

**Offeror Name :** Center for Biological Evaluation and Research-Blood Research and Review  
**Duns:** 004177146

**PART 1 – GENERAL INFORMATION**

This is a combined synopsis/solicitation prepared in accordance with FAR 13.106-1. Quotes are being requested and this announcement constitutes the only solicitation. The Government contemplates issuing a firm fixed-price purchase order resulting from this solicitation. The solicitation document and incorporated provisions and clauses are those in effect through Federal Acquisition Circular (FAC) 2021-04 dated January 19, 2021.

The associated North American Industrial Classification System (NAICS) code for this procurement is 811219 – Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology). This requirement is being solicited as a sole source acquisition.

**PART 2 – SUPPLIES OR SERVICES AND PRICES/COSTS**

**Contract Type:** The Government intends to issue a firm fixed-price purchase order resulting from this solicitation.

**Pricing Table:**

Quantity	Catalog #	Variant #	Product	Product Description	Unit Price [USD]	Total Price [USD]
1.00	338902	CS0001	General Service - Project setup fee			
75.00	338916	CS0162	Sequencing (NGS) Services - RNA QC (qPCR-based)			
75.00	338916	CS0202	Sequencing (NGS) Services - miRNA library prep			
75.00	338916	CS0143	Sequencing (NGS) Services - QC library prep			
75.00	338916	CS0166	Sequencing (NGS) Services - 1x75bp, 1x12M reads on average			
75.00	338916	CS0169	Sequencing (NGS) Services - miRNA NGS s/p (analysis)			
1.00	338916	CS0201	Sequencing (NGS) Services - Online data delivery_NGS			
1.00	338903	CS0100	Services fee - Sample return shipment fee			

Quote Total Price [USD]:

Price per Sample [USD]:

**PART 3 – DESCRIPTION OF REQUIREMENT**

**Background**

The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the

safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable, and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

The Center for Biologics Evaluation and Review (CBER) regulates HIV diagnostic kits and viral load assays. This study is essential to public health regarding blood transfusion and transmission. Standard diagnostic assays do not detect various strains due to HIV diversity caused by high mutation rates and the slow-growing disposition of many strains. The earliest detection needs novel biomarkers like exosome miRNA, which has been the hot field in recent years. It is imperative to detect all types of new infections in individuals at the earliest. This detection will help control the spread of AIDS and assist in treatment development.

### **Purpose**

Over the course of the last couple of years (75F40122P00472, 75F40121C00056), we conducted initial studies on 75 plasma exosome small RNA NGS and identified several miRNAs expressed differentially. We further want to validate the identified miRNAs using more than 60 plasma exosome samples using the same method. As the exosome method is not standardized and different ways give different results, we must follow the same process to finish our study.

The process involves:

1. Incoming RNA QC
2. Determine the purity and concentration of total RNA
3. Assess the integrity of total RNA
4. Sequencing library preparation
5. Sequencing by Illumina platform
6. Data extraction, analysis, and summarization

The laboratory will isolate the exosome, and the company will give us a Trizol solution to denature the HIV virus. When the lab isolates exosomes, there will be HIV, but when Trizol solution is added, the HIV dies. From there onwards, further RNA extraction and quality check are done. This process is done because many companies cannot handle HIV-infected samples. Therefore, we isolate exosomes as suggested by the company and put them in a solution called Trizol, which kills HIV, and we send this solution as this is not infectious.

The research requires further miRNA profiling from more than 60 plasma Exosome samples for different strains of HIV to identify markers and new miRNAs for HIV infection

### **Deliverables**

Provide sample QC report and data in Fastaq format. Sequence the miRNA and do the data analysis for biomarker identification and novel miRNA identification of both host and virus.

## **PART 4 – INSPECTION AND ACCEPTANCE**

Inspection and acceptance will be performed at the delivery location. The Project Officer will perform inspection and acceptance of the materials delivered. Acceptance is communicated in writing unless otherwise indicated by the Contracting Officer of Technical POC within 30 days of receipt of the deliverable(s). If a rejection is issued, the Contractor shall correct any deficiencies within fifteen (15) days from the time the Government issues the rejection notice. If the Contractor cannot correct the

deficiencies within this time frame, the contractor shall immediately notify the Technical POC of the reason for the delay and provide a proposed corrective action plan within three (3) business days.

