Solicitation No: 75F40124Q00047
Center for Devices and Radiological Health
Indefinite Delivery Indefinite Quantity (IDIQ) Contract
3D Microscopy, Artificial Intelligence-based Quantification
and Modeling for Non-Clinical Evaluation
and Regulatory Support of Complex Drug Products

Issue Date: May 8, 2024

Contents

A. BACKGROUND

The Food and Drug Administration (FDA) protests 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.

The Office of Generic Drugs (OGD) within FDA is responsible for the review and approval of abbreviated new drug applications. OGD's mission is to ensure, through a scientific and regulatory progress, that generic drugs are safe and effective for the American public. The Office of Research and Standards (ORS) within OGD has been leading research efforts to facilitate generic development and approval.

The Code of Federal Regulations (CFR) Title 21 Part 7 (21CFR7) governs the practices and procedures applicable to regulatory enforcement actions initiated by the FDA pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and other laws that it administers. A recall is a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers.

NOTICE OF SYNOPSIS/SOLICITATION

This is a solicitation for the acquisition of services prepared in accordance with the format in Federal Acquisition Regulation (FAR) 15.204-1. In accordance with FAR Part 5.201.

This competitive solicitation authorized under FAR Part 12 "Acquisition of Commercial Products and Commercial Services" and 13.5 "Simplified Procedures for Certain Commercial Products and Commercial Services" for the award of one (1) Indefinity Delivery Indefinite Quantity (IDIQ) contract.

NOTICE OF FAC

This solicitation document incorporates provisions and clauses in effect through Federal Acquisition Circular FAC 2024-04, effective May 1, 2024.

FAR provisions and clauses referenced in this solicitation can be found on the following website: www.acquisition.gov

Health and Human Services Acquisition Regulation (HHSAR) provisions and clauses referenced in this solicitation can be found on the following website: https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html

B. SERVICES AND PRICES

Tests	Gov't Estimate QTY	Unit Price	Base Year	Option Year 1	Option Year 2	Option Year 3	Option Year 4
2D FIB SEM imaging	**20**						
3D FIB SEM imaging	**10**						
EDS spectrum/mapping	**20**						
Synchrotron X-Ray Imaging	**5**						
3D FIB SEM imaging and analysis	**10**						
XRM uniforminty analysis	**10**						
XRM Density characterization	**20**						
2D FIB SEM imaging and analysis	**10**						
AI based 3D FIB-SEM quantitative analysis	**10**						
Advanced Segmentation for Synchrotron	**5**						
Complex API and porosity segmentation	**20**						
Porosity variation and release simulation	**20**						
Release simulation	**20**						
Permeability simulation	**10**						
AI generation of potential formulation	**10**						

The Contractor's pricing schedules shall contain firm fixed-prices for each test listed.

Pricing Terms

The Contractor shall comply with FAR Clause 52.212-4, Contract Terms and Conditions – Commercial Items (Oct 2018) in regard to the firm-fixed-prices for individual task orders. 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 52.212-4, Alt I, Contract Terms and Conditions – Commercial Items (Oct 2018) with regard to the ceiling price for each task order. Minimum and Maximum Contract Value

IDIQ Minimum: The minimum guarantee for this IDIQ contract is $500.00, which will be obligated at the time of 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 $4,999,999.00.

See FAR Clause 52.216-19 (Oct 1995) for individual task order limitations.

C. STATEMENT OF WORK

See Attachment C

D. PACKAGING and MARKING

N/A

E. INSPECTION and ACCEPTANCE

All work under this contract is subject to inspection and final acceptance by the Contracting Officer or the COR. The COR is responsible for inspection and acceptance of all items to be delivered under this contract.

• Accuracy: Work products shall be accurate in presentation, technical content, and adherence to accepted elements of style.

• Technical Soundness: Work products, especially digital work products, shall exhibit no technical flaws.

• Comprehensiveness: Work products, especially qualitative and quantitative research, shall have sufficient strength to make the research sufficiently measurable and therefore meaningful.

• Clarity: Work products shall be clear and concise. Diagrams shall be easy to understand and be relevant to the supporting narrative.

• Creative: Work products shall exhibit fresh, new ideas and innovative tools and materials that effectively reach and engage target audiences.

• Consistency to Requirements: All work products must satisfy the requirements of the statement of work.

• Timeliness: Work products shall be submitted by the due date specified in this statement of work or submitted in accordance with a later scheduled date determined by the Government.

• File Editing: All text and diagrammatic files shall be editable by the Government.

• Format: Work products shall be submitted electronically and, in the format, mutually agreed upon prior to submission.

• Quality: Work products shall be void of errors passing quality control measures designated by Government.

All services delivered to the COR will be deemed to have been accepted 30 calendar days after date of delivery, except as otherwise specified in this contract, if written approval or disapproval has not been given within such period. The COR's approval or revision to the services delivered shall be within the general scope of work stated in this contract.

F. PERFORMANCE

PLACE OF PERFORMANCE

The Contractor shall perform all work under this contract at the Contractor's site. Remote work acceptable, as approved by the COR.

PERIOD OF PERFORMANCE

This IDIQ has 12-month base year, four (4) 12-month option years. Any extension shall be completed by adding funds to the contract and will be based on availability of those funds. Estimate Period of Performance provided below:

Base Year: May 28, 2024, through May 27, 2025
Option Year 1: May 28, 2025, through May 27, 2026
Option Year 2: May 28, 2026, through May 27, 2027
Option Year 3: May 28, 2027, through May 27, 2028
Option Year 4: May 28, 2028, through May 27, 2029

HOLIDAYS AND GOVERNMENT CLOSURES

The Contractor is not required to provide on-site services on the following days that are Federal Holidays or on any other day designated as a Federal holiday for the Washington, DC area:

New Year's Day
Martin Luther King Day
President's Day
Memorial Day
Juneteenth Day
Independence Day
Labor Day
Columbus Day
Veteran's Day
Thanksgiving Day
Christmas Day

*Any other day designated by Federal statue
*Any other day designated by Executive Order

Observance of such days by Government personnel shall not be cause for an extension to the delivery schedule or period of performance or adjustment to the price, except as set forth in the contract. Except for designated around-the-clock or emergency operations, Contractor personnel will not be able to perform on-site under this contract with FDA on holidays set forth above. The Contractor will not charge any holiday as direct charge to the contract. In the event Contractor personnel work during a holiday observed by the Contractor other than those above, no form of holiday or other premium compensation will be reimbursed as either a direct or indirect cost. However, this does not preclude reimbursement for authorized overtime work.

In the event the FDA grants administrative leave to its Government employees at the site, on-site Contractor personnel shall also be dismissed if the site is being closed. However, the Contractor shall continue to provide sufficient personnel to perform around-the-clock requirements of critical efforts already in progress or scheduled and shall be guided by the instructions issued by the Contracting Officer or her/his

duly appointed representative. In each instance when the site is closed to Contractor personnel as a result of

inclement weather, potentially hazardous conditions, explosions, or other special circumstances, the Contractor will direct its staff as necessary to take actions such as reporting to its own site(s) or taking appropriate leave consistent with its policies.

