Request for Proposal-SB-ALP 134042

Title: Request for Service: Pulse Field Ablation Comparative Assessment Development

DESCRIPTION

This is a combined synopsis/solicitation for commercial items prepared in accordance with the format in Federal Acquisition Regulation (FAR) Subpart 12.6, as supplemented with additional information included in this notice. This announcement constitutes the only solicitation; quotes are being requested, and a separate written solicitation shall not be issued.

This solicitation is a Request for Quote (RFQ) using FAR Part 12 procedures. The solicitation document and incorporated provisions and clauses are those in effect through Federal Acquisition Circular (FAC) 2025-03. The North American Industry Classification System (NAICS) code for the proposed acquisition is 541714: Research and Technology in Biotechnology (except Nanobiotechnology) with a business size standard or 1000 in number of employees. This solicitation is set aside for small business.

PLACE OF PERFORMANCE

Contractor's Facility

PART 1-BACKGROUND

The Center for Devices and Radiological Health (CDRH), through its Office of Science and Engineering Laboratories (OSEL), is committed to advancing medical device innovation and safety through the development of new test standards and methodologies. A key strategic priority for CDRH is to reduce the reliance on animal testing by developing robust in vitro evaluation methods. In support of this goal, OSEL's Division of Applied Mechanics (DAM) has initiated a project to create a novel benchtop test method to assess the hemolytic potential of Pulsed Field Ablation (PFA) devices. The successful development of this test will enable early-stage differentiation between hemolytic and non-hemolytic devices, thereby reducing the reliance on resource intensive animal studies. However, our division currently lacks the specialized expertise in PFA technology required to build reusable catheters and establish a repeatable, quality-controlled PFA test methodology. Therefore, we are seeking a contract with an partner possessing this critical expertise to collaborate on this vital project.

PART 2-SUPPLIES OR SERVICES AND PRICES/COSTS

PRICE SCHEDULE

DESCRIPTION		**PRICE**
Base Year	$	$
Option Year	$	$
TOTAL COST		$

PART 3-DESCRIPTION/SPECIFICATIONS

CONTRACT TYPE

Firm Fixed Price

PERIOD OF PERFORMANCE

Base Year: 12 months from date of award
Option Year: 6 months

STATEMENT OF WORK

This requisition is initiated by OSEL's Division of Applied Mechanics. The objective of this project is to collaborate with an partner to develop an in vitro test platform for evaluating the hemolytic potential of PFA devices. The scope of this work includes three primary deliverables:

1. Fabrication of multiple, quality-controlled, reusable PFA catheters for research purposes

2. Development of a robust, comparative PFA hemolysis benchtop test platform

3. Creation of a detailed standard operating procedure (SOP) for conducting hemolysis bench tests.

SOURCE SELECTION PROCEDURES/CRITERIA

Proposals will be evaluated based on the following criteria:

General Qualifications

- Demonstrated expertise and a strong publication record in Pulsed Field Ablation (PFA) research, specifically involving the application of pulsed electric fields to biological tissue or cells within a Biosafety Level 2 (BSL-2) or higher laboratory environment.
- The proposal must identify dedicated personnel for this project, including a Principal Investigator and at least one full-time PhD student or Post-Doctoral researcher.
- Has access to a pulsed field ablation catheter (also referred to as electrode) fabrication facility (including soldering) or in-house fabrication for developing platinum-iridium or gold electrodes
- The contracting research group must demonstrate access to animal and/or human blood for use within 48 hours of collection to maintain biological viability.
- The contractor must confirm access to and operational knowledge of a spectrophotometer to measure the released plasma free hemoglobin

- The contracting group will participate in at least bi-weekly teleconference meetings with the FDA project team to provide status updates, discuss challenges, and review data
- The contractor must demonstrate they have access to and are proficient with a function generator capable of simulating the required PFA waveform parameters (detailed under static blood testing). The proposal must provide details on their function generator and what pulse parameters they can modify.

Project Requirements

- Fabricate a minimum of 30 newly-fabricated pulse field ablation electrodes that meet the following specifications:
- The electrode designs will be sent to the FDA for approval prior to fabrication. FDA agreement must be reached.
- The electrodes will be constructed from clinically relevant gold or platinum iridium to prevent corrosion.

- The electrodes must be reusable and evaluated through quality control testing (detailed below) to ensure consistent fabrication, performance, and cleaning.

- 30 catheters will be constructed with two distinct electrode designs (Ex. Circle, lines, point, etc.) to evaluate the effects of geometry and surface area on hemolysis. 15catheters will be of one geometry and the other 15 will be of a second geometry.

- 18 of the 30 electrodes will be reserved for conducting testing at the contractor's facilityvfor the quality control testing and the static blood testing. The 18 electrodes include 9 of each design.

- The remaining 12 unused electrodes will be sent to the FDA with the completed quality control procedure and cleaning protocol (detailed below). The 12 electrodes will include 6 of each of the two designs.