## **PART 5 – DELIVERIES OR PERFORMANCE**

### **Deliveries and Place of Performance**

Satisfactory performance of this contract shall be deemed to occur upon delivery of services described above and/or upon acceptance by the Contracting Officer or the Technical Representative of these products/services. Place of performance is:

Attn: Mohan Kumar Haleyr Giri Setty ,CBER/FDA  
Bldg. 72, Rm 4322  
White Oak Campus,  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002  
Ph: 240-402-8233  
Email: [Mohan.Haleyurgirisetty@fda.hhs.gov](mailto:Mohan.Haleyurgirisetty@fda.hhs.gov)

The POC will be identified at the time of award. The Contractor shall contact the Government POC at least 24 hours prior to delivery or service. Deliveries, installation and trainings shall occur at the place of performance specified above during regular business hours (Monday-Friday) during the times of 8:00 AM – 4:00 PM, excluding holidays, in accordance of the delivery location time zone (Eastern Time, Central Time, or Pacific Time). Supplies or services scheduled for delivery on a Federal holiday shall be made the next business day.

### **Period of Performance:**

**9/25/2023 – 4/25/2024**

The anticipated period of performance is 8 months after the date of award.

## **PART 6 – CONTRACT ADMINISTRATION DATA**

The following personnel shall represent the Government for the purpose of this contract:

### **Technical Representative:**

To be determined upon contract award

The Technical Representative is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

### **Contracting Officer (CO):**

Ian Weiss  
4041 Powder Mill Road  
Beltsville, MD 20705

### **Contract Specialist (CS):**

Shobana Vengadasami  
4041 Powder Mill Road  
Beltsville, MD 20705

[Ian.Weiss@fda.hhs.gov](mailto:Ian.Weiss@fda.hhs.gov)

Tel: (301) 796-5782

[Shobana.Vengadasami@fda.hhs.gov](mailto:Shobana.Vengadasami@fda.hhs.gov)

Tel: (240) 402-6604

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to (1) Direct or negotiate any changes in the RFQ; (2) Modify or extend the period of performance; (3) Change the delivery schedule; (4) Authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) Otherwise change any terms and conditions of this contract.

### **FDA Invoicing Instructions:**

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

(a) Definitions. As used in this clause-

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at [www.ipp.gov](http://www.ipp.gov) or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(END OF CLAUSE)

#### **FDA Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP)**

- 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 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.eroctwai.gov](mailto:ipp.noreply@mail.eroctwai.gov). Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to [IPPCustomerSupport@fiscal.treasury.gov](mailto: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](mailto: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.

(END OF CLAUSE)

**FAR 52.204-26 Covered Telecommunications Equipment or Services-Representation (Dec 2019)**

(a) *Definitions.* As used in this provision, “covered telecommunications equipment or services” has the meaning provided in the clause [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

(b) *Procedures.* The Offeror shall review the list of excluded parties in the System for Award Management (SAM) (<https://www.sam.gov>) for entities excluded from receiving federal awards for “covered telecommunications equipment or services”.

(c) *Representation.* The Offeror represents that it  does,  does not provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument.

(End of provision)

**FAR 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items (Jan 2021)**

(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 items:

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

(2) [52.204-23](#), Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

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

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

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

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

[Contracting Officer check as appropriate.]

(1) [52.203-6](#), Restrictions on Subcontractor Sales to the Government (June 2020), with Alternate I (Oct 1995) ([41 U.S.C. 4704](#) and [10 U.S.C. 2402](#)).

(2) [52.203-13](#), Contractor Code of Business Ethics and Conduct (Jun 2020) ([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.)

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

(5) [Reserved].

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

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

(8) [52.209-6](#), Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Jun 2020) ([31 U.S.C. 6101 note](#)).

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

(10) [Reserved].

(11)

(i) [52.219-3](#), Notice of HUBZone Set-Aside or Sole-Source Award (Mar 2020) ([15 U.S.C. 657a](#)).

(ii) Alternate I (Mar 2020) of [52.219-3](#).

