SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS

OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30

1. REQUISITION NUMBER	PAGE	OF
	1	39

2. CONTRACT NO.	3. AWARD/ EFFECTIVE DATE	4. ORDER NUMBER	5. SOLICITATION NUMBER	6. SOLICITATION ISSUE DATE
			75F40126R00031	06/04/2026

7. FOR SOLICITATION INFORMATION CALL:	a. NAME	b. TELEPHONE NUMBER (No collect calls)	8. OFFER DUE DATE/LOCAL TIME
	JANICE HEARD	215-717-3093	07/06/2026 1400 ET

9. ISSUED BY	CODE	10. THIS ACQUISITION IS	% FOR:
DHHS/FDA/OAGS/DAP 11601 Landsdown St. 13th Floor North Bethesda MD 20852	DAP	☒ UNRESTRICTED OR ☐ SET ASIDE: ☐ SMALL BUSINESS ☐ HUBZONE SMALL BUSINESS ☐ SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS (SDVOSB) ☐ WOMEN-OWNED SMALL BUSINESS (WOSB) ☐ ECONOMICALLY DISADVANTAGED WOMEN-OWNED SMALL BUSINESS (EDWOSB) ☐ 8(A)	NORTH AMERICAN INDUSTRY CLASSIFICATION STANDARD (NAICS): 541690 SIZE STANDARD: $19

11. DELIVERY FOR FREE ON BOARD (FOB) DESTINATION UNLESS BLOCK IS MARKED	12. DISCOUNT TERMS	13a. THIS CONTRACT IS A RATED ORDER UNDER THE DEFENSE PRIORITIES AND ALLOCATIONS SYSTEM - DPAS (15 CFR 700)	13b. RATING	14. METHOD OF SOLICITATION
☐ SEE SCHEDULE		☐		☒ REQUEST FOR QUOTE (RFQ) ☐ INVITATION FOR BID (IFB) ☐ REQUEST FOR PROPOSAL (RFP)

15. DELIVER TO	CODE	16. ADMINISTERED BY	CODE

17a. CONTRACTOR/ OFFEROR	CODE	FACILITY CODE	18a. PAYMENT WILL BE MADE BY	CODE

TELEPHONE NO.

☐ 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED ☐ SEE ADDENDUM

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	Investigating associations between acute abuse liability outcomes and switching behavior *(Use Reverse and/or Attach Additional Sheets as Necessary)*				

25. ACCOUNTING AND APPROPRIATION DATA

26. TOTAL AWARD AMOUNT *(For Government Use Only)*

☐ 27a. SOLICITATION INCORPORATES BY REFERENCE (FEDERAL ACQUISITION REGULATION) FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.

☐ 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.

☐ 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.

☐ 29. AWARD OF CONTRACT: REFERENCE _____ OFFER DATED _____. YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:

30a. SIGNATURE OF OFFEROR/CONTRACTOR		31a. UNITED STATES OF AMERICA *(SIGNATURE OF CONTRACTING OFFICER)*	
30b. NAME AND TITLE OF SIGNER *(Type or print)*	30c. DATE SIGNED	31b. NAME OF CONTRACTING OFFICER *(Type or print)* JANICE S. HEARD	31c. DATE SIGNED

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT

32a. QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED ☐ INSPECTED ☐ ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED: _____

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	32c. DATE	32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE	32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE
	32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE

33. SHIP NUMBER	34. VOUCHER NUMBER	35. AMOUNT VERIFIED CORRECT FOR	36. PAYMENT	37. CHECK NUMBER
☐ PARTIAL ☐ FINAL			☐ COMPLETE ☐ PARTIAL ☐ FINAL	

38. S/R ACCOUNT NUMBER	39. S/R VOUCHER NUMBER	40. PAID BY

41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT		42a. RECEIVED BY *(Print)*	
41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER	41c. DATE	42b. RECEIVED AT *(Location)*	
		42c. DATE REC'D *(YY/MM/DD)*	42d. TOTAL CONTAINERS

Offeror Name **UEI**

Study Title: Investigating associations between acute abuse liability outcomes and switching behavior

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SECTION 1 - COMBINED SYNOPSIS SOLICITATION

This is a combined synopsis/solicitation for commercial products or commercial services prepared in accordance with the format in Far part 12. This announcement constitutes the only solicitation. Offers are being requested, and a separate solicitation will not be issued. This acquisition is not set-aside for small business concerns. This solicitation incorporates provisions and clauses by reference. The full text of provisions and clauses may be accessed electronically at www.acquisition.gov.

The solicitation number is **75F40126R00031** and is issued as a Request for Proposal (RFP). This solicitation and incorporated provisions and clauses are those in effect through Federal Acquisition Circular 2026-01, effective March 13, 2026. The North American Industry Classification Systems (NAICS) Code 541690 - Other Scientific and Technical Consulting Services.

SECTION 2 – SUPPLIES OR SERVICES/PARTS

The Government intends to award a firm-fixed price contract resulting from this solicitation. Offerors are requested to provide a fixed price proposal in accordance with the Statement of Work.

SECTION 3 – STATEMENT OF WORK (SOW)

3.1 Background

The primary function of the Food and Drug Administration (FDA) is to promote public health associated with the use of foods, dietary supplements, cosmetics, drugs, tobacco, and other products under its jurisdiction. FDA's Center for Tobacco Products (CTP) implements PL 111-31 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which was signed into law on June 22, 2009. The Tobacco Control Act granted the FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health. Research that informs our understanding of tobacco product abuse liability and use behavior plays an important role in these regulatory activities. However, to date, no prospective clinical studies have been designed with the primary aim of evaluating the relationships between tobacco product abuse liability outcomes (e.g., nicotine pharmacokinetics (PK), self-administration, subjective effects) collected under acute laboratory conditions and actual use outcomes (e.g., product switching, cessation) associated with use of the same products under real-world conditions. The current study will recruit individuals who smoke combusted cigarettes (CC) and examine the relationships between abuse liability outcomes of a study electronic nicotine delivery system (ENDS) assessed within a laboratory setting and product switching (i.e., uptake of the study ENDS, reduction in CC use) assessed under real-world conditions in the same participants using the same study ENDS. The primary aim of this study is to determine whether the abuse liability outcomes associated with use of the study ENDS in the laboratory are associated with subsequent reduction in CC use in the same individuals when they are provided with the study ENDS for use at home over an extended period (e.g., 3 months). A secondary aim is to determine whether ENDS nicotine concentration influences uptake of the study ENDS and reduction in CC use.

3.2 SCOPE OF WORK

The primary objectives of this requirement are to determine the relationships between acute abuse liability outcomes associated with use of an ENDS and actual use behaviors under real-world conditions. A secondary objective of this requirement is to assess if ENDS nicotine concentration is associated with differences in actual use behaviors. The Contractor shall recommend an ENDS with both a high and low nicotine concentration that has received FDA marketing authorization. The Contractor shall recommend participant recruitment criteria to achieve sufficient power to evaluate the relationship between acute abuse liability outcomes and actual use behaviors in a two-phase (i.e., acute, ambulatory) parallel randomized controlled trial. Urine samples and expired carbon monoxide (eCO) from every enrolled participant shall be collected at screening. The Contractor shall recommend and measure urinary biomarkers of exposure (BOE), such as metabolites of nicotine (e.g., cotinine), tobacco-specific nitrosamines (TSNAs; e.g., 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol (NNAL)), Polycyclic Aromatic Hydrocarbons (PAH; e.g., 1-hydroxypyrene (1-OHP)), and volatile organic compounds (VOCs; e.g., S-phenylmercapturic acid (S-PMA)). Qualified participants will be provided instruction on using the study ENDS and an opportunity to familiarize with study ENDS use at the screening visit.

