity designation levels apply to this solicitation/contract: Tier 2

F. Homeland Security Presidential Directive (HSPD)-12

The Contractor (and/or any subcontractor) and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, *Policy for a Common Identification Standard for Federal Employees and Contractors*; OMB M-05-24; FIPS 201, *Personal Identity Verification (PIV) of Federal Employees and Contractors*; HHS HSPD-12 policy; and *Executive Order 13467, Part 1 §1.2.*

Roster. The Contractor (and/or any subcontractor) shall submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster and any revisions to the roster as a result of staffing changes shall be submitted to the COR and/or CO per the COR or CO's direction. Any revisions to the roster as a result of staffing changes. The COR will notify the Contractor of the appropriate level of investigation required for each staff member.

If the employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate suitability level.

G. Contract Initiation and Expiration

1) **General Security Requirements.** The Contractor (and/or any subcontractor) shall comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the Contractor shall follow the FDA EPLC framework and methodology in accordance with the HHS Contract Closeout Guide (2012). HHS EA

requirements may be located here: https://www.hhs.gov/ocio/ea/documents/proplans.html

2) **System Documentation.** Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-64, *Security Considerations in the System Development Life Cycle*, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.

3) **Sanitization of Government Files and Information.** As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) shall provide all required documentation in accordance with FDA OAGS SMGs to the CO and/or COR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, Guidelines for Media Sanitization and FDA IS2P Appendix T: *Sanitization of Computer-Related Storage Media*

4) **Notification.** The Contractor (and/or any subcontractor) shall notify the CO and/or COR as soon as it is known that an employee will stop working under this contract.

5) **Contractor Responsibilities Upon Physical Completion of the Contract**. The Contractor (and/or any subcontractors) shall return all government information and IT resources (i.e., government information in non-government-owned systems, media, and backup systems) acquired during the term of this contract to the CO and/or COR. Additionally, the Contractor shall provide a certification that all government information has been properly sanitized and purged from Contractor-owned systems, including backup systems and media used during contract performance, in accordance with HHS and/or FDA policies.

6) The Contractor (and/or any subcontractor) shall coordinate with the COR via email, coping the Contract Specialist, to ensure that the appropriate person performs and documents the actions identified in the FDA eDepart system http://inside.fda.gov:9003/EmployeeResources/NewEmployee/eDepartDepartureSystem/default.htm as soon as it is known that an employee will terminate work under this contract within days of the employee's exit from the contract. All documentation shall be made available to the CO and/or COR upon request.

H. Records Management and Retention

The Contractor (and/or any subcontractor) shall maintain all information in accordance with Executive Order 13556 -- Controlled Unclassified Information, National Archives and Records Administration (NARA) records retention policies and schedules and HHS/FDA policies and shall not dispose of any records unless authorized by HHS/*FDA*.

In the event that a contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper authorization, it shall be documented and reported as an incident in accordance with HHS/FDA policies.

7.5 SECURITY REQUIREMENTS FOR PROCUREMENTS INVOLVING INFORMATION PROCESSED ON GOVERNMENT-OWNED CONTRACTOR-OPERATED (GOCO) OR CONTRACTOR-OWNED CONTRACTOR-OPERATED (COCO) RESOURCES

A. Security Requirements for GOCO and COCO Resources

1) **Federal Policies.** The Contractor (and/or any subcontractor) shall comply with applicable federal laws that include, but are not limited to, the *FDA Information Security and Privacy Policy (IS2P)*, *Federal Information Security Modernization Act (FISMA) of 2014, (44 U.S.C. 101)*; National Institute of Standards and Technology (NIST) Special Publication (SP) 800-53, *Security and Privacy Controls for Federal Information Systems and* Organizations; Office of Management and Budget (OMB) Circular A-130*, Managing Information as a Strategic Resource*; and other applicable federal laws, regulations, NIST guidance, and Departmental policies.

2) **Security Assessment and Authorization (SA&A)**. A valid authorization to operate (ATO) certifies that the Contractor's information system meets the contract's requirements to protect the agency data. If the system under this contract does not have a valid ATO, the Contractor (and/or any subcontractor) shall work with the agency and supply the deliverables required to complete the ATO within the specified timeline(s). The Contractor shall conduct the SA&A requirements in accordance with *FDA IS2P*, NIST SP 800- 37, *Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach* (latest revision).

For an existing ATO, FDA must make a determination if the existing ATO provides appropriate safeguards or *if an additional ATO is required for the performance of the contract and state as such.*

FDA acceptance of the ATO does not alleviate the Contractor's responsibility to ensure the system security and privacy controls are implemented and operating effectively.

a. SA&A Package Deliverables - The Contractor (and/or any subcontractor) shall provide a SA&A package within a timeline directed by the COR, per to FDA EPLC process, to the CO and/or COR. The following SA&A deliverables are required to complete the SA&A package:

- **System Security Plan (SSP)** – due a week prior to the start of the annual security assessment. The SSP shall comply with the NIST SP 800-18, *Guide for Developing Security Plans for Federal Information Systems*, the Federal Information Processing Standard (FIPS) 200, *Recommended Security Controls for Federal Information Systems*, and NIST SP 800-53, *Security and Privacy Controls for Federal Information Systems and Organizations* applicable baseline requirements, and other applicable NIST guidance as well as HHS and FDA policies and other guidance. The SSP shall be consistent with and detail the approach to IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The SSP shall provide an overview of the system environment and security requirements to protect the information system, as well as describe all applicable security controls in place or planned for meeting those requirements. It should provide a structured process for planning adequate, cost-effective security protection for a system. The Contractor shall update the SSP at least ***annually*** thereafter. **Security Assessment Plan/Report**

(SAP/SAR) – due before the system is made available to standard users. The security assessment shall be conducted by FDA's team of security assessors, unless otherwise noted and be consistent with NIST SP 800-53A, NIST SP 800-30, and HHS and FDA policies. The assessor will document the assessment results in the SAR.

- **Independent Assessment –** This shall be coordinated through the FDA Information Security program.
- **POA&M** – due as part of the SAR. The POA&Ms shall be documented consistent with the HHS and FDA Standard for Plan of Action and Milestones and FDA policies. All high-risk weaknesses must be mitigated within 30 and all medium weaknesses must be mitigated within *[*60 from the date the weaknesses are formally identified and documented. FDA's assessors will determine the risk rating of vulnerabilities.

  Identified risks stemming from deficiencies related to the security control baseline implementation, assessment, continuous monitoring, vulnerability scanning, and other security reviews and sources, as noted in the SAR, shall be documented and tracked by the Contractor for mitigation in the POA&M document. Depending on the severity of the risks, FDA may require designated POA&M weaknesses to be remediated before an ATO is issued. Thereafter, the POA&M shall be updated at least ***quarterly***.
- **Contingency Plan and Contingency Plan Test** – due before the start of the annual security assessment. The Contingency Plan must be developed in accordance with NIST SP 800-34, *Contingency Planning Guide for Federal Information Systems*, and be consistent with HHS and FDA policies. Upon acceptance by the System Owner, the Contractor, in coordination with the System Owner, shall test the Contingency Plan and prepare a Contingency Plan Test Report that includes the test results, lessons learned and any action items that need to be addressed. Thereafter, the Contractor shall update and test the Contingency Plan at least annually.
- **E-Authentication Questionnaire** – The contractor (and/or any subcontractor) shall collaborate with government personnel to ensure that an E-Authentication Threshold Analysis (E-Auth TA) is completed to determine if a full E-Authentication Risk Assessment (E-Auth RA) is necessary. System documentation developed for a system using E-Auth TA/E-Auth RA methods shall follow OMB 04-04 and NIST SP 800-63 Digital Identity Guidelines document suite.

  Based on the level of assurance determined by the E-Auth, the Contractor (and/or subcontractor) must ensure appropriate authentication to the system, including remote authentication, is in-place in accordance with the assurance level determined by the E- Auth (when required) in accordance with HHS and FDA policies.

b. Information Security Continuous Monitoring. Upon the government issuance of an Authority to Operate (ATO), the Contractor (and/or subcontractor)-owned/operated systems that input, store, process, output, and/or transmit government information, shall meet or exceed the information security continuous monitoring (ISCM) requirements in accordance with FISMA and NIST SP 800-137*, Information Security Continuous Monitoring (ISCM) for Federal Information Systems and Organizations*, and FDA IS2P. The following are the minimum requirements for ISCM:

- **Annual Assessment/Pen Test -** Assess the system security and privacy controls (or

ensure an assessment of the controls is conducted) at least annually to determine the implemented security and privacy controls are operating as intended and producing the desired results (this may involve penetration testing conducted by the agency or an FDA-authorized independent third-party for all high impact systems. In addition, review all relevant SA&A documentation (SSP, POA&M, Contingency Plan, etc.) and provide updates by specified due date.

- **Asset Management -** Using an FDA-approved Security Content Automation Protocol (SCAP)-compliant automated tool for active/passive scans, provide an inventory of all information technology (IT) assets for hardware and software, (computers, servers, routers, databases, operating systems, etc.) that are processing FDA-owned information/data. It is anticipated that this inventory information will be required to be produced at least annually. IT asset inventory information shall include IP address, machine name, operating system level, security patch level, and SCAP-compliant format information. The Contractor shall maintain a capability to provide an inventory of 100% of its IT assets using SCAP-compliant automated tools.
- **Configuration Management** - Use FDA-approved SCAP-compliant automated tools, per NIST IR 7511, for authenticated scans to provide visibility into the security configuration compliance status of all IT assets, (computers, servers, routers, databases, operating systems, application, etc.) that store and process government information. Compliance will be measured using IT assets and standard HHS and government configuration baselines at least annually. The Contractor shall maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP-compliant automated tools.
- **Vulnerability Management -** Use FDA-approved SCAP-compliant automated tools for authenticated scans to scan information system(s) and detect any security vulnerabilities in all assets (computers, servers, routers, Web applications, databases, operating systems, etc.) that store and process government information. Contractors shall actively manage system vulnerabilities using automated tools and technologies where practicable and in accordance with HHS and FDA policy. Automated tools shall be compliant with NIST-specified SCAP standards for vulnerability identification and management. The Contractor shall maintain a capability to provide security vulnerability scanning information for 100% of IT assets using SCAP-compliant automated tools and report to the agency at least monthly.
- **Patching and Vulnerability Remediation** - Install vendor released security patches and remediate critical and high vulnerabilities in systems processing government information in an expedited manner, within vendor and FDA specified timeframes (follow the FDA patch management policy).
- **Secure Coding** - Follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.
- **Boundary Protection** - The Contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities is routed through a Trusted Internet Connection (TIC).

3) **Government Access for Security Assessment**. In addition to the Inspection Clause in the contract, the Contractor (and/or any subcontractor) shall afford the Government access to

the Contractor's facilities, installations, operations, documentation, information systems, and personnel used in performance of this contract to the extent required to carry out a program of security assessment (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the confidentiality, integrity, and availability of federal data or to the protection of information systems operated on behalf of HHS, including but are not limited to:

a. At any tier handling or accessing information, consent to and allow the Government, or an independent third party working at the Government's direction, without notice at any time during a weekday during regular business hours contractor local time, to access contractor and subcontractor installations, facilities, infrastructure, data centers, equipment (including but not limited to all servers, computing devices, and portable media), operations, documentation (whether in electronic, paper, or other forms), databases, and personnel which are used in performance of the contract.

   The Government includes, but is not limited to, the U.S. Department of Justice, U.S. Government Accountability Office, the HHS Office of the Inspector General (OIG), and FDA Information Security. The purpose of the access is to facilitate performance inspections and reviews, security and compliance audits, and law enforcement investigations. For security audits, the audit may include, but not be limited to, such items as buffer overflows, open ports, unnecessary services, lack of user input filtering, cross site scripting vulnerabilities, SQL injection vulnerabilities, and any other known vulnerabilities.

b. At any tier handling or accessing protected information, fully cooperate with all audits, inspections, investigations, forensic analysis, or other reviews or requirements needed to carry out requirements presented in applicable law or policy. Beyond providing access, full cooperation also includes, but is not limited to, disclosure to investigators of information sufficient to identify the nature and extent of any criminal or fraudulent activity and the individuals responsible for that activity. It includes timely and complete production of requested data, metadata, information, and records relevant to any inspection, audit, investigation, or review, and making employees of the contractor available for interview by inspectors, auditors, and investigators upon request. Full cooperation also includes allowing the Government to make reproductions or copies of information and equipment, including, if necessary, collecting a machine or system image capture.

c. Segregate Government protected information and metadata on the handling of Government protected information from other information. Commingling of information is prohibited. Inspectors, auditors, and investigators will not be precluded from having access to the sought information if sought information is commingled with other information.

d. Cooperate with inspections, audits, investigations, and reviews.

4) **End of Life Compliance.** The Contractor (and/or any subcontractor) must use Commercial off the Shelf (COTS) software or other software that is supported by the manufacturer. In addition, the COTS/other software need to be within one major version of the current version. The Contractor shall retire and/or upgrade all software/systems that have reached end-of- life in accordance with FDA *End-of-Life Operating Systems, Software, and Applications Policy*.

