Notice of Intent to Sole Source - Training Courses for Advanced Model-informed Drug Development (MIDD) Program

The U.S. Food and Drug Administration (FDA) intends to solicit a sole source, firm-fixed-price type purchase order from University of Florida, 1523 Union RD RM207, Gainesville, FL, 32611-1941, in accordance with the authority under Federal Acquisition Regulation (FAR) 13.501(a)(1)(ii). This procurement will be conducted using FAR subpart 13.5 Simplified Procedures for Certain Commercial Products and Commercial Services in accordance with 41 U.S. Code § 1901. The North American Industry Classification System (NAICS) code is 611430 - Professional and Management Development Training. The anticipated period of performance consists of one (1) 5-month period beginning January 2025.

The Office of Clinical Pharmacology (OCP) is dedicated to strengthening training programs and clearly defining roles to advance its core mission in clinical pharmacology. With the PDUFA VIII reauthorization, OCP's mission has expanded to focus on optimizing data, analytics, and resources to enable more informed decision-making in evaluating human drug applications. This approach emphasizes quantitative clinical pharmacology and model-informed drug development (MIDD) to enhance recommendations and improve the drug review process, aligning with the Center for Drug Evaluation and Research's (CDER) public health goals. To support this mission, OCP is committed to developing staff skills in innovation, strategic planning, modeling, and decision-making to set foundational goals and directions across key areas such as dosing, safety, and efficacy, while fostering cross-functional collaboration within the FDA.

The objective of the proposed contract action is to enhance decision-making, optimize drug dosing, and improve overall drug efficacy and safety assessments requirement include the following advanced Clinical Pharmacology specific trainings:

Model-informed drug development (MIDD) is a field that uses mathematical modeling and simulations to predict drug behavior and optimize drug development processes. This approach is highly valued in regulatory science and is commonly applied in pharmacokinetics, pharmacodynamics, and clinical pharmacology.

The University of Florida (UF) is the sole provider that meets the outlined OCP training requirements due to the unique, comprehensive, and specialized offerings of its MIDD (Model-Informed Drug Development) Program.

The UF's MIDD Program is uniquely positioned to meet the precise educational and practical training requirements for OCP staff. The specialized nature of its courses, combined with their alignment to the regulatory mission and the broad spectrum of covered tools and techniques, makes UF the only vendor capable of fulfilling these needs effectively. While there are other pharmacokinetics/pharmacodynamics training programs, none match UF's combination of: industry relevance, specificity in regulatory applications, and comprehensive software training. UF's program is designed with an explicit focus on regulatory science, addressing gaps in expertise that other vendors do not cover comprehensively.

The courses offered by UF directly align with the mission of the Office of Clinical Pharmacology (OCP) to advance knowledge in pharmacokinetics and pharmacodynamics for regulatory and clinical decision-making. Population Pharmacokinetics and Pharmacodynamics and Introduction to Physiologically Based

Modeling address critical knowledge areas required to develop, evaluate, and apply advanced PK/PD and PBPK models in real-world drug development scenarios. The courses provide a balance of theoretical understanding and hands on applications, which ensures trainees are not only conceptually equipped but also practically adept in using advanced modeling tools. Exposure to multiple industry-standard software platforms, including Monolix, Pumas, and Phoenix for PK/PD modeling and PBPK tools, ensures participants are well-prepared to tackle the software-specific challenges in regulatory and clinical environments. This broad exposure enhances the ability to interpret and apply model-informed strategies, a necessity for fulfilling OCP's regulatory mission. The emphasis on Monte Carlo simulation, nonlinear mixed-effects modeling, and PBPK-specific steps ensures that trainees understand cutting-edge methodologies.

This notice is not a request for competitive quotes. However, any party that believes it is capable of meeting the requirements as stated herein may submit a written response (i.e., capability statement) which clearly supports and demonstrates its ability to perform the requirements. Any response must be received by the response date and time set forth in this notice. Any response will undergo a review to determine if the respondent can meet the requirements. A determination by the Government not to compete this proposed requirement based upon a response to this notice is solely within the discretion of the Government.

Response Date and Time: 2:00 p.m. ET on December 3rd, 2024. Responses must be emailed to Lawrence Edelmann at Lawrence.edelmann@fda.hhs.gov, with a CC: to Nicholas Bisher at Nicholas.Bisher@fda.hhs.gov.

1. DESCRIPTION/COMMERICAL ITEM PROCUREMENT

This is Request for Quotation (RFQ) No. 75F40125Q00044 for commercial services in accordance with the procedures of FAR Part 12 - Acquisition of Commercial Products and Commercial Services, and FAR Subpart 13.5- Simplified Procedures for Certain Commercial Products and Commercial Services.

The associated North American Industry Classification System (NAICS) code is 611430 - Professional and Management Development Training. The associated small business size standard is $15.0 million.

2. NOTICE OF FAC

This solicitation document incorporates provisions and clauses in effect through Federal Acquisition Circular (FAC) 2023-04, effective August 29, 2024.

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

The Department of Health and Human Services (HHS) 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

3. PURCHASE ORDER REQUIREMENTS

See Section 7, **Statement of Work,** for a full description of the services to be acquired.

4. ORDER TYPE

The Government anticipates awarding one (1) Firm-Fixed-Price (FFP) type Purchase Order.

5. PERIOD OF PERFORMANCE

The anticipated period of performance is the Spring Semester 2025:
January 3, 2025 through May 2, 2025

6. PRICING

See Attachment A – Pricing Table

7. STATEMENT OF WORK

Project Title: Training courses for advanced 'model-informed drug development (MIDD)' program from University of Florida for review staff in Office of Clinical Pharmacology (OCP)

1. BACKGROUND

The Office of Clinical Pharmacology (OCP) is dedicated to strengthening training programs and clearly defining roles to advance its core mission in clinical pharmacology. With the PDUFA VIII reauthorization, OCP's mission has expanded to focus on optimizing data, analytics, and resources to enable more informed decision-making in evaluating human drug applications. This approach emphasizes quantitative clinical pharmacology and model-informed drug development (MIDD) to enhance recommendations and improve the drug review process, aligning with the Center for Drug Evaluation and Research's (CDER) public health goals. To support this mission, OCP is committed to developing staff skills in innovation, strategic planning, modeling, and decision-making to set foundational goals and directions across key areas such as dosing, safety, and efficacy, while fostering cross-functional collaboration within the FDA.