3.3 OBJECTIVES

The Contractor shall conduct a study with two phases: an acute phase (i.e., two experimental sessions conducted in a laboratory setting) and an ambulatory phase (i.e., continued use of the assigned product outside of the laboratory). Participants will be randomized to use ENDS with high (e.g., 5%) or low (e.g., 3%) nicotine concentrations. During the acute phase, participants will be instructed to abstain from using tobacco products (e.g., overnight, 12 hours) prior to each of two experimental sessions. At one session, participants will use their own brand CC, and at the other session, participants will use their assigned ENDS. During each experimental session, participants will use the study product (i.e., CC, ENDS) in a prescribed manner (e.g., 10 puffs with 30 second intervals between puffs) followed by at least 60 minutes of serial blood sample collection. During prescribed product use, the Contractor shall measure plasma nicotine PK (e.g., peak plasma nicotine concentration, area under the nicotine concentration-time curve), pharmacodynamic effects (e.g., heart rate, blood pressure, pulmonary function as assessed by spirometry or other measures), and subjective effects (e.g., product liking, withdrawal symptoms, sensory effects). The blood sample collection period will also serve as a washout period prior to participants completing single-item and cross-commodity (i.e., substitution) hypothetical purchasing tasks and a progressive-ratio self-administration task, during which the input requirement (e.g., lever pulls, mouse clicks, key presses) to receive a puff of the CC or ENDS increases with each subsequent puff over a period of at least 120 minutes. After a second washout period (e.g., 30-60 mins.), the experimental session will conclude with an *ad libitum* use period in which participants will then be permitted to use the study ENDS or CC for at least 180 minutes. During *ad libitum* use, the Contractor shall measure use topography (e.g., number of CC used, number of ENDS puff bouts, total puff number, inter-use-interval). Additionally, a safety analysis will be conducted to assess exhaled carbon monoxide (eCO) and blood

carboxyhemoglobin (COHb) levels at screening and at the beginning and end of each experimental session, and adverse experiences throughout the study.

At the conclusion of the two experimental sessions, participants will begin the ambulatory phase of the study. The Contractor shall recommend the duration of the ambulatory phase (e.g., 3 months). Participants will be provided with a study ENDS and refill pods, and they will be instructed to substitute the ENDS for their CC for the duration of the study. The Contractor will identify a means (e.g., daily diaries, interactive voice recording, ecological momentary assessment) for participants to self-report CC and ENDS use behaviors (e.g., CC per day, ENDS puffs per day, ENDS use bouts per day, e-liquid consumption). The Contractor shall schedule regular (e.g., monthly) check-in visits with participants to review self-reported use behavior and collect specimens for biomarker of exposure analysis (e.g., eCO, urinary BOE, including metabolites of nicotine, TSNA, VOC, PAH). Check-in visits should occur throughout and at the conclusion of the ambulatory phase.

The primary analyses will evaluate the relationship between the abuse liability outcomes collected during the experimental sessions and use behaviors measured during the ambulatory phase. The study should be powered to address the primary outcome of reduction in CC consumption (i.e., CC/day). Secondary analyses may include outcomes of complete switching (e.g., 7-day point prevalence abstinence), changes in urinary BOE, ENDS consumption, and other CC and ENDS use behavior variables.

The Contractor shall perform all data analyses, provide FDA all raw data, and write study reports. All results and source documents shall be submitted to the Contracting Officer's Representative (COR) and Study Project Lead(s).

LINE ITEMS AND PRICES

PRICING TABLE

Task	Deliverable	Quantity	Price
1	Kick-off Meeting	1	$
2	Non-disclosure of Private Information (NPI) Forms	1 for each staff member involved in clinical study	$
3	Biweekly Meetings	1 meeting every 2 weeks	$
4	Monthly Progress Reports	1 electronic version per month	$
5	Selection of Study Products	1	$
6	Draft Clinical Study Protocol	1 electronic version; preliminary drafts may be needed	$
7	Peer Review of Clinical Study Protocol	1 electronic version	$
8	Final Clinical Study Protocol	1 electronic version	$
9	Obtain Clearances for the Study (OMB and IRB)	1 electronic version each	$

10	Perform Clinical Study	1	$
11	Clinical Recruitment Updates	1 electronic version per week once recruitment begins	$
12	Draft Clinical Study Report	1 electronic version; additional drafts may be needed	$
13	Final Clinical Study Report	1 electronic version	$
	OPTION – FDA Audit Costs	1 audit (max)	$

3.4 - TASKS

Task 1 – Kick-off Meeting
Within ten (10) business days of award, the Contractor shall set up and host a kick-off teleconference with the Study Project Lead(s), COR, and other FDA personnel to discuss roles, expectations, and deliverables associated with this requirement.

Task 2 – NPI Forms
All Contractor staff shall sign NPI forms prior to commencing work. All signed forms shall be submitted electronically to the COR/Contract Specialist within thirty (30) days of contract award. If additional staff are added to this contract after contract award, Contractor staff shall sign the NPI form immediately, and the COR shall be notified.

Task 3 – Biweekly Meetings
The Contractor shall set up biweekly teleconferences, for the duration of the contract, with the Study Project Lead(s), COR, and other FDA personnel (as necessary) to discuss study progress, challenges, and other study details every two (2) weeks and as needed. Within five (5) business days following each teleconference, the Contractor shall submit teleconference meeting minutes to FDA that include a detailed summary of the discussion as well as the contract progress status.

Task 4 – Monthly Progress Reports
The Contractor shall submit monthly progress reports on the 10th day of each month, for the duration of the contract, to the Study Project Lead(s), COR, and Contract Specialist detailing study progress, challenges (and solutions to those challenges), contract budget status, recruitment status, study deviations, adverse events, and other study details pertaining to the prior months progress. Progress reports shall indicate which deliverables or percentages of deliverables were completed during the month and overall progress of the contract and budget.

Task 5 – Selection of Study Products
The Contractor shall recommend and, upon FDA approval, obtain the ENDS to be used in the clinical study.

Study ENDS
The Contractor shall recommend an ENDS after consideration of marketplace popularity, FDA marketing authorization, and availability. The Contractor shall recommend at least two ENDS, each available with multiple e-liquid nicotine strengths, and two e-liquid nicotine strengths (i.e., high and low nicotine concentrations) for the recommended ENDS. Selection of high and low nicotine concentration shall be made with consideration to the study ENDS product and marketplace popularity and availability.

At the first biweekly teleconference, approximately 20 business days after contract award, the Contractor shall recommend at least two ENDS with marketing authorization and multiple available e-liquid nicotine concentrations to be used in the study. The selected study ENDS should have prior FDA marketing authorization (https://www.accessdata.fda.gov/scripts/searchtobacco/), pod-based e-liquid refills, and with at least two available e-liquid nicotine concentrations. The Contractor's recommendation shall include: proposed brands, flavors, and nicotine strengths; how the proposed products meet the criteria outlined in the SOW; relevant published data on nicotine PK, abuse liability, HPHC analysis, or chemical characterization of the proposed products; and any potential risks, drawbacks and benefits to using each product in the study.