(12)

- (i) [52.219-4](#), Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Mar 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) ([15 U.S.C. 657a](#)).
  - (ii) Alternate I (Mar 2020) of [52.219-4](#).
  - (13) [Reserved]
  - (14)
- (i) [52.219-6](#), Notice of Total Small Business Set-Aside (Nov 2020) ([15 U.S.C. 644](#)).
  - (ii) Alternate I (Mar 2020) of [52.219-6](#).
  - (15)
- (i) [52.219-7](#), Notice of Partial Small Business Set-Aside (Nov 2020) ([15 U.S.C. 644](#)).
  - (ii) Alternate I (Mar 2020) of [52.219-7](#).
  - (16) [52.219-8](#), Utilization of Small Business Concerns (Oct 2018) ([15 U.S.C. 637\(d\)\(2\)](#) and (3)).
  - (17)
- (i) [52.219-9](#), Small Business Subcontracting Plan (Jun 2020) ([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 (Jun 2020) of [52.219-9](#).
  - (18)
- (i) [52.219-13](#), Notice of Set-Aside of Orders (Mar 2020) ([15 U.S.C. 644\(r\)](#)).
  - (ii) Alternate I (Mar 2020) of [52.219-13](#).
  - (19) [52.219-14](#), Limitations on Subcontracting (Mar 2020) ([15 U.S.C. 637\(a\)\(14\)](#)).
  - (20) [52.219-16](#), Liquidated Damages-Subcontracting Plan (Jan 1999) ([15 U.S.C. 637\(d\)\(4\)\(F\)\(i\)](#)).
  - (21) [52.219-27](#), Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Mar 2020) ([15 U.S.C. 657f](#)).
  - (22)
- (i) [52.219-28](#), Post Award Small Business Program Rerepresentation (Nov 2020) ([15 U.S.C. 632\(a\)\(2\)](#)).
  - (ii) Alternate I (MAR 2020) of [52.219-28](#).
  - (23) [52.219-29](#), Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Mar 2020) ([15 U.S.C. 637\(m\)](#)).
  - (24) [52.219-30](#), Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Mar2020) ([15 U.S.C. 637\(m\)](#)).
  - (25) [52.219-32](#), Orders Issued Directly Under Small Business Reserves (Mar 2020) ([15 U.S.C. 644\(r\)](#)).
  - (26) [52.219-33](#), Nonmanufacturer Rule (Mar 2020) ([15U.S.C. 637\(a\)\(17\)](#)).
  - (27) [52.222-3](#), Convict Labor (Jun 2003) (E.O.11755).
  - (28) [52.222-19](#), Child Labor-Cooperation with Authorities and Remedies (Jan2020) (E.O.13126).
  - (29) [52.222-21](#), Prohibition of Segregated Facilities (Apr 2015).
  - (30)
- (i) [52.222-26](#), Equal Opportunity (Sep 2016) (E.O.11246).
  - (ii) Alternate I (Feb 1999) of [52.222-26](#).
  - (31)
- (i) [52.222-35](#), Equal Opportunity for Veterans (Jun 2020) ([38 U.S.C. 4212](#)).
  - (ii) Alternate I (Jul 2014) of [52.222-35](#).
  - (32)
- (i) [52.222-36](#), Equal Opportunity for Workers with Disabilities (Jun 2020) ([29 U.S.C. 793](#)).
  - (ii) Alternate I (Jul 2014) of [52.222-36](#).