2. OBJECTIVES

For OCP staff to enhance decision-making, optimize drug dosing, and improve overall drug efficacy and safety assessments requirement include the following advanced Clinical Pharmacology specific trainings:

- Model-informed drug development (MIDD) that is a field that uses mathematical modeling and simulations to predict drug behavior and optimize drug development processes. This approach is highly valued in regulatory science and is commonly applied in pharmacokinetics, pharmacodynamics, and clinical pharmacology.

3. SCOPE

Training courses from University of Florida program based on Market Research document, for OCP review staff is designed to address the following SPRING semester three credit two topics:

PHA 6131 Introduction to Physiologically-Based Modeling
PHA 6122 Population Pharmacokinetics and Pharmacodynamics

• Model-informed drug development (MIDD) serves as a broad overview of applying modeling and simulation strategies to improve drug development decision-making and trial designs and enables to apply the following concepts:

Discuss and appreciate the role of model-informed drug development during the following stages: discovery, preclinical, clinical, regulatory review, and post-approval.

Identify specific drug development questions or issues that can be addressed using MIDD.

Select and apply pharmacometrics method(s) used in MIDD: population PK or PK-PD, clinical trial simulation, meta-analysis, systems pharmacology, PBPK, etc.

Contrast MIDD applications to support regulatory agency decisions versus drug development decisions within the pharmaceutical industry.

Understand the development strategies for various therapeutic areas and identify the question that needed to be answered using MIDD

Describe MIDD approaches used to answer the above question: e.g., modeling, simulation, results, key assumptions, and uncertainties.

Explain the impact of MIDD on specific drug development examples and regulatory decisions or interactions.

Apply MIDD concepts to all Phase(s) of drug development: preclinical, Phase 1, 2, 3, regulatory agency interactions, and post-regulatory approval.

Explain the critical aspects of conducting clinical trials, including human subject protections, Phase 1, 2, and 3 trials, regulatory requirements, and clinical data management.

Answer specific drug development questions or issues that MIDD can address dose selection, trial design for Phase 1, 2, or 3, go/no go, labeling, development strategy, avoiding the need to conduct a clinical trial, selecting between compounds in development, etc.

Apply MIDD to various therapeutic areas: cardiovascular, neuroscience, metabolic diseases, oncology, rare diseases, etc.

4. DELIVERABLES / SPECIFIC TASKS

Deliverables	Training Program: Estimated Quantity/Frequency/COST	Training invoice or Delivery Date
OCP staff - (up to 12 students, 1 course per student) between the two training courses at 3 credits each.		
Spring 2025, two clinical pharmacology MIDD program training courses for up to 12 students (1 course per student).	PHA 6131 Introduction to Physiologically-Based Modeling College of Pharmacy » University of Florida (ufl.edu) 3 credit courses PHA 6122 Population Pharmacokinetics and Pharmacodynamics College of Pharmacy » University of Florida (ufl.edu) 3 credit courses	Jan -April 2025

THE BREAKDOWN OF STUDENTS PER COURSE WILL BE DETERMINED BY THEIR INDIVIDUAL REGISTRATIONS.

5. GOVERNMENT FURNISHED EQUIPMENT (GFE)/ GOVERNMENT FURNISHED INFORMATION (GFI)

Contractor is not provided any Government furnished property. OCP staff/management schedules use of conference rooms and equipment at FDA White Oak campus to conduct meetings, face to face and briefings.

6. TRAVEL

OCP Staff work from FDA White Oak campus or designated duty station through virtual training or in person. No contractor travel is anticipated for this requirement.

7. SPECIAL MATERIAL REQUIREMENTS

Any software required on FDA client computers, or in FDA data centers, shall not conflict with FDA technical standards. FDA's Master Approved Technology List (MAT) contains a list of approved and not approved technologies, including applications (software), infrastructure and peripherals (hardware), and scientific software and devices.

8. SERVICE PERFORMANCE & LOCATION

Satisfactory performance of this contract shall be deemed to occur upon performance of the work described in Section 3 of this statement of work and upon acceptance of all services required.

Training will be on-line/virtual.

9. PERIOD OF PERFORMANCE

The period of performance for this requirement shall be:

Base Period: January 3, 2025 - May 2, 2025

10. CONTRACT TYPE

This will be a Firm Fixed Price (FFP) type contract.

11. GOVERNMENT POINTS OF CONTACT

Contracting Officer's Representative (COR)
Name: Padmaja Mummaneni
Phone: 301-796-2027
Email: Padmaja.mummaneni@fda.hhs.gov

Contracting Officer (CO)
Name: Nicholas Bisher
Phone: 240-402-2773
Email: Nicholas.Bisher@fda.hhs.gov

Contract Specialist (CS)
Name: Lawrence Edelmann
Phone: 240-402-9179
Email: Lawrence.Edelmann@fda.hhs.gov

12. 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 contractor or become a part of the Government organization.

13. PROCUREMENTS REQUIRING INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY

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.

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:** [X] Low [ ] Moderate [ ] High
- **Integrity:** [X] Low [ ] 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) and the Contracting Officer's Representative (COR) 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.

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/Purchase Order 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.

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/Purchase Order (e.g. tier 1, 2, or 4): N/A

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/EPLCHome.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.

