



April 8, 2021

**SUBJECT: Request for Quote (RFQ-FDA-1239460) for One (1) each 16-EMG + IMU Sensor Research System.**

This is a combined synopsis/solicitation for commercial services prepared in accordance with the format in FAR 12.6 as supplemented with FAR 13 and additional information included in this notice. The incorporated provisions and clauses are those in effect through Federal Acquisition Circular (FAC) 2021-05.

THIS ANNOUNCEMENT CONSTITUTES THE ONLY SOLICITATION AND A SEPARATE SOLICITATION WILL NOT BE ISSUED.

The solicitation number for this acquisition is RFQ-FDA-1239460 and is being issued as a Request for Quote (RFQ). The NAICS Code for this solicitation: 334510 Electromedical and Electrotherapeutic Apparatus Manufacturing. The Small Business Size Standard is 1,250 employees. The requirement will be awarded as Firm-Fixed Price and 100% small business set-aside. The Government reserves the right to award without discussions if the Contracting Officer determines that the initial offer is providing the Best Value and discussions are not necessary.

The U. S Food & Drug Administration (FDA), Office of Acquisitions and Grant Services is procuring One (1) each 16-EMG + IMU Sensor Research System.

**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 mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote the public health. CDRH assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. CDRH provides consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. CDRH facilitates medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.



The Office of Science and Engineering Laboratories (OSEL) supports CDRH's mission of protecting and promoting public health. OSEL undertakes the highest quality science to provide their customers with the best methods, tools and expertise to:

- Ensure readiness for emerging and innovative medical technologies
- Develop appropriate evaluation strategies and testing standards
- Create accessible and understandable public health information and,
- Deliver timely and accurate decisions for products across their life cycle.

Under OSEL, the Division of Biomedical Physics (DBP) The Division of Biomedical Physics (DBP) participates in the Center's mission of protecting and promoting public health by identifying and investigating the biophysical interactions between medical devices and the human body. The division accomplishes this through activities supporting the OSEL mission.

DBP investigates gender-based differences in cardiac resynchronization therapy for pacemakers, development of phantoms (physical models) to assess the measurement of eye disease by optical imaging systems, evaluation and improvement of electrode reliability in neural prosthetics used to control artificial limbs, and computational modeling of active and passive implants to determine if unsafe levels of heating arise during a patient's exposure to magnetic resonance imaging (MRI) systems. These serve the Center's mission of advancing regulatory science, facilitating consistent and efficient regulatory pathways, and assuring continued access to safe, effective, and high-quality medical devices.

Specifically, DBP focuses on device issues that involve:

- Biomedical and tissue optics
- Biophysics and electrophysiology
- Electrical engineering
- Functional device performance and human factors, and
- Wireless communication and electromagnetic interference and compatibility

In collaboration with the Human-Device Interaction lab within the OSEL, the DBP seeks to order an Electromyography (EMG) plus inertial measurement unit (IMU) sensor system, commonly referred to as an EMG+IMU sensor system. The Human-Device Interaction lab within the OSEL addresses regulatory science research questions related to diagnostic, therapeutic, and assistive medical devices. Understanding human interaction with these medical devices requires biomechanics equipment that quantifies human movement. Electromyography (EMG) and motion analysis (e.g. inertial measurement unit – IMUs) are two methods by which human movement can be quantified.

For this acquisition, an EMG + IMU sensor system is needed to collect more robust, high quality signals of muscle activity and subject movement. The overall objective is to acquire this equipment which will enable FDA scientists to address regulatory science research questions related to the interaction of humans with diagnostic, therapeutic, and assistive medical devices. An EMG + IMU sensor system will collect more robust, high quality signals of muscle activity and



subject movement and when synchronized with a Vicon motion capture system, will allow for simultaneous monitoring of muscle activity, sensor movement, and subject movement.