Task 6 – Draft Clinical Study Protocol

The Contractor shall develop a Draft Clinical Study Protocol for the study titled "Investigating associations between acute abuse liability outcomes and switching behavior" based on the following study objectives and protocol requirements:

Clinical Study Objectives:

1. Measure the associations between outcomes assessed during an acute abuse liability clinical study of ENDS and CC use and real-world use behaviors assessed in a subsequent ambulatory phase.

2. Identify which acute abuse liability outcomes best predict subsequent ambulatory use behaviors.

3. Determine whether ENDS nicotine concentration influences uptake of the study ENDS and reduction in CC use.

Protocol Requirements:

1. The study shall consist of two phases: an acute phase consisting of two experimental sessions and an ambulatory phase consisting of a randomized controlled trial of switching. Participants will be adult users of CC with minimal ENDS use experience (e.g., <100 lifetime uses, no use in the past 30 days). Full eligibility criteria will be proposed by the Contractor. The study shall consist of a screening visit, two experimental sessions, and an ambulatory phase with periodic check-in clinic visits. Prior to the first experimental session, participants will be randomized to use ENDS with high (e.g., 5%) or low (e.g., 3%) nicotine concentrations, and they will receive instruction on using the study ENDS and have an opportunity to use and familiarize with the study ENDS. At each experimental session, one study product will be used (i.e., usual-brand CC, assigned study ENDS). Each experimental session shall include a period of prescribed use, progressive ratio self-administration, and *ad libitum* use of the session study product (i.e., CC, ENDS). The Contractor shall provide statistical considerations for sample size based on study objectives.

   At each experimental session, inclusion and exclusion criteria shall be reviewed to ensure participants remain qualified for the study. Participants shall be randomized to determine

the order of experimental conditions. During prescribed use, participants shall be directed to take 10-puffs with 30 second intervals between puffs (or an alternative prescribed puffing regimen as recommended by the Contractor) followed by a washout period (e.g., 1 hour) during which additional, acute abuse liability data shall be collected. Following the prescribed use period, participants will complete a hypothetical purchasing task and a progressive-ratio self-administration component in which the response requirement (e.g., lever pulls, key presses, mouse clicks) to receive one puff of the CC or ENDS increases with each subsequent puff (e.g., 10 responses for the first puff, 20 for the second, 40 for the third, etc.). The duration of the progressive-ratio self-administration component shall be recommended by the contractor (e.g., 3 hours). The experimental session shall conclude with an *ad libitum* use period of a duration recommended by the contractor (e.g., 3 hours).

The following methodological details shall be included:

a. Serial blood samples shall be collected to assess plasma nicotine PK during the prescribed use component of each experimental session (e.g., pre-dose, 1, 3, 5, 7, 10, 15, 30, 45, 60 min following prescribed ENDS or CC use). Maximum blood draw volume shall not exceed 100 mL per participant per study day.
b. Pharmacodynamic endpoints (e.g., vital signs) shall be collected throughout each experimental session, as proposed by the Contractor.
c. Subjective effects measures (e.g., product liking, withdrawal symptoms, sensory effects) shall be measured during the prescribed use phase of each experimental session with existing scales and assessments as proposed by the Contractor, with timing and frequency recommended by the Contractor.
d. Following prescribed use but prior to the onset of the progressive ratio component, participants shall complete hypothetical purchasing tasks for the study product. Participants should also complete a cross-commodity purchasing task during the ENDS session in which participants' usual CC are available at increasing prices and the study ENDS is available at a fixed price to evaluate substitution.
e. Breakpoint (i.e., the highest response requirement at which a participant earns a puff) and total number of responses should be recorded during the progressive-ratio self-administration component.
f. Product use topography shall be measured during the *ad libitum* use period (e.g., puff number, puff duration, inter-puff-interval, number of products used, number of ENDS puff bouts, ENDS puff bout duration). Other abuse liability outcomes recommended by the Contractor (e.g., nicotine exposure, subjective effects) may also be measured during the *ad libitum* use period.

2. The ambulatory phase shall begin at the conclusion of the second experimental study session. Participants should be provided with study ENDS and sufficient e-liquid pods to last until the first check-in visit, which will be scheduled at a duration recommended by the contractor (e.g., two weeks, one month). Participants will be instructed on how to record their CC and ENDS use (e.g., CC/day, ENDS puffs/day, ENDS use periods/day, daily e-liquid consumption) through a mechanism proposed by the Contractor (e.g., daily diary, interactive voice recording, ecological momentary assessment).

The following methodological details shall be included:

a. The Contractor will propose a total duration for the ambulatory phase (e.g., 3 months).
b. The Contractor will propose an in-person check-in frequency throughout the duration of the ambulatory phase (e.g., biweekly, monthly), including a final visit at the conclusion of the ambulatory phase.
c. The Contractor shall recommend a means for measuring CC and ENDS use behavior (e.g., daily consumption), such as interactive voice recording, daily diary, ecological momentary assessment, or others.
d. The Contractor shall recommend and measure other nicotine (e.g., cotinine) and non-nicotine biomarkers (e.g., TSNA, VOC, and PAH) in urine.
e. The contractor shall conduct a safety analysis which may include assessing eCO, carboxyhemoglobin (COHb), and adverse experiences during the screening visit and at the beginning and end of each experimental session. In addition, participants shall be monitored for adverse events throughout the study.

3. The Draft Clinical Study Protocol shall include: study procedures, human subjects' protection documentation (e.g., consent form, adverse event reporting), data handling and record keeping, publication plan (if applicable), quality assurance plan, and administrative information.

4. A Proposed Statistical Analysis Plan document which shall include:
   a. Details regarding data collection, organization, analysis, and interpretation as well as information on the personnel who shall conduct the statistical analyses and their credentials (e.g., training and courses completed).
   b. The statistical model(s) and software program(s) that shall be used to analyze the data.
   c. Methods and criteria for outlier detection and removal, where applicable.
   d. Information on the selection of the significance level and post- hoc analysis, when applicable.
   e. Multiple iterations of the protocol draft may be necessary to address feedback from all FDA review processes, but this process shall not exceed 3 protocol iterations

Data Monitoring
The draft and final clinical study protocols shall include a section describing the proposed plan for interim data monitoring. This section shall explain who is to be responsible for interim monitoring, what data will be monitored (e.g., performance, risk assessment), the timing of the first data review, and the frequency of interim reviews (which will depend on such factors as the study design, interventions, and anticipated recruitment rate). The plan shall specify "stopping guidelines" and other criteria, if appropriate, for the monitors/auditors to follow in their review of the interim data. Guidance on these topics is available at: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127073.pdf.

With appropriate notification, FDA/CTP/Office of Compliance and Enforcement Quality Assurance and Quality Improvement (QA/QI) Human Subjects Protection Program has the authority to audit this study at any time in order to ensure research activities comply with the study protocol, standard operating procedures, Good Clinical Practice standards and Federal Regulation HHS 45 CFR § 46, as well as any additional applicable agency regulatory

requirements. Federal or state laws may require FDA to show information to university or government officials (or sponsors), who are responsible for monitoring the safety of this study. To the extent possible, directly identifying information (e.g., names, addresses) will be safeguarded and maintained under controlled conditions as appropriate. If this study is selected for audit, the Contractor may bill for costs incurred as determined in the optional line item.