14. CONFORMANCE WITH APPLICABLE LAWS, REGULATIONS, POLICIES, AND STANDARDS

a. Contractor Compliance

The Contractor shall be responsible for knowledge of and compliance with all applicable federal information technology and information management laws, regulations, policies, and standards at the government-wide, HHS, and FDA levels. At the government-wide level, these include Office of Management and Budget (OMB), National Institute of Standards and Technology (NIST), and General Accounting Office (GAO). These can be primarily found at or through the Federal CIO Council website at: http://www.cio.gov/. HHS documents are found at: http://www.hhs.gov/oirm/.

b. Section 508 Standard Requirements

The Contractor should be familiar with Section 508 requirements as described at http://www.section508.gov/ in order to ensure that documents generated as part of the tasks are fully Section 508-accessible using the available COTS tools.
508 Standard Requirements include:

1194.21 Software applications and operating systems (a – l)
1194.22 Web-based intranet and internet information and applications (a - p)
1194.31 Functional performance criteria (a – f)

All electronic and information technology (EIT) must meet the applicable accessibility standards at 36 CFR 1194, unless an agency exception to this requirement exists. 36 CFR 1194 implements Section 508 of the Rehabilitation Act of 1973, as amended, and is viewable at http://www.accessboard.gov/sec508/508standards.htm - Part 1194

Contract Administration Data

Contracting Officer:

Nicholas Bisher
FDA/OO/OFBAP/OAGS/DAO/SCB
Nicholas.Bisher@fda.hhs.gov

Contract Specialist:

Lawrence Edelmann

FDA/OO/OFBAP/OAGS/DAO/SCB
Lawrence.Edelmann@fda.hhs.gov

Contracting Officer's Representative:
Name: Padmaja Mummaneni
Phone: 301-796-2027
Padmaja.Mummaneni@fda.hhs.gov

Contracting Officer's Authority

The Contracting Officer (CO) has responsibility for 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 purchase order and is the only person authorized to approve changes to any of the requirements under this order, and notwithstanding any provision contained elsewhere in this purchase order, this authority remains solely with the CO.

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

Contracting Officer's Representative (COR)

The Contracting Officer may designate other Government personnel, known as the Contracting Officer's Representative (COR) to act as his or her authorized representative for contract administration functions which do not involve changes to the scope, price, schedule, or terms and conditions of the purchase 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 purchase order. Such designation will not contain authority to sign contractual documents, purchase 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 purchase 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 purchase 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 purchase order, approval of technical reports, drawings, specifications, and technical information to be delivered by the Contractor to the Government under the purchase order.

Technical direction must be within the general scope of work stated in this purchase order. The COR does not have the authority to and may not issue any technical direction which:

- Constitutes an assignment of additional work outside this purchase order.
- In any manner cause an increase or decrease in the total purchase order price or the time required for purchase order performance.
- Change any of the expressed terms, conditions, or specifications of the purchase 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.

The Contractor shall proceed promptly with the performance of technical direction duly issued by the COR in the manner prescribed by this article and within his/her authority under the provisions of this article.

If, in the opinion of the Contractor, any instructions or direction issued by the COR is within one of the categories described above, the Contractor shall not proceed but shall notify the Contracting Officer in writing within 5 working days after the receipt of any such instructions or direction and shall request the Contracting Officer issue a formal modification accordingly. Upon receiving such notification from the Contractor, the Contracting Officer shall issue an appropriate formal remedy or advise the Contractor in writing that, in his/her opinion, the technical direction is within the scope of the purchase order.

The Contractor shall immediately contact the Contracting Officer if there is any question regarding the authority of an individual to act on behalf of the Contracting Officer under this purchase order.

The Government may unilaterally change its COR designation.

The following person has been appointed as the purchase order COR:

Name: Padmaja Mummaneni
Phone: 301-796-2027
Padmaja.Mummaneni@fda.hhs.gov

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.

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): http://www.acquisition.gov/comp/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) PROVISIONS:

NUMBER	TITLE	DATE
52.203-18	PROHIBITION ON CONTRACTING WITH ENTITIES THAT REQUIRE CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS OR STATEMENTS - REPRESENTATION	JAN 2017
52.204-7	SYSTEM FOR AWARD MANAGEMENT	OCT 2018
52.204-16	COMMERCIAL AND GOVERNMENT ENTITY CODE REPORTING	AUG 2020
52.204-17	OWNERSHIP OR CONTROL OF OFFEROR	AUG 2020
52.204-24	REPRESENTATION REGARDING CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT	NOV 2021
52.204-26	COVERED TELECOMMUNICATIONS EQUIPMENT OR SERVICES-REPRESENTATION	OCT 2020
52.209-2	PROHIBITION ON CONTRACTING WITH INVERTED DOMESTIC CORPORATIONS-REPRESENTATION	NOV 2015
52-212-1	INSTRUCTIONS TO OFFERORS – COMMERCIAL PRODUCTS AND SERVICES	MAR 2023

FAR 52.212-3 Offeror Representations and Certifications-Commercial Items (Jun 2020)
This provision applies to this solicitation. Offerors shall provide the required data with their quotations in accordance with FAR 52.212-3. (Please include Completed representations and certifications, not already completed in SAM.gov.)

FAR PROVISIONS INCORPORATED BY FULL TEXT:

FAR 52.216-1 TYPE OF CONTRACT (APR 1984)

The Government contemplates award of a Firm-Fixed-Price (FFP) type Purchase Order resulting from this solicitation.