NOTICE TO THE GOVERNMENT OF DELAYS

In the event the Contractor encounters difficulty in meeting performance requirements, or when the Contractor anticipates difficulty in complying with the contract delivery schedule or completion date, or whenever the Contractor has knowledge that any actual or potential situation is delaying or threatens to delay the timely performance of this contract, the Contractor shall immediately notify the Contracting Officer and COR in writing, giving pertinent details. This data shall be informational only in character and this provision shall not be construed as a waiver by the Government of any delivery schedule or date, or any rights or remedies provided by law or under this contract.

ORDERING PROCEDURES

This is a single award IDIQ with the issuance of firm-fixed price task orders.

Contractual technical surge capacity and expertise may be required to complete such proposed tasks but will ultimately depend on internal prioritization, strategic planning, and financial resources.

Orders shall be placed against the IDIQ in accordance with FAR 16.505.

Any Contracting Officer (CO) of the Food and Drug Administration (FDA) is authorized and may place orders under this IDIQ. Each individual task order will describe the specific performance requirements.

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

All orders against the IDIQ will be issued via email. All proposals received in accordance with the RFTOP requirements will be fairly considered, and award will be made in accordance with the selection procedures provided in the IDIQ order RFTOP.

When a need for services within the scope of this IDIQ arises, the process for issuing task orders is as follows:

1. The FDA CO will issue a RFTOP to the IDIQ awardee 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
g. Any terms, conditions and instructions specific to the task order

2. The Contractor(s) 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 extended pricing and total task order pricing)
c. Resumes of any key personnel identified in the RFTOP

3. The FDA will evaluate the task order proposals and price reasonableness. If the FDA has questions or concerns, the Contracting Officer will contact the Contractor and may request a revised proposal. At a minimum, the price proposal **must** be submitted with any proposal submitted in response to a RFTOP.

PRICING 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.

These Ordering Pricing terms and conditions apply to all task orders issued against this IDIQ. During the performance period of this IDIQ, by mutual agreement of the parties, additional rates may be added to support the objectives in the SOW.

All orders issued hereunder are subject to the terms and conditions of this contract. This contract shall control in the event of conflict with any order.

SECURITY AND PRIVACY

Security requirements will be identified at the order level, if applicable.

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

• Integrity, which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and for protecting personal privacy and proprietary information;
• 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.
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.

c. 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 [X] Moderate [ ] High
Integrity: [ ] Low [X] Moderate [ ] High
Availability: [X] Low [ ] Moderate [ ] High
Overall Risk Level: [ ] Low [X] Moderate [ ] High

Based on information provided by the Privacy Office, system/data owner, or other privacy representative, it has been determined that this solicitation/contract involves:
[X] No PII [ ] Yes PII

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.

Physical Security
If applicable, the Contractor shall safeguard all Government property provided for the Contractor's use. At the close of each work period, Government facilities and materials shall be secured by the Contractor. The Contractor shall insure keys and/or electronic access entry cards issued to the Contractor by the Government are not lost or misplaced and are not used by unauthorized persons. Keys issued to the Contractor by the Government will be duplicated by designated Government personnel only. The Government may, as its option, require the Contractor to replace, re-key, or reimburse the Government for replacement of locks or re-keying of combination locks as a result of the Contractor's negligence. In the event a master key is lost or duplicated without authorization, all locks and keys for that system will be rep1aced by the Government and the total cost deducted from the Contractor's subsequent monthly invoice. The Government will provide identification badges to be used during all hours of operation by the Contractor personnel working at the FDA facilities.

The Contractor shall report the occurrences of a lost key to the Task Order COR(s) immediately. The Contractor shall not grant access to any locked areas to permit entrance of persons other than the Contractor's employees engaged in the performance of assigned work in these areas.

Performance Standard: The Contractor shall comply with all security requirements.

TRAVEL

No travel will be required for this contract.

OTHER CONSIDERATIONS

Each consultant shall meet with FDA collaborators as needed to complete each project.

Non-Personal Services

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.

LIMITATION ON GOVERNMENT'S OBLIGATION

This contract does not obligate any funds beyond the minimum guarantee. The Government is obligated only to the extent specified in the individual task orders issued under this award.

The maximum aggregate dollar value of all task orders shall not exceed the established agreement ceiling.

G. CONTRACT ADMINISTRATION

CONTRACTING OFFICER
Lillian Lamb
Contract Specialist
Office of Operations, Office of Finance Budget & Acquisitions
Office of Acquisitions and Grants Services, HFA-500
U.S. Food and Drug Administration
4041 Powder Mill Road
Beltsville, MD 20705
Tel: 301-796-1316
lillian.lamb@fda.hhs.gov

Contracting Officer Representative: *To be determined at award*

CONTRACTING OFFICER'S AUTHORITY

a. The Contracting Officer (CO) has responsibility for ensuring the performance of all necessary actions for effective contracting, ensuring compliance with the terms of the contract, and safeguarding the interests of the United States in its contractual relationships. The CO 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 and resulting orders, and notwithstanding any provision contained elsewhere in this contract, this authority remains solely with the CO.

b. No statement, whether oral or written, by anyone other than the CO, shall be interpreted as modifying the terms and conditions of 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. The Government will not reimburse the Contractor for any work not authorized by the CO, including work outside the scope of the contract.

CONTRACTING OFFICER REPRESENTATIVE

The Contracting Officer may designate other Government personnel, known as the 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 order. 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 IDIQ contract and orders issued against the IDIQ 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 order.

The COR will provide the technical direction for the required work. The term "technical direction" is defined

to include, without limitation, the following:

- Directions to the Contractor which redirect the Task Order 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 descriptions.
- Review and, where required by the Task Order, approval of technical reports, drawings, specifications, and technical information to be delivered by the Contractor to the Government under the Task Order. Technical direction must be within the general scope of work stated in this IDIQ and subsequent Task Orders. The COR does not have the authority to and may not issue any technical direction which:
- Constitutes an assignment of additional work outside this agreement's general scope of work or any of the issued Orders.
- In any manner cause an increase or decrease in the total Order price or the time required for Order performance.
- Change any of the expressed terms, conditions, or specifications of the Order.

All technical direction shall be issued orally and/or in writing by the COR or shall be confirmed by him/her in writing within 5 working days after issuance.

Task Order Contracting Officer Representative

A. For each Task Order, a Contracting Officer's Representative (COR) will be assigned. The COR shall 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 evaluations as required; (4) Performing technical inspections and acceptances required by this IDIQ; (5) Assisting in the resolution of technical problems encountered during performance; and (6) Providing technical direction in accordance with section 13; and (7) Reviewing invoices/vouchers.

B. The Government may unilaterally change its COR designation.

C. The Task Order COR does not have authority to act as agent of the Government under this IDIQ. 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 IDIQ; or (5) otherwise change any terms and conditions of this IDIQ.