5) **Desktops, Laptops, and Other Computing Devices Required for Use by the Contractor**. The Contractor (and/or any subcontractor) shall ensure that all IT equipment (e.g., laptops, desktops, servers, routers, mobile devices, peripheral devices, etc.) used to process information on behalf of FDA are deployed and operated in accordance with approved security configurations and meet the following minimum requirements:

   a. Encrypt equipment and sensitive information stored and/or processed by such equipment in accordance with HHS, FDA, and FIPS 140-2 encryption standards.
   b. Configure laptops and desktops in accordance with the latest applicable United States Government Configuration Baseline (USGCB), FDA Configuration Baselines, , and FDA Minimum Security Configuration Standards;
   c. Maintain the latest operating system patch release and anti-virus software definitions, per FDA patch management policy;
   d. Validate the configuration settings after hardware and software installation, operation, maintenance, update, and patching and ensure changes in hardware and software do not alter the approved configuration settings; and
   e. Automate configuration settings and configuration management in accordance with HHS and FDA security policies, including but not limited to:
      - Configuring its systems to allow for periodic Federal vulnerability and security configuration assessment scanning; and
      - Using FDA-approved Security Content Automation Protocol (SCAP)-validated tools with USGCB Scanner capabilities to scan its systems at least on a ***monthly*** basis and report the results of these scans to the CO and/or COR, Project Officer, and any other applicable designated POC.

7.6 ACCOUNTABILITY AND SECURITY

All Contractor and subcontractor employees who will have access to Government information and/or sensitive materials must sign a Contractor's Commitment to Protect Non-Public Information (NPI) Agreement (Form FDA 3398). It is the responsibility of the Contractor to assure that such Agreements have been signed before access is permitted. Copies of signed agreements must be provided to the Contracting Officer Representative.

The following procedures and rules shall be followed by the Contractor according to the Privacy Act of 1974, as amended, and the FDA security and confidentiality procedures applicable to this contract:

A. All information and reports generated from this project are, and will remain, the property of the FDA. No Government document or information, oral or written, either in final or draft form, will be provided to non-FDA sources by any Contractor personnel without the written approval of the Contracting Officer during this contract or at any later date.
B. No data covered by privacy laws may leave the United States for any purpose or under any circumstances unless prior approval by the Contracting Officer is first obtained.
C. The Contractor must ensure that all FDA data or documents processed or developed under this contract, and the information contained therein, are protected from unauthorized use and mishandling by assigned personnel
D. There shall be no dissemination or publication, except within and between Contractor personnel, of information developed under this contract or contained in the reports to be

furnished pursuant to this contract, without the prior written approval of the Contracting Officer. Further, the Contractor shall not reveal, during the performance of this contract or later, any of the operating methods or systems, contents of files, names of persons, firms, or places mentioned under the contract that the Contractor may acquire, unless approved in writing by the Contracting Officer.

E. Under the provisions of the Privacy Act of 1974, as amended, that is applicable to this contract, the Contractor and Contractor personnel may be subject to its criminal penalties. The Contractor agrees that, upon termination of the contract, whether with or without cause, the Contractor has no property or possessor right to any of the correspondence, files or materials, of whatever kind and description, or any copies or duplicates of such, whether developed/prepared by the Contractor or furnished to the Contractor by the technical office concerning the performance of this contract; and that, upon demand, the Contractor will surrender immediately to the Contracting Officer such items, matters, materials, and copies. A restraining order or an injunction may be issued against the Contractor for any violation of this provision, besides any other right or penalty by law that the Government may have.

The above terms and conditions of this contract clause are subject to formal modification or amendment by the Government in those instances in which the courts (e.g., grand jury investigations), statutory requirements (e.g., civil investigative demands), or specific circumstances dictate such changes.

7.7 BRIEFINGS

An FDA representative (typically, the Contracting Officer's Representative) will conduct an orientation briefing for the Contractor and subcontractor employees. The briefing will stress:

1) the importance of protecting non-public information;
2) specified computer/IT requirements as outlined in the DHHS Automated Information Systems Security Program Handbook; and
3) the consequences of unauthorized disclosure of non-public information. Briefing updates may be conducted annually.

The Contractor shall brief all Contractor employees, subcontractors and consultants regarding the sensitivity of the information to be handled under the contract and of their responsibility to protect it. The briefing shall stress that the information is non-public and shall not be disclosed to any unauthorized party. The Contractor shall conduct an updated briefing annually and shall submit a report to the FDA COR within ten (10) days after the briefing which includes: an outline of the briefing; copies of any briefing materials; the date the briefing was conducted; and the names of the attendees.

If this is an information technology/telecommunication (IT/TC) contract, in addition to the above briefings, the FDA COR and the FDA Center/Office Information Systems Security Officer (ISSO) will brief Contractor and subcontractor personnel on security measures required pertinent to any hardware/software being utilized. Furthermore, appropriate Contractor and subcontractor personnel shall attend training courses as directed by the FDA to fulfill requirements of the Computer Security Act

of 1987. These courses are generally one (1) day in length, and attendance at one (1) course is sufficient. This training will be provided at no cost to the Contractor.

7.8 ORGANIZATIONAL CONFLICTS OF INTEREST

As a regulatory agency charged with protection of the public health, the Food and Drug Administration (FDA) must maintain public confidence in the integrity of its decisions. The FDA has various policies and procedures that safeguard against both actual and apparent conflict of interest (COI) on the part of its employees. It is additionally critical that the FDA be assured that there is not actual or apparent COI on the part of either the Contractor's organization of its individual employees in performance of this contract action.

The Contractor must assure the protection of the information and data it receives in performance of this contract from unauthorized use or disclosure, and must avoid actions that would cause a reasonable person to question the impartiality of the Contractor, its employees, or the Government in the performance of this immediate contract and potential participation in future actions. The Contractor will be held to the restrictions of the Organizational Conflict of Interest clause, unless an acceptable mitigation of risk plan is proposed, is found acceptable by the Government and enforced.

Potential Conflicts of Interest Specific to this Contract: The Contractor shall review the Statement of Work in detail to identify any particular aspects that may present organizational or individual COI, either actual or apparent.

Definition of Conflict of Interest: Conflict of interest means that because of other activities or relationships with other persons or organizations, a person or organization is unable or potentially unable to render impartial assistance or advice to the Government, that the person's or organization's objectivity in performing the contract is or might be otherwise impaired, or that the person or organization has or might acquire an unfair competitive advantage (See FAR 9.501).

(a) Purpose. The purpose of this clause is to ensure that the contractor and its subcontractors:

(1) Are not biased because of their financial, contractual, organizational, or other interests which relate to the work under this contract, and

(2) Do not obtain any unfair competitive advantage over other parties by virtue of their performance of this contract.

(b) Scope. This clause applies to performance or participation by the contractor, its parents, affiliates, divisions and subsidiaries, and successors in interest (hereinafter collectively referred to as "contractor") in the performance of this contract as a prime contractor, subcontractor, co-sponsor, joint venturer, consultant, or in any similar capacity.

(c) Warrant and Disclosure. The warrant and disclosure requirements apply to both the contractor and all subcontractors. The contractor warrants that, to the best of the contractor's knowledge and belief, there are no relevant facts or circumstances which would give rise to an organizational conflict of interest, as defined in FAR Subpart 9.5, and that the contractor has disclosed all relevant information regarding any actual or potential conflict. The contractor agrees it shall make an immediate and full disclosure, in writing, to the Contracting Officer of any potential or actual organizational conflict of

interest or the existence of any facts that may cause a reasonably prudent person to question the contractor's impartiality because of the appearance or existence of bias or an unfair competitive advantage. Such disclosure shall include a description of the actions the contractor has taken or proposes to take in order to avoid, neutralize, or mitigate any resulting conflict of interest.

(d) Remedies. The Contracting Officer may terminate this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid, neutralize or mitigate an actual or apparent organizational conflict of interest. If the contractor fails to disclose facts pertaining to the existence of a potential or actual organizational conflict of interest or misrepresents relevant information to the Contracting Officer, the Government may terminate the contract for default, suspend or debar the contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

(e) Subcontracts. The contractor shall include a clause substantially similar to this clause, including paragraphs (f) and (g), in any subcontract or consultant agreement.

(f) Prime Contractor Responsibilities. Contractor shall determine in writing whether the interests disclosed present an actual, or significant potential for, an organizational conflict of interest. The contractor shall identify and avoid, neutralize, or mitigate any subcontractor organizational conflict prior to award of the contract to the satisfaction of the Contracting Officer. If the subcontractor's organizational conflict cannot be avoided, neutralized, or mitigated, the contractor must obtain the written approval of the Contracting Officer prior to entering into the subcontract. If the contractor becomes aware of a subcontractor's potential or actual organizational conflict of interest after contract award, the contractor agrees that the Contractor may be required to eliminate the subcontractor from its team, at the contractor's own risk. The contractor shall obtain from its subcontractors or consultants the disclosure required in FAR Part 9.507

(g) Waiver. The contractor may seek a waiver from the Head of the Contracting Activity by submitting such waiver request to the Contracting Officer, including a full written description of the requested waiver and the reasons in support thereof.

(h) As a regulatory agency charged with protection of the public health, the Food and Drug Administration (FDA) must maintain public confidence in the integrity of its decisions. The FDA has various policies and procedures that safeguard against both actual and apparent conflict of interest (COI) on the part of its employees. It is additionally critical that the FDA be assured that there is no actual or apparent COI on the part of either the Contractor's organization or its individual employees in performance of this contract action.

(i) Offerors submitting proposals to perform work under this contract must assure the protection of the information and data they receive in performance or under this contract from unauthorized use or disclosure, and must avoid actions that would cause a reasonable person to question the impartiality of the Contractor, its employees, or the Government in the performance of this immediate contract and potential participation in future actions. Contractor will be held to the restrictions of the Organizational Conflict of Interest clause, unless an acceptable mitigation of risk plan is proposed, found acceptable by the Government and enforced.

7.9 DISCLOSURE OF INFORMATION

Contractors are reminded that information furnished under this solicitation and resulting contract may be subject to disclosure under the Freedom of Information Act (FOIA). Therefore, all items that are confidential to business, or contain trade secrets, proprietary, or personnel information must be clearly marked. Marking of items will not necessarily preclude disclosure when the U.S. Office of Personnel Management (OPM or The Government) determines disclosure is warranted by FOIA. However, if such items are not marked, all information contained within the submitted documents will be deemed to be releasable.

Any information made available to the Contractor by the Government must be used only for the purpose of carrying out the provisions of this contract and must not be divulged or made known in any manner to any person except as may be necessary in the performance of the contract.

In performance of this contract, the Contractor assumes responsibility for protection of the confidentiality of Government records and must ensure that all work performed by its subcontractors shall be under the supervision of the Contractor or the Contractor's responsible employees.

Each officer or employee of the Contractor or any of its subcontractors to whom any Government record may be made available or disclosed must be notified in writing by the Contractor that information disclosed to such officer or employee can be used only for a purpose and to the extent authorized herein, and that further disclosure of any such information, by any means, for a purpose or to an extent unauthorized herein, may subject the offender to criminal sanctions imposed by 19 U.S.C. § 641. That section provides, in pertinent part, that whoever knowingly converts to their use or the use of another, or without authority, sells, conveys, or disposes of any record of the United States or whoever receives the same with intent to convert it to their use or gain, knowing it to have been converted, shall be guilty of a crime punishable by a fine of up to $10,000, or imprisoned up to ten years, or both.

7.10 INSURANCE REQUIREMENTS

The Contractor shall maintain the types of insurance and coverage required in FAR 28.307-2, Liability and per FAR 52.228-5, Insurance – Work on A Government Installation.

Upon contract award, the contractor shall furnish to the Contracting Officer a certificate or written statement of insurance prior to commencement of work under this contract. The written statement of insurance must contain the following information: policy number, policyholder, carrier, amount of coverage, dates of effectiveness and contract number. The contract number and task order number (if applicable) shall be cited on the certificate of insurance.

7.11 ADDITIONAL SECURITY AND CONFIDENTIALITY REQUIREMENTS

The Contractor shall realize the regulatory nature of FDA and accepts responsibility for diligence in protecting the security and confidentiality of any information acquired with the FDA networking infrastructure, staff projects, meetings, seminary or other sensitive information.

During the course of the contract, if questions arise as to what information can be shared with potential solution providers, others performing maintenance on systems, third party or other staff, the Contractor shall seek guidance and approval from the COR.

7.12 TRAVEL

No travel is anticipated under this contract. Any travel costs incurred by the Contractor within the Washington, DC-metropolitan area, including to/from the Contractor's facility, shall be considered local travel and will not be reimbursed.

If necessary, individual task orders may include travel. All travel must be pre-negotiated in individual task orders and approved and authorized by the Task Order COR. Travel shall be reimbursed in accordance with FAR 31.205-46 and Federal Travel Regulations (https://www.gsa.gov/policy-regulations/regulations/federal-travel-regulation-ftr). Travel requirements under this contract shall be met using the most economical form of transportation available. If economy class transportation is not available, the request for payment voucher must be submitted with justification for use of higher-class travel indicating dates, times, and flight numbers. All travel shall be scheduled sufficiently in advance to take advantage of offered discount rates, unless otherwise directed by the Contracting Officer.