Task 7 – Peer Review of Clinical Study Protocol

In order to ensure a robust study design, the clinical protocol will need be reviewed by experts in the field. These experts may be external to FDA or may be internal depending on the subject. Once the Contractor submits the first draft protocol, FDA and the Contractor shall not exceed 3 rounds of edits. Following these edits, the clinical study protocol will undergo peer review by Special Government Employees (SGEs) and/or Regular Government Employees (RGEs). The Project leads and Contractor will edit the protocol based on SGE/RGE feedback and then the clinical study protocol will undergo an FDA internal review process. The Project leads and Contractor may need to edit the protocol based on this internal review process. Together, these two review processes will take up to 2-3 months.

Task 8 – Final Clinical Study Protocol

The Contractor shall incorporate FDA feedback (including SGE/RGE and FDA Internal Review feedback) from the Draft Clinical Study Protocol development phase and deliver a Final Clinical Study Protocol for FDA approval. This version of the clinical study protocol will then be submitted for human subjects protections review and approvals (Task 9).

Task 9 – Obtain Required Human Subjects Clearances for the Study

The Contractor shall work with the FDA to submit proper human subjects' clearance documents and obtain necessary human subjects' clearances to perform the study, including:

1. Institutional Review Board (IRB) approval, as applicable
2. Office of Management and Budget (OMB) approval, if applicable

Approval from the OMB, consistent with the Paperwork Reduction Act, is necessary for data collection from ten (10) or more individuals. Some studies may be granted exemption from OMB based on study procedures. The Contractor shall be responsible for providing the COR and Study Project Lead (s) with the necessary information about the Contractor's procedures for data collection.

For research exempt from the requirements of 45 CFR Part 46:

(a) The Contractor will submit to FDA a letter from their IRB or human subjects protection entity that the proposed research is exempt (see 45 CFR 46.104).

(b) In accordance with SMG 9001.4, FDA will follow its procedures for exempt research determination. Data collection from human subjects cannot commence under this contract until the FDA COR provides the Contractor with the outcome of the FDA determination.

For nonexempt human subjects research:

(a) The Contractor agrees to protect the rights and welfare of human subjects involved in research under this contract by complying with 45 CFR Part 46 and the clause at HHSAR 352.270-4b.

(b) Initial proof of compliance with 45 CFR Part 46 shall consist of:

(1) A copy of a current Federal-wide Assurance on file with OHRP (https://www.hhs.gov/ohrp/federalwide-assurances-fwas.html). The copy of a current Federal–wide Assurance shall be included with the Contractor's proposal;

(2) A letter from the Contractor's local IRB (the Institutional Review Board (IRB) specified in the Offeror's Assurance of Compliance) stating that it has reviewed and approved the proposed research protocol. The letter from the local IRB shall be submitted to the Contracting Officer Representative (COR).

(3) In accordance with SMG 9001.4, the FDA will determine if FDA is considered engaged in the research for purposes of 45 CFR part 46. Data collection from human subjects cannot commence under this contract until the FDA COR provides the Contractor with the outcome of the FDA determination. When that determination is made, the FDA will confirm the extent to which the terms of "352.270-11 Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required" apply.

In addition, the Contractor shall obtain all necessary internal approvals, such as determination from its own IRB prior to any human subject data collection. All staff working with human subjects or having access to human subjects' data must complete human subjects training appropriate for this type of clinical study.

Task 10 – Perform Clinical Study

Clinical study recruitment should begin within five (5) business days of IRB approval. The Contractor shall perform the clinical study using the Final Clinical Study Protocol developed in Task 8. The Contractor shall submit any relevant source documents to the Study Project Lead(s) upon request. Within five (5) business days of IRB approval, the Contractor shall begin recruitment activities such as posting advertisements, contacting participants in their database, and preparing staff/materials at the clinical site.

The Contractor shall select the clinical research facilities which are equipped to perform the study. The Contractor shall provide nurses, laboratory technicians, and other clinical staff to perform the screening, behavioral assessments, and laboratory tests, to collect specimen samples, and to assay the biologic samples.

The Contractor shall recruit healthy, volunteer, adult male and female current users of combusted cigarettes for the study and assess their inclusion and exclusion criteria to satisfy the protocol. The Contractor is responsible for proactively ensuring recruitment can be achieved and for identifying measures to increase recruitment, if needed.

The Contractor shall inform the FDA for the measures taken to ensure the confidentiality of data.

Task 11 – Clinical Recruitment Updates

The Contractor shall deliver informal weekly updates via email to the Study project Lead(s) and the COR on the status of recruitment and progress of research for the duration of recruitment. Recruitment updates shall begin one week after the start of recruitment and shall be delivered on the same day of the week throughout the duration of the study.

Recruitment updates shall include the number of participants screened/scheduled/completed/withdrawn for the prior week's duration, the number of participants screened/scheduled/completed/withdrawn from the start of recruitment, the number of participants who are deemed ineligible during pre-screening and screening, and reasons for ineligibility, and any recruitment challenges.

The contractor shall notify the Study Project Leads in writing within five (5) business days if actual enrollment falls more than 15% below the projected enrollment targets for any consecutive two-month period, or if enrollment is delayed by more than thirty (30) calendar days from milestone dates specified in the enrollment timeline. The contractor shall submit a Corrective Action Plan (CAP) within fifteen (15) business days of the notification requirement, or upon request by the Study Project Leads, and implement approved corrective actions within the timeframes specified in the CAP. The CAP shall include, at minimum:

1.Root cause analysis of recruitment shortfalls, including site-specific barriers and systemic issues
2.Specific, measurable corrective measures with implementation timelines
3.Revised enrollment projections with supporting rationale
4.Additional recruitment strategies, which may include expansion of eligibility criteria (if scientifically justified), activation of additional study sites, enhanced advertising and outreach efforts, increased site training and support, or modification of study procedures to reduce participant burden
5.Resource requirements and budget implications for proposed corrective measures
6.Metrics for evaluating effectiveness of corrective actions

Task 12 – Draft Clinical Study Report

Within two (2) months of completing the final study participant, the Contractor shall deliver a Draft Study Report to the COR and Study Project Lead(s) containing: the background and purpose of the project, summary of recruiting, biological sampling frame, data collection techniques and procedures, PK analyses, pharmacodynamic analyses, subjective effects analyses, self-administration analyses, use topography analyses, adverse events, any significant problems encountered during the study and their solutions, data preparation and processing, any information necessary to reproduce statistical results and reanalyze datasets (e.g., coding procedures, statistical/analytic code), analyses of the relationships between acute abuse liability outcomes and actual use behaviors, any significant problems encountered during the clinical study and their solutions, and conclusions.

All raw data and data analysis files will be submitted in SAS transport format and Microsoft Excel. The Contractor shall submit all documents relating to study monitoring to the COR. The Contractor shall write up the results of the study in the form of an expanded American Psychological Association (APA; http://www.apastyle.org) format introduction section. The Contractor shall write these documents in MS Word compatible software.

Data files shall be prepared and delivered according to the following specifications:

1. Each record shall be uniquely identified and shall correspond to one respondent's data
2. All data values shall be numeric rather than character
3. Adverse events description with the time in the event table

4. One (1) electronic copy of a finalized, complete, and correct Coding Book
5. One (1) electronic copy of the data analyses report, including files, tables and figures, and appropriate statistical analyses of the results.

Task 13 – Final Clinical Study Report

The Contractor shall address all feedback and deliver a Final Study Report to the COR and Study Project Lead(s) within two (2) months after receiving comments from the FDA on the Draft Study Report.

Should the FDA have any additional comments on the Final Study Report, the Contractor shall respond to any comments from the FDA in a revised report to be submitted within one (1) month after receipt of FDA comments.