- X (33) [52.222-37](#), Employment Reports on Veterans (Jun 2020) ([38 U.S.C. 4212](#)).
- X (34) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
- X (35)
- (i) [52.222-50](#), Combating Trafficking in Persons (Oct 2020) ([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).
- (36) [52.222-54](#), Employment Eligibility Verification (Oct 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in [22.1803](#).)
- (37)
- (i) [52.223-9](#), Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) ([42 U.S.C. 6962\(c\)\(3\)\(A\)\(ii\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- (ii) Alternate I (May 2008) of [52.223-9](#) ([42 U.S.C. 6962\(i\)\(2\)\(C\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- (38) [52.223-11](#), Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).
- (39) [52.223-12](#), Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).
- (40)
- (i) [52.223-13](#), Acquisition of EPEAT®-Registered Imaging Equipment (Jun 2014) (E.O.s 13423 and 13514).
- (ii) Alternate I (Oct 2015) of [52.223-13](#).
- (41)
- (i) [52.223-14](#), Acquisition of EPEAT®-Registered Televisions (Jun 2014) (E.O.s 13423 and 13514).
- (ii) Alternate I (Jun 2014) of [52.223-14](#).
- (42) [52.223-15](#), Energy Efficiency in Energy-Consuming Products (May 2020) ([42 U.S.C. 8259b](#)).
- (43)
- (i) [52.223-16](#), Acquisition of EPEAT®-Registered Personal Computer Products (Oct 2015) (E.O.s 13423 and 13514).
- (ii) Alternate I (Jun 2014) of [52.223-16](#).
- X (44) [52.223-18](#), Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020) (E.O. 13513).
- X (45) [52.223-20](#), Aerosols (Jun 2016) (E.O. 13693).
- (46) [52.223-21](#), Foams (Jun 2016) (E.O. 13693).
- (47)
- (i) [52.224-3](#) Privacy Training (Jan 2017) (5 U.S.C. 552 a).
- (ii) Alternate I (Jan 2017) of [52.224-3](#).
- X (48) [52.225-1](#), Buy American-Supplies (May 2014) ([41 U.S.C. chapter 83](#)).
- (49)
- (i) [52.225-3](#), Buy American-Free Trade Agreements-Israeli Trade Act (May 2014) ([41 U.S.C. chapter 83](#), [19 U.S.C. 3301](#) note, [19 U.S.C. 2112](#) note, [19 U.S.C. 3805](#) note, [19 U.S.C. 4001](#) note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43).
- (ii) Alternate I (May 2014) of [52.225-3](#).
- (iii) Alternate II (May 2014) of [52.225-3](#).
- (iv) Alternate III (May 2014) of [52.225-3](#).
- (50) [52.225-5](#), Trade Agreements (Oct 2019) ([19 U.S.C. 2501](#), et seq., [19 U.S.C. 3301](#) note).
- X (51) [52.225-13](#), Restrictions on Certain Foreign Purchases (Jun 2008) (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. 2302](#)Note).
- \_\_\_ (53) [52.226-4](#), Notice of Disaster or Emergency Area Set-Aside (Nov2007) ([42 U.S.C. 5150](#)).
- \_\_\_ (54) [52.226-5](#), Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov2007) ([42 U.S.C. 5150](#)).
- \_\_\_ (55) [52.229-12](#), Tax on Certain Foreign Procurements (Jun 2020).
- X (56) [52.232-29](#), Terms for Financing of Purchases of Commercial Items (Feb 2002) ([41 U.S.C. 4505](#), [10 U.S.C. 2307\(f\)](#)).
- \_\_\_ (57) [52.232-30](#), Installment Payments for Commercial Items (Jan 2017) ([41 U.S.C. 4505](#), [10 U.S.C. 2307\(f\)](#)).
- X (58) [52.232-33](#), Payment by Electronic Funds Transfer-System for Award Management (Oct2018) ([31 U.S.C. 3332](#)).
- \_\_\_ (59) [52.232-34](#), Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) ([31 U.S.C. 3332](#)).
- \_\_\_ (60) [52.232-36](#), Payment by Third Party (May 2014) ([31 U.S.C. 3332](#)).
- \_\_\_ (61) [52.239-1](#), Privacy or Security Safeguards (Aug 1996) ([5 U.S.C. 552a](#)).
- \_\_\_ (62) [52.242-5](#), Payments to Small Business Subcontractors (Jan 2017) ([15 U.S.C. 637\(d\)\(13\)](#)).
- \_\_\_ (63)
- (i) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) ([46 U.S.C. Appx. 1241\(b\)](#) and [10 U.S.C. 2631](#)).
- \_\_\_ (ii) Alternate I (Apr 2003) of [52.247-64](#).
- \_\_\_ (iii) Alternate II (Feb 2006) 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 items:  
[Contracting Officer check as appropriate.]
- \_\_\_ (1) [52.222-41](#), Service Contract Labor Standards (Aug 2018) ([41 U.S.C. chapter 67](#)).
- \_\_\_ (2) [52.222-42](#), Statement of Equivalent Rates for Federal Hires (May 2014) ([29 U.S.C. 206](#) and [41 U.S.C. chapter 67](#)).
- \_\_\_ (3) [52.222-43](#), Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (Aug 2018) ([29 U.S.C. 206](#) and [41 U.S.C. chapter 67](#)).
- \_\_\_ (4) [52.222-44](#), Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (May 2014) ([29 U.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](#)).
- \_\_\_ (7) [52.222-55](#), Minimum Wages Under Executive Order 13658 (Nov 2020).
- \_\_\_ (8) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
- \_\_\_ (9) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) ([42 U.S.C. 1792](#)).
- (d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR [2.101](#), on the date of award of this contract, and does not contain the clause at [52.215-2](#), Audit and Records-Negotiation.
- (1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