7.13 OTHER DIRECT COSTS

Allowable other direct costs in support of specific task orders shall be proposed and evaluated at the task order level.

Any Other Direct Costs (ODCs) shall be submitted through the invoice. All ODCs over $3,000, other than those ODC acquired under the firm fixed price line items, must be pre-approved by the Contracting Officer, if not already approved through the issuance of a task order or modification.

To be eligible to receive reimbursement for ODCs, the Contractor must obtain at least three (3) quotes for each transaction in excess of $3,000.00 to ensure that adequate price competition was sought, or the Contractor must provide an acceptable justification as to why it was impracticable to do so. For purchases of ODCs, the Contractor shall provide the aforementioned documentation only when requested by the Contracting Officer.

The Contractor shall maintain documentation of all reimbursable purchases until three (3) years after the contract is completed and shall provide access to and copies of such documentation, when requested by the Contracting Officer.

7.14 REPORTING MATTERS INVOLVING FRAUD, WASTE, AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in FDA funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll-free number is 1-800-HHS-TIPS (1-800-447-8477), 8:00 am – 5:30 pm Eastern Time, Monday –Friday. Fax 1-800-223-8164, TTY 1-800-377-4950. All telephone calls will be handled confidentially. The e-mail address is hhstips@oig.hhs.gov and the mailing address is:

HHS TIPS Hotline
P.O. Box 23489
Washington, D.C. 20026

7.15 CONTRACTOR CONFORMANCE WITH APPLICABLE LAWS, REGULATIONS, POLICIES, AND STANDARDS

The Contractor shall be responsible for knowledge of and compliance with all applicable Federal information technology management laws, regulations, policies and standards at the Government-wide, HHS and FDA levels.

7.16 CONTRACTOR ADVERTISING OF CONTRACT AWARD

The Contractor shall not refer to the product or service awarded under this contract in commercial advertising, as defined in FAR 31.205–1, in any manner which states or implies the Food and Drug Administration's approval or endorsement of the product or service being provided; or, states or implies that the product or service being provided is considered to be superior to other industry products or services. The Contractor may request the Contracting Officer to make a determination as to the propriety of promotional material.

7.17 HANDLING OF NON-PUBLIC RECORDS MATERIAL

Accountability of NPI is essential to maintaining a history of what an organization has and where NPI is located. Through effective accounting procedures, it must be possible to trace the movement and detect the loss of NPI in a timely manner. Adequate accountability record systems shall be in place to track NPI received, generated, transmitted or destroyed.

Inventories. Periodic inventories shall be conducted for all NPI documents. Inventory record shall be retained until the next inventory has been completed.

Report of Lost Documents. All physical losses of NPI shall be reported to the FDA Physical Security Staff, the ARLO, IDIQ COR, and TO COR. The report shall include the identification and description of the missing document(s), the name and organizational location of the individual to whom the document(s) were last charged, and a summary of the efforts made to locate the missing document(s). Contractors are responsible for following supplemental instructions for reporting lost documents as identified in ITO's. Contractors shall make every reasonable effort to comply with NPI policies as identified in this contract.

Storage. During working hours, individuals shall take all necessary precautions to prevent access to NPI by unauthorized persons (i.e., persons who do not possess an appropriate security clearance and/or who do not possess the required need-to-know). Emphasis shall be placed on administrative safeguards and individual security responsibilities during normal working hours. NPI documents, when removed from storage for working purposes, shall be kept under constant surveillance and turned face-down or covered when not in use. NPI documents shall not be left unattended. If this is not possible, the safeguarding requirements for after working hours apply. NPI created on automated information systems are susceptible to interception by unauthorized persons due to the compromising emanations threat. Computers used frequently to handle NPI shall have a reduced level of emanations or located in an area with sufficient perimeter of control. Computers used to handle NPI shall have the proper safeguards to ensure that all data is protected from disclosure. All system vulnerabilities must be

identified, and the risk minimized. After working hours, NPI documents shall be stored in approved secure file areas or containers.

Recalled Documents. NPI documents retrieved/recalled from storage at the Federal Records Center shall be provided the same protection they received before transfer to the Center. All recalled documents shall be entered in their accountability system. Accountability and safeguarding requirements shall continue until the documents are returned to the Federal Records Center or disposed of by other means, e.g., destroyed.

Contractor Facility. Storage locations at a Contractor facility shall be approved (in writing) by the FDA Physical Security Staff (HFA-204).

Transmission. NPI shall be transmitted either in the custody of an appropriately cleared and authorized individual (preferred method) or by an approved system or carrier (with signature receipt), as outlined below:

Courier/Personal Delivery. Individuals delivering NPI documents shall be briefed on their responsibilities on security precautions to prevent the unauthorized disclosure of the information until the delivery is complete. Documents shall remain in the physical possession of the individual delivering the NPI at all times. Documents shall not be read, studied, displayed, discussed or used in any manner in public places.

Mail. U.S. Registered/Certified, or commercial carrier express mail (with signature receipt) may be used for the transmission of NPI (paper copies, disks, CDs, or other media in hard copy form).

Fax. NPI documents may be transmitted via the fax machine only upon verification that the intended recipient (or other authorized individual) is available to immediately retrieve the information to prevent potential review by unauthorized individuals.

Computers/networks/portable devices. NPI documents must be protected during transmission when using computer devices. Only FDA issued computers may be used for processing or storing NPI. Transmission of NPI by e-mail, Intranet, or Internet is not allowed unless FDA authorized encryption is used.

Permanent Transfer. The only Agency that records can be permanently transferred to is NARA. The sender shall provide an SF 258, Agreement to Transfer Records to the National Archives of the United States, to the Agency Records Officer

Temporary Transfer. Permanent records may be temporarily transferred to the FRC for storage until they are permanently transferred to NARA. The sender shall provide an SF 135, Records Transmittal and Receipt, to the Agency Records Officer.

Temporary Records. Temporary NPI records that are no longer needed on a frequent basis - but should be retained for legal retention until their disposition date - may be transferred to the Federal Records Center for storage.

Reproduction. NPI documents shall be reproduced only as required in the performance of official business. The accountability and safeguarding requirements of reproduced copies shall be the same as that given to the original document(s) from which they were reproduced.

Violations. The loss or misuse of privileged information may seriously hamper FDA in the conduct of its mission. Violations may be punishable by criminal penalties and/or corrective, disciplinary or adverse action. Contractor employees who inappropriately release documents containing NPI may be fined, imprisoned and/or disciplined by action up to and including removal from the Federal service.

Audits. The FDA Privacy and Physical Security Staff may conduct scheduled and unscheduled inspections and/or inventories of NPI document control systems within FDA components and Contractor facilities to ensure effective operation and compliance with this Guide.

8. CONTRACT CLAUSES

8.1 FAR 52.252-2 – CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):
https://www.acquisition.gov/?q=browsefar

FAR Clauses Incorporated by Reference:

FAR Clause	Clause Title	Date
52.204-13	System for Award Management Maintenance	Oct 2018
52.204-18	Commercial and Government Entity Code Maintenance	Aug 2020
52.212-4	Contract Terms and Conditions-Commercial Items	Dec 2022
52.212-4	Contract Terms and Conditions-Commercial Items (Alt I)	Nov 2021
52.227-14	Rights in Data—General	May 2014
52.228-5	Insurance -- Work on a Government Installation	Jan 1997
52.232-39	Unenforceability of Unauthorized Obligations	Jun 2013
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	Nov 2021
52.237-3	Continuity of Services	Jan 1991
52.242-15	Stop-Work Order	Aug 1989
52.242-17	Government Delay of Work	Apr 1984
52.247-35	F.o.b. Destination, Within Consignee's Premises	Apr 1984
52.245-1	Government Property	Sept 2021
52.245-9	Use and Charges	Apr 2012

8.2 HHSAR CLAUSES INCORPORATED BY REFERENCE

This contract incorporates one or more HHSAR clauses or provision by reference, with the same force and effect as if they were given in full text. HHSAR Clauses and Provisions can be viewed in full text at:
https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html

HHSAR Clause	Clause Title	Date
352.203-70	Anti-Lobbying	Dec 2015
352.208-70	Printing and Duplication	Dec 2015
352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations	Dec 2015
352.223-70	Safety and Health	Dec 2015
352.227-70	Publications and Publicity	Dec 2015
352.231-70	Salary Rate Limitation	Dec 2015
352.239-73	Electronic and Information Technology Accessibility Notice	Dec 2015
352.170-5b	Care of Live Vertebrate Animals	Dec 2015

8.3 FAR CLAUSES IN FULL TEXT

FAR 52.216-18 – Ordering (Aug 2020)

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from the period of performance start date of the IDIQ through five years.

(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

(c) If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

(End of Clause)

FAR 52.216-19 – Order Limitations (Oct 1995)

(a) *Minimum order.* When the Government requires supplies or services covered by this contract in an amount of less than $3,000.00, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

(b) *Maximum order.* The Contractor is not obligated to honor -

(1) Any order for a single item in excess of $10,000,000.00;

(2) Any order for a combination of items in excess of $10,000,000.00; or

(3) A series of orders from the same ordering office within fifteen (15) days that together call for quantities exceeding the limitation in subparagraph (b)(1) or (2) of this section.

(c) If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) of this section.

(d) Notwithstanding paragraphs (b) and (c) of this section, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within five (5) business days after issuance, with written notice stating the

Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

(End of Clause)

FAR 52.216-22 – Indefinite Quantity (Oct 1995)
(a) This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.

(b) Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum." The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum."

(c) Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.

(d) Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after 60 months following the IDIQ contract expiration date.

(End of Clause)

FAR 52.222-42 – Statement of Equivalent Rates for Federal Hires (May 2014)
In compliance with the Service Contract Labor Standards statute and the regulations of the Secretary of Labor (29 CFR part 4), this clause identifies the classes of service employees expected to be employed under the contract and states the wages and fringe benefits payable to each if they were employed by the contracting agency subject to the provisions of 5 U.S.C. 5341 or 5332.

This Statement is for Information Only:
It is not a Wage Determination

Employee Class	Monetary Wage -- Fringe Benefits
Driver Courier	$13.98/hour - $3.81/hour

(End of Clause)

The following clause is applicable at the IDIQ and task order level:

FAR 52.217-8 – Option to Extend Services (Nov 1999)
The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor

rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within any time before the contract expires.

(End of Clause)

The following clause may be applicable at the task order level and may be tailored in individual task orders:

FAR 52.217-9 – Option to Extend the Term of the Contract (Mar 2000)
(a) The Government may unilaterally extend the term of the task order at any time prior to the expiration of the task order; provided that the Government gives the Contractor a preliminary written notice of its intent to extend prior to task order expiration. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended task order shall be considered to include this option clause.

(c) The total duration of the task order, including the exercise of any options under this clause, shall not exceed five (5) years and six (6) months.

(End of Clause)

FAR 52.212-5 – Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items (May 2022)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial products and commercial services:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Nov 2021) (Section 1634 of Pub. L. 115-91).

(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Nov 2021) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).

(5) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).

(6) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial products and commercial services:

[*Contracting Officer check as appropriate*.]

_X_ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Jun 2020), with *Alternate I* (Nov 2021) (41 U.S.C. 4704 and 10 U.S.C. 2402).

_X_ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (Nov 2021) (41 U.S.C. 3509)).

__ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)

_X_ (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (Jun 2020) (Pub. L. 109-282) (31 U.S.C. 6101 note).

__ (5) [Reserved].

__ (6) 52.204-14, Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

_X_ (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

_X_ (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Nov 2021) (31 U.S.C. 6101 note).

_X_ (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Oct 2018) (41 U.S.C. 2313).

__ (10) [Reserved].

__ (11) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (Sep 2021) (15 U.S.C. 657a).

__ (12) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Sep 2021) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).

__ (13) [Reserved]

__ (14)

(i) 52.219-6, Notice of Total Small Business Set-Aside (Nov 2020) (15 U.S.C. 644).

__ (ii) Alternate I (Mar 2020) of 52.219-6.

__ (15)

(i) 52.219-7, Notice of Partial Small Business Set-Aside (Nov 2020) (15 U.S.C. 644).

__ (ii) Alternate I (Mar 2020) of 52.219-7.

_X_ (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).

_X_ (17)

(i) 52.219-9, Small Business Subcontracting Plan (Nov 2021) (15 U.S.C. 637(d)(4)).

__ (ii) Alternate I (Nov 2016) of 52.219-9.

_X_ (iii) Alternate II (Nov 2016) of 52.219-9.

__ (iv) Alternate III (Jun 2020) of 52.219-9.

__ (v) Alternate IV (Sep 2021) of 52.219-9.

__ (18)

(i) 52.219-13, Notice of Set-Aside of Orders (Mar 2020) (15 U.S.C. 644(r)).

__ (ii) Alternate I (Mar 2020) of 52.219-13.

__ (19) 52.219-14, Limitations on Subcontracting (Sep 2021) (15 U.S.C. 637s).

_X_ (20) 52.219-16, Liquidated Damages—Subcontracting Plan (Sep 2021) (15 U.S.C. 637(d)(4)(F)(i)).

__ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Sep 2021) (15 U.S.C. 657f).

_X_ (22)

(i) 52.219-28, Post Award Small Business Program Rerepresentation (Sep 2021) (15 U.S.C. 632(a)(2)).

__ (ii) Alternate I (Mar 2020) of 52.219-28.

__ (23) 52.219-29, Notice of Set-Aside for, or Sole-Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Sep 2021) (15 U.S.C. 637(m)).

__ (24) 52.219-30, Notice of Set-Aside for, or Sole-Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Sep 2021) (15 U.S.C. 637(m)).

__ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (Mar 2020) (15 U.S.C. 644(r)).

__ (26) 52.219-33, Nonmanufacturer Rule (Sep 2021) (15U.S.C. 637(a)(17)).

_X_ (27) 52.222-3, Convict Labor (Jun 2003) (E.O.11755).

_X_ (28) 52.222-19, Child Labor-Cooperation with Authorities and Remedies (Jan 2022) (E.O.13126).

_X_ (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

_X_ (30)
(i) 52.222-26, Equal Opportunity (Sep 2016) (E.O.11246).

__ (ii) Alternate I (Feb 1999) of 52.222-26.

_X_ (31)
(i) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C. 4212).

__ (ii) Alternate I (Jul 2014) of 52.222-35.

_X_ (32)
(i) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C. 793).

__ (ii) Alternate I (Jul 2014) of 52.222-36.

_X_ (33) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).

_X_ (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).

_X_ (35)
(i) 52.222-50, Combating Trafficking in Persons (Nov 2021) (22 U.S.C. chapter 78 and E.O. 13627).

__ (ii) Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

_X_ (36) 52.222-54, Employment Eligibility Verification (May 2022) (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial products or commercial services as prescribed in FAR 22.1803.)

__ (37)
(i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

__ (ii) Alternate I (May 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

__ (38) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).

__ (39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).

__ (40)
(i) 52.223-13, Acquisition of EPEAT®-Registered Imaging Equipment (Jun 2014) (E.O.s 13423 and 13514).

__ (ii) Alternate I (Oct 2015) of 52.223-13.

__ (41)
(i) 52.223-14, Acquisition of EPEAT®-Registered Televisions (Jun 2014) (E.O.s 13423 and 13514).

__ (ii) Alternate I (Jun2014) of 52.223-14.

__ (42) 52.223-15, Energy Efficiency in Energy-Consuming Products (May 2020) (42 U.S.C. 8259b).

__ (43)
(i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (Oct 2015) (E.O.s 13423 and 13514).

__ (ii) Alternate I (Jun 2014) of 52.223-16.

_X_ (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020) (E.O. 13513).

__ (45) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).

__ (46) 52.223-21, Foams (Jun2016) (E.O. 13693).

__ (47)

(i) 52.224-3 Privacy Training (Jan 2017) (5 U.S.C. 552 a).

__ (ii) Alternate I (Jan 2017) of 52.224-3.

__ (48) 52.225-1, Buy American-Supplies (Nov 2021) (41 U.S.C. chapter 83).

__ (49)

(i) 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act (Nov 2021) (41 U.S.C.chapter83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

__ (ii) Alternate I (Jan 2021) of 52.225-3.

__ (iii) Alternate II (Jan 2021) of 52.225-3.

__ (iv) Alternate III (Jan 2021) of 52.225-3.

__ (50) 52.225-5, Trade Agreements (Oct 2019) (19 U.S.C. 2501, *et seq*., 19 U.S.C. 3301 note).

_X_ (51) 52.225-13, Restrictions on Certain Foreign Purchases (Feb 2021) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

__ (52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302Note).

__ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150).

__ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov2007) (42 U.S.C. 5150).

__ (55) 52.229-12, Tax on Certain Foreign Procurements (Feb 2021).

__ (56) 52.232-29, Terms for Financing of Purchases of Commercial Products and Commercial Services (Nov 2021) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

__ (57) 52.232-30, Installment Payments for Commercial Products and Commercial Services (Nov 2021) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

_X_ (58) 52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct2018) (31 U.S.C. 3332).

__ (59) 52.232-34, Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).

__ (60) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).

__ (61) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).

__ (62) 52.242-5, Payments to Small Business Subcontractors (Jan 2017) (15 U.S.C. 637(d)(13)).

__ (63)

(i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Nov 2021) (46 U.S.C. 55305 and 10 U.S.C. 2631).

__ (ii) Alternate I (Apr 2003) of 52.247-64.

__ (iii) Alternate II (Nov 2021) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial products and commercial services:

(d) *Comptroller General Examination of Record*. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this contract, and does not contain the clause at 52.215-2, Audit and Records-Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)

(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial products or commercial services. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (Nov 2021) (41 U.S.C. 3509).

(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(iii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Nov 2021) (Section 1634 of Pub. L. 115-91).

(iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Nov 2021) (Section 889(a)(1)(A) of Pub. L. 115-232).

(v) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(vi) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

(vii) 52.222-26, Equal Opportunity (Sep 2015) (E.O.11246).

(viii) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C. 4212).

(ix) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C. 793).

(x) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).

(xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.

(xii) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter 67).

(xiii)

(A) 52.222-50, Combating Trafficking in Persons (Nov 2021) (22 U.S.C. chapter 78 and E.O 13627).

(B) Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

(xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May2014) (41 U.S.C. chapter 67).

(xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) (41 U.S.C. chapter 67).

(xvi) 52.222-54, Employment Eligibility Verification (May 2022) (E.O. 12989).

(xvii) 52.222-55, Minimum Wages for Contractor Workers Under Executive Order 14026 (Jan 2022).

(xviii) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2022) (E.O. 13706).

(xix)

(A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).

(B) Alternate I (Jan 2017) of 52.224-3.

(xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

(xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xxii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Nov 2021) (46 U.S.C. 55305 and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial products and commercial services a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

Alternate I (Feb 2000). As prescribed in 12.301(b)(4)(i), delete paragraph (d) from the basic clause, redesignate paragraph (e) as paragraph (d), and revise the reference to "paragraphs (a), (b), (c), or (d) of this clause" in the redesignated paragraph (d) to read "paragraphs (a), (b), and (c) of this clause".

Alternate II (May 2022). As prescribed in 12.301(b)(4)(ii), substitute the following paragraphs (d)(1) and (e)(1) for paragraphs (d)(1) and (e)(1) of the basic clause as follows:

(d)(1) The Comptroller General of the United States, an appropriate Inspector General appointed under section 3 or 8 G of the Inspector General Act of 1978 (5 U.S.C. App.), or an authorized representative of either of the foregoing officials shall have access to and right to—

(i) Examine any of the Contractor's or any subcontractors' records that pertain to, and involve transactions relating to, this contract; and

(ii) Interview any officer or employee regarding such transactions.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), and (c), of this clause, the Contractor is not required to flow down any FAR clause in a subcontract for commercial products or commercial services, other than—

(i) *Paragraph (d) of this clause*. This paragraph flows down to all subcontracts, except the authority of the Inspector General under paragraph (d)(1)(ii) does not flow down; and

(ii) *Those clauses listed in this paragraph (e)(1)*. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-

(A) 52.203-13, Contractor Code of Business Ethics and Conduct (Nov 2021) (41 U.S.C. 3509).

(B) 52.203-15, Whistleblower Protections Under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub. L. 111-5).

(C) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Nov 2021) (Section 1634 of Pub. L. 115-91).

(D) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Nov 2021) (Section 889(a)(1)(A) of Pub. L. 115-232).
(E) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
(F) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
(G) 52.222-26, Equal Opportunity (Sep 2016) (E.O. 11246).
(H) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C. 4212).
(I) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C. 793).
(J) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.
(K) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter 67).
(L) ___ *(1)* 52.222-50, Combating Trafficking in Persons (Nov 2021) (22 U.S.C. chapter 78 and E.O 13627).
___ *(2)* Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
(M) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) (41 U.S.C. chapter 67).
(N) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) (41 U.S.C. chapter 67).
(O) 52.222-54, Employment Eligibility Verification (May 2022) (Executive Order 12989).
(P) 52.222-55, Minimum Wages for Contractor Workers Under Executive Order 14026 (Jan 2022).
(Q) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2022) (E.O. 13706).
(R) *(1)* 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).
(2) Alternate I (Jan 2017) of 52.224-3.
(S) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
(T) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations. (Jun 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
(U) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Nov 2021) (46 U.S.C. 55305 and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64

(End of clause)

8.4 HHSAR Clauses in Full Text

HHSAR 352.237-75 – Key Personnel (Dec 2015)
The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human

Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days' notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

(End of clause)

Key Personnel may be specified in individual task orders and are subject to the requirements in HHSAR 352.237-75.

HHSAR 352.239-74 – Electronic and Information Technology Accessibility (Dec 2015)
(a) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the "Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of Section 508 Final Provisions can be accessed at http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards.

(b) The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(c) The Section 508 accessibility standards applicable to this contract will be provided at the task order level, if applicable.

(d) In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS website: (http://www.hhs.gov/web/508). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(e) If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at http://www.hhs.gov/web/508. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(End of clause)

9. SOLICITATION PROVISIONS

9.1 SOLICITATION PROVISIONS

9.1.1. FAR 52.252-1 – Solicitation Provisions Incorporated by Reference (Feb 1998)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these address(es): www.acquisition.gov/browsefar

Provisions Incorporated by Reference:

FAR Provision	Provision Title	Date
52.203-18	Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation	Jan 2017
52.204-7	System for Award Management	Oct 2018
52.204-24	Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment.	Nov 2021
52.212-1	Instructions to Offerors-Commercial Items (and additional instructions in this section)	Nov 2021
52.212-2	Evaluation – Commercial Products and Commercial Services	Nov 2021
52.216-31	Time-and-Materials/Labor-Hour Proposal Requirements – Commercial Item Acquisition	Nov 2021
52.222-24	Preaward On-Site Equal Opportunity Compliance Evaluation	Feb 1999

HHS Provision Incorporated by Reference:

HHS Provision	Provision Title	Date
352.270-5a	Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals	Dec 2015

9.1.2. FAR 52.216-1 – Type of Contract (Apr 1984)

The Government contemplates award of an IDIQ contract authorizing LH, T&M and FFP task order types resulting from this solicitation.

9.2 OFFEROR REPRESENTATIONS AND CERTIFICATIONS

The representations and certifications required by this acquisition can be accessed through the System for Award Management (SAM) on the Internet at: https://sam.gov/

If you are unable to access this document, you may request a copy from the Contracting Officer identified on the cover page of this solicitation. **Offerors submitting a proposal must complete the representations and certifications online at https://sam.gov/.**

(This area is left intentionally blank)

FAR 52.212-3 – Offeror Representations and Certifications – Commercial Items (Dec 2022)

The Offeror shall complete only paragraph (b) of this provision if the Offeror has completed the annual representations and certification electronically in the System for Award Management (SAM) accessed through https://www.sam.gov. If the Offeror has not completed the annual representations and certifications electronically, the Offeror shall complete only paragraphs (c) through (v)) of this provision.

(a) *Definitions*. As used in this provision—

"Covered telecommunications equipment or services" has the meaning provided in the clause 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

Economically disadvantaged women-owned small business (EDWOSB) concern means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States and who are economically disadvantaged in accordance with 13 CFR part 127. It automatically qualifies as a women-owned small business eligible under the WOSB Program.

Forced or indentured child labor means all work or service—

(1) Exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily; or

(2) Performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.

Highest-level owner means the entity that owns or controls an immediate owner of the offeror, or that owns or controls one or more entities that control an immediate owner of the offeror. No entity owns or exercises control of the highest level owner.

Immediate owner means an entity, other than the offeror, that has direct control of the offeror. Indicators of control include, but are not limited to, one or more of the following: ownership or interlocking management, identity of interests among family members, shared facilities and equipment, and the common use of employees.

Inverted domestic corporation, means a foreign incorporated entity that meets the definition of an inverted domestic corporation under 6 U.S.C. 395(b), applied in accordance with the rules and definitions of 6 U.S.C. 395(c).

Manufactured end product means any end product in product and service codes (PSCs) 1000-9999, except—

(1) PSC 5510, Lumber and Related Basic Wood Materials;

(2) Product or Service Group (PSG) 87, Agricultural Supplies;

(3) PSG 88, Live Animals;

(4) PSG 89, Subsistence;

(5) PSC 9410, Crude Grades of Plant Materials;

(6) PSC 9430, Miscellaneous Crude Animal Products, Inedible;

(7) PSC 9440, Miscellaneous Crude Agricultural and Forestry Products;

(8) PSC 9610, Ores;

(9) PSC 9620, Minerals, Natural and Synthetic; and

(10) PSC 9630, Additive Metal Materials.

Place of manufacture means the place where an end product is assembled out of components, or otherwise made or processed from raw materials into the finished product that is to be provided to the Government. If a product is disassembled and reassembled, the place of reassembly is not the place of manufacture.

Predecessor means an entity that is replaced by a successor and includes any predecessors of the predecessor.