H. SPECIAL CONTRACT REQUIREMENTS

CLASSIFIED INFORMATION

Classified material will not be issued or supported by this contract. General security requirements will be established, maintained, and monitored per the applicable FDA security standards.

DATA RIGHTS

The FDA shall have unlimited rights to, and ownership of all deliverables provided under this IDIQ,

including consumer and industry materials, reports, recommendations, briefings, work plans and all other deliverables as applicable and defined by the order or ad-hoc service request. Including any optional order deliverables exercised by the contracting officer.
Also, it includes any additional deliverables required by contract change. The definition of "unlimited rights" is contained in Federal Acquisition Regulation (FAR) 27.401, "Definitions." FAR clause 52.227-14, "Rights in Data-General," is hereby incorporated by reference and made a part of this contract/order.

SECTION 508 STANDARD REQUIREMENTS

HHS 352.239-74 Electronic and Information Technology Accessibility (December 18, 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 are:

1194.21 – Software Applications and Operating Systems
1194.22 – Web based intranet and internet information and applications
1194.24 – Video and Multimedia Products
1194.31 – Functional performance criteria
1194.41 – Information, documentation, and support

(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.

INFORMATION SECURITY REQUIREMENTS

1. Baseline Security Requirements

a. Applicability. The requirements herein apply whether the entire contract or modification (hereafter "contract"), or portion thereof, includes either or both of the following:

i. Access (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.

ii. 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 FDA 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.

b. Safeguarding Information and Information Systems. All government information and information systems must be protected in accordance with FDA policies and level of risk. At a minimum, the Contractor (and/or any subcontractor) must:

i. Protect the:

- 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.

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ii. Categorize all information owned and/or collected/managed on behalf of FDA and information systems that store, process, and/or transmit FDA information 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 Categories. Based on information provided by the System/Data Owner, ISSO, privacy representative, or other POC, the impact level for each Security Objective (Confidentiality, Integrity, and Availability) and the Overall Impact Level, which is the highest watermark of the three factors of the information or information system are the following:

- Confidentiality: [ ] Low [X] Moderate [ ] High
- Integrity: [ ] Low [X] Moderate [] High
- Availability: [X] Low [ ] Moderate [ ] High
- Overall Impact Level: [X] Low [ ] Moderate [ ] High

iii. Based on the agreed-upon level of impact, implement the necessary safeguards to protect all information systems and information collected and/or managed on behalf of FDA regardless of location or purpose.

iv. Report any discovered or unanticipated threats or hazards by either the agency or contractor, or if existing safeguards have ceased to function immediately after discovery, within one (1) hour or less, to the government representative(s). This includes notifying the FDA Cybersecurity and Infrastructure Operations Coordination Center (CIOCC) within one (1) hour of discovery/detection in the event of a cybersecurity or privacy incident.

v. Adopt and implement all applicable policies, procedures, controls, and standards required by the 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 Protection (IS2P) policy, by contacting the CO/COR or emailing your ISSO.

c. Privacy Act. Comply with the Privacy Act requirements (when applicable), and tailor FAR and HHSAR clauses as needed. It has been determined that this order is not subject to the Privacy Act of 1974.

d. Privacy Compliance. Comply with the E-Government Act of 2002, NIST SP 800-53, and applicable FDA privacy policies and complete all the requirements below:

i. Per the Office of Management and Budget (OMB) Circular A-130, Personally Identifiable Information (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.

ii. Based on information provided by the ISSO, System/Data Owner, or other security or privacy representative, it has been determined that this solicitation/contract involves:
[X] No PII [ ] PII

iii. The Contractor must support the agency with conducting a Privacy Threshold Analysis (PTA) for the information system and/or information handled under this contract to determine whether or not a full Privacy Impact Assessment (PIA) needs to be completed.

- If the results of the PTA show that a full PIA is needed, the Contractor must support the agency 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).

 The Contractor must support the agency in reviewing the PIA at least every three years throughout the system development lifecycle (SDLC)/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.

e. Controlled Unclassified Information (CUI). Executive Order 13556 defines CUI 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. The requirements below apply only to nonfederal systems that process, store, or transmit CUI, or that provide security protection for such components. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, must be:

i. Marked appropriately;

ii. Disclosed to authorized personnel on a Need-To-Know basis;

iii. Protected in accordance with NIST SP 800-53, Security and Privacy Controls for 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

iv. Returned to FDA control, destroyed when no longer needed, or held until otherwise directed. Information and/or data must be disposed of in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

f. 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) must protect all government information that is or may be sensitive by securing it with a solution that is validated with current FIPS 140 validation certificate from the NIST CMVP.

g. Government Furnished Equipment (GFE) for Foreign Travel. FDA personnel are prohibited from taking GFE when participating in personal, unofficial travel to foreign countries. FDA personnel are strictly prohibited from teleworking using GFE in foreign countries. FDA personnel must also request loaner GFE from the FDA Foreign Travel program for official travel to any foreign country. Please see the FDA IS2P, Appendix T Government Furnished Equipment for Foreign Travel.

h. 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 must be used only for the purpose of carrying out the provisions of this contract and must 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 must ensure that all work performed by its employees and subcontractors must 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 must 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 must be protected in accordance with HHS and FDA policies. Unauthorized disclosure of information will be subject to the HHS and FDA sanction policies and/or governed by the following laws and regulations:

i. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);

ii. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and

iii. 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

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

j. Information and Communications Technology (ICT). ICT products and services from prohibited entities/sources must not be used/acquired in compliance with Public Law 115-232, Section 889 Parts A and B, FAR 4.21, FAR 52.204.23, FAR 52.204.24, and FAR 52.204.25. The contractor (and/or any subcontractor) must notify the government if they identify prohibited ICT products and/or services are used during the contract performance.

k. 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 must 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, HTTPS is not required, but it is highly recommended. Consult the HHS Policy for Internet and Email Security for additional information.

l. Contract Documentation. The Contractor must use provided templates, policies, forms, and other agency documents to comply with contract deliverables as appropriate.

m. Standard for Encryption. The Contractor (and/or any subcontractor) must:
i. Comply with the HHS Standard for Encryption of Computing Devices and Information to prevent unauthorized access to government information.

ii. 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 an encryption solution that is validated with current FIPS 140 validation certificates from the NIST CMVP.

iii. Secure all devices (i.e.: desktops, laptops, mobile devices, etc.) that store and process government information and ensure devices 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).

iv. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with current FIPS 140 validation certificates from the NIST CMVP. The Contractor must provide a written copy of the validation documentation to the COR.

v. 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 http://csrc.nist.gov/publications/. Encryption keys must be provided to the COR upon request and at the conclusion of the contract.

n. Contractor Non-Disclosure Agreement (NDA). Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract must complete the FDA non-disclosure agreement (3398 Form)], as applicable. Contractors (and/or subcontractors) must submit a copy of each signed and witnessed NDA to the Contracting Officer (CO) and/or CO Representative (COR) prior to performing any work under this acquisition.