## 1) STATEMENT OF WORK SPECIFICATIONS

The Vendor shall indicate if the minimum salient characteristics have been met to be considered responsive for this requirement;

**Item:** The DBP seeks to order an EMG + IMU sensor system.

The EMG + IMU sensor system ordered shall have the following salient characteristics:

- 1.1 Shall consist of at least 16-wireless sensors with combined EMG and IMU sensing capabilities with at least four recording options: EMG only, EMG + 3D accelerometer, EMG + 3D gyroscope, and EMG + IMU
- 1.2 Shall have the ability to wirelessly transmit data to a PC via receiver with an inter-sensor latency less than 500 microseconds
- 1.3 Shall contain a small sensor size with dimensions less than 30 x 40 x 15 mm and weight less than 15g per sensor
- 1.4 Shall have a sampling rate for EMG sensors up to at least 4 kHz
- 1.5 Shall have a selectable sampling rates for accelerometer and gyroscope sensors up to at least 950 Hz
- 1.6 System shall have a trigger module for synchronization with a Vicon motion capture system using Bonita B10 and Vero 1.2 cameras and Vicon Nexus Acquisition software v2.9. At a minimum, the EMG+IMU system shall be able to connect to the Option Slot on the rear panel of an MX Giganet from Vicon that contains the Analog ADC option card connector. This is a 100-way socket for a third-party device for capturing analog data such as force plates, electromyography (EMG) equipment, potentiometers, and accelerometers. For additional specifications, please refer to Vicon's website for detailed specifications on the hardware and software listed in this requirement.
- 1.7 Shall have the ability to do digital synchronization as well as analog synchronization
- 1.8 System shall come with data acquisition and analysis software with data collection, signal quality evaluation, and data analysis capabilities. Specific capabilities include, but are not limited to, anatomical map to aid in consistent sensor placement, real-time RMS filters with selectable window, support for multiple data acquisition cards simultaneously, and real-time signal quality assessment.
- 1.9 Shall be capable of streaming EMG and IMU sensor data to Android mobile devices/tablets via Bluetooth
- 1.10 System shall include new Android tablet (Android 6.0 or above with Bluetooth 4.1 or above) with at least 1 GB RAM and 8 GB storage for mobile data recording and analysis
- 1.11 **Other Requirements: Warranty Maintenance and Technical Support**
  - 1.11.1 Maintenance and technical support shall be of quality and availability to ensure the successful installation, configuration, and management of the equipment within the Human-Device Interaction Lab.



- 1.11.2 The Contractor shall adhere to the following specifications for purchase, warranty, maintenance and technical support:
- A) The system shall have at least one-year warranty for parts and labor from the date of equipment FDA acceptance.
  - B) The Vendor shall provide continuous application support via phone, email, or in person during the one-year warranty period

## 2) **Assembly and Delivery Requirements**

The Contractor shall deliver(s) in this purchase order as follows:

- 2.1 The Contractor shall deliver the quantities ordered within 30 days of contract award
- 2.2 Within thirty (30) days after contract award the Contractor shall supply all hardware and any associated software with appropriate license keys, expiration dates and proof of entitlement certificates; maintenance support confirmation has been delivered to the FDA, COR
- 2.3 All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications
- 2.4 At a minimum, all deliverables shall be marked with the contract number and contractor's name
- 2.5 The Contractor shall guarantee that all required materials shall be delivered in immediate new, usable and acceptable condition
- 2.6 Contractor shall contact the Technical Point of Contact (TPOC) to schedule the delivery. All deliveries shall be made during normal FDA delivery hours: 8:00AM to 3:30PM
- 2.7 The Contracting Officer (CO) or their designee has the authority to accept or reject deliverables. The acceptance of deliverables and satisfactory work performance required herein shall be based upon the timeliness, accuracy and suitability of the deliverable. The specific deliverables and schedule for delivery shall be as agreed upon and documented.
- 2.8 The Contractor shall also demonstrate a well-documented customer base, preferably in the US and for government facilities, within at least the last three years.

The equipment and all accessories shall be delivered to:

U.S. Food and Drug Administration  
CDRH/OSEL/DBP  
**Attention:** TBD  
10903 New Hampshire Ave  
WO62 RM 1105  
Silver Spring, MD 20993

## 3) **Period of Performance:**

The Contractor shall deliver the item within 30 days after award.

The period of performance is 12 months from the acceptance of all equipment and accessories.



#### 4) Inspection and Acceptance Criteria

FOB: Destination

The Government shall have 30 working days after installation to inspect and verify that the equipment is operational and functional.