Reasonable inquiry has the meaning provided in the clause 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

9.2.1. *Restricted business operations* means business operations in Sudan that include power production activities, mineral extraction activities, oil-related activities, or the production of military equipment, as those terms are defined in the Sudan Accountability and Divestment Act of 2007 (Pub. L. 110-174). Restricted business operations do not include business operations that the person (as that term is defined in Section 2 of the Sudan Accountability and Divestment Act of 2007) conducting the business can demonstrate—

(1) Are conducted under contract directly and exclusively with the regional government of southern Sudan;

(2) Are conducted pursuant to specific authorization from the Office of Foreign Assets Control in the Department of the Treasury, or are expressly exempted under Federal law from the requirement to be conducted under such authorization;

(3) Consist of providing goods or services to marginalized populations of Sudan;

(4) Consist of providing goods or services to an internationally recognized peacekeeping force or humanitarian organization;

(5) Consist of providing goods or services that are used only to promote health or education; or

(6) Have been voluntarily suspended."Sensitive technology"—

Sensitive technology—

(1) Means hardware, software, telecommunications equipment, or any other technology that is to be used specifically—

(i) To restrict the free flow of unbiased information in Iran; or

(ii) To disrupt, monitor, or otherwise restrict speech of the people of Iran; and

(2) Does not include information or informational materials the export of which the President does not have the authority to regulate or prohibit pursuant to section 203(b)(3)of the International Emergency Economic Powers Act (50 U.S.C. 1702(b)(3)).

Service-disabled veteran-owned small business concern—

(1) Means a small business concern—

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veteransor, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service connected, as defined in 38 U.S.C. 101(16).

Small business concern—

(1) Means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and size standards in this solicitation.

(2) *Affiliates*, as used in this definition, means business concerns, one of whom directly or indirectly controls or has the power to control the others, or a third party or parties control or have the power to control the others. In determining whether affiliation exists, consideration is given to all appropriate factors including common ownership, common management, and contractual relationships. SBA determines affiliation based on the factors set forth at 13 CFR 121.103.

Small disadvantaged business concern, consistent with13 CFR 124.1002, means a small business concern under the size standard applicable to the acquisition, that—

(1) Is at least 51 percent unconditionally and directly owned (as defined at 13 CFR 124.105) by—

(i) One or more socially disadvantaged (as defined at13 CFR 124.103) and economically disadvantaged (as defined at 13 CFR 124.104) individuals who are citizens of the United States; and

(ii) Each individual claiming economic disadvantage has a net worth not exceeding $750,000 after taking into account the applicable exclusions set forth at 13 CFR124.104(c)(2); and

(2) The management and daily business operations of which are controlled (as defined at 13.CFR 124.106) by individuals, who meet the criteria in paragraphs (1)(i) and (ii) of this definition.

Subsidiary means an entity in which more than 50 percent of the entity is owned—

(1) Directly by a parent corporation; or

(2) Through another subsidiary of a parent corporation

Successor means an entity that has replaced a predecessor by acquiring the assets and carrying out the affairs of the predecessor under a new name (often through acquisition or merger). The term "successor" does not include new offices/divisions of the same company or a company that only changes its name. The extent of the responsibility of the successor for the liabilities of the predecessor may vary, depending on State law and specific circumstances.

Veteran-owned small business concern means a small business concern—

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

Women-owned business concern means a concern which is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of its stock is owned by one or more women; and whose management and daily business operations are controlled by one or more women

Women-owned small business concern means a small business concern—

(1) That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

Women-owned small business (WOSB) concern eligible under the WOSB Program (in accordance with 13 CFR part 127), means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States.

(b)

(1) *Annual Representations and Certifications*. Any changes provided by the Offeror in paragraph (b)(2) of this provision do not automatically change the representations and certifications in SAM.

(2) The offeror has completed the annual representations and certifications electronically in SAM accessed through http://www.sam.gov. After reviewing SAM information, the Offeror verifies by submission of this offer that the representations and certifications currently posted electronically at FAR 52.212-3, Offeror Representations and Certifications-Commercial Products and Commercial Services, have been entered or updated in the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard(s) applicable to the NAICS code(s) referenced for this solicitation), at the time this offer is submitted and are incorporated in this offer by reference (see FAR 4.1201), except for paragraphs _____.

[*Offeror to identify the applicable paragraphs at (c) through (v) of this provision that the offeror has completed for the purposes of this solicitation only, if any.*

These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted electronically on SAM.]

(c) Offerors must complete the following representations when the resulting contract is for supplies to be delivered or services to be performed in the United States or its outlying areas, or when the contracting officer has applied part 19 in accordance with 19.000(b)(1)(ii). Check all that apply.

(1) *Small business concern*. The offeror represents as part of its offer that it □ is, □ is not a small business concern.

(2) *Veteran-owned small business concern*. [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision*.] The offeror represents as part of its offer that it □ is, □ is not a veteran-owned small business concern.

(3) *Service-disabled veteran-owned small business concern*. [*Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (c)(2) of this provision*.] The offeror represents as part of its offer that it □ is, □ is not a service-disabled veteran-owned small business concern.

(4) *Small disadvantaged business concern*. [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision*.] The offeror represents, that it □ is, □ is not a small disadvantaged business concern as defined in 13 CFR124.1002.

(5) *Women-owned small business concern*. [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision*.] The offeror represents that it □ is, □ is not a women-owned small business concern.

(6) WOSB concern eligible under the WOSB Program. [Complete only if the offeror represented itself as a women-owned small business concern in paragraph (c)(5) of this provision.] The offeror represents that-

(i) It □ is, □ is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It □ is, □ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(6)(i) of this provision is accurate for each WOSB concern eligible under the WOSB Program participating in the joint venture. [The offeror shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture: _____.] Each WOSB concern eligible under the WOSB Program participating in the joint venture shall submit a separate signed copy of the WOSB representation.

(7) Economically disadvantaged women-owned small business (EDWOSB) concern. [Complete only if the offeror represented itself as a WOSB concern eligible under the WOSB Program in (c)(6) of this provision.] The offeror represents that-

(i) It □ is, □ is not an EDWOSB concern, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It □ is, □ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(7)(i) of this provision is accurate for each EDWOSB concern participating in the joint venture. [*The offeror shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture:* _____.] Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

Note: Complete paragraphs (c)(8) and (c)(9) only if this solicitation is expected to exceed the simplified acquisition threshold.

(8) *Women-owned business concern (other than small business concern*). [*Complete only if the offeror is a women-owned business concern and did not represent itself as a small business concern in paragraph (c)(1) of this provision*.] The offeror represents that it □ is a women-owned business concern.

(9) *Tie bid priority for labor surplus area concerns*. If this is an invitation for bid, small business offerors may identify the labor surplus areas in which costs to be incurred on account of manufacturing or production (by offeror or first-tier subcontractors) amount to more than 50 percent of the contract price:_____

(10) *HUBZone small business concern*. [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision*.] The offeror represents, as part of its offer, that–

(i) It □ is, □ is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material changes in ownership and control, principal office, or HUBZone employee percentage have occurred since it was certified in accordance with 13 CFR Part 126; and

(ii) It □ is, □ is not a HUBZone joint venture that complies with the requirements of 13 CFR Part 126, and the representation in paragraph (c)(10)(i) of this provision is accurate for each HUBZone small business concern participating in the HUBZone joint venture. [The offeror shall enter the names of each of the HUBZone small business concerns participating in the HUBZone joint venture: _____.] Each HUBZone small business concern participating in the HUBZone joint venture shall submit a separate signed copy of the HUBZone representation.

(d) Representations required to implement provisions of Executive Order11246-

(1) Previous contracts and compliance. The offeror represents that-

(i) It □ has, □ has not participated in a previous contract or subcontract subject to the Equal Opportunity clause of this solicitation; and

(ii) It □ has, □ has not filed all required compliance reports.

(2) *Affirmative Action Compliance*. The offeror represents that-

(i) It □ has developed and has on file, □ has not developed and does not have on file, at each establishment, affirmative action programs required by rules and regulations of the Secretary of Labor (41 CFR parts 60-1 and 60-2), or

(ii) It □ has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

(e) *Certification Regarding Payments to Influence Federal Transactions (31 http://uscode.house.gov/ U.S.C. 1352)*. (Applies only if the contract is expected to exceed $150,000.) By submission of its offer, the offeror certifies to the best of its knowledge and belief that no Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress or an employee of a Member of Congress on his or her behalf in connection with the award of any resultant contract. If any registrants under the Lobbying Disclosure Act of 1995 have made a lobbying contact on behalf of the offeror with respect to this contract, the offeror shall complete and submit, with its offer, OMB Standard Form LLL, Disclosure of Lobbying Activities, to provide the name of the registrants. The offeror need not report regularly employed officers or employees of the offeror to whom payments of reasonable compensation were made.

(f) *Buy American Certificate*. (Applies only if the clause at Federal Acquisition Regulation (FAR) 52.225-1, Buy American-Supplies, is included in this solicitation.)

(1)

(i) The Offeror certifies that each end product, except those listed in paragraph (f)(2) of this provision, is a domestic end product.

(ii) The Offeror shall list as foreign end products those end products manufactured in the United States that do not qualify as domestic end products.

(iii) The terms "domestic end product," "end product," "foreign end product," and "United States" are defined in the clause of this solicitation entitled "Buy American-Supplies."

(2) Foreign End Products:

Line Item No.	
_____	_____
_____	_____
_____	_____

[*List as necessary*]

(3) The Government will evaluate offers in accordance with the policies and procedures of FAR part 25.

(g)

(1) *Buy American-Free Trade Agreements-Israeli Trade Act Certificate*. (Applies only if the clause at FAR 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act, is included in this solicitation.)

(i)

(A) The Offeror certifies that each end product, except those listed in paragraph (g)(1)(ii) or (iii) of this provision, is a domestic end product.

(B) The terms "Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end product," "domestic end product," "end product," "foreign end product," "Free Trade Agreement country," "Free Trade Agreement country end product," "Israeli end product," and "United States" are defined in the clause of this solicitation entitled "Buy American-Free Trade Agreements-Israeli Trade Act."

(ii) The Offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end products) or Israeli end products as defined in the clause of this solicitation entitled "Buy American-Free Trade Agreements-Israeli Trade Act."

Free Trade Agreement Country End Products (Other than Bahrainian, Moroccan, Omani, Panamanian, or Peruvian End Products) or Israeli End Products:

Line Item No.	Country of Origin
_____	_____
_____	_____
_____	_____

[*List as necessary*]

(iii) The Offeror shall list those supplies that are foreign end products (other than those listed in paragraph (g)(1)(ii) of this provision) as defined in the clause of this solicitation entitled "Buy American-Free Trade Agreements-Israeli Trade Act." The Offeror shall list as other foreign end products those end products manufactured in the United States that do not qualify as domestic end products.

Other Foreign End Products:

Line Item No.	Country of Origin
_____	_____
_____	_____
_____	_____

[List as necessary]

(iv) The Government will evaluate offers in accordance with the policies and procedures of FAR part 25.

(2) *Buy American-Free Trade Agreements-Israeli Trade Act Certificate, Alternate I*. If Alternate I to the clause at FAR 52.225-3 is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

Line Item No.	Country of Origin
_____	_____
_____	_____
_____	_____

(g)(1)(ii) The offeror certifies that the following supplies are Canadian end products as defined in the clause of this solicitation entitled "Buy American-Free Trade Agreements-Israeli Trade Act":

Canadian End Products:

Line Item No.

_____

_____

_____

[*List as necessary*]

(3) *Buy American-Free Trade Agreements-Israeli Trade Act Certificate, Alternate II*. If Alternate II to the clause at FAR 52.225-3 is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Canadian end products or Israeli end products as defined in the clause of this solicitation entitled "Buy American-Free Trade Agreements-Israeli Trade Act":

Canadian or Israeli End Products:

[*List as necessary*]

(4) *Buy American-Free Trade Agreements-Israeli Trade Act Certificate, Alternate III*. If Alternate III to the clause at 52.225-3 is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Korean, Moroccan, Omani, Panamanian, or Peruvian end products) or Israeli end products as defined in the clause of this solicitation entitled "Buy American-Free Trade Agreements-Israeli Trade Act":

Free Trade Agreement Country End Products (Other than Bahrainian, Korean, Moroccan, Omani, Panamanian, or Peruvian End Products) or Israeli End Products:

Line Item No.	Country of Origin
_____	_____
_____	_____
_____	_____

[*List as necessary*]

(5) *Trade Agreements Certificate*. (Applies only if the clause at FAR 52.225-5, Trade Agreements, is included in this solicitation.)

(i) The offeror certifies that each end product, except those listed in paragraph (g)(5)(ii) of this provision, is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled "Trade Agreements."

(ii) The offeror shall list as other end products those end products that are not U.S.-made or designated country end products.

Other End Products:

Line Item No.	Country of Origin
_____	_____
_____	_____
_____	_____

[*List as necessary*]

(iii) The Government will evaluate offers in accordance with the policies and procedures of FAR part 25. For line items covered by the WTO GPA, the Government will evaluate offers of U.S.-made or designated country end products without regard to the restrictions of the Buy American statute. The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation.