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

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: https://www.acquisition.gov/browse/index/far.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSES:

NUMBER	TITLE	DATE
52.204-13	SYSTEM FOR AWARD MANAGEMENT MAINTENANCE	OCT 2019
52.204-18	COMMERCIAL AND GOVERNMENT ENTITY CODE MAINTENANCE	AUG 2020
52.204-19	INCORPORATION BY REFERENCE OF REPRESENTATIONS AND CERTIFICATIONS	DEC 2014

52.212-4	CONTRACT TERMS AND CONDITIONS—COMMERCIAL ITEMS	DEC 2022
52.226-7	DRUG-FREE WORKPLACE	MAY 2024
52.226-8	ENCOURAGING CONTRACTOR POLICIES TO BAN TEXT MESSAGING WHILE DRIVING	MAY 2024
52.232-1	PAYMENTS	APR 1984
52.232-23	ASSIGNMENT OF CLAIMS	MAY 2014
52.232-39	UNENFORCEABILITY OF UNAUTHORIZED OBLIGATIONS	JUN 2013
52.232-40	PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS CONTRACTORS	MAR 2023
52.233-1	DISPUTES	MAY 2014
52.233-4	APPLICABLE LAW FOR BREACH OF CONTRACT CLAIM	OCT 2004
52.242-15	STOP-WORK ORDER ALTERNATE I (APR 1984)	AUG 1989
52.242-17	GOVERNMENT DELAY OF WORK	APR 1984
52.243-1	CHANGES-FIXED-PRICE	AUG 1987
52.243-1	CHANGES-FIXED-PRICE, ALT I	APR 1984
52.246-4	INSPECTION OF SERVICES—FIXED-PRICE	AUG 1996
52.246-25	LIMITATION OF LIABILITY-SERVICES	FEB 1997
52.249-1	TERMINATION FOR CONVENIENCE OF THE GOVERNMENT (FIXED-PRICE) (SHORT FORM)	APR 1984

FAR 52.212-5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items (June 2023)
The additional FAR clauses cited in this clause that have an "X" next to them are applicable to this solicitation. Full text of this clause is provided in (Attachment B).

FAR CLAUSES IN FULL TEXT:

52.203-19 Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017)

(a) Definitions. As used in this clause-

Internal confidentiality agreement or statement means a confidentiality agreement or any other written statement that the contractor requires any of its employees or subcontractors to sign regarding nondisclosure of contractor information, except that it does not include confidentiality agreements arising out of civil litigation or confidentiality agreements that contractor employees or subcontractors sign at the behest of a Federal agency.

Subcontract means any contract as defined in subpart 2.1 entered into by a subcontractor to furnish supplies or services for performance of a prime contract or a subcontract. It includes but is not limited to purchase orders, and changes and modifications to purchase orders.

Subcontractor means any supplier, distributor, vendor, or firm (including a consultant) that furnishes supplies or services to or for a prime contractor or another subcontractor.

(b) The Contractor shall not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (e.g., agency Office of the Inspector General).

(c) The Contractor shall notify current employees and subcontractors that prohibitions and restrictions of any preexisting internal confidentiality agreements or statements covered by this clause, to the extent that such prohibitions and restrictions are inconsistent with the prohibitions of this clause, are no longer in effect.

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

(e) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015, (Pub. L. 113-235), and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions) use of funds appropriated (or otherwise made available) is prohibited, if the Government determines that the Contractor is not in compliance with the provisions of this clause.

(f) The Contractor shall include the substance of this clause, including this paragraph (f), in subcontracts under such contracts.

(End of clause)

FAR 52.204-21 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)

FAR 52.204-27 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.

Health and Human Services Acquisition Regulation (HHSAR) Provisions and Clauses

DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) PROVISIONS AND CLAUSES IN FULL TEXT:

HHSAR Clauses can be viewed in full text at: https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/part-352-solicitation-provisions-contract-clauses/index.html

HHSAR Clauses incorporated by reference:

HHSAR 352.222-70 Contractor Cooperation in Equal Employment Opportunity Investigations (December 18, 2015)

HHSAR 352.224-71 Confidential Information (December 18, 2015)

HHSAR Provisions Incorporated in Full Text:

HHSAR 352.232-71 Electronic Submission of Payment Requests (FEB 2022)

(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)

HHSAR 352.239-73 Electronic and Information Technology Accessibility Notice (December 18, 2015)

(a) Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

(b) Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of the Section 508 Final Provisions can be accessed at http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards.

(c) The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility.

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document—in detail—whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS website http://www.hhs.gov/web/508.

In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

(d) Respondents to this solicitation must identify any exception to Section 508 requirements. If an offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

HHSAR 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 Purchase order are:

- Must meet WCAG 2.0 A and AA
- E101.2 Equivalent Facilitation (Appendix A, Application and Scoping Requirements)
- E203 Access to Functionality (Appendix A, Application and Scoping Requirements)
- E204 Functional Performance Criteria (Appendix A, Application and Scoping Requirements)
- E205 Electronic Content (Appendix A, Application and Scoping Requirements)
- 302 Functional Performance Criteria (Appendix C, Functional Performance Criteria and Technical Requirements)
- Electronic content must be accessible to HHS acceptance criteria. Checklists for various formats are available at https://www.hhs.gov/web/section-508/accessibility-checklists/index.html, https://www.fda.gov/about-fda/accessibility-fda/accessibility-guidance-and-checklists, or from the Section 508 Coordinator listed at https://www.fda.gov/about-fda/about-website/accessibility-fda. Materials that are final items for delivery should be accompanied by the appropriate checklist, except upon approval of the Contracting Officer or Contracting Officer's Representative.
- E208 Support Documentation and Services (Appendix A, Application and Scoping Requirements)
- Chapter 6 Support Documentation and Services (Appendix C, Functional Performance Criteria and Technical Requirements)

(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.

FDA Clauses Incorporated in Full Text

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 FAR 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 purchase

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.

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. 2002

Identification of Vendor Employees
During the period of this purchase order, the rights of ingress and egress to and from any Government office for Vendor representatives shall be made available as required. All Vendor employees whose duties under this purchase order 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 Vendor personnel. All on-site Vendor personnel shall abide by security regulations applicable to that site.