PERIOD OF PERFORMANCE

Four years in length after issuing the contract.

3.5 List of Deliverables

DELIVERABLE SCHEDULE

Task Number	Deliverable	Quantity	Delivery Date after Task Award
1	Kick-off Meeting	1	Within 10 business days of award.
2	NPI forms	1 per staff member	Within 30 business days of award.
3	Biweekly Meetings	Biweekly	Biweekly for the duration of the contract. Start within 10 business days of Kick-off Meeting.
4	Monthly Progress Reports	1 electronic version per month for contract duration	Electronically submit to the COR by the 10th of each month for each thirty-day period prior to the report due date.
5	Selection of Study Products	1	Within 10 business days of Kick-off Meeting.
6	Draft Clinical Study Protocol	1 electronic version	Initial draft within 30 business days of award kick-off meeting. Multiple iterations (no more than 3) may be necessary to

			address feedback from all FDA review processes.
7	Peer Review of Clinical Study Protocol	1 electronic version	Within 10 business days of receiving final SGE/RGE comments on Draft Protocol.
8	Final Clinical Study Protocol	1 electronic version	Within 10 business days of receiving final Government comments on Draft Clinical Study Protocol.
9	Obtain Clearances for the Study (OMB and IRB)	1 each	Variable, approximately 4 months is anticipated. Clearance must be obtained prior to any data collection.
10	Perform Clinical Study	1 study	Within 5 business days of final IRB approval.
11	Clinical Recruitment Updates	1 electronic version per week	Weekly for the duration of the clinical study.
12	Draft Clinical Study Report	1 electronic version	2 months after completion of the last participants. Approximately 15 months after human subject approval, anticipating the clinical study will take 12 months.
13	Final Clinical Study Report	1 electronic version.	2 months after receiving FDA comments on Draft Clinical Study Report.

INSPECTION AND ACCEPTANCE

The COR shall review and inspect all deliverables furnished under this contract in accordance with the deliverables cited herein.

SECTION 4 - CONTRACT REQUIREMENTS

4.1 CONFLICT OF INTEREST

a) The purpose of this section is to ensure that the contractor and its subcontractors:

(1) Are not biased because of their financial, contractual, organizational, or other interests which relate to the work under this contract, and
(2) Do not obtain any unfair competitive advantage over other parties by virtue of their performance of this contract.

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

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

(d) Contractor's Conflict of Interest Responsibilities
The individual contractor must be free of interest prior to performing under this contract. Any time prior to or during the performance of the contract the individual contractor believes that a potential or actual conflict exists, the individual should notify the contract officer and project officer. The contract officer will determine whether or not a conflict of interest exists and how to resolve or mitigate it. The contractor should not commence or continue working on the contract until directed by the contract officer.

(e) Warrant and Disclosure. The warrant and disclosure requirements apply to both the contractor and all subcontractors. The contractor warrants that, to the best of the contractor's knowledge and belief, there are no relevant facts or circumstances which would give rise to an organizational conflict of interest, as defined in FAR Subpart 9.5, and that the contractor has disclosed all relevant information regarding any actual or potential conflict. The contractor agrees it shall make an immediate and full disclosure, in writing, to the Contracting Officer of any potential or actual organizational conflict of interest or the existence of any facts that may cause a reasonably prudent person to question the contractor's impartiality because of the appearance or existence of bias or an unfair competitive advantage. Such disclosure shall include a description of the actions the contractor has taken or proposes to take in order to avoid, neutralize, or mitigate any resulting conflict of interest.

Prior to award, contractors that disclose potential or actual conflicts of interest shall submit a mitigation of conflicts of interest plan along with their technical and business proposals.

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

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

(h) Prime Contractor Responsibilities– The contractor shall identify and avoid, neutralize, or mitigate any subcontractor organizational conflict prior to award of the contract to the

satisfaction of the Contracting Officer. If the subcontractor's organizational conflict cannot be avoided, neutralized, or mitigated, the contractor must obtain the written approval of the Contracting Officer prior to entering into the subcontract. If the contractor becomes aware of a subcontractor's potential or actual organizational conflict of interest after contract award, the contractor agrees that the Contractor may be required to eliminate the subcontractor from its team, at the contractor's own risk. The contractor shall obtain from its subcontractors or consultants the disclosure required in FAR Part 9.507

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

4.2 Government-Furnished Property, Material, Equipment, or Information (GFP, GFM, GFE, or GFI)
None. GFP will not be furnished to the Contractor.

4.3 Security
There are no unique security requirements associated with performance of this contract.

4.4 Travel
There are no travel requirements associated with performance of this contract.

4.5 Special Material Requirements
There are no special material requirements with this contract.

4.6 OTHER REQUIREMENTS

FDA considers the sharing of FDA-funded research, including digital data, an important means to enhance its value and support future research. When the findings associated with research developed with FDA funds are published, they are required to be made readily available to the public. In addition, investigators seeking FDA funding, in whole or in part, via a contract, grant, or assistance agreement must have an FDA-approved Data Management Plan – a plan for digital data management and sharing – prior to commencing any related services or work.

Upon acceptance for publication, researchers are also responsible for submitting the author’s final manuscript of any peer-reviewed scientific publication resulting from research supported, in whole or in part, with FDA funds to the NIH National Library of Medicine's (NLM) PubMed Central (PMC). FDA defines the author's final manuscript as the final version accepted for journal publication, which includes all modifications resulting from the publishing peer review process. The PMC archive is the designated repository for these manuscripts for use by the public, health care providers, educators, scientists, and FDA. FDA expects timely release and sharing of final research data from FDA-funded studies for the research community’s use in accordance with the submitted Data Management Plan. Please see the FDA Public Access Policy available at:
http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/staffmanualguides/ucm479268.pdf).

4.7 Place of Performance

The performance of this contract will be conducted at the Contractor's facility.

Delivery, Installation, and Training visits shall not be scheduled during Federal Holidays or Federal Closures as determined by Executive Orders or opm.gov. Federal Holidays are as follows:

New Year's Day	Labor Day
Martin Luther King, Jr.'s Birthday	Columbus Day
Washington's Birthday	Veterans Day
Memorial Day	Thanksgiving
Juneteenth	Day Christmas
Independence	Day
Day	

4.8 Period of Performance

The period of performance of this contract is Four years from date of award.

4.9 Contract Type

This will be a Firm-fixed price contract.

SECTION 5 - GENERAL EVALUATION INFORMATION EVALUATION AND AWARD

The Government intends to make award based on best value trade-off.

Parties responding to this solicitation may submit their offer in accordance with their standard commercial practices (e.g. on company letterhead, formal quote form, etc.) but shall include the following information: 1) company's complete mailing and remittance addresses 2) discounts for prompt payment if applicable; 3) Unique Entity Identification (UEI); 4) Taxpayer ID number; 5) Catalog or Published Price Listing applicable to the service; 6) Offerors shall meet specifications as noted in the synopsis. The total number of pages for the technical proposal shall not exceed fifteen (15) pages.

The solicitation does not commit and obligate the Government to the expenditure of public funds in connection with the proposed acquisition.

SECTION 6 – CONTRACT CLAUSES AND PROVISIONS / ADDITIONAL TERMS AND CONDITIONS

6.1 Solicitation Provisions:

This solicitation incorporates one or more solicitation provisions by reference, with the same

force and effect as if they were given in full text. 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. Full text of any provision may be accessed electronically at this/these address(es): https://www.acquisition.gov/far-overhaul and https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html.