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2. Training Requirements

a. Mandatory Training for All Contractor Staff. All Contractor (and/or any subcontractor) employees assigned to work on this contract must complete the applicable FDA information security awareness, privacy, and records management training (provided upon contract award) before performing any work under this contract. Thereafter, the employees must complete FDA information security awareness, privacy, and records management training at least annually, during the life of this contract. All provided training must be compliant with HHS training policies.

b. 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.

c. Training Records. The Contractor (and/or any subcontractor) must maintain training records for all its employees working under this contract in accordance with HHS and FDA policy. A copy of the training records must be provided to the CO and/or COR within 30 days after contract award and annually thereafter or upon request.

3. Rules of Behavior

a. The Contractor (and/or any subcontractor) must ensure that all employees performing on the contract comply with the HHS Information Technology General Rules of Behavior, HHS Rules of Behavior for Privileged Users, and FDA policies and standards.

b. All Contractor employees performing on the contract must read and adhere to the Rules of Behavior before accessing Agency 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 above.

4. Incident Response

a. The Contractor (and/or any subcontractor) must respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/FDA CIOCC /Incident Response Team 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. In accordance with OMB M-17-12, Preparing for and Responding to a Breach of

Personally Identifiable Information (PII), an incident is "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" and a privacy breach is "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." For additional information on the HHS breach response process, please see the FDA IS2P Appendix F: Incident Response and the HHS Policy and Plan for Preparing for and Responding to a Breach of Personally Identifiable Information (PII)."

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

i. Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract, with encryption solution that is validated with current FIPS 140 validation certificates from the NIST CMVP.
ii. 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 must send FDA approved notifications to affected individuals as directed by FDA's SOP.

iii. Report all suspected and confirmed information security and privacy incidents and breaches to the FDA CIOCC, COR, CO, FDA SOP (or his or her designee), and other stakeholders, including breaches 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, 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, contact information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor must:

- Cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;

- Not include any sensitive information in the subject or body of any reporting e-mail; and

- Encrypt sensitive information in attachments to email, media, etc.

iv. Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information, and HHS and FDA breach response policies when handling PII breaches.

v. 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 on demand.

5. 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.

6. Homeland Security Presidential Directive (HSPD)-12

The Contractor (and/or any subcontractor) and its employees must comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; OMB M-05-24; OMB M-19-17; FIPS 201, Personal Identity Verification (PIV) of Federal Employees and Contractors; HHS HSPD-12 policy; and Executive Order 13467, Part 1 §1.2.

7. Roster

The Contractor (and/or any subcontractor) must 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 must 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 must be submitted within a timeline as directed by the COR and/or CO. 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 must provide a position description and the Government will determine the appropriate suitability level.

8. Contract Initiation and Expiration

a. General Security Requirements. The Contractor (and/or any subcontractor) must 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 must follow the FDA EPLC framework and methodology in accordance with the FDA EPLC Project documentation, located here: http://sharepoint.fda.gov/orgs/DelMgmtSupport/IntakeProc/EPLCv2/SitePages/v2/EPL CHome.aspx and in accordance with the HHS Contract Closeout Guide (2012).

b. System Documentation. Contractors (and/or any subcontractors) must follow and adhere to HHS System Development Life Cycle requirements, 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.

c. Sanitization of Government Files and Information. As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) must provide all required documentation in accordance with SMGs published by FDA's Office of Acquisitions and Grant Services (OAGS) 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.

d. Notification. The Contractor (and/or any subcontractor) must notify the CO and/or COR and system ISSO as soon as it is known that a contract employee will stop working under this contract.

e. Contractor Responsibilities upon Physical Completion of the Contract. The contractor (and/or any

subcontractors) must 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 must 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 FDA policies.

f. The Contractor (and/or any subcontractor) must perform and document 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 a contract an employee will terminate work under this contract. The Contractor (and/or any subcontractor) shall coordinate with the COR via email, copying the Contract Specialist, to ensure that the appropriate person performs and documents the actions identified in the FDA eDepart system. All documentation must be available to the CO and/or COR upon request.

9. Records Management and Retention

a. The Contractor (and/or any subcontractor) must 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 Policy for Records Management and HHS and FDA policies and must not dispose of any records unless authorized by HHSFDA.

b. In the event that a contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper authorization, he/she must document and report the incident in accordance with HHS and FDA policies.

10. High Value Asset (HVA)

If a system is identified as HVA, the contractor must comply with the FDA IS2P Appendix AB: High Value Asset (HVA) Program, the HHS Policy for the High Value Asset (HVA) Program, and the DHS HVA Control Overlay in addition to the above requirements.

INVOICING INSTRUCTIONS AND REQUIREMENTS

FDA Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP) (Jan 2022)

a. All Invoice submissions for goods and or services must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP). http://www.ipp.gov/vendors/index.htm

b. Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract, or the clause 52.212-4 Contract Terms and Conditions - Commercial Items included in commercial items contracts. The IPP website address is: https://www.ipp.gov

c.
1. The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 - 5 business days of the contract award for new contracts or date of modification for existing contracts.

2. Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.
3. The Contractor POC will receive two emails from **IPP Customer Support**, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.
4. If your company is already registered to use IPP, you will not be required to re-register.
5. If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

d. Invoices that include time and materials or labor hours Line Items must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).

e. Invoices that include cost-reimbursement Line Items must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts. At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.
• Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
• Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
• Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;

Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
• Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
• Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
• Fee - amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

f. Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:
(a) list of all invoices submitted to date under the subject award, including the following:
(1) invoice number, amount, & date submitted (2) corresponding payment amount & date received
(b) total amount of all payments received to date under the subject contract or order (c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance.

g. Payment of invoices will be made based upon acceptance by the Government of the entire task or the tangible product deliverable(s) invoiced. Payments shall be based on the Government certifying that satisfactory services were provided, and the Contractor has certified that labor charges are accurate.

h. If the services are rejected for failure to conform to the technical requirements of the order, or any other contractually legitimate reason, the Contractor shall not be paid, or shall be paid an amount negotiated by the CO.

i. Payment to the Contractor will not be made for temporary work stoppage due to circumstances beyond

the control of U.S. Food and Drug Administration such as acts of God, inclement weather, power outages, and results thereof, or temporary closings of facilities at which Contractor personnel are performing. This may, however, be justification for excusable delays.

j. The Contractor agrees that the submission of an invoice to the Government for payment is a certification that the services for which the Government is being billed, have been delivered in accordance with the hours shown on the invoices, and the services are of the quality required for timely and successful completion of the effort.

k. Questions regarding invoice payments that cannot be resolved by the IPP Helpdesk should be directed to the FDA Employee Resource and Information Center (ERIC) Helpdesk at 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742); or, by email at ERIC@fda.hhs.gov. Refer to the Call-in menu options and follow the phone prompts to dial the option that corresponds to the service that's needed. All ERIC Service Now Tickets will either be responded to or resolved within 48 hours (2 business days) of being received. When emailing, please be sure to include the contract number, invoice number and date of invoice, as well as your name, phone number, and a detailed description of the issue.