#### 5) IT Purchasing Requirements:

NOTE to Contractor: Before the contract is awarded, FDA is required to get Pre-Approval of all the IT Hardware and/or Software-Firmware-Freeware from the FDA Chief Information Officer (CIO). For IT Hardware, this includes any device that process or stores data or controlled by data (computers/data switches, etc..) but does not include passive hardware (rack, network cables, power supplies/cords). This will require the applicable contractor to provide a complete list of Hardware and/or Software-Firmware-Freeware that the contractor will use in fulfilling this contract.

This list will need to include: IT hardware: Manufacture, nomenclature and model number Software (all types). Manufacture, nomenclature and version number Item(s) rejected by the CIO will need to be changed and the replacement item(s) would need to go through the same approval process.

Deliverables will conform to 36 CFR Part 1194.41, "Information, Documentation and Support," and 36 CFR Part 1194.24 "Video and Multimedia Products" which are of particular importance with regard to all written, graphical or broadcast, video materials or products produced for HHS (to include training). 36 CFR Part 1194.41 outlines the requirements supporting services for products accommodating the communication needs of end-users with disabilities. The deliverables will be provided in Microsoft Word and Adobe PDF formats and compatible with versions currently used at FDA. C.A. Section 508.

This language is applicable to Statements of Work (SOW) or Performance Work Statements (PWS) generated by the Department of Health and Human Services (HHS) that require a contractor or consultant to (1) produce content in any format that could be placed on a Department-owned or Department-funded Web site; or (2) write, create or produce any communications materials intended for public or internal use; to include reports, documents, charts, posters, presentations (such as Microsoft PowerPoint) or video material that could be placed on a Department-owned or Department-funded Web site

### 1. SECTION 508 STANDARDS

Electronic and information technology (EIT) supplies and services shall comply with Section 508 of the Rehabilitation Act (the Act) of 1973 (29 U.S.C. 794d). See *HHSAR Subpart 339.2*.

Section 508 Standards are applicable to this requirement. Electronic and Information Technology (EIT) developed, procured, or maintained for used by federal agencies by a



contractor shall comply with the standards and regulations. Standards are organized into four subparts:

Subpart A – General (36 CFR §§ 1194.1-1194.5): Describes the types of covered technologies and applications, explains what is exempt, defines terminology, and recognizes that acceptable alternatives that provide equivalent access to and use of a product for people with disabilities are permissible.

Subpart B – Technical Standards (36 CFR § 1194.21-1194.26): Provides criteria specific to various types of technologies and provides performance-based requirements for systems and applications.

- Software applications and operating systems (36 CFR § 1194.21)
- Web-based intranet and internet information and applications (1194.22)
- Telecommunications products (36 CFR § 1194.23)
- Video and multimedia products (36 CFR § 1194.24)
- Self contained, closed products (36 CFR § 1194.25)
- Desktop and portable computers (36 CFR § 1194.26)

Subpart C – Functional Performance Criteria (36 CFR § 1194.31): Provides performance requirements for overall product evaluation and for technologies or components for which there is no specific requirement under the technical standards in Subpart B.

Subpart D – Information, Documentation, and Support (36 CFR § 1194.41): Addresses access to all information, documentation, and support provided to end-users of covered technologies, and identifies formats to be used.

## 6) GOVERNMENT HOLIDAYS

a. The Government hereby provides notification that Government personnel observe the listed days as holidays:

- |                                   |                      |
|-----------------------------------|----------------------|
| (1) New Year's Day                | (6) Labor Day        |
| (2) Martin Luther King's Birthday | (7) Columbus Day     |
| (3) President's Day               | (8) Veterans' Day    |
| (4) Memorial Day                  | (9) Thanksgiving Day |
| (5) Independence Day              | (10) Christmas Day   |

b. In addition to the days designated as holidays, the Government observes the following days:

- (1) Any other day designated by Federal Statute
- (2) Any other day designated by Executive Order
- (3) Any other day designated by the President's Proclamation



c. When any such day falls on a Saturday, the following Monday is observed. Except for designated around-the-clock or emergency operations, Contractor personnel will not be able to perform on-site under this contract with FDA on holidays set forth above. The Contractor will not charge any holiday as direct charge to the award.

d. It is understood and agreed between the Government and the Contractor that observance of such days by Government personnel shall not otherwise be a reason for an additional period of performance, or entitlement of compensation except as set forth within the award.

e. Nothing in this clause abrogates the rights and responsibilities of the parties relating to stop work provisions as cited in other sections of this contract.