FAR Provisions:

52.204-7, System for Award Management—Registration 52.204-7 System for Award Management (DEVIATION) (RFO AUG 2025)
52.240-90, Security Prohibitions and Exclusions Representations and Certifications 52.204-90 Offeror Identification (DEVIATION) (RFO AUG 2025)

The provision at FAR 52.212-1 Instructions to Offerors - Commercial Products and Commercial Services (DEVIATION)(RFO APRIL 2026) applies to this solicitation. The following addenda apply:

Instructions to Offerors—Commercial Products and Commercial Services (Deviation Date)
(a) *Submission of offers*. Submit signed and dated offers to the office specified in this solicitation at or before the exact time specified in this solicitation. As a minimum, offers shall include—
(1) The solicitation number;
(2) The name, address, telephone number of the Offeror;
(3) The Offeror's Unique Entity Identifier (UEI) and, if applicable, Electronic Funds Transfer (EFT) indicator;
(4) Information necessary to evaluate the factors contained in the provision at 52.212-2 or as described in the solicitation;
(5) Responses to provisions that require Offeror completion of information, representations, and certifications (other than those collected via the System for Award Management (SAM)); and
(6) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and any solicitation amendments.
(b) *Period for acceptance of offers*. The Offeror agrees to hold the prices in its offer firm for 60 calendar days from the date specified for receipt of offers, unless another time period is specified in an addendum to the solicitation.
(c) *Late submissions, modifications, revisions, and withdrawals of offers*.
(1) Offerors are responsible for submitting offers and any modifications or revisions to the Government office designated in the solicitation by the time specified in the solicitation.
(2) Any offer, modification, or revision received after the time specified for receipt of offers is "late" and will not be considered unless it is received before award is made and the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition. However, a late modification of an otherwise successful offer that makes its terms more favorable to the Government will be considered at any time it is received and

may be accepted.
(3) If an emergency or unanticipated event interrupts normal Government processes so that offers cannot be received at the Government office designated for receipt of offers by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation or other notice of an extension of the closing date, the time specified for receipt of offers will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
(4) Offerors may withdraw their offers by written notice to the Government received at any time before award.
(d) *Contract award (not applicable to Invitation for Bids)*. The Government intends to evaluate offers and award a contract without discussions with Offerors. Therefore, the Offeror's initial offer should contain the Offeror's best terms. However, the Government reserves the right to conduct discussions, if necessary. The Government may reject any or all offers if such action is in the public interest, accept other than the lowest offer, and waive informalities and minor irregularities in offers received.
(e) *Debriefings*. If a post award debriefing is given to requesting Offerors, the Government will disclose the following information, if applicable:
(1) The agency's evaluation of the significant weak or deficient factors in the debriefed Offeror's offer.
(2) The overall evaluated cost or price and technical rating of the successful Offeror and the debriefed Offeror and past performance information on the debriefed Offeror.
(3) The overall ranking of all Offerors when any ranking was developed by the agency during source selection.
(4) A summary of the rationale for award.
(5) For acquisitions of commercial products, the make and model of the product to be delivered by the successful Offeror.
(6) Reasonable responses to relevant questions posed by the debriefed Offeror as to whether the agency followed source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities.

(End of provision)

Unique Entity Identifier (UEI):
To be considered for an award the offeror shall be registered and active in SAM (www.sam.gov) by the date and time set forth for receipt of quotes/proposals.

Buy American Act and Executive Order 14005:
If applicable, respondent shall provide place (country) of product/service manufacture or performance and any other applicable information to enable review and analysis pertaining to the requirements under the Buy American Act and requirements relating to Executive Order 14005 Ensuring the Future is Made in All of America by All of America's Workers, in the event that a nonavailability waiver request submitted through the Made in America Office (MIAO) Digital Waiver Portal is required.

The provision at 52.212-2 Evaluation—Commercial Products and Commercial Services (DEVIATION) (RFO APRIL 2026) is applicable to this solicitation.

EVALUATION—COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES (OCT. 28, 2025)

(a) Evaluation factors. The Government will award a contract resulting from this solicitation to the responsible Offeror whose offer conforming to the solicitation will be most advantageous to the Government, price and other factors considered. The following factors will be used to evaluate offers:

FACTOR 1 – Technical Understanding and Approach
FACTOR 2 – Relevant Past Performance
FACTOR 3 – Staffing Plan
FACTOR 4 – Key Personnel
FACTOR 5 – Pricing

Evaluation factors other than price when combined are significantly more important than price.

(b) *Options (if applicable)*. The Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. The Government may determine that an offer is unacceptable if the option prices are significantly unbalanced. The evaluation of options does not obligate the Government to exercise the option(s).

(c) *Notice of award*. A written notice of award or acceptance of an offer furnished to the successful Offeror within the time for acceptance specified in the offer, shall result in a binding contract without further action by either party. Before the offer's specified expiration time, the Government may accept an offer (or part of an offer), whether or not there are negotiations after its receipt, unless a written notice of withdrawal is received before award.

(End of provision)

NOTICE

System updates may lag policy updates. The System for Award Management (SAM) may continue to require entities to complete representations based on provisions that are not included in agency solicitations. Examples include 52.222-25, Affirmative Action Compliance, and paragraph (d) of 52.212-3, Offeror Representations and Certifications — Commercial Products and Commercial Services. Contracting officers will not consider these representations when making award decisions or enforce requirements. Entities are not required to, nor are they able to, update their entity registration to remove these representations in SAM.

6.2 Contract Clauses:

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

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

52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS—COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES (MAR 2026)

(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).
_**X**_ (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].
_**X**_ (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).
__ (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.
_X_ (12) 52.209-6, Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, Proposed for *Debarment*, or Voluntarily Excluded. (Jan 2025) (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 (Jan 2025)(15 U.S.C. 637(d)(2) and (3)).
__ (21)
(i) 52.219-9, Small Business Subcontracting Plan (Jan 2025) (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 (Jan 2025) 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, Postaward Small Business Program Rerepresentation (Jan 2025) (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 (Mar 2026)(E.O. 13126).
_**X**_ (33) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
__ (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).
_**X**_ (38) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
__ (39)
(i) 52.222-50, Combating Trafficking in Persons (Oct 2025) (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 (Jan 2025) (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.)
_**X**_ (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).
__ (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 (Jan 2025) of 52.225-3.
__ (iv) *Alternate* III (Feb 2024) of 52.225-3.
__ (v) *Alternate* IV (Oct 2022) of 52.225-3.
_**X**_ (50) 52.225-5, Trade Agreements (NOV 2023) (19 U.S.C. 2501, *et seq*., 19 U.S.C. 3301 note).
__ (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).
__ (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).
_**X**_ (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.*]
_**X**_ (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).
_**X**_ (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).
_**X**_ (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).
__ (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).
_**X**_ (7) 52.222-55, Minimum Wages for Contractor Workers Under Executive Order 14026 (Jan 2022).
_**X**_ (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).
__ (10) 52.247-69, Reporting Requirement for U.S.-Flag Air Carriers Regarding Training to Prevent Human Trafficking (Jan 2025) (49 U.S.C. 40118(g)).
(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 (Jan 2025) (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 2016) (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 (Oct 2025) (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 (Jan 2025) (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 (Oct 2025). 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 (Jan 2025) (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 (Oct 2025) (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 (Jan 2025) (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.

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

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer shall

make their full text available. Also, the full text of a clause may be accessed electronically at:

1) www.acquisition.gov/far/index.html.