CONTRACTOR PERFORMANCE EVALUATION(S)

In accordance with Federal Acquisition Regulation (FAR) 42.15, FDA will complete annual and final contractor performance evaluations. Annual evaluations will be prepared to coincide with the anniversary date of the contract. Additional interim performance evaluations may be prepared at Contracting Officer discretion, as necessary. Final performance evaluations will be completed upon contract expiration.
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.

Once a performance evaluation is issued, the Contractor's primary and alternate CPARS contact will receive an email instructing them to logon to CPARS in order to review the performance evaluation. The Contractor has 60 days from the date of performance evaluation issuance in which to review the evaluation. 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 the CPARS within 14 days from date the evaluation was issued by FDA. Any disagreement between the Contracting Officer and the Contractor will be referred to a contracting official one level above the Contracting Officer, whose decision will be final.
Copies of each performance evaluation and contractor responses, if any, will be retained as part of the official contract file and will be used to support future award decisions. Evaluations will also be stored for a 3 year period in the Past Performance Information Retrieval System (PPIRS) at www.ppirs.gov.

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.

I. CONTRACT PROVISIONS/CLAUSES

FEDERAL ACQUISITION REGULATIONS (FAR) PROVISIONS

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):

FAR: www.acquisition.gov
HHSAR: https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html

FAR PROVISION #	TITLE	DATE
FAR 52.203-11	CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS	(SEP 2007)
FAR 52.203-18	PROHIBITION ON CONTRACTING WITH ENTITIES THAT REQUIRE CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS OR STATEMENTS-REPRESENTATION	(JAN 2017)
FAR 52.204-4	PRINTED OR COPIED DOUBLE SIDED ON RECYCLED PAPER	(MAY 2011)
FAR 52.204-16	COMMERCIAL AND GOVERNMENT ENTITY CODE REPORTING	(AUG 2020)
FAR 52.204-17	OWNERSHIP OR CONTROL OF OFFEROR	(AUG 2020)
FAR 52.209-7	INFORMATION REGARDING RESPONSIBILITY MATTERS	(OCT 2018)
FAR 52.212-1	INSTRUCTIONS TO OFFERIRS-COMMERCIAL SERVICES	(MAR 2023)
FAR 52.217-5	EVALUATION OF OPTIONS	(JUL 1990)

Access to Market Share and Survey Data Food Supply Monitoring and Surveillance of the U.S. Market

FULL TEXT

52.212-2 Evaluation—Commercial Items (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:

Factor 1: Technical (Technical Approach; Management Approach; Relevant Experience)
Factor 2: Past Performance
Factor 3: Price

Technical (Factor 1) and Past Performance (Factor 2) when combined are more important than Price (Factor 3).

(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.

(End of provision)

FAR 52.212-3 Offeror Representations and Certifications—Commercial Items (DEC 2022)
This provision applies to this acquisition. Offerors are to provide required data as (**Attachment B)** with their proposals.

FEDERAL ACQUISITION REGULATIONS (FAR) CLAUSES

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):

FAR: www.acquisition.gov
HHSAR: https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html
(End of Clause)

FAR CLAUSE #	TITLE	DATE
52.203-19	PROHIBITION ON REQUIRING CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS OR STATEMENTS	(JAN 2017)
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 Alt I	CONTRACT TERMS AND CONDITIONS – COMMERCIAL ITEMS	(NOV 2021)

Access to Market Share and Survey Data Food Supply Monitoring and Surveillance of the U.S. Market

52.212-5	Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Products and Commercial Services	(FEB 2024)
52.227-14	RIGHTS IN DATA – GENERAL	(MAY 2014)
52.247-34	F.O.B DESTINATION	(SEP 2021)
52.247-35	F.O.B DESTINATION, WITHIN CONSIGNEE'S PREMISES	(NOV 1991) (APR 1984)

FULL TEXT

52.204-21 Basic Safeguarding of Covered Contractor Information Systems.

Basic *Safeguarding* of *Covered Contractor Information Systems* (Nov 2021)

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

Covered contractor information system means an *information system* that is owned or operated by a contractor that processes, stores, or transmits *Federal contract information*.

Federal contract information means *information*, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including *information* provided by the Government to the public (such as on public websites) or simple transactional *information*, such as necessary to process payments.

Information means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

Information system means a discrete set of *information* resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of *information* (44 U.S.C. 3502).

Safeguarding means measures or controls that are prescribed to protect *information systems*.

(b) *Safeguarding* requirements and procedures.

(1) The Contractor *shall* apply the following basic *safeguarding* requirements and procedures to protect *covered contractor information systems*. Requirements and procedures for basic *safeguarding* of *covered contractor information systems shall* include, at a minimum, the following security controls:

(i) Limit *information system* access to authorized users, processes acting on behalf of authorized users, or devices (including other *information systems*).

(ii) Limit *information system* access to the types of transactions and functions that authorized users are permitted to execute.

(iii) Verify and control/limit connections to and use of external *information systems*.

(iv) Control *information* posted or processed on publicly accessible *information systems*.

(v) Identify *information system* users, processes acting on behalf of users, or devices.

(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational *information systems*.

(vii) Sanitize or destroy *information system* media containing *Federal Contract Information* before disposal or release for reuse.

(viii) Limit physical access to organizational *information systems*, equipment, and the respective operating environments to authorized individuals.

(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

(x) Monitor, control, and protect organizational communications (*i.e.*, *information* transmitted or received by organizational *information systems*) at the external boundaries and key internal boundaries of the *information systems*.

(xi) Implement subnetworks for publicly accessible system *components* that are physically or logically separated from internal networks.

(xii) Identify, report, and correct *information* and *information system* flaws in a timely manner.

(xiii) Provide protection from malicious code at appropriate locations within organizational *information systems*.

(xiv) Update malicious code protection mechanisms when new releases are available.

(xv) Perform periodic scans of the *information system* and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) *Other requirements.* This clause does not relieve the Contractor of any other specific *safeguarding* requirements specified by *Federal agencies* and departments relating to *covered contractor information systems* generally or other Federal *safeguarding* requirements for controlled unclassified *information* (CUI) as established by Executive Order 13556.

(c) *Subcontracts.* The Contractor *shall* include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the *acquisition* of *commercial products* or *commercial services*, other than commercially available off-the-shelf items), in which the subcontractor *may* have *Federal contract information* residing in or transiting through its *information system*.

(End of clause)

52.204-27 Prohibition on a ByteDance Covered Application.

Prohibition on a ByteDance *Covered Application* (Jun 2023)

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

Covered application means the social networking service TikTok or any successor application or service developed or provided by ByteDance Limited or an entity owned by ByteDance Limited.

Information technology, as defined in 40 U.S.C. 11101(6)—

(1) Means any equipment or interconnected system or subsystem of equipment, used in the automatic *acquisition*, storage, analysis, evaluation, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information by the *executive agency*, if the equipment is used by the *executive agency* directly or is used by a contractor under a contract with the *executive agency* that requires the use—

(i) Of that equipment; or

(ii) Of that equipment to a significant extent in the performance of a service or the furnishing of a product;

(2) 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; but

(3) Does not include any equipment acquired by a Federal contractor incidental to a Federal contract.