(h) *Certification Regarding Responsibility Matters (Executive Order 12689*). (Applies only if the contract value is expected to exceed the simplified acquisition threshold.) The offeror certifies, to the best of its knowledge and belief, that the offeror and/or any of its principals–

(1) □ Are, □ are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(2) □ Have, □ have not, within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a Federal, state or local government contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property;

(3) □ Are, □ are not presently indicted for, or otherwise criminally or civilly charged by a Government entity with, commission of any of these offenses enumerated in paragraph (h)(2) of this clause; and

(4) □ Have, □ have not, within a three-year period preceding this offer, been notified of any delinquent Federal taxes in an amount that exceeds the threshold at 9.104-5(a)(2) for which the liability remains unsatisfied.

(i) Taxes are considered delinquent if both of the following criteria apply:

(A) *The tax liability is finally determined*. The liability is finally determined if it has been assessed. A liability is not finally determined if there is a pending administrative or judicial challenge. In the case of a judicial challenge to the liability, the liability is not finally determined until all judicial appeal rights have been exhausted.

(B) *The taxpayer is delinquent in making payment*. A taxpayer is delinquent if the taxpayer has failed to pay the tax liability when full payment was due and required. A taxpayer is not delinquent in cases where enforced collection action is precluded.

(ii) *Examples*.

(A) The taxpayer has received a statutory notice of deficiency, under I.R.C. §6212, which entitles the taxpayer to seek Tax Court review of a proposed tax deficiency. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek Tax Court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(B) The IRS has filed a notice of Federal tax lien with respect to an assessed tax liability, and the taxpayer has been issued a notice under I.R.C. §6320 entitling the taxpayer to request a hearing with the IRS Office of Appeals contesting the lien filing, and to further appeal to the Tax Court if the IRS determines to sustain the lien filing. In the course of the hearing, the taxpayer is entitled to contest the underlying tax liability because the taxpayer has had no prior opportunity to contest the liability. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek tax court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(C) The taxpayer has entered into an installment agreement pursuant to I.R.C. §6159. The taxpayer is making timely payments and is in full compliance with the agreement terms. The taxpayer is not delinquent because the taxpayer is not currently required to make full payment.

(D) The taxpayer has filed for bankruptcy protection. The taxpayer is not delinquent because enforced collection action is stayed under 11 U.S.C. §362 (the Bankruptcy Code).

(i) *Certification Regarding Knowledge of Child Labor for Listed End Products (Executive Order 13126). [The Contracting Officer must list in paragraph (i)(1) any end products being acquired under this solicitation that are included in the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor, unless excluded at 22.1503(b).]*

(1) *Listed end products.*

Listed End Product	Listed Countries of Origin
_____	_____
_____	_____

(2) *Certification. [If the Contracting Officer has identified end products and countries of origin in paragraph (i)(1) of this provision, then the offeror must certify to either (i)(2)(i) or (i)(2)(ii) by checking the appropriate block.]*

(i) The offeror will not supply any end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product.

(ii) The offeror may supply an end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product. The offeror certifies that it has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture any such end product furnished under this contract. On the basis of those efforts, the offeror certifies that it is not aware of any such use of child labor.

(j) *Place of manufacture.* (Does not apply unless the solicitation is predominantly for the acquisition of manufactured end products.) For statistical purposes only, the offeror shall indicate whether the place of manufacture of the end products it expects to provide in response to this solicitation is predominantly-

(1) □ In the United States (Check this box if the total anticipated price of offered end products manufactured in the United States exceeds the total anticipated price of offered end products manufactured outside the United States); or

(2) □ Outside the United States.

(k) *Certificates regarding exemptions from the application of the Service Contract Labor Standards* (Certification by the offeror as to its compliance with respect to the contract also constitutes its certification as to compliance by its subcontractor if it subcontracts out the exempt services.) [*The contracting officer is to check a box to indicate if paragraph (k)(1) or (k)(2) applies.*]

(1) Maintenance, calibration, or repair of certain equipment as described in FAR 22.1003-4(c)(1). The offeror □ does □ does not certify that–

(i) The items of equipment to be serviced under this contract are used regularly for other than Governmental purposes and are sold or traded by the offeror (or subcontractor in the case of an exempt subcontract) in substantial quantities to the general public in the course of normal business operations;

(ii) The services will be furnished at prices which are, or are based on, established catalog or market prices (see FAR 22.1003-4(c)(2)(ii)) for the maintenance, calibration, or repair of such equipment; and

(iii) The compensation (wage and fringe benefits) plan for all service employees performing work under the contract will be the same as that used for these employees and equivalent employees servicing the same equipment of commercial customers.

(2) Certain services as described in FAR 22.1003-4(d)(1). The offeror □ does □ does not certify that-

(i) The services under the contract are offered and sold regularly to non-Governmental customers, and are provided by the offeror (or subcontractor in the case of an exempt subcontract) to the general public in substantial quantities in the course of normal business operations;

(ii) The contract services will be furnished at prices that are, or are based on, established catalog or market prices (see FAR 22.1003-4(d)(2)(iii));

(iii) Each service employee who will perform the services under the contract will spend only a small portion of his or her time (a monthly average of less than 20 percent of the available hours on an annualized basis, or less than 20 percent of available hours during the contract period if the contract period is less than a month) servicing the Government contract; and

(iv) The compensation (wage and fringe benefits) plan for all service employees performing work under the contract is the same as that used for these employees and equivalent employees servicing commercial customers.

(3) If paragraph (k)(1) or (k)(2) of this clause applies–

(i) If the offeror does not certify to the conditions in paragraph (k)(1) or (k)(2) and the Contracting Officer did not attach a Service Contract Labor Standards wage determination to the solicitation, the offeror shall notify the Contracting Officer as soon as possible; and

(ii) The Contracting Officer may not make an award to the offeror if the offeror fails to execute the certification in paragraph (k)(1) or (k)(2) of this clause or to contact the Contracting Officer as required in paragraph (k)(3)(i) of this clause.

(l) *Taxpayer Identification Number (TIN) (* 26 U.S.C. 6109, 31 U.S.C. 7701). (Not applicable if the offeror is required to provide this information to the SAM to be eligible for award.)

(1) All offerors must submit the information required in paragraphs (l)(3) through (l)(5) of this provision to comply with debt collection requirements of 31 U.S.C. 7701(c) and 3325(d), reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M, and implementing regulations issued by the Internal Revenue Service (IRS).

(2) The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror's relationship with the Government (31 U.S.C. 7701(c)(3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror's TIN.

(3) *Taxpayer Identification Number (TIN)*.

TIN: _____.

TIN has been applied for.

TIN is not required because:

Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the United States and does not have an office or place of business or a fiscal paying agent in the United States;

Offeror is an agency or instrumentality of a foreign government;

Offeror is an agency or instrumentality of the Federal Government.

(4) *Type of organization*.

Sole proprietorship;

Partnership;

Corporate entity (not tax-exempt);

Corporate entity (tax-exempt);

Government entity (Federal, State, or local);

Foreign government;

International organization per 26 CFR1.6049-4;

Other _____.

(5) *Common parent*.

Offeror is not owned or controlled by a common parent;

Name and TIN of common parent:

Name _____.

TIN _____.

(m) *Restricted business operations in Sudan*. By submission of its offer, the offeror certifies that the offeror does not conduct any restricted business operations in Sudan.

(n) Prohibition on Contracting with Inverted Domestic Corporations.

(1) Government agencies are not permitted to use appropriated (or otherwise made available) funds for contracts with either an inverted domestic corporation, or a subsidiary of an inverted domestic corporation, unless the exception at 9.108-2(b) applies or the requirement is waived in accordance with the procedures at 9.108-4.

(2) *Representation*. The Offeror represents that–

(i) It □ is, □ is not an inverted domestic corporation; and

(ii) It □ is, □ is not a subsidiary of an inverted domestic corporation.

(o) Prohibition on contracting with entities engaging in certain activities or transactions relating to Iran.

(1) The offeror shall e-mail questions concerning sensitive technology to the Department of State at CISADA106@state.gov.

(2) *Representation and Certifications*. Unless a waiver is granted or an exception applies as provided in paragraph (o)(3) of this provision, by submission of its offer, the offeror-

(i) Represents, to the best of its knowledge and belief, that the offeror does not export any sensitive technology to the government of Iran or any entities or individuals owned or controlled by, or acting on behalf or at the direction of, the government of Iran;

(ii) Certifies that the offeror, or any person owned or controlled by the offeror, does not engage in any activities for which sanctions may be imposed under section 5 of the Iran Sanctions Act; and

(iii) Certifies that the offeror, and any person owned or controlled by the offeror, does not knowingly engage in any transaction that exceeds the threshold at FAR 25.703-2(a)(2) with Iran's Revolutionary Guard Corps or any of its officials, agents, or affiliates, the property and interests in property of which are blocked pursuant to the International Emergency Economic Powers Act (et seq.) (see OFAC's Specially Designated Nationals and Blocked Persons List at https://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx).

(3) The representation and certification requirements of paragraph (o)(2) of this provision do not apply if-

(i) This solicitation includes a trade agreements certification (*e.g.*, 52.212-3(g) or a comparable agency provision); and

(ii) The offeror has certified that all the offered products to be supplied are designated country end products.

(p) *Ownership or Control of Offeror*. (Applies in all solicitations when there is a requirement to be registered in SAM or a requirement to have a unique entity identifier in the solicitation).

(1) The Offeror represents that it □ has or □ does not have an immediate owner. If the Offeror has more than one immediate owner (such as a joint venture), then the Offeror shall respond to paragraph (2) and if applicable, paragraph (3) of this provision for each participant in the joint venture.

(2) If the Offeror indicates "has" in paragraph (p)(1) of this provision, enter the following information:

Immediate owner CAGE code: _____.

Immediate owner legal name: _____.

(Do not use a "doing business as" name)

Is the immediate owner owned or controlled by another entity: □ Yes or □ No.

(3) If the Offeror indicates "yes" in paragraph (p)(2) of this provision, indicating that the immediate owner is owned or controlled by another entity, then enter the following information:

Highest-level owner CAGE code: _____.

Highest-level owner legal name: _____.

(*Do not use a "doing business as" name*)

(q) *Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law.*

(1) As required by sections 744 and 745 of Division E of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235), and similar provisions, if contained in subsequent appropriations acts, The Government will not enter into a contract with any corporation that–

(i) Has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, where the awarding agency is aware of the unpaid tax liability, unless an agency has considered suspension or debarment of the corporation and made a determination that suspension or debarment is not necessary to protect the interests of the Government; or

(ii) Was convicted of a felony criminal violation under any Federal law within the preceding 24 months, where the awarding agency is aware of the conviction, unless an agency has considered suspension or debarment of the corporation and made a determination that this action is not necessary to protect the interests of the Government.

(2) The Offeror represents that–

(i) It is □ is not □ a corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability; and

(ii) It is □ is not □ a corporation that was convicted of a felony criminal violation under a Federal law within the preceding 24 months.

(r) *Predecessor of Offeror.* (Applies in all solicitations that include the provision at 52.204-16, Commercial and Government Entity Code Reporting.)

(1) The Offeror represents that it □ is or □ is not a successor to a predecessor that held a Federal contract or grant within the last three years.

(2) If the Offeror has indicated "is" in paragraph (r)(1) of this provision, enter the following information for all predecessors that held a Federal contract or grant within the last three years (if more than one predecessor, list in reverse chronological order):

Predecessor CAGE code: (or mark "Unknown").

Predecessor legal name:____.

(*Do not use a "doing business as" name*).

(s) [Reserved].

(t) *Public Disclosure of Greenhouse Gas Emissions and Reduction Goals*. Applies in all solicitations that require offerors to register in SAM (12.301(d)(1)).

(1) This representation shall be completed if the Offeror received $7.5 million or more in contract awards in the prior Federal fiscal year. The representation is optional if the Offeror received less than $7.5 million in Federal contract awards in the prior Federal fiscal year.

(2) Representation. [Offeror to check applicable block(s) in paragraph (t)(2)(i) and (ii)].

(i) The Offeror (itself or through its immediate owner or highest-level owner) □ does, □ does not publicly disclose greenhouse gas emissions, i.e., makes available on a publicly accessible website the results of a greenhouse gas inventory, performed in accordance with an accounting standard with publicly available and consistently applied criteria, such as the Greenhouse Gas Protocol Corporate Standard.

(ii) The Offeror (itself or through its immediate owner or highest-level owner) □ does, □ does not publicly disclose a quantitative greenhouse gas emissions reduction goal, i.e., make available on a publicly accessible website a target to reduce absolute emissions or emissions intensity by a specific quantity or percentage.

(iii) A publicly accessible website includes the Offeror's own website or a recognized, third-party greenhouse gas emissions reporting program.

(3) If the Offeror checked "does" in paragraphs (t)(2)(i) or (t)(2)(ii) of this provision, respectively, the Offeror shall provide the publicly accessible website(s) where greenhouse gas emissions and/or reduction goals are reported:_____.