### **7) FDA Invoice Submission Instructions.**

#### FDA Three-Way Match Invoicing Procedures

A. The Contractor shall submit all invoices to:

U.S. FOOD AND DRUG ADMINISTRATION

Attn: Vendor Payments  
Division of Payment Services  
10903 New Hampshire Ave  
WO32 - Second Floor  
MAIL HUB 2145  
Silver Spring, MD 20993-0002  
301-827-3742  
FDAVendorPaymentsTeam@fda.hhs.gov

\*\*\* Acceptable methods of delivery include: E-mail (preferred) and Standard Mail. Provide a copy marked courtesy to the Technical Point of Contact (TPOC).

B. Invoices submitted under this contract must comply with the requirements set forth in FAR Clauses 52.232-25 (Prompt Payment) and 52.232-33 (Payment by Electronic Funds Transfer - System for Award Management) and/or other applicable FAR clauses specified herein. To constitute a proper invoice, the invoice must be submitted on company letterhead and include each of the following:

(i) Name and address of the vendor;

(ii) Invoice date and invoice number;

(iii) Contract/Order number (including a reference to any base award for Indefinite-Delivery/Indefinite-Quantity Contracts or Blanket Purchase Agreements);



(iv) Description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed, including:

- (a) period of performance for which costs are claimed;
- (b) itemized travel costs, including origin and destination;
- (c) any other supporting information necessary to clarify questionable expenditures;
- (d) the contractor shall include the award item number for each description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed;

(v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on government bill of lading;

(vi) Terms of any discount for prompt payment offered (Prompt Payment terms other than NET 30);

(vii) Name and address of official to whom payment is to be sent (must be the same as that in the purchase order/award, or in a proper notice of assignment);

(viii) Name, title, and phone number of person to notify in event of defective invoice;

(ix) Taxpayer Identification Number (TIN);

(x) banking routing transit number of the financial institution receiving payment for Electronic funds transfer (EFT);

(xi) Name and telephone number of the FDA TPOC, as referenced on the award;

(xii) For all Inspections, Time-and-Materials and Labor-Hour Awards, 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;

(xiii) Any other information or documentation required by the award.

C. An electronic invoice is acceptable if submitted in Adobe Acrobat (PDF) format. All items listed in (i) through (xiii) of this clause must be included in the electronic invoice. Electronic invoices must be on company letterhead and must contain no ink changes and be legible for printing.





D. Questions regarding invoice payments should be directed to the 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.

## 8) CLAUSES:

### 52.212-4 Contract Terms and Conditions—Commercial Items (Oct 2018)

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

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:



\_\_\_ (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]

X (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](#)).

\_X\_ (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](#).
- (33) [52.222-37](#), Employment Reports on Veterans (JUN 2020) ([38 U.S.C. 4212](#)).
- (34) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496).
- (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).

\_X\_ (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).

\_\_\_ (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 (JAN 2021) ([41 U.S.C. chapter 83](#)).

\_\_\_ (49) (i) [52.225-3](#), Buy American-Free Trade Agreements-Israeli Trade Act (JAN 2021)([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 (JAN 2021) of [52.225-3](#).

\_\_\_ (iii) Alternate II (JAN 2021) of [52.225-3](#).



\_\_ (iv) Alternate III (JAN 2021) of [52.225-3](#).

\_\_ (50) [52.225-5](#), Trade Agreements (OCT 2019) ([19 U.S.C. 2501](#), *et seq.*, [19 U.S.C. 3301](#) note).

\_\_ (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 (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) [52.229-12](#), Tax on Certain Foreign Procurements (JUN 2020).

\_\_ (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 (OCT 2018) ([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](#)).

X (61) [52.239-1](#), Privacy or Security Safeguards (AUG 1996) ([5 U.S.C. 552a](#)).

X (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:

\_\_\_ (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) ([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](#)).

(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.

**52.232-40 - Providing Accelerated Payments to Small Business Subcontractors (Dec 2013)**

**52.217-8 -- Option to Extend Services. Option to Extend Services (Nov 1999)**

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 1 day.

**FAR 52.204-25-Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2020)**

**FAR 52.227-14 Rights in Data-General (May 2014)**

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

**HHSAR 352.239-74 Electronic and Information Technology Accessibility. (Dec 2015)**

**HHSAR 352.223-70 Safety and Health (Dec 2015)**

Provisions:

**9) Pricing Schedule:**

The Offeror shall submit a fixed price, including details of all costs supporting the price for the requested items/services.