(b) *Prohibition*. Section 102 of Division R of the Consolidated Appropriations Act, 2023 (Pub. L. 117-328), the No TikTok on Government Devices Act, and its implementing guidance under Office of Management and Budget (OMB) Memorandum M-23-13, dated February 27, 2023, "No TikTok on Government Devices" Implementation Guidance, collectively prohibit the presence or use of a *covered application* on *executive agency information technology*, including certain equipment used by Federal contractors. The Contractor is prohibited from having or using a *covered application* on any *information technology* owned or managed by the Government, or on any *information technology* used or provided by the Contractor under this contract, including equipment provided by the Contractor's employees; however, this prohibition does not apply if the *Contracting Officer* provides written notification to the Contractor that an exception has been granted in accordance with OMB Memorandum M-23-13.

(c) *Subcontracts*. The Contractor *shall* insert the substance of this clause, including this paragraph (c), in all subcontracts, including subcontracts for the *acquisition* of *commercial products* or *commercial services*.

(End of clause)

52.212-5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items (MAY 2022)

The additional FAR clauses cited in this clause that have a "check" or an "x" next to them are applicable to the acquisition. (Full text of this clause is in **Attachment C** – FAR 52.212-5 In Full Text Applicable To This Acquisition.)

52.216-19 Order Limitations.

As prescribed in 16.506(b), insert a clause substantially the same as follows:

3D Microscopy, Artificial Intelligence-based Quantification, and Modeling for Non-Clinical Evaluation and Regulatory Support of Complex Drug Products

ORDER LIMITATIONS (OCT 1995)

(a) *Minimum order*. When the Government requires supplies or services covered by this contract in an amount of less than $1,000.00, 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 $4,999,999.00;

(2) Any order for a combination of items in excess of $4,999,999.00; or

(3) A series of orders from the same ordering office within ***3*** days that together call for quantities exceeding the limitation in paragraph (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 ***3*** 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)

52.216-22 Indefinite Quantity.

As prescribed in 16.506(e), insert the following clause:

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 **March 25, 2029**.

(End of clause)

52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)
(applicable to orders issued under this contract)

(a) The Government may extend the term of this contract by written notice to the Contractor prior to contract expiration; provided that the Government gives the Contractor a preliminary written notice of its intent to extend prior to contract expiration. The preliminary notice does not commit the Government to an extension.
(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.
(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed five (5) years and six (6) months.

(End of clause)

Health & Human Services Acquisition Regulation (HHSAR) Clauses

HHSAR CLAUSE #	TITLE	DATE
352.211-3	PAPERWORK REDUCTION ACT	(DEC 2015)
352.224-70	PRIVACY ACT	(DEC 2015)
352.227-70	PUBLICATIONS AND PUBLICITY	(DEC 2015)
352.231-70	SALARY RATE LIMITATION	(DEC 2015)

FULL TEXT

HHSAR 352.203-70 ANTI-LOBBYING (DEC 2015)

Pursuant to the HHS annual appropriations acts, except for normal and recognized executive-legislative relationships, the Contractor shall not use any HHS contract funds for:
(a) Publicity or propaganda purposes;
(b) The preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any state or local legislature itself; or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any state or local government, except in presentation to the executive branch of any state or local government itself; or
(c) Payment of salary or expenses of the Contractor, or any agent acting for the Contractor, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government.
(d) The prohibitions in subsections (a), (b), and (c) above shall include any activity to advocate or promote any proposed, pending, or future federal, state, or local tax increase, or any proposed, pending, or future

requirement for, or restriction on, any legal consumer product, including its sale or marketing, including, but not limited to, the advocacy or promotion of gun control.

(End of clause)

HHSAR 352.208-70 PRINTING AND DUPLICATION (DEC 2015)

a) Unless otherwise specified in this contract, no printing by the Contractor or any subcontractor is authorized under this contract. All printing required must be performed by the Government Printing Office except as authorized by the Contracting Officer. The Contractor shall submit camera-ready copies to the Contracting Officer's Representative (COR). The terms "printing" and "duplicating/copying" are defined in the Government Printing and Binding Regulations of the Joint Committee on Printing.

(b) If necessary for performance of the contract, the Contractor may duplicate or copy less than 5,000 production units of only one page, or less than 25,000 production units in aggregate of multiple pages for the use of a department or agency. A production unit is defined as one sheet, size 8.5 x 11 inches, one side only, and one color. The pages may not exceed a maximum image size of 10-3/4 by 14-1/4 inches. This page limit applies to each printing requirement and not for all printing requirements under the entire contract.

(c) Approval for all printing, as well as duplicating/copying in excess of the stated limits, shall be obtained from the COR who will consult with the designated publishing services office and provide direction to the contractor. The cost of any unauthorized printing or duplicating/copying under this contract will be considered an unallowable cost for which the Contractor will not be reimbursed.

(End of clause)

HHSAR 352.222-70 CONTRACTOR COOPERATION IN EQUAL EMPLOYMENT OPPORTUNITY INVESTIGATIONS (DEC 2015)

(a) In addition to complying with the clause at FAR 52.222-26, Equal Opportunity, the Contractor shall, in good faith, cooperate with the Department of Health and Human Services (Agency) in investigations of Equal Employment Opportunity (EEO) complaints processed pursuant to 29 CFR part 1614. For purposes of this clause, the following definitions apply:

(1) Complaint means a formal or informal complaint that has been lodged with Agency management, Agency EEO officials, the Equal Employment Opportunity Commission (EEOC), or a court of competent jurisdiction.

(2) Contractor employee means all current Contractor employees who work or worked under this contract. The term also includes current employees of subcontractors who work or worked under this contract. In the case of Contractor and subcontractor employees, who worked under this contract, but who are no longer employed by the Contractor or subcontractor, or who have been assigned to another entity within the Contractor's or subcontractor's organization, the Contractor shall provide the Agency with that employee's last known mailing address, e-mail address, and telephone number, if that employee has been identified as a witness in an EEO complaint or investigation.

(3) Good faith cooperation cited in paragraph (a) includes, but is not limited to, making Contractor employees available for:

(i) Formal and informal interviews by EEO counselors or other Agency officials processing EEO complaints;

(ii) Formal or informal interviews by EEO investigators charged with investigating complaints of unlawful discrimination filed by Federal employees;

(iii) Reviewing and signing appropriate affidavits or declarations summarizing statements provided by such Contractor employees during the course of EEO investigations;

(iv) Producing documents requested by EEO counselors, EEO investigators, Agency employees, or the EEOC in connection with a pending EEO complaint; and

(v) Preparing for and providing testimony in depositions or in hearings before the MSPB, EEOC and U.S. District Court.

(b) The Contractor shall include the provisions of this clause in all subcontract solicitations and subcontracts awarded at any tier under this contract.

(c) Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause may be grounds for the Contracting Officer to terminate this contract for default.