Notice to the Government of Delays
In the event the Vendor encounters difficulty in meeting performance requirements, or when the Vendor anticipates difficulty in complying with the purchase order delivery schedule or completion date, or whenever the Vendor has knowledge that any actual or potential situation is delaying or threatens to delay the timely performance of this purchase order, the Vendor 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 purchase order.

Insurance Requirements
The Vendor shall maintain the types of insurance and coverage required in FAR 28.307-2.

Vendor Conformance with Applicable Laws, Regulations, Policies, and Standards
The Vendor shall be responsible for knowledge of and compliance with all applicable federal information technology and information management laws, regulations, policies and standards at the government-wide, HHS and FDA levels.

Quotation Preparation Instructions

Prospective Contractors may submit a quotation that will be considered by the Agency. Quotations must be submitted no later than **2:00 PM, Eastern Time**, **December 3, 2024.** Quotations shall be submitted electronically via email to the Contract Specialist, Lawrence Edelmann, at Lawrence.Edelmann@fda.hhs.gov (with a CC to Nicholas.Bisher@fda.hhs.gov). The subject line shall read: **Request for Quotations (RFQ) No. 75F40125Q00044 - Training Courses for Advanced Model-informed Drug Development (MIDD) Program.**

Late submissions may not be evaluated. Fax submissions are NOT authorized. Requests for information concerning this requirement must be submitted in writing and must be e-mailed to the above Contract Specialist's e-mail addresses.

Offerors must submit all questions regarding the RFQ to Lawrence Edelmann, at Lawrence.Edelmann@fda.hhs.gov (with a CC to Nicholas.Bisher@fda.hhs.gov). The FDA must receive any **questions no later than 2:00 PM, Eastern Time, December 6, 2024.** The subject line shall read: **Request for Quotations (RFQ) No. 75F40125Q00044 - Training Courses for Advanced Model-informed Drug Development (MIDD) Program**. FDA may not answer questions received after this date and time, and will not answer questions submitted to individuals other than the named contacts. It is the vendor's responsibility to confirm receipt of all quotations and/or questions by the closing date of this announcement by contacting the above Contract Specialist.

Quotations must clearly demonstrate an understanding of the purchase order requirement. A complete quote shall consist of a cover letter, Volume 1 - Technical Quotation and Volume 2 – Business/Price Quote, as detailed below. Incomplete quotations will be considered non-responsive and may not be further evaluated. The cover letter and each volume shall be sent as a separate attachment. ***The Technical Quotation (Volume 1) and Business/Price Quotation (Volume 2) must be kept separate from each other. Kept separate is defined as not including any cost/price information in the Technical Quotation (Volume 1). The Technical Quotation must not make reference to pricing data in order that the technical evaluation may be made strictly on the basis of technical merit. For submission purposes, it is acceptable for Volume 1 and Volume 2 to be submitted in the same email (along with the other required attachments, such as the Cover Letter); however, each attachment must be clearly marked as to which Volume it belongs.***

Any assumptions forming the basis of the submittal must be clearly identified in the cover letter submitted with the RFQ.

All Contractors whose quotations are not considered or selected for award will be so notified. Such notification will state in general terms the basis of non-selection.

All quotations will be handled in accordance with FAR Subpart 3.104.

Information requested herein must be furnished in writing and be fully and completely in compliance with RFQ instructions. The information requested and the manner of submission is essential to permit prompt evaluation of all quotations on a fair and uniform basis. Simple statements of compliance without the detailed description of how compliance will be accomplished will not be considered sufficient evidence that the Contractor can meet the technical requirements.

Contractor employees responsible for preparing material that may be proprietary information must mark each page that the Contractor believes contains proprietary information with the legend "Proprietary Information."

The signature of an official authorized to bind the Offeror shall be on each volume.

Each quote shall consist of a Cover Letter, and two (2) separate volumes (attachments):

- **Cover Letter/Executive Summary (No Page Limitations)**
- **Volumes:**
  - Volume 1 – Technical Quote (Page Limitation – 30 pages)
  - Volume 2 – Business Quote/Price (No Page Limitations)

Note: Attachments must be clearly labeled as to which volume they correspond.
Each volume shall be submitted as follows:

I. Cover Letter/Executive Summary

Includes the following information:

- Cover Letter – Must be signed by an individual that has the authority to bind the company. The cover letter must include the following, at a minimum:
  - Name of Offeror and Address
  - SAM Unique Entity ID (UEI)
  - Point of Contact – Name, telephone number and email address
  - Acknowledgement of Latest Amendment – Offerors who fail to acknowledge the most recent amendment, may be considered non-responsive
  - Statement that the quote is valid for 90 days
  - Identification of any contractor teaming arrangements, joint ventures, mentor-protégé relationships, subcontracting relationships, etc.
- Organizational Conflict of Interest (OCI) – The offeror shall identify any possible OCIs and plan to mitigate any OCI issues, if they exist. If there is no potential OCI, offerors must provide a written statement indicating so. If the OCI mitigation plan is deemed unacceptable, the offeror will not be eligible for award.
- **To facilitate the award process, ALL quotations must include a statement regarding the terms and conditions herein, as follows:**

  "The terms and conditions in the solicitation are acceptable to be included in the award document without modification, deletion, or addition."

I. Volume 1 – Technical Quote

Technical Subfactor 1 – Technical Capability

Quotes shall include: Information supporting the Offeror's technical understanding and capability to perform all of the requirements of the SOW, including a description of the Offeror's proposed approach and the deliverables.

The technical quote is the most important item in the evaluation of your capability to perform the desiredrequirement. Therefore, your quote must present sufficient information to reflect a thorough understanding of the work requirements and a detailed technical approach for achieving project objectives as set forth in the SOW.