(u)

(1) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), Government agencies are not permitted to use appropriated (or otherwise made available) funds for contracts with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(2) The prohibition in paragraph (u)(1) of this provision does not contravene requirements applicable to Standard Form 312 (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

(3) *Representation*. By submission of its offer, the Offeror represents that it will not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (*e.g.*, agency Office of the Inspector General).

(v) *Covered Telecommunications Equipment or Services-Representation.* Section 889(a)(1)(A) and section 889 (a)(1)(B) of Public Law 115-232.

(1) The Offeror shall review the list of excluded parties in the System for Award Management (SAM) (https://www.sam.gov) for entities excluded from receiving federal awards for "covered telecommunications equipment or services".

(2) The Offeror represents that–

(i) It□ does, □ does not provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument.

(ii) After conducting a reasonable inquiry for purposes of this representation, that it □ does, □ does not use covered telecommunications equipment or services, or any equipment, system, or service that uses covered telecommunications equipment or services.

(End of Provision)

FAR 52.204-16 – Commercial and Government Entity Code Reporting (Aug 2020)

(a) *Definition.* As used in this provision –

Commercial and Government Entity (CAGE) code means–

(1) An identifier assigned to entities located in the United States or its outlying areas by the Defense Logistics Agency (DLA) Commercial and Government Entity (CAGE) Branch to identify a commercial or government entity by unique location; or

(2) An identifier assigned by a member of the North Atlantic Treaty Organization (NATO) or by the NATO Support and Procurement Agency (NSPA) to entities located outside the United States and its outlying areas that the DLA Commercial and Government Entity (CAGE) Branch records and maintains in the CAGE master file. This type of code is known as a NATO CAGE (NCAGE) code.

(b) The Offeror shall provide its CAGE code with its offer with its name and location address or otherwise include it prominently in its proposal. The CAGE code must be for that name and location address. Insert the word "CAGE" before the number. The CAGE code is required prior to award.

(c) CAGE codes may be obtained via–

(1) Registration in the System for Award Management (SAM) at www.sam.gov. If the Offeror is located in the United States or its outlying areas and does not already have a CAGE code assigned, the DLA Commercial and Government Entity (CAGE) Branch will assign a CAGE code as a part of the SAM registration process. SAM registrants located outside the United States and its outlying areas shall obtain a NCAGE code prior to registration in SAM (see paragraph (c)(3) of this provision).

(2) *The DLA Contractor and Government Entity (CAGE) Branch.* If registration in SAM is not required for the subject procurement, and the Offeror does not otherwise register in SAM, an Offeror located in the United States or its outlying areas may request that a CAGE code be assigned by submitting a request at https://cage.dla.mil.

(3) The appropriate country codification bureau. Entities located outside the United States and its outlying areas may obtain an NCAGE code by contacting the Codification Bureau in the foreign entity's country if that country is a member of NATO or a sponsored nation. NCAGE codes may be obtained from the NSPA at https://eportal.nspa.nato.int/AC135Public/scage/CageList.aspx if the foreign entity’s country is not a member of NATO or a sponsored nation. Points of contact for codification bureaus, as well as additional information on obtaining NCAGE codes, are available at http://www.nato.int/structur/AC/135/main/links/contacts.htm.

(d) Additional guidance for establishing and maintaining CAGE codes is available at https://cage.dla.mil.

(e) When a CAGE code is required for the immediate owner and/or the highest-level owner by Federal Acquisition Regulation (FAR) 52.204-17 or 52.212-3(p), the Offeror shall obtain the respective CAGE code from that entity to supply the CAGE code to the Government.

(f) Do not delay submission of the offer pending receipt of a CAGE code.

(g) If the solicitation includes FAR clause 52.204-2, Security Requirements, a subcontractor requiring access to classified information under a contract shall be identified with a CAGE code on the DD Form 254. The Contractor shall require a subcontractor requiring access to classified information to provide its CAGE code with its name and location address or otherwise include it prominently in the proposal. Each location of subcontractor performance listed on the DD Form 254 is required to reflect a corresponding unique CAGE code for each listed location unless the work is being performed at a Government facility, in which case the agency location code shall be used. The CAGE code must be for that name and location address. Insert the word "CAGE" before the number. The CAGE code is required prior to award.

(End of provision)

FAR 52.209-7 – Information Regarding Responsibility Matters (Oct 2018)

(a) *Definitions*. As used in this provision—

"Administrative proceeding" means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (*e.g.*, Securities and Exchange Commission Administrative Proceedings, Civilian Board of Contract Appeals Proceedings, and Armed Services Board of Contract Appeals Proceedings). This includes administrative proceeding at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include agency actions such as contract audits, site visits, corrective plans, or inspection of deliverables.

"Federal contracts and grants with total value greater than $10,000,000" means—

(1) The total value of all current, active contracts and grants, including all priced options; and

(2) The total value of all current, active orders including all priced options under indefinite-delivery, indefinite-quantity, 8(a), or requirements contracts (including task and delivery and multiple-award Schedules).

"Principal" means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (*e.g.*, general manager; plant manager; head of a division or business segment; and similar positions).

(b) The offeror [_] has [_] does not have current active Federal contracts and grants with total value greater than $10,000,000.

(c) If the offeror checked "has" in paragraph (b) of this provision, the offeror represents, by submission of this offer, that the information it has entered in the Federal Awardee Performance and Integrity Information System (FAPIIS) is current, accurate, and complete as of the date of submission of this offer with regard to the following information:

(1) Whether the offeror, and/or any of its principals, has or has not, within the last five years, in connection with the award to or performance by the offeror of a Federal contract or grant, been the subject of a proceeding, at the Federal or State level that resulted in any of the following dispositions:

(i) In a criminal proceeding, a conviction.

(ii) In a civil proceeding, a finding of fault and liability that results in the payment of a monetary fine, penalty, reimbursement, restitution, or damages of $5,000 or more.

(iii) In an administrative proceeding, a finding of fault and liability that results in—

(A) The payment of a monetary fine or penalty of $5,000 or more; or

(B) The payment of a reimbursement, restitution, or damages in excess of $100,000.

(iv) In a criminal, civil, or administrative proceeding, a disposition of the matter by consent or compromise with an acknowledgment of fault by the Contractor if the proceeding could have led to any of the outcomes specified in paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii) of this provision.

(2) If the offeror has been involved in the last five years in any of the occurrences listed in (c)(1) of this provision, whether the offeror has provided the requested information with regard to each occurrence.

(d) The offeror shall post the information in paragraphs (c)(1)(i) through (c)(1)(iv) of this provision in FAPIIS as required through maintaining an active registration in the System for Award Management which can be accessed via https://beta.sam.gov/ (see 52.204-7).

(End of provision)

10. PROPOSAL INSTRUCTIONS

10.1 SOLICITATION INQUIRIES AND QUESTIONS

All questions regarding this solicitation, of a contractual nature or technical nature, shall be submitted in writing and sent via email to the Contract Specialist (Nikola.Zuber@fda.hhs.gov), by no later than **12:00 PM Eastern Time, on 3/23/2023**. The Government may not consider questions received after this date and time. The email subject line shall read: **FDA-RFP-75F40122R00067**. It is the Offeror's responsibility to confirm receipt of all proposals and/or questions by the closing date of this announcement by contacting the above Contract Specialist/Contracting Officer.

10.2 PROPOSAL SUBMISSION DUE DATE

The Offeror's proposal shall be received by no later than **5:30 PM Eastern Time, on 4/5/2023**. Proposals shall be submitted electronically via email to the Contract Specialist (CS) (Nikola.Zuber@fda.hhs.gov). The subject line shall read: **FDA-RFP-75F40122R00067**. Late submissions may not be evaluated. Fax submissions are NOT authorized.

10.3 PROPOSAL FORMAT AND INSTRUCTIONS

10.3.1. General Format of Proposals

A complete Proposal shall consist of and be submitted in four parts:

1) **Cover Letter**;
2) **Volume I** – Technical Proposal; Technical Approach, Management Approach and Relevant Experience
3) **Volume II** – Price Proposal.
4) **Subcontracting Plan** – Submission into SBCX

Each part shall be submitted as **separate** documents and shall be complete so that evaluation of one part may be independent of, and concurrently with, evaluation of another. For submission purposes, it is acceptable for all volumes to be submitted in the same email; however, each attachment must be

clearly marked to which volume it belongs to. Each volume shall include a cover sheet which clearly identifies each volume by volume number and volume name (i.e., Volume I - Technical Proposal), solicitation number, and date of submission, and shall include page headers with the same information.

The Offeror shall submit each part in native format (Microsoft (MS) Word, Excel, etc.) or as PDF files, however, MS Word/Excel formats are preferred. Failure to provide the required documents in response to this solicitation may render the offeror's proposal non-responsive.

The offeror shall submit all electronic documents for Microsoft Office suite products **without the use of "macros"**. If the offeror submits documents that contain macros, the Government will not be able to view or open such documents and the submission will be considered non-responsive to the solicitation. No additional time will be given to an offeror to correct the document submission and the Government will not inform the offeror that their submission is non-responsive prior to award. It is the offeror's responsibility to ensure all electronic documents are submitted without the use of macros.

All text in the proposal must be single-spaced, and each paragraph must be separated by at least one (1) blank line. The Offeror is encouraged to use Calibri 11-point font. However, a font of equivalent size may be used. Tables and illustrations may use a reduced font size not less than 9-point and may be landscape. Offerors must use the following page setup parameters: Page size – 8.5" x 11", Margins (top, bottom, left and right) – 1", Gutter – 0", From edge (header and footer) – 0.5".

All proposals will be handled in accordance with FAR Subpart 3.104. Individuals responsible for preparing material that may be source selection information, as described at paragraph (10) of the "source selection information" definition in FAR 2.101, must mark the cover page and each page that the individual believes contains source selection information with the legend "Source Selection Information -- See FAR 2.101 and 3.104." Although the information in paragraphs (1) through (9) of the definition in FAR 2.101 is considered to be source selection information whether or not marked, all reasonable efforts must be made to mark such material with the same legend. Contractor employees responsible for preparing material that may be proprietary information must mark each page that the Contractor believes contains proprietary information with the legend "Proprietary Information."

Information requested herein must be furnished in writing and be fully and completely in compliance with solicitation instructions. The information requested and the manner of submission is essential to permit prompt evaluation of all quotes on a fair and uniform basis.

10.3.2. Cover Letter

Offerors shall include a cover letter that contains, at a minimum, the following information:

- Name of Offeror and Address
- Offeror DUNS number
- Point of Contact – Name, telephone number, and email address
- Business size and type (e.g., small, 8(a) small businesses, HUBZone, etc.)
- Statement that the proposal is valid for 120 days
- Identification of any teaming arrangements, joint ventures, mentor-protégé relationships, subcontracting relationships, etc.

- Signature of Authorized Official – The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of the solicitation
- As an addendum to the cover letter:
    - Completed Representation and certifications: Offerors **must** have an active registration in SAM.gov (https://beta.sam.gov/), with completed representations and certifications, by the close date of the solicitation. Proposals submitted by offerors not registered in SAM.gov will not be considered. The Offeror shall provide a statement certifying **that all company information listed in the SAM.gov website is complete, accurate, and current.** If the offeror's current SAM.gov registration is incorrect or out of date, the Offeror shall complete Section 9.2 of the solicitation, "Offeror Representations and Certifications." In such a circumstance, one (1) originally signed copy of Section 9.2 shall be included in the offeror's proposal.
    - Organizational Conflict of Interest (OCI) statement: Offerors shall identify any possible actual, potential or apparent OCIs which may affect the offeror's ability to perform this requirement in an impartial and objective manner or that may result in an unfair competitive advantage and any plans to mitigate any OCI issues. If the OCI mitigation plan is deemed unacceptable, the offeror will not be eligible for award. If there is no potential OCI, the offeror must provide a written statement indicating this.

10.3.3. Volume I – Technical Proposal

The technical volume is limited to **25 pages**. A page in the technical volume that contains a table, chart, graph, etc., is subject to the page limitation, unless otherwise excluded. Cover pages, table of contents, dividers, resumes, and commitment documentation are **not** included in the page limit. **Volume I shall not make reference to any pricing data.**

The following instructions summarize the information required to facilitate the Government's evaluation of each Offeror's technical capabilities:

10.3.3.1 Technical Approach and Capability to Perform the Requirement

The technical proposal is the most important item in the evaluation of an Offeror's capability to perform the desired services. Therefore, offerors proposals must present sufficient information and detail to permit the Government to make an evaluation of the technical proposal without further information being required. General statements that the Offeror can or will "comply with the requirements", that "standard procedures will be used", that "well-known techniques will be used", or paraphrases of the solicitation's Statement of Work in whole or in part, will not constitute compliance. The offeror shall clearly state any areas in which assumptions are based or clearly state areas that deviate from the requirements stated in the scope of work.

Offerors must possess or demonstrate the ability to meet the requirements as outlined in the Statement of Work (SOW) and demonstrate that it is capable of meeting all IDIQ Performance Area requirements.

The Offeror shall provide a detailed narrative that clearly and completely demonstrates its technical approach to execute the activities in IDIQ SOW task that is comprehensive, feasible, and likely to be effective.