The Offeror shall complete the pricing chart below. Pricing shall include all applicable fees including shipping, warranty and handling. Any charges presented after contract award shall not be acceptable.

Line Item 1	Description	Qty.	Unit Price	Price
	Purchase of 16-EMG + IMU Sensor Research System and accessories including shipping and warranty	1 EA		\$
<b>GRAND TOTAL PRICE</b>				<b>\$</b>



Pricing should be outlined as shown above.

NOTE: ONLY ONE PRICE SUMMARY REPORT AND AGREGATE TOTAL WILL BE CONSIDERED FOR EVALUATION/AWARD WITH ALL PROPOSED PRICING ASSOCIATED WITH THE RFQ REQUIREMENTS. NO ADDITIONAL PRICING SCHEDULES WILL BE EVALUATED BY THE GOVERNMENT.

- a) The Contractor's quotation shall include: All items requested or none.
- b) Contractors are required to fill in the above pricing table
- c) Contractor shall show any pricing related to labor hours, materials associated with providing design, delivery and installation.
- d) Offerors shall submit a complete schedule of prices and a single summary total amount shall be furnished for the entire requirement.
- e) The quotation shall contain sufficient information to allow the Government to perform a basic analysis of the proposed price of the work.

#### **10) EVALUATION AND AWARD:**

Lowest Priced, Technically Acceptable (LPTA)

#### **11) INSTRUCTION TO CONTRACTORS:**

- 11.1 The Contractor shall complete the Pricing Schedule above.
- 11.2 Deadline for questions: April 13, 2020 at 11 AM Eastern Time, no phone calls will be accepted. Email questions to: [sarah.hussain@fda.hhs.gov](mailto:sarah.hussain@fda.hhs.gov)
- 11.3 **Offer due date/local time: April 20, 2020 at 11:00 AM Eastern Time. Email quotes to [sarah.hussain@fda.hhs.gov](mailto:sarah.hussain@fda.hhs.gov)**
- 11.4 **Quote submission format:**

\*\*\*Quote shall be in 2 volumes: 1 Technical and 2 Price. The volumes shall be separate and complete. The volumes shall be separate and complete, so that evaluation of one may be accomplished independently of, and concurrently with, the evaluation of the other. No pricing information shall be provided in volume 1.\*\*\*

The total number of pages for the technical quote shall not exceed ten (10) pages, using 1" margins, single spaced, font type Time New Roman, and a font size of 12.

\*\*\*The solicitation does not commit the Government to pay any cost for the preparation and submission of a quote or proposal. It is also advised that the Contracting Officer (CO) is the only individual who can legally commit and obligate the



Government to the expenditure of public funds in connection with the proposed acquisition.\*\*\*

#### 11.5 CONTRACTING POINT OF CONTACT:

Sarah Hussain, Contract Specialist  
4041 Powder Mill Road  
Beltsville, MD 20705  
Email: [sarah.hussain@fda.hhs.gov](mailto:sarah.hussain@fda.hhs.gov)

#### **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 shall be completed by the offeror and submitted with the proposal. 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 the proposal. Also, the full text of a solicitation provision may be accessed electronically at this address: [www.acquisition.gov/far/index.html](http://www.acquisition.gov/far/index.html).

#### **FAR 52.212-3** Offeror Representations and Certifications - Commercial Items (Feb 2021) applies to this acquisition.

The offeror shall complete only paragraphs (b) of this provision if the Offeror has completed the annual representations and certification electronically via the System for Award Management (SAM) Web site accessed through <http://www.acquisition.gov> . If the Offeror has not completed the annual representations and certifications electronically, the Offeror shall complete only paragraphs (c) through (p) of this provision.

Offerors that fail to complete the required representations and certifications, or reject the terms and conditions of the solicitation, may be excluded from award consideration.

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) Dun & Bradstreet number; 4) Taxpayer ID number; 5) Catalog or Published Price Listing applicable to the service; 6) Vendors shall meet specifications as noted in the synopsis. Note: Contractor shall be registered and active in the System for Award Management (SAM) prior to the award of a contract. You may register by going to [www.sam.gov](http://www.sam.gov).