To permit a thorough and effective evaluation, the technical portion of your quote must be as concise, complete and clear as possible to enable the Government to make a sound determination of your ability to successfully complete the requirements set forth in the SOW. The inclusion of any important considerations not covered by this request is encouraged. Statements to the effect that the Offeror "understands and will comply" with the SOW (in whole or in part) or phrases such as "standard procedures will be used" or "well- known techniques will be utilized," and other such generalities will not constitute compliance with the requirements. It is essential that you present in your quote, information in sufficient detail to permit the Government to make an evaluation of the technical quote without further information being required. The Government reserves the right to award based upon initial quotes received. The Offeror shall clearly state any areas in which assumptions are based or clearly state areas that deviate from the requirements stated in the SOW.

II. Volume 2 – Business Quote/Price

The Business Volume pricing worksheet Attachment A shall be submitted in Excel and PDF format. Any supporting documents/information to the business tables shall be submitted in PDF format. All total dollar amounts provided shall be rounded to the nearest cent.

Additional Quotation Submission Instructions

Each volume shall include a cover sheet which clearly identifies each volume by number, solicitation name ("**Request for Quotations (RFQ) No. 75F40125Q00044 - Training Courses for Advanced Model-informed Drug Development (MIDD) Program,** and date of submission. The pages of the Offeror's quote shall include page headers with the same information and page numbers. The Offeror shall submit each volume in its native format (e.g., Word, Excel) and PDF format.

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

The specific formatting instructions for each volume are as follows:

Note: The Offeror shall ensure that the non-price volumes are free of any pricing information.
General Formatting Instructions:

Offerors shall use the following page setup parameters:

- Font Type - Calibri, Arial, Times New Roman or similar font style
- Font Size – Minimum of 11 pt.
- Margins – Top, Bottom, Left, Right – 1”
- Gutter – 0”
- From Edge – Header, Footer – 0.5”
- Page Size, Width – 8.5”
- Page Size, Height – 11”
- Pages must be numbered

Each paragraph shall be separated by at least one (1) blank line. Tables and illustrations may use a reduced font size not less than 10-point and may be landscape.

The following items are not included in the stated page limitations:

- Cover Sheet
- Table of Contents
- Glossary
- Resumes, no more than 3 pages in length

Basis of Award and Evaluation Criteria

ORDER QUOTE EVALUATION

The Government will review the technical acceptability of the technical quote in accordance with the Statement of Work (SOW) requirements. **To be deemed technically acceptable, the Quote must respond to all the requirements of the SOW and the Offeror shall submit all required documents. A Quote will be deemed unacceptable if the quote does not respond to all requirements of the SOW and any of the required documents are missing.**

Price will be evaluated separately from technical and will be evaluated for fairness and reasonableness.

FDA reserves the right to make an award decision without conducting post-quotation communications.

Responsibility - To be eligible for an award, the Offeror must be determined responsible in accordance with the standards in FAR Part 9.104.

FAR 52.212-2 Evaluation—Commercial Items (NOV 2021)

(a) **The Government will award a purchase order 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 Capability: The technical quote will be evaluated to determine whether the Offeror demonstrates a clear understanding of the requirements of the SOW and provides a logical approach to successfully achieving the required tasks within the established period of performance.

Factor 2 - Price: The Government will evaluate the Offeror's total price submitted in its Volume II – Business Quote. A price analysis will be performed to determined whether the quoted price is fair and reasonable.

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.

Communications

(a) Communications prior to Contract Award

The Offeror shall direct all communications to the attention of the Contract Specialist Kimberly Pennix, Lawrence.Edelmann@fda.hhs.gov and Contracting Officer, Nicholas Bisher Nicholas.Bisher@fda.hhs.gov. Communications with other officials may compromise this acquisition and result in cancellation of the requirement.

(b) Release of Information

Contract selection and award information will be disclosed to Offerors in accordance with regulations applicable to negotiated acquisition.

(c) Preparation Costs

This RFQ does not commit the Government to pay any cost for the preparation and submission of a quote. In addition, the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed acquisition.

(End of provision)

List of Attachments

Attachment A: Pricing Table

Attachment B: FAR 52.212-5 Contract Terms and Conditions

ATTACHMENT A - PRICING TABLE

Deliverables	Training Program	Training invoice or Delivery Date	Proposed Price
OCP staff - (up to 12 students, 1 course per student) between the two training courses at 3 credits each.			
Spring 2025, two clinical pharmacology MIDD program training courses for up to 12 students (1 course per student).	PHA 6131 Introduction to Physiologically-Based Modeling College of Pharmacy » University of Florida (ufl.edu) 3 credit courses PHA 6122 Population Pharmacokinetics and Pharmacodynamics College of Pharmacy » University of Florida (ufl.edu) 3 credit courses	Jan - Apr 2025	$
Total Proposal Price			$

THE BREAKDOWN OF STUDENTS PER COURSE WILL BE DETERMINED BY THEIR INDIVIDUAL REGISTRATIONS.

52.212-5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Products and Commercial Services.

As prescribed in 12.301(b)(4), insert the following clause:

Contract Terms and Conditions Required To Implement Statutes or Executive Orders—*Commercial Products* and *Commercial Services* (Nov 2024)

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

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

(2) 52.204-23, Prohibition on *Contracting* for Hardware, Software, and Services Developed or Provided by Kaspersky Lab Covered Entities (Dec 2023) (Section 1634 of Pub. L. 115-91).

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

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

(5) 52.232-40, Providing Accelerated Payments to *Small Business Subcontractors* (Mar 2023) (31 U.S.C. 3903 and 10 U.S.C. 3801).

(6) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).

(7) 52.233-4, Applicable Law for Breach of Contract *Claim* (Oct 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

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

[*Contracting Officer check as appropriate*.]

_x_ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Jun 2020), with *Alternate I* (Nov 2021) (41 U.S.C. 4704 and 10 U.S.C. 4655).

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

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

_x_ (4) 52.203-17, Contractor Employee Whistleblower Rights (Nov 2023) (41 U.S.C. 4712); this clause does not apply to contracts of DoD, NASA, the Coast Guard, or applicable elements of the intelligence community—see FAR 3.900(a).