FAR NUMBER	TITLE	DATE
52.204-7	System for Award Management	NOV 2024
52.204-13	System for Award Management Maintenance	OCT 2018
52.204-21	Basic Safeguarding of Covered Contractor Information Systems	NOV 2021
52.212-3	Offeror Representations and Certifications—Commercial Products and Commercial Services	MAY 2024
52.212-4	Contract Terms and Conditions – Commercial Products and Commercial Services **(DEVIATION) (RFO APRIL 2026)**	APRIL 2026

HHSAR Clauses:

HHSAR Clauses Incorporated by Reference

HHSAR 352.203-70 Anti-Lobbying (Dec 2015)
HHSAR 352.223-70 Safety and Health (Dec 2015)
HHSAR 352.227-70 Publications and Publicity (DEC 2015)
HHSAR 352.232-71 Electronic Submission of Payment Requests (Dec 2015)
HHSAR 352.237-75 Key Personnel (Dec 2015)
HHSAR 352.239-74 Electronic and Information Technology Accessibility (DEC 2015)

6.3 INVOICE INSTRUCTIONS

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

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

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

c.

1. The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for

submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 - 5 business days of the contract award for new contracts or date of modification for existing contracts.

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

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

e. Invoices that include cost-reimbursement Line Items must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts. At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.

- Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
- Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
- Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
- Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
- Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
- Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
- Fee - amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

f. Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:
(a) list of all invoices submitted to date under the subject award, including the following:
(1) invoice number, amount, & date submitted
(2) corresponding payment amount & date received
(b) total amount of all payments received to date under the subject contract or order

(c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance.
g. Payment of invoices will be made based upon acceptance by the Government of the entire task or the tangible product deliverable(s) invoiced. Payments shall be based on the Government certifying that satisfactory services were provided, and the Contractor has certified that labor charges are accurate.
h. If the services are rejected for failure to conform to the technical requirements of the task 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.

6.4 RFP INQUIRIES AND QUESTIONS DUE DATE

All questions regarding the solicitation, of a contractual nature or technical nature, must be submitted in writing and sent via email to Janice.Heard@fda.hhs.gov by 06/22/2026, no later than 2:00 P.M. Eastern Time (ET). The Government may not consider any questions received after this date and time. All questions received and any amendments to this solicitation will be answered and posted on sam.gov.

6.5 PROPOSAL SUBMISSION

Offerors who are interested in this RFP must submit their proposal to Janice.Heard@fda.hhs.gov by July 6, 2026 no later than 2:00 P.M. Eastern Time (ET). Offerors shall submit one (1) electronic copy to Janice.Heard@fda.hhs.gov.
All electronic submissions must contain the RFP solicitation number and titled in the subject of the electronic submission email.

SECTION 7 PROPOSAL INSTRUCTIONS

The offeror or applicant shall submit all electronic documents for Microsoft Office suite

products without the use of "macros". ***When submitting proposals via email, DO NOT include; exe,. mso, or any other executable file types that could potentially trigger email security protections (i.e. email blocks, quarantine).*** If the offeror or applicant submits documents that contain macros**,** ***macro referenced files, and/or executable files*****,** the Government will not be able to view or open such documents and the submission will be considered non-responsive to the solicitation. No additional time will be given to an offeror or applicant to correct the document submission, and the Government will not inform the offeror or applicant that their submission is non-responsive prior to award. It is the offerors or applicant's responsibility to ensure all electronic documents are submitted without the use of macros.

Proposals shall demonstrate: (1) qualifications, expertise, and availability of proposed professional and technical personnel, as evidenced by education, experience, and the successful performance of the specific duties assigned for the award; and (2) demonstrated experience and accomplishments of key personnel in managing similar or related projects/tasks of comparable scientific complexity, as evidenced by the Offeror's response to the requirements of the SOW.

Cover Page: The Offeror shall include a cover page which shall include a point of contact (name, telephone number, and email address). Unique Entity Identification (UEI); number, country of manufacturing of equipment, and certification that all company information listed in the System for Award Management (SAM) database is complete, accurate, and current.

The Offeror shall include a project timeline to accompany the technical proposal. The timeline shall depict how all contract milestones will be accomplished during the period of performance including but not limited to: protocol development and review (FDA and Contractor review timelines), human subject protections review (FDA and External), purchase of study product(s), laboratory study, clinical study, data analysis, and reporting. Specifically, the Offeror shall provide in weeks or months how long they anticipate each deliverable will take to complete, as well as a visual timeline.

Offerors shall ensure the solicitation number is visible in the header of the email transmission of their proposal.

Faxed proposals will not be accepted.

7.1 EVALUATION FACTOR FOR AWARD

The Government will evaluate the extent to which the Contractor's proposal clearly and completely demonstrates the contractor's understanding of the requirement and the contractors' capabilities to address all the evaluation factors listed below. All evaluation factors and subfactors are listed in descending order of importance and when combined, are significantly more important than price.

The evaluation factors for this requirement are as follows:

FACTOR 1 – Technical Understanding and Approach
FACTOR 2 – Relevant Past Performance

FACTOR 3 – Staffing Plan
FACTOR 4 – Key Personnel
FACTOR 5 – Pricing

Evaluation of Factor 1 – Technical Understanding and Approach

TECHNICAL UNDERSTANDING/APPROACH
The Offeror shall provide a narrative description of the approach to performing the work described in the SOW. The narrative should describe the Offeror's understanding of the project (both from a business and technical standpoint) and its relevance to CTP regulatory activities, how the Offeror intends to satisfy the technical requirements, any risks it foresees in carrying out its approach, along with mitigation strategies for those risks. This shall also include a project timeline for the life of the contract. The timeline will be evaluated on reasonableness and the Offeror's ability to complete the project within the specific period of performance. The Offeror shall demonstrate when each deliverable will be completed and all target milestones.

The Offeror's technical approach will be evaluated by how the Offeror demonstrates in-depth knowledge, expertise, and experience on:

- Recruiting, screening, and selecting experienced combusted cigarette users as participants for clinical studies
- Identifying tobacco products to be used in the clinical study with consideration of the specifications outlined in the SOW
- Administering tobacco products within experimental and laboratory settings
- Collection of behavioral, pharmacological, and biological data from clinical subjects, in acute laboratory and ambulatory settings as outlined in the SOW
- Performing statistical analyses of user behaviors and nicotine pharmacokinetics

Confidence Ratings:

High Confidence – The Government has high confidence that the contractor understands the requirement, proposes a sound approach, and will be successful in performing the contract with little or no Government intervention.

Some Confidence – The Government has some confidence that the contractor understands the requirement, proposes a sound approach, and will be successful in performing the contract with some Government intervention.

Low Confidence – The Government has low confidence that the contractor understands the requirement, proposes a sound approach, or will be successful in performing the contract even with Government intervention.

Evaluation of Factor 2 – Relevant Past Performance

RELEVANT PAST PERFORMANCE

This section in the Technical Proposal Volume shall describe the Offeror's success in performing comparable contracts/orders where the tobacco products studied, and methods used were similar to those proposed in this SOW. The Offeror should submit this information directly to the Government as part of their proposal:

A list of up to three contracts or research grants (federal, foundation, or private funding), similar in scope, duration, and price to the work described in this SOW.