(End of clause)

HHSAR 352.224-71 CONFIDENTIAL INFORMATION (DEC 2015)

(a) Confidential Information, as used in this clause, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
(b) Specific information or categories of information that the Government will furnish to the Contractor, or that the Contractor is expected to generate, which are confidential may be identified elsewhere in this contract. The Contracting Officer may modify this contract to identify Confidential Information from time to time during performance.
(c) Confidential Information or records shall not be disclosed by the Contractor until:
(1) Written advance notice of at least 45 days shall be provided to the Contracting Officer of the Contractor's intent to release findings of studies or research, to which an agency response may be appropriate to protect the public interest or that of the agency.
(2) For information provided by or on behalf of the government,
(i) The publication or dissemination of the following types of information are restricted under this contract:
Source selection information
Any information contained within the following:

- PSC acquisitions
- Prism contract writing system
- Other acquisition systems providing protected data

All data from these systems, all physical contract files and any acquisition system implemented during the course of this contract will need to be kept restricted within specific OHR groups.
(ii) The reason(s) for restricting the types of information identified in subparagraph (i) is/are: Exemption #2 under the Freedom of Information Act: Information related solely to the internal personnel rules and practices of an agency.

(iii) Written advance notice of at least 45 days shall be provided to the Contracting Officer of the Contractor's intent to disseminate or publish information identified in subparagraph (2)(i). The contractor shall not disseminate or publish such information without the written consent of the Contracting Officer.

(d) Whenever the Contractor is uncertain with regard to the confidentiality of or a property interest in information under this contract, the Contractor should consult with the Contracting Officer prior to any release, disclosure, dissemination, or publication.

(End of clause)

HHSAR 352.232-71, Electronic Submission of Payment Requests (DEC 2015)

(a) Definitions. As used in this clause-
Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.
(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.
(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.
(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(End of clause)

FOOD & DRUG ADMINISTRATION (FDA) REQUIREMENTS

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.

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
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

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 shall 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.

K. OFFEROR'S CERTIFICATION

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 no actual, potential, or apparent COI on the part of either the Contractor's organization or its individual employees in performance of this contract.

Offeror(s) submitting proposal(s) 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 contract 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, found to be acceptable by the Government, and enforced.

(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 cause, 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

(j) POTENTIAL CONFLICTS OF INTEREST SPECIFIC TO THIS CONTRACT - Offerors shall review the Statement of Work included in each RFTOP in detail to identify any 47 particular aspects that may present organizational or individual COI, either actual or apparent.

(k) 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).

PERSONNEL

The Contractor shall ensure that all Contractor support personnel are adequately trained and are otherwise fully qualified to provide the high level of support required by this contract prior to being assigned to orders awarded.

NON-PERSONAL SERVICES AND INHERENTLY GOVERNMENT FUNCTIONS

Pursuant to FAR 37.1, no personal services shall be performed under this contract. All work requirements shall flow only from the Project Officer to the Contractor's Project Manager. 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.

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 insure 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.

L. INSTRUCTIONS TO OFFEROR

QUESTIONS SUBMITTAL INSTRUCTIONS

Offeror(s) may submit questions for clarification in reference to any areas of the solicitation using Attachment F (RFQ Question Template). Questions must be submitted via email to Food and Drug Administration/OAGS: Lillian Lamb, Contracting Officer, lillian.lamb@fda.hhs.gov. The subject line of the email must read: **Contractor Questions –FDA 75F40124Q00047.**

Questions submitted by any other means will not be accepted. Questions must identify the applicable section of the solicitation. Questions will be answered in an amendment to the solicitation. Questions will not be discussed over the phone.

All questions must be submitted by **4:00 PM Eastern time (ET) on May 16, 2024**. Questions submitted after the due date and time may not be answered.

Offerors will receive a confirmation email within two (2) business days that their questions were received. If an offeror does not receive a confirmation email within two (2) business days, it is their responsibility to

follow up with the contract specialist to ensure their questions were received.

QUOTE SUBMITTAL DUE DATE

Your quote is due no later than **4:00 PM Eastern time (ET) on May 23, 2024** and shall contain the signed DD 1449 and also acknowledgement of any amendments to the solicitation. Quotes must be submitted via email to Food and Drug Administration/OAGS: Lillian Lamb, Contracting Officer, at lillian.lamb@fda.hhs.gov.

The subject line of the email must read: **FDA-75F40123Q00047 3D Microscopy, Artificial Intelligence-based Quantification, and Modeling for Non-Clinical Evaluation and Regulatory Support of Complex Drug Products.** If submitting multiple emails, the subject line must clearly identify the total number of emails and which sequence the submission is for. All emails providing proposal submission must be received by the due date and time. The late submission instruction found in FAR provision 52.212-1(f) regarding electronic submissions, applies to this solicitation. Please submit in advance for timely submission of your quote.

PROPOSAL FORMAT AND SUBMITTAL REQUIREMENTS

Offeror(s) shall submit four (4) quote volumes as further detailed below:

- Volume 1 Executive Summary (No page limitation)
- Volume 2: Technical Proposal (Page limitation – 50 pages)
- Volume 3: Past Performance (Past 3 years)
- Volume 4: Price Proposal (Attachment D, Excel Spreadsheet)

Each proposal Volume must include a cover sheet which clearly identifies each by volume number, solicitation number (**75F40124Q00047**) and the date of submission. The pages of the Offeror's proposal must include page headers with the same information and page numbers. The Offeror must submit each volume in its native format (e.g., Microsoft Word, Excel) and PDF format. The offeror or applicant shall submit all electronic documents for Microsoft Office suite products without the use of "macros". When submitting proposals via email, DO NOT include .exe, .mso, or any other executable file types that could potentially trigger email security protections (i.e. email blocks, quarantine). If the offeror or applicant submits documents that contain macros, macro referenced files, and/or executable files, 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 or applicant to correct the document submission and the Government will not inform the offeror or applicant that their submission is non-responsive prior to award. It is the offeror's or applicant's responsibility to ensure all electronic documents are submitted without the use of macros.

M. EVALUATION FACTORS FOR AWARD

BASIS FOR AWARD AND EVALUATION FACTORS

(a) Basis for Award – This will be a best value selection conducted using the FAR 15.101-1 **Tradeoff** process. The Government intends to award one (1) award IDIQ resulting from this solicitation; however, the Government reserves the right not to award a contract at all. The award resulting from this solicitation will be made to the responsible offeror whose offer, conforming to this solicitation, is determined to be the best value to the Government, technical, price and other factors considered.

For the purposes of the solicitation, non-price factors are significantly more important than the price factors. The Government reserves the right to make an award to other than the lowest priced offeror or the highest technically rated offeror. The Government also reserves the right to award without discussions and to make an award based upon initial offers; thus, offerors should ensure that their initial quote represents their best offer.

A quote which merely paraphrases the requirements stated in the Statement of Work (SOW) will be ineligible for award. In addition, a proposal that addresses only a part of the requirements will be considered nonresponsive to the solicitation and unacceptable for award.

EVALUATION FACTORS

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 Government will make award to the Offeror(s), whose proposal(s) represents the best value to the Government. The following factors, listed in order of importance, will be considered: Technical Approach and Price.