__ (5) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (Jun 2020) (Pub. L. 109-282) (31 U.S.C. 6101 note).

__ (6) [Reserved].

__ (7) 52.204-14, Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

__ (8) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

_x_ (9) 52.204-27, Prohibition on a ByteDance Covered Application (Jun 2023) (Section 102 of Division R of Pub. L. 117-328).

__ (10) 52.204-28, Federal *Acquisition* Supply Chain Security Act Orders—Federal Supply Schedules, Governmentwide *Acquisition* Contracts, and Multi-Agency Contracts. (Dec 2023) (Pub. L. 115–390, title II).

__ (11)

(i) 52.204-30, Federal *Acquisition* Supply Chain Security Act Orders—Prohibition. (Dec 2023) (Pub. L. 115–390, title II).

__ (ii) *Alternate* I (Dec 2023) of 52.204-30.

__ (12) 52.209-6, Protecting the Government’s Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for *Debarment*. (Nov 2021) (31 U.S.C. 6101 note).

__ (13) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Oct 2018) (41 U.S.C. 2313).

__ (14) [Reserved].

__ (15) 52.219-3, Notice of *HUBZone* Set-Aside or Sole-Source Award (Oct 2022) (15 U.S.C. 657a).

__ (16) 52.219-4, Notice of Price Evaluation Preference for *HUBZone* Small Business Concerns (Oct 2022) (if the *offeror* elects to waive the preference, it *shall* so indicate in its *offer*) (15 U.S.C. 657a).

__ (17) [Reserved]

__ (18)

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

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

__ (19)

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

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

__ (20) 52.219-8, Utilization of Small Business Concerns (Feb 2024) (15 U.S.C. 637(d)(2) and (3)).

__ (21)

(i) 52.219-9, Small Business Subcontracting Plan (Sep 2023) (15 U.S.C. 637(d)(4)).

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

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

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

__ (v) *Alternate* IV (Sep 2023) of 52.219-9.

__ (22)

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

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

__ (23) 52.219-14, Limitations on Subcontracting (Oct 2022) (15 U.S.C. 657s).

__ (24) 52.219-16, Liquidated Damages—Subcontracting Plan (Sep 2021) (15 U.S.C. 637(d)(4)(F)(i)).

__ (25) 52.219-27, Notice of Set-Aside for, or Sole-Source Award to, Service-Disabled Veteran-Owned Small Business (SDVOSB) Concerns Eligible Under the SDVOSB Program (Feb 2024) (15 U.S.C. 657f).

__ (26)

(i) 52.219-28, Post Award Small Business Program Rerepresentation (Feb 2024)

(15 U.S.C. 632(a)(2)).

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

__ (27) 52.219-29, Notice of Set-Aside for, or Sole-Source Award to, Economically Disadvantaged *Women-Owned Small Business Concerns* (Oct 2022) (15 U.S.C. 637(m)).

__ (28) 52.219-30, Notice of Set-Aside for, or Sole-Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Oct 2022) (15 U.S.C. 637(m)).

__ (29) 52.219-32, Orders Issued Directly Under Small Business Reserves (Mar 2020) (15 U.S.C. 644(r)).

__ (30) 52.219-33, Nonmanufacturer Rule (Sep 2021) (15 U.S.C. 637(a)(17)).

_x_ (31) 52.222-3, Convict Labor (Jun 2003) (E.O.11755).

_x_ (32) 52.222-19, Child Labor-Cooperation with Authorities and Remedies (Feb 2024).

_x_ (33) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

_x_ (34)

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

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

__ (35)

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

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

__ (36)

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

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

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

__ (38) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).

_x_ (39)

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

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

__ (40) 52.222-54, Employment Eligibility Verification (*May* 2022) (Executive Order 12989). (Not applicable to the *acquisition* of commercially available off-the-shelf items or certain other types of *commercial products* or *commercial services* as prescribed in FAR 22.1803.)

__ (41)

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

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

__ (42) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (*May* 2024) (42 U.S.C. 7671, *et seq.*).

__ (43) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (*May* 2024) (42 U.S.C. 7671, *et seq.*).

__ (44) 52.223-20, Aerosols (*May* 2024) (42 U.S.C. 7671, *et seq.*).

__ (45) 52.223-21, Foams (*May* 2024) (42 U.S.C. 7671, *et seq.*).

__ (46) 52.223-23, *Sustainable Products and Services* (*May* 2024) (E.O. 14057, 7 U.S.C. 8102, 42 U.S.C. 6962, 42 U.S.C. 8259b, and 42 U.S.C. 7671l).

_x_ (47)

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

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

__ (48)

(i) 52.225-1, Buy American-*Supplies* (Oct 2022) (41 U.S.C. chapter 83).

__ (ii) *Alternate* I (Oct 2022) of 52.225-1.

__ (49)
(i) 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act (NOV 2023) (19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, 19 U.S.C. chapter 29 (sections 4501-4732), Public Law 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

__ (ii) *Alternate* I [Reserved].

__ (iii) *Alternate* II (Dec 2022) of 52.225-3.

__ (iv) *Alternate* III (Feb 2024) of 52.225-3.

__ (v) *Alternate* IV (Oct 2022) of 52.225-3.

__ (50) 52.225-5, Trade Agreements (NOV 2023) (19 U.S.C. 2501, *et seq*., 19 U.S.C. 3301 note).

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

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

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

__ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or *Emergency* Area (Nov 2007) (42 U.S.C. 5150).

_x_ (55) 52.226-8, Encouraging Contractor Policies to Ban Text Messaging While Driving (*May* 2024) (E.O. 13513).

__ (56) 52.229-12, Tax on Certain Foreign *Procurements* (Feb 2021).

__ (57) 52.232-29, Terms for Financing of Purchases of *Commercial Products* and *Commercial Services* (Nov 2021) (41 U.S.C. 4505, 10 U.S.C. 3805).