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

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

(e)

(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. 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 (Jun 2020) ([41 U.S.C. 3509](#)).
- (ii) [52.203-19](#), Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).
- (iii) [52.204-23](#), Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).
- (iv) [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).
- (v) [52.219-8](#), Utilization of Small Business Concerns (Oct 2018) ([15 U.S.C. 637\(d\)\(2\)](#) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR [19.702\(a\)](#) on the date of subcontract award, the subcontractor must include [52.219-8](#) in lower tier subcontracts that offer subcontracting opportunities.
- (vi) [52.222-21](#), Prohibition of Segregated Facilities (Apr 2015).
- (vii) [52.222-26](#), Equal Opportunity (Sep 2015) (E.O.11246).
- (viii) [52.222-35](#), Equal Opportunity for Veterans (Jun 2020) ([38 U.S.C. 4212](#)).
- (ix) [52.222-36](#), Equal Opportunity for Workers with Disabilities (Jun 2020) ([29 U.S.C. 793](#)).
- (x) [52.222-37](#), Employment Reports on Veterans (Jun 2020) ([38 U.S.C. 4212](#)).
- (xi) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause [52.222-40](#).
- (xii) [52.222-41](#), Service Contract Labor Standards (Aug 2018) ([41 U.S.C. chapter 67](#)).
- (xiii)
- (A) [52.222-50](#), Combating Trafficking in Persons (Oct 2020) ([22 U.S.C. chapter 78](#) and E.O 13627).
- (B) Alternate I (Mar 2015) of [52.222-50](#) ([22 U.S.C. chapter 78](#) and E.O. 13627).
- (xiv) [52.222-51](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May2014) ([41 U.S.C. chapter 67](#)).
- (xv) [52.222-53](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) ([41 U.S.C. chapter 67](#)).
- (xvi) [52.222-54](#), Employment Eligibility Verification (Oct 2015) (E.O. 12989).
- (xvii) [52.222-55](#), Minimum Wages Under Executive Order 13658 (Nov 2020).
- (xviii) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

(xix)

(A) [52.224-3](#), Privacy Training (Jan 2017) ([5 U.S.C. 552a](#)).(B) Alternate I (Jan 2017) of [52.224-3](#).(xx) [52.225-26](#), Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; [10 U.S.C. 2302 Note](#)).(xxi) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) ([42 U.S.C. 1792](#)). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.(xxii) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) ([46 U.S.C. Appx. 1241\(b\)](#) 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 items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

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

Alternate II. (Nov 2020) 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 items, 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 (Jun 2020) ([41 U.S.C. 3509](#)).

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

(C) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(D) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

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

(F) [52.222-21](#), Prohibition of Segregated Facilities (Apr 2015).

(G) [52.222-26](#), Equal Opportunity (Sep 2016) (E.O. 11246).

(H) [52.222-35](#), Equal Opportunity for Veterans (Jun 2020) ([38 U.S.C. 4212](#)).

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

- (J) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause [52.222-40](#).
- (K) [52.222-41](#), Service Contract Labor Standards (Aug 2018) ([41 U.S.C. chapter 67](#)).
- (L) \_\_\_ (1) [52.222-50](#), Combating Trafficking in Persons (Oct 2020) ([22 U.S.C. chapter 78](#) and E.O. 13627).
- \_\_\_ (2) Alternate I (Mar 2015) of [52.222-50](#) ([22 U.S.C. chapter 78](#) and [E.O. 13627](#)).
- (M) [52.222-51](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) ([41 U.S.C. chapter 67](#)).
- (N) [52.222-53](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) ([41 U.S.C. chapter 67](#)).
- (O) [52.222-54](#), Employment Eligibility Verification (Oct 2015) (Executive Order 12989).
- (P) [52.222-55](#), Minimum Wages Under Executive Order 13658 (Nov 2020).
- (Q) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
- (R) (1) [52.224-3](#), Privacy Training (Jan 2017) ([5 U.S.C. 552a](#)).
- (2) Alternate I (Jan 2017) of [52.224-3](#).
- (S) [52.225-26](#), Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; [10 U.S.C. 2302](#) Note).
- (T) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations. (Jun 2020) ([42 U.S.C. 1792](#)). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
- (U) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) ([46 U.S.C. Appx. 1241\(b\)](#) and [10 U.S.C. 2631](#)). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(End of clause)