1. Technical Approach

The offeror shall provide a brief narrative description of the offeror's general capability and approach to conduct imaging characterization on various complex products and perform artificial intelligence (AI) based image analysis. The offeror shall address their technical understanding and analytical capabilities to perform the research as well as identify any risks it foresees in the execution of their approach, and mitigation strategies to be employed for those risks.

The offeror shall also provide a narrative description of all complex products that can be characterized with relevant supportive preliminary data/information if available. As a minimal, the offeror should be able to 1) conduct imaging characterization on polymeric solid implants, microspheres, and intrauterine systems using multiple imaging techniques including, but not limited to focused ion beam-scanning electron microscopy and X-ray, 2) analyze imaging data using artificial intelligence (AI) based quantification. In addition, it is desired if the offeror can also demonstrate their capability to develop image-based in silico release modeling tools. The offeror shall address any research study obstacles, performance risks, and/or schedule delays it foresees in their approach and the mitigation strategies to be employed for those risks.

Key Personnel

The Offeror shall provide its staffing plan and identify key personnel, integral to the performance of this requirement. The staffing plan should consist of individuals with the necessary education, experience and skills necessary to complete the work. Offerors shall submit resumes of all Key Personnel proposed along with letters of commitment. Resumes should not only reference academic qualifications, but also length and variety of experience in performing similar tasks, and relevant training experience. Additionally, the Offerors shall:

a) Demonstrate having the necessary staff with the skills and experience on imaging characterization using various advanced imaging techniques and AI based image analysis and in silico modeling.
b) Include a description of the labor categories with roles and responsibilities, including a realistic estimate of the level of effort and workload balancing.
c) Demonstrate that qualified resources are available at the start of and throughout the Period of Performance;
d) If sub-contractors are proposed, information shall be provided to support the qualifications of the

sub-contractors, along with letters of commitments.

2. Past Performance
   The Offerors past performance information shall demonstrate the Offerors success in performing comparable contracts/orders. Past performance shall be based on the provided list of two contracts/orders, similar in scope, duration, and price to the work described in the SOW.

   The Government will assess the relative risks associated with each offer. Performance risks are those associated with an Offerors likelihood of success in performing the acquisition requirements as indicated by that Offerors record of past performance.

   The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the Offerors performance.

   The lack of a past performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the Offeror.

3. Price
   The business proposal/price evaluation shall represent the Offerors response to the requirements of the solicitation. The price evaluation consists of the combination of all proposed pricing over the contract's performance period. The Offerors pricing schedules shall represent firm fixed-pricing.

EVALUATION ADJECTIVAL RATINGS

3D Microscopy, Artificial Intelligence-based Quantification, and Modeling for Non-Clinical Evaluation and Regulatory Support of Complex Drug Products

The evaluation system used by the Government this RFQ is as follows; the proposal will be evaluated using adjectival ratings (Excellent, Very Good, Acceptable and Unacceptable).

Category	Definition
Excellent	The Offeror **convincingly demonstrates** that the RFQ requirements have been analyzed, evaluated, and synthesized into proposed approaches, plans, and techniques that, when implemented, ***will result*** in **superior and efficient performance**. The proposal has **significant strengths**, which indicate beneficial features or innovations that will substantially benefit the program. The proposal has **no significant weaknesses**. Any minor weaknesses are insignificant when compared to the strengths.
Very Good	The Offeror **demonstrates** that the RFQ requirements have been analyzed, evaluated, and synthesized into proposed approaches, plans, and techniques that, when implemented, ***should result*** in **effective and efficient performance**. The proposal has **significant strengths** and/or **several minor strengths**, which indicate a proposed approach that will benefit the program. The proposal has **few weaknesses**, and the **strengths** of the proposal **more than offset any weaknesses**.
Acceptable	The Offeror **demonstrates** that the RFQ requirements have been analyzed, evaluated, and synthesized into proposed approaches, plans, and techniques that, when implemented, ***should result*** in **adequate performance**. The proposal has **modest strengths**. The **weaknesses** in the proposal **are offset by the strengths**.
Unacceptable	The Offeror **demonstrates a superficial, incomplete, or incorrect understanding** of the RFQ requirements, resulting in proposed approaches, plans, and techniques that are **deficient** and ***should result*** in **poor performance** when implemented. The proposal has **few strengths**. The proposal has **significant weaknesses** and/or many minor weaknesses that are **not offset by strengths**.

LIST OF ATTACHMENTS

Attachment A – FAR Class Deviation 2020-05 (PDF)
Attachment B – FAR Provision 52.212-3 (PDF)
Attachment C – Statement of Work (PDF)
Attachment D – IDIQ Pricing Schedule (Separate, fillable Excel spreadsheet)

Attachment E – Contractor Personnel Security Clearance Standards and Residency Requirements for Foreign Nationals (Attached below)
Attachment F – RFQ Question Template (Separate, fillable Excel spreadsheet)
Attachment G – FAR Clause 52.212-5 (PDF)

Attachment F

Contractor Personnel Security Clearance Standards and Residency Requirements for Foreign Nationals

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 shall submit the following items to the Contracting Officer's Representative (COR), within 5 business days of commencement of work under this contract:

   a. A roster of contractor employee names, identifying Key Personnel and Tier designation(s)

   b. A confirmation that all individual employee security information has been submitted properly.

   c. "Contractor's Commitment to Protect Non-public Information Agreement" forms signed by each employee named in the roster.

Pursuant to HSPD-12, the Contractor shall 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 shall 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.

3. 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 shall advise the FDA Personnel Security Staff of the details of such clearance.

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

4. PROCESS - 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 badging 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 Position Risk Designation for this contract is Tier 2.

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

a. 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. Contractor employees assigned to Tier 1 who receive a favorable security screening and are to be issued a PIV card will be required to provide security information as specified in Paragraph 4 below.

b. 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. The forms set forth by the FDA Personnel Security Specialist are

required for Public Trust Positions. Contractor employees assigned Tier 2 or 4 must complete a favorable background investigation suitable for the issuance of a PIV card.

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.

5. PERSONAL IDENTITY VERIFICATION (PIV) CARDS - All PIV Cards or any other type of Government-issued security badge 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 shall 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 shall immediately return the PIV Card(s) to the COR.

   Because Government-issued security badges 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. 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.

6. BADGING 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 shall 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 badge. One form of identification must be a government-issued photo identification document. Acceptable forms of identification are listed in Appendix 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.

7. 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 three (3) of the past five (5) years. [Note: the residency requirement applies only to foreign nationals.] Quoters/Contractors are strongly advised to inquire of any prospective foreign national hires as to whether or not they have resided in the U.S. for a total of three (3) of the past five (5) years. **If any foreign national prospective hires cannot meet the residency requirement, they cannot qualify for PIV cards under HSPD-12**.

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

***Upon a favorable fingerprint return, the Contractor will be notified to return to the badging 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
Phone: (301) 796-4000

Attachment E Chart

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
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		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:		
		10. School record or report card		
		11. Clinic, doctor, or hospital record		
		12. Day-care or nursery school record		