The Offeror shall adhere to the following guidelines in generating this list:

- These contracts, grants, or orders must have been completed within the past 5 years and before the request for proposals (RFP) due date.
- The list may include contracts or grants on which the Offeror served as a subcontractor, provided that the subcontract was similar in scope, duration, and price to this effort.
- The list should include both a contractual and technical point of contact (email addresses and phone numbers) for each of the contracts.
- If a subcontract is being used as a past performance reference, contact information for the prime Contractor, not the customer, should be included.
- The list should include the contract or grant number, title, period of performance, and the total dollar value of the contract.
- If the contract or grant is not described in Relevant Experience Section of the Technical Volume, the Offeror shall include a one-page narrative of the contract, describing the nature of the work performed and emphasizing outcomes reached.
- Provide details about the contract’s or grant’s study recruitment to include: proposed recruitment size and timelines, actual recruitment size and timelines, as well as any necessary summary/justification for recruitment efforts that fell short.

Offerors are cautioned that the Government may use data provided by each Offeror as well as data obtained from possible other sources such as the Contractor Performance Assessment Reporting System (CPARS) in the evaluation of past performance.

The Offeror’s past performance information shall be evaluated by how the Offeror demonstrates their success in performing comparable contracts/grants, with a sharp focus on clinical study recruitment and study implementation. Evaluation of past performance shall be based on the provided list of up to three contracts/grants, similar in scope, duration, and price to the work described in this SOW.

The Government shall consider the currency and relevance of the information, source of the information, context of the data, and general trends in the Offeror’s performance.

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

Past Performance will be rated Acceptable, Unacceptable or Neutral. This determination will be made by reviewing the totality of the Offeror’s submission. Past performance information shall pertain to work performed that is similar to that anticipated by the Statement of Work. In determining relevance, consideration will be given to contracts of similar project complexity, scope, type, and schedule. Past Performance shall be evaluated on the following criteria: quality

of service provided, timeliness of performance, effectiveness of management, compliance with price estimates, customer satisfaction, and overall performance. Past Performance questionnaires will also be used and evaluated to determine contractor capability.

In accordance with FAR 15.305(a)(2)(iv), in the case of an Offeror without a record of relevant past performance or for whom information on past performance is not available, the Offeror may not be evaluated favorably or unfavorably on past performance. Therefore, the Offeror shall be determined to have "Neutral" rating or neutral past performance. See below for Past Performance ratings.

Acceptable - Based on the Offeror's recent and relevant performance record, the Government has a reasonable expectation that the Offeror will successfully perform.

Unacceptable - Based on the Offeror's recent and relevant performance record, the Government has a low expectation that the Offeror will successfully perform.

Neutral - The Offeror does not have any performance record; or the Offeror's performance record is not available, a meaningful confidence rating cannot be reasonably assigned.

Evaluation of Factor 3 – Staffing Plan

STAFFING PLAN

The Offeror shall provide a narrative description of the approach to staffing the project. This should include discussion of how it shall ensure that the project is adequately staffed. Representative resumes of proposed personnel for the contract shall be provided by the Offeror.

The Offeror shall provide a Staffing Plan that shows the positions to be used to support this effort. The plan should conform to the following requirements:

- Shows all proposed positions by labor category
- Indicate with a "Yes" or "No", whether it is a key position
- Lists the number of hours for each proposed position
- Calculates subtotals, segregated by the CLINs delineated
- Calculates total hours
- Describes the functional/technical role corresponding to each position

The Offeror's staffing plan shall be evaluated how the Contractor demonstrated the proposed staffing in an accompanying narrative that includes:

- Proposed team's roles and responsibilities
- Explains the proposed organizational structure and how the proposed key, leads, and working-level staff shall be applied to accomplishing the work
- Explains how staff is trained to develop and maintain the technical expertise, project management, and communication required to efficiently and effectively support the required work.

Confidence Ratings:

High Confidence – The Government has high confidence that the contractor understands the staffing requirement and will be successful in performing the contract with little or no Government intervention.

Some Confidence – The Government has some confidence that the contractor understands the staffing requirement and will be successful in performing the contract with some Government intervention.

Low Confidence – The Government has low confidence that the contractor understands the staffing requirement or will be successful in performing the contract even with Government intervention.

Evaluation of Factor 4 – Key Personnel

KEY PERSONNEL

The Offeror shall provide a narrative in which the Offeror identifies key personnel. The narrative should describe the roles of key personnel and expected contributions of each individual identified. The following labor categories are considered key personnel, but others may be specified by the Offeror: Clinical Data Manger, Pharmacokineticist, Project Director/Manager, and Senior Scientist.

Clinical Data Manager – Requires a master's degree and experience managing data associated with at least three (3) clinical research studies. Manages all aspects of clinical data collection and safety. Establishes and maintains policies and procedures for gathering, coding, analyzing, and reporting clinical data.

Pharmacokineticist – Requires a Ph.D. and experience in evaluating pharmacokinetic data in at least two (2) clinical research studies. Provides extensive experience and judgment to plan and analyze clinical data.

Project Director/Manager – Requires a bachelor's degree and extensive experience in managing clinical research studies. Organizes, directs, and manages support services for all activities coved by this contract. Ensures adherence to contracts, protocols, and schedules; develops solutions to program problems; and directs work of incumbents assigned to program from various departments. Ensures projects are completed on time and within budget**.**

Senior Scientist – Requires a Ph.D. and experience as lead scientist on at least three (3) clinical research projects. Supervises and works alongside other scientists in their daily operations and clinical research. Provides extensive experience and judgment to plan and accomplish study goals.

The Offeror shall submit a resume for each proposed key personnel describing experience, education, work history, professional certifications, and any other relevant information regarding their qualifications. Each resume shall be limited to three (3) 8.5 x 11 inch pages (anything over this limit shall be ignored).

The Offeror shall submit a letter of commitment on company letterhead for each key person proposed who is not already an employee of the proposed prime or subcontractor. This includes any key person that is a 1099/consultant/or subcontractor employee. Date the letter, list the named individual and position, show dates of committed employ, and have the letter signed by both parties. Any salary amounts shall be redacted from the letter.

Confidence Ratings:

High Confidence – The Government has high confidence that the contractor has provided an adequate number of key personnel and will be successful in performing the contract with little or no Government intervention.

Some Confidence – The Government has some confidence that the contractor has provided an adequate number of key personnel and will be successful in performing the contract with some Government intervention.

Low Confidence – The Government has low confidence that the contractor has provided an adequate number of key personnel or will be successful in performing the contract even with Government intervention.

Evaluation of Factor 5 – Price

PRICE/BUSINESS VOLUME INSTRUCTIONS

The Offeror shall prepare a price volume that contains all information necessary to allow for a comprehensive evaluation of the prices offered. The price proposal shall consist of pricing discounts, the proposed labor categories, and hours, as applicable.

The pricing information shall include a completed Pricing Table.

The price/business volume should also include all other information required by this RFP in these instructions such as the Offeror Representations and Certifications.

SECTION 8 - BASIS FOR AWARD

The Government shall award one contract resulting from this solicitation to the most highly rated offeror whose offer, conforming to this solicitation, is determined to be the best value to the Government, technical, price and other factors considered. The Evaluation Factors (Technical Understanding, Approach, Past Performance, Staffing Plan and Qualifications of Key Personnel and Price) are listed below in descending order of importance. Technical factors, when combined, are significantly more important when compared to price. The Government reserves the right to make an award to other than the lowest priced offeror. The Government also reserves the right to award without discussions and to make an award based upon initial offers; thus, offerors shall ensure that their proposal represents their best offer. As technical merit of an offeror's proposals becomes equal, the evaluated price shall become the determining factor. Proposals determined to be unacceptable will not be considered for award.