#### **HHSAR Clauses:**

HHSAR Clauses and Provisions can be viewed in full text at:

<https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/part-352-solicitation-provisions-contract-clauses/index.html>

352.222-70 -- Contractor Cooperation in Equal Employment Opportunity Investigations (Dec 2015)

#### **FAR 52.252-1 Solicitation Provisions Incorporated by Reference (Feb 1998)**

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

52.212-1 - Instructions to Offerors – Commercial Items (Mar 2020)

- See Part 8 below

52.212-2 - Evaluation – Commercial Items (Oct 2014)

- See Part 9 below

52.204-7 - System for Award Management (Oct 2018)

- All offerors shall be registered in the SAM database with completed representations and certifications.

52.204-16 - Commercial and Government Entity Code Reporting (Jul 2016)

52.204-18 - Commercial and Government Entity Code Maintenance (Jul 2016)

52.212-3 - Offeror Representations and Certifications -- Commercial Items (Jun 2020)

- If an offeror has not completed annual representations and certifications in the SAM database, offerors shall include a completed copy of the provision at 52.212-3 with this offer

(End of provision)

## **PART 8 – INSTRUCTIONS TO THE OFFEROR**

The provision at FAR 52.212-1 incorporated above is tailored as follows. Quotes shall be submitted no later than **3:00 p.m. (Eastern Time) on Friday, September 15, 2023**. Questions shall be submitted no later than **3:00 p.m. (Eastern Time) on Wednesday, September 13, 2023**. Quotes shall be submitted via email in native MS Word or Excel or PDF format to the Contract Specialist, Shobana Vengadasami at [Shobana.Vengadasami@fda.hhs.gov](mailto:Shobana.Vengadasami@fda.hhs.gov).

The offeror's quote must outline all characteristics of the requirement listed in Part 3 – Description of Requirements. The contractor quote shall provide sufficient information to allow the Government to evaluate that the Contractor is capable of meeting the requirement. The Government is not responsible for locating or securing any information which is not identified in the quote.

The Offeror shall submit a completed pricing table in Part 2 for a firm fixed-price order. The Contractor shall provide the price and all detailed documentation to support the total cost of the quote. The firm fixed-price proposed shall be inclusive of all shipping and any other costs associated with meeting all the requirements listed in Part 3 – Description of Requirements. If an offeror has not completed annual representations and certifications in the SAM database, offerors shall also include a completed copy of the provisions at 52.212-3 and 52.219-1.

## **PART 9 – GENERAL EVALUATION INFORMATION**

The Government intends to award a firm-fixed price purchase order resulting from this solicitation to the responsible offeror whose offer conforming to the solicitation will be most advantageous to the Government, price and other factors considered. Contractor selection will be based on the lowest price technically acceptable (LPTA) offer that can “meet or exceed” the requirements stated in this solicitation. The Government reserves the right to award without discussions. The following factors shall be used to evaluate offers:

**Technical Acceptability:** The Government will evaluate the degree to which the quote meets or exceeds the requirements and specifications described in this solicitation. The Offeror's quote shall demonstrate the ability to “meet or exceed” the technical specifications of this requirement. Quotes will be rated either “Technically Acceptable” or “Technically Unacceptable.”

**Price:** Prices quoted shall be evaluated to ensure the best value to the Government and must be determined to be fair and reasonable in order to be considered for award. The sum of the offeror's proposed prices for all CLINs in the table in Part 2 will be evaluated. This RFQ does not commit the Government to pay any costs incurred in the preparation of the submission of the quotation or to contract for the supplies or services.