10.3.4. Volume I – Management Approach

10.3.4.1 Management Approach

The Offeror shall provide a detailed draft Program Management Plan (PMP) that demonstrates the Offeror's approach to executing program management and task order management is comprehensive and likely to be effective.

The PMP shall also include a staffing plan to be used to meet the IDIQ requirements that are comprehensive, feasible and likely to be effective. The staffing plan, at a minimum, consists of the proposed labor categories and labor category minimum requirements.

10.3.5. Volume I – Relevant Experience

10.3.5.1 Relevant Experience

The Offeror shall describe recent and relevant experience which demonstrates their ability to efficiently perform base tasks required under the contract.

The Offeror shall identify two (2) recent and relevant experiences within the last five years that are similar to the Non-Clinical Studies and Laboratory Support IDIQ in terms of size, scope and complexity in which the Offeror has performed as the Prime.

Size: IDIQ/BPA/BOA or Total Task Orders/BPA Orders presented shall have an annual value of at least $1 Million.

Scope and Complexity: Task Order/BPA Order or Contract which encompasses variations of the task areas within the tier that the offeror is responding to.

In addition to the narrative described above, for each contract provide the following information:

1. Name of contracting activity (Federal Government agency, local government, commercial customer);
2. Contract number;
3. Contract type;
4. Total contract value;
5. Contract work (description of experience, degree of involvement, size of the organization, etc.);
6. Contracting Officer contact information (phone, fax, email);
7. Project Officer/Contracting Officer's Technical Representative contact information (phone, fax, email).

Offerors are cautioned that the Government may use data provided by each offeror as well as data obtained from possible other sources, such as Government past performance databases (i.e., Past Performance Information Retrieval System (PPIRS), CPARS) in the evaluation of past performance. Offerors are urged to verify accuracy of all data provided. Past Performance information regarding predecessor companies, key personnel who have relevant experience, and subcontractors that will perform major or critical aspects of the requirement may be provided as past performance submissions.

This is solely at the discretion of the Contracting Officer, with the understanding that e-mail systems, servers, internet, intranets and extranets are not considered secure. The Government reserves the right

to contact references for verification or additional information, and the right to consider other relevant past performance information. The Government may call customers, whether or not listed on the provided list, to inquire about the offeror's past performance. The Government does not assume the duty to search for data to cure the problems it finds in the information provided by the offeror. The burden of providing thorough and/or complete past performance information remains with the offeror.

10.3.6. Volume II – Price Proposal

The offeror shall submit a price proposal fully supported by cost information adequate to determine the reasonableness of the proposed burdened labor rates and to evaluate whether the proposed prices are consistent with the level of effort described in the technical proposal. There is no page limitation for the business volume.

Cost or Pricing Data

The Offeror shall submit other than cost or pricing data. The offeror's proposal must include the identification of pricing data and an explanation of the estimating process. All costs/pricing shall be submitted in part in native format (Microsoft (MS) Word, Excel, etc.) or as PDF files, however, MS Word/Excel formats are preferred. The breakdown of costs/price shall be shown for each ordering period of the contract.

Loaded Labor Hour Rates – Proposed hourly rates shall be supported by the submission of cost and pricing data that justifies the proposed hourly rates for the contract. Loaded bill rates shall include wages, indirect costs, general and administrative expense and profit.

The offeror's proposal shall indicate whether annual escalation rates are proposed. If escalation is included, the offeror shall state the percent and methodology (e.g., annual flat rate applied to a base rate as of a specific date, or a midpoint rate for the period of performance). Salary increases that are anticipated during contract performance must be claimed under the contract. Plans for any additional compensation resulting from employee relations, profit sharing, pensions or health and welfare benefits must also be included. The offeror must also state whether an overtime premium rate is to be applied for all labor proposed, if overtime is required.

The offeror must indicate in its proposal whether it has the necessary financial capacity, working capital and other resources to perform the contract without assistance from any outside sources (if not, the offeror must indicate the amount required and the anticipated source).

Additional Documents to be Submitted with the Business Proposal:

1. Completed Pricing Schedule (Attachment 1) for the IDIQ
2. Disclosure and Use of Lobbying Activities: If the offeror has any activity to report, the offeror shall complete Standard Form (SF) LLL and shall include one originally signed copy with the business proposal. SF LLL, "Disclosure of Lobbying Activities," is included for use in accordance with FAR 52.203-11, Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions (Sep 2007). The form is accessible at https://www.gsa.gov/forms-library/disclosure-lobbying-activities.

10.3.7. Offeror Subcontracting Plan Submission – Small Business Customer Experience (SBCX) System

In accordance with FAR 19.704 and FAR Clause 52.219-9, the submission of a subcontracting plan by other than small business offeror(s) is a requirement as a part of the proposal submission process and is to be submitted separately from the technical and cost proposals. An offeror's subcontracting plan must be determined to be acceptable, by the Contracting Officer, prior to the contract award. An offeror is to submit their respective subcontracting plan electronically using the U.S. Department of Health and Human Services (HHS) Small Business Customer Experience (SBCX) system at https://osdbu.hhs.gov. The offeror shall follow the instructions outlined in the SBCX Industry Guide [Attachment #6] to successfully submit their subcontracting plan by the proposal submission deadline.

The official point of receipt for determining timely submission of an offeror's subcontracting plan is the SBCX system and/or email notification. Once the subcontracting plan is successfully submitted in the SBCX system the offeror should receive an email notification and confirmation message of completion upon submission.

If an offeror's subcontracting plan is not confirmed as received within the SBCX system by the proposal submission date specified in the solicitation, it will be considered late in accordance with subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offeror—Competition Acquisition. Disposition of late submittals of a subcontracting plan by an offeror via the SBCX system is at the discretion of the Contracting Officer.

Any technical questions regarding the use of the SBCX system may be submitted via email message to the SBCX help desk at client.support@apexlogic.com. The client support hours of operation are Monday – Friday, 6:00 a.m. – 8:00 p.m. Eastern Standard Time (EST). Note: help desk tickets can be submitted 24 hours a day / 7 days a week and a representative will respond within the presented client support hours of operation for assistance.

10.4 General Proposal Information

10.4.1. Communications Prior to Contract Award

The Offeror shall direct all communications to the attention of the Contract Specialist, Nikola Zuber (Nikola.Zuber@fda.hhs.gov). Communications with other officials may compromise this acquisition and result in cancellation of the requirement.

10.4.2. Release of Information

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition.

10.4.3. Preparation Costs

This Request for Proposal does not commit the Government to pay any costs for the preparation and submission of a proposal. In addition, the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed acquisition.

10.4.4. Restrictions on Disclosure

The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act.

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C 552, as amended, (the Act) as determined by Freedom of Information (FOI) Officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc., by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI Officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act. If a contract is awarded to the offeror as a result of, or in connection with the submission of this proposal, the Government shall have the right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

In addition, the offeror should mark each page of data it wishes to restrict with the following legend:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

11. BASIS FOR AWARD AND EVALUATION FACTORS

11.1 FAR 52.212-2 – COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES (NOV 2021)

(a) The Government will award a contract resulting from this solicitation to the responsible offeror whose offer conforming to the solicitation will be most advantageous to the Government, price and other factors considered. The following factors shall be used to evaluate offers:

a. Technical Approach and Capability to Perform the Requirement
b. Management Approach
c. Relevant Experience
d. Price

All non-price factors, combined, are significantly more important than cost or price. The Technical Factors 1-3 are listed in descending order of importance. As technical merit and past performance of offeror proposals approach equivalence, the more important evaluated price may become in determining the awardee.

(b) *Options.* The Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. The Government may determine that an offer is unacceptable if the option prices are significantly unbalanced. Evaluation of options shall not obligate the Government to exercise the option(s).

(c) A written notice of award or acceptance of an offer, mailed or otherwise furnished to the successful offeror within the time for acceptance specified in the offer, shall result in a binding contract without further action by either party. Before the offer's specified expiration time, the Government may accept an offer (or part of an offer), whether or not there are negotiations after its receipt, unless a written notice of withdrawal is received before award.

The Government reserves the right to make an award without discussions

11.2 EVALUATION FACTORS

This section supplements the information provided in Section 11.1 above. The following factors will be used to evaluate offers:

- Technical Evaluation
  - Technical Factor 1 – Technical Approach and Capability to Perform the Requirement

    The offeror will be evaluated by demonstrating the following:

    a. Does the contractor's proposal identify access to facilities to address each performance area?
    b. Does the contractor identify personnel with the required technical expertise to perform the tasks within each performance area?
    c. Does the contractor have access to data and equipment needed to perform tasks within each performance area?
    d. Is the contractor able to provide the required data reports and raw data to the FDA:
       - Upon the FDA's request when needed?

- At the pre-specified timelines?

e. The Government will evaluate the quote to ensure that it is technically acceptable in accordance with the requirements.

- Technical Factor 2 – Management Approach
  a. The Offeror shall provide a detailed draft Program Management Plan (PMP) that demonstrates the Offeror's approach to executing program management and task order management is comprehensive and likely to be effective.
  b. The PMP shall also include a staffing plan to be used to meet the IDIQ requirements that are comprehensive, feasible and likely to be effective.
  c. Are the proposed labor categories and labor category minimum requirements qualified to perform the required tasks of the contract?

- Technical Factor 3 – Relevant Experience

  The offeror will be evaluated by demonstrating the following:

  a. Does the list of prior studies conducted by the contractor support the contractor's ability to perform the study?

  Relevant experience is **not** past performance information. The Offeror shall provide information on two (2) IDIQ, BPA, or complex time and material (T&M), labor hour (LH) or firm-fixed price (FFP) efforts that are most similar to this effort in terms of scope, complexity and size. At least one (1) of the two (2) efforts shall be experiences of the offeror acting in the capacity of a prime contractor. IDIQ, BPA or complex T&M, LH, or FFP efforts performed by contractors other than the prime offeror, such as teaming partners or subcontractors, will not be evaluated as prime contractor relevant experience, unless those other contractors are part of a joint venture offeror as demonstrated by a signed joint venture agreement. IDIQ, BPA, or complex T&M, LH or FFP efforts performed by corporate parent and affiliates will not be considered.

  The response shall provide a narrative describing the Offeror's current or previous experience within **the past five (5) years**. The Offeror shall identify other organizations in which it has performed similar tasks, including the degree of its involvement (prime or subcontractor), the size of the client's organization, and other information to describe its expertise and performance in the subject areas, highlighting the organization's experience. Offerors must provide a breakdown of the resources leveraged to accomplish the cited work that explains the type and scope of work provided. Relevant experience may include a mix of the Prime and proposed teaming partners' information. When considered together, the relevant experiences cited must cover the entire Work Requirements (section 2; tasks 2.1-2.4) in the IDIQ SOW scope. Complexity and size are defined as:

  Scope: Identifies the aspects of the scope that are the same or similar to the work requirements as listed in the Statement of Work.

Complexity: Describes the engagement, expertise, multiple concurrent task orders or BPA Calls or contracts and/or locations.

Size: Identifies the dollar value of the contract, the duration of the contract, and the number of personnel engaged for the effort.

Projects listed may include those entered into by the Federal Government, agencies of state and local Governments and commercial customers. In order to meet the specialized experience requirements of the subject procurement, offerors are required to discuss the relevant experience obtained servicing a Federal Agency or component thereof. The list may include contracts and orders on which the Offeror served as a subcontractor, provided that the subcontract was similar in scope, duration, and price to this effort. If a subcontract example is used, contact information for the prime contractor, not the customer, must be provided in items 6, 7, and 8, below. For each project identified above, the Offeror shall submit the following information:

- Price Evaluation
  - Total price will be evaluated for fair and reasonableness.

All non-price factors, combined, are significantly more important than cost or price. The Technical Factors 1-3 are listed in descending order of importance. As technical merit and past performance of offeror proposals approach equivalence, the more important evaluated price may become in determining the awardee. The technical factors will be evaluated adjectivally and categorized as Outstanding, Good, Acceptable, Marginal or Unacceptable.

Price will not be a numerically weighted factor in the evaluation of proposals, nor does the importance of price bear a linear relationship to the technical proposal. The importance of price in the evaluation for award will increase with the degree of equality in the non-price factors of the proposals.

11.3 RESPONSIBILITY

To be eligible for award, the Offeror must be determined responsible in accordance with the standards in FAR 9.104.

12. DPAS RATING

This acquisition is rated under the Defense Priorities and Allocations System (DPAS) as: Not Applicable.

13. LIST OF ATTACHMENTS

Attachment 1	Pricing Schedule
Attachment 2	Labor Categories Minimum Qualification

Attachment 3	FDA IPP Invoicing Instructions
Attachment 4	Department of Health and Human Service (HHS) Federal Acquisition Regulation (FAR) Class Deviation 18-01, Whistleblower Protection for Contractor Employees (Commercial Items/Services)
Attachment 5	Department of Health and Human Service (HHS) Federal Acquisition Regulation (FAR) Class Deviation 20-02, Accelerated Payments to Small Business Contractors and Subcontractors
Attachment 6	SBCX Industry Subcontracting Guide