__ (58) 52.232-30, Installment Payments for *Commercial Products* and *Commercial Services* (Nov 2021) (41 U.S.C. 4505, 10 U.S.C. 3805).

__ (59) 52.232-33, Payment by *Electronic Funds Transfer-System for Award Management* (Oct2018) (31 U.S.C. 3332).

__ (60) 52.232-34, Payment by *Electronic Funds Transfer*-Other than *System for Award Management* (Jul 2013) (31 U.S.C. 3332).

__ (61) 52.232-36, Payment by Third Party (*May* 2014) (31 U.S.C. 3332).

__ (62) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).

__ (63) 52.240-1, Prohibition on Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act-Covered Foreign Entities (Nov 2024) (Sections 1821-1826, Pub. L. 118-31, 41 U.S.C. 3901 note prec.).

__ (64) 52.242-5, Payments to *Small Business Subcontractors* (Jan 2017) (15 U.S.C. 637(d)(13)).

__ (65)

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

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

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

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

[*Contracting Officer check as appropriate.*]

__ (1) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter67).

__ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (*May* 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

__ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and *Option* Contracts) (Aug 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

__ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (*May* 2014) (29U.S.C.206 and 41 U.S.C. chapter 67).

__ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (*May* 2014) (41 U.S.C. chapter 67).

_x_ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (*May* 2014) (41 U.S.C. chapter 67).

__ (7) 52.222-55, Minimum Wages for Contractor Workers Under Executive Order 14026 (Jan 2022).

__ (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2022) (E.O. 13706).

__ (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792).

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

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

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

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

(e)

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

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

(ii) 52.203-17, Contractor Employee Whistleblower Rights (Nov 2023) (41 U.S.C. 4712).

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

(iv) 52.204-23, Prohibition on *Contracting* for Hardware, Software, and Services Developed or Provided by Kaspersky Lab Covered Entities (Dec 2023) (Section 1634 of Pub. L. 115-91).

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

(vi) 52.204-27, Prohibition on a ByteDance Covered Application (Jun 2023) (Section 102 of Division R of Pub. L. 117-328).

(vii)

(A) 52.204–30, Federal *Acquisition* Supply Chain Security Act Orders—Prohibition. (Dec 2023) (Pub. L. 115–390, title II).

(B) *Alternate* I (Dec 2023) of 52.204–30.

(viii) 52.219-8, Utilization of Small Business Concerns (Feb 2024) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that *offer* further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor *must* include 52.219-8 in lower tier subcontracts that *offer* subcontracting opportunities.

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

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

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

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

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

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

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

(xvi)

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

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

(xvii) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (*May* 2014) (41 U.S.C. chapter 67).

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

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

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

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

(xxii)

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

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

(xxiii) 52.225-26, Contractors Performing Private Security Functions Outside the *United States* (Oct 2016) (Section 862, as amended, of the *National Defense* Authorization Act for Fiscal Year 2008; 10 U.S.C. Subtitle A, Part V, Subpart G Note).

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

(xxv) 52.232-40, Providing Accelerated Payments to *Small Business Subcontractors* (Mar 2023) (31 U.S.C. 3903 and 10 U.S.C. 3801). Flow down required in accordance with paragraph (c) of 52.232-40.

(xxvi) 52.240-1, Prohibition on Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act-Covered Foreign Entities (Nov 2024) (Sections 1821-1826, Pub. L. 118-31, 41 U.S.C. 3901 note prec.).

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

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

(End of clause)

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

(d) of this clause" in the redesignated paragraph (d) to read "paragraphs (a), (b), and (c) of this clause".

Alternate II (Nov 2024) . As prescribed in 12.301 (b)(4)(ii), substitute the following paragraphs (d)(1) and (e)(1) for paragraphs (d)(1) and (e)(1) of the basic clause as follows:

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

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

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

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

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

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

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

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

(C) 52.203-17, Contractor Employee Whistleblower Rights (Nov 2023) (41 U.S.C. 4712).

(D) 52.204-23, Prohibition on *Contracting* for Hardware, Software, and Services Developed or Provided by Kaspersky Lab Covered Entities (Dec 2023) (Section 1634 of Pub. L. 115-91).

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

(F) 52.204-27, Prohibition on a ByteDance Covered Application (Jun 2023) (Section 102 of Division R of Pub. L. 117-328).

(G)__(*1*) 52.204–30, Federal *Acquisition* Supply Chain Security Act Orders— Prohibition. (Dec 2023) (Pub. L. 115–390, title II).

__(*2*) *Alternate* I (Dec 2023) 52.204-30.

(H) 52.219-8, Utilization of Small Business Concerns (Feb 2024) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that *offer* further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor *must* include 52.219-8 in lower tier subcontracts that *offer* subcontracting opportunities.

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

(J) 52.222-26, Equal Opportunity (Sep 2016) (E.O. 11246).

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

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

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

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

(O) __ *(1)* 52.222-50, Combating Trafficking in Persons (Nov 2021) (22 U.S.C. chapter 78 and E.O 13627).

__ *(2) Alternate* I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

(P) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (*May* 2014) (41 U.S.C. chapter 67).

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

(R) 52.222-54, Employment Eligibility Verification (*May* 2022) (Executive Order 12989).

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

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

(U)__ *(1)* 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).

__ *(2) Alternate* I (Jan 2017) of 52.224-3.

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

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

(X) 52.232-40, Providing Accelerated Payments to *Small Business Subcontractors* (MAR 2023) (31 U.S.C. 3903 and 10 U.S.C. 3801). Flow down required in accordance with paragraph (c) of 52.232-40.

(Y) 52.240-1, Prohibition on Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act-Covered Foreign Entities (Nov 2024) (Sections 1821-1826, Pub. L. 118-31, 41 U.S.C. 3901 note prec.).

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

Parent topic: 52.212 [Reserved]