- All catheters must be compatible with FDA's Energy Pulse Systems EPULSUS-FBMI-5 high-performance pulse generator

- All catheters must come with detailed instructions for set up with the FDA function generator and use

- All catheters must be functional and in working condition

- Quality Control testing:

- All quality control protocols must be agreed upon by FDA prior to testing

- At least 5 of each catheter design that are staying, with the contractor must undergo a robust quality control assessment to evaluate the following:
    - Manufacturing variability between the fabricated electrodes
    - Electrical performance between electrodes
    - A macro and micro surface assessment to ensure the cleaning protocol prevents protein adhesion to the electrode after each individual blood test (ex. Scanning electron microscopy)
    - An assessment of blood testing must demonstrate repeatability by using the same electrode, cleaning protocol, and blood pool.
    - An assessment of electrode must demonstrate reproducibility by using
    - The contractor should keep track of each electrode used and how many times each one was used
- After quality control testing, the contractor will provide the following data and protocols:
    - Detailed protocols of electrode fabrication, set up, cleaning, and all quality control tests
    - Raw and summarized data for all quality control testing results including plasma free hemoglobin (pfHb) measurements for the repeatability and reproducibility testing
    - Six electrodes of each catheter design that have undergone manufacturing and electrical performance verification but no blood testing will be sent to the FDA.

Option Year : Static Blood Testing

- The contractor will verify the static blood testing protocol with the FDA prior to conducting testing.

- The contractor will determine if a static blood test in a beaker (made of polypropylene, polyethylene, polycarbonate, or polymethylpentene) can be used as a sensitive hemolysis test to distinguish the hemolytic potential between pulse parameters or device design.
- PFA pulse bursts with 5 of each catheter design will be applied to porcine and human blood to investigate if this test platform can differentiate between catheter geometry and the following parameters:
    - Number of pulse bursts: 10-100
    - Pulse Frequency per burst (Hz): 1-100 Hz
    - Pulse Width (µs or ns): 0.2-100 µs
    - Electric Field Strength V: 50-1000 V
    - Inter-pulse Delay

- The contractor will develop a tissue phantom for characterization of electrical fields when in contact with tissue
- All blood samples will be adjusted to 35 +/-2% hematocrit.
- The contractor will record the near catheter temperature, collect blood samples to measure the plasma free hemoglobin vs. burst number, and record the pulse waveform to evaluate pulse performance.
- The contractor will also report the blood draw date and blood hematocrit before and after adjustment.
- The contract will draft their static blood test results and electrode manufacturing protocols in the format of a journal of FDA's choice.

Quote must include all costs related to this purchase (shipping, staff, documentation, supplies).

No additional fees/costs will be allowed outside the quoted amount.

DELIVERY REQUIREMENTS

All data, analysis, and protocols for quality controls will be delivered to FDA 1 year after award date by September 2027.

SOURCE SELECTION PROCEDURES/CRITERIA

In addition to the vendor's ability to meet the Statement of Work, selection will be based on the following

criteria:

Demonstrated expertise and a strong publication record in PFA research, specifically involving

- the application of pulsed electric fields to biological tissue or cells within a Biosafety Level 2 (BSL-2) or higher laboratory environment.
- Dedicated personnel for this project, including a Principal Investigator and at least one full time PhD student or Post-Doctoral researcher.
- Demonstrated access to animal and/or human blood for use within 48 hours of collection to maintain biological viability.
- Access to and operational knowledge of a spectrophotometer to measure the released plasma free hemoglobin

<u>CONTRACT CLAUSES</u>

FAR Clauses Incorporated by Reference:

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect

as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at: www.acquisition.gov/far/index.html

52.202-1 Definitions (June 2020)
52.203-5 Covenant Against Contingent Fees (May 2014)
52.203-7 Anti-Kickback Procedures (June 2020)
52.212-4 Contract Terms and Conditions-Commercial Items (Nov 2023)
52.217-8 Option to Extend Services (NOV 1999)
52.217-9 Option to Extend the Term of the Contract (MAR 2000)
52.227-14 Rights in Data (MAY 2014)
52.233-4 Applicable Law for Breach of Contract Claim (Oct 2004)

FAR Clauses in Full Text:

52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items (Jan 2025)

(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 2019) (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) (41U.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).

_X_ (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 (Mar 2020) of 52.219-6 (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 (Mar 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.

_X_ (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 (May 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)).

_X_ (27) 52.222-3, Convict Labor (Jun 2003) (E.O.11755).

_X_ (28) 52.222-19, Child Labor-Cooperation with Authorities and Remedies (Jan2020) (E.O.13126).

_X_ (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

_X_ (30) (i) 52.222-26, Equal Opportunity (Sep 2016) (E.O.11246).

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

_X_ (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.

X__ (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 (Jan 2019) (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).

_X_ (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 (Jun2014) 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 (Jun2016) (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.chapter83, 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.

_X_ (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. 2302Note).

__ (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).

__ (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 (Jan2017) (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).

_X_ (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. chapter67).

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

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

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

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

__ (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 (Dec 2015).

__ (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 2019) (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 (Aug2018) (41 U.S.C. chapter 67).

(xiii) (A) 52.222-50, Combating Trafficking in Persons (Jan 2019) (22 U.S.C. chapter 78 and E.O 13627).

(B) Alternate I (Mar2015) 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 (May2014) (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 (Dec 2015).

(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)

HHSAR Clauses Incorporated by Reference

This order incorporates the following U.S. Department of Health and Human Services Acquisition Regulation (HHSAR) 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 the following website: http://www.hhs.gov/policies/hhsar/.

HHSAR Clause	Description	Date
352.203-70	Anti-lobbying	(Dec 2015)
352.215-70	Late proposals and revisions	(Dec 2015)
352.223-70	Safety and health	(Dec 2015)
352.233-71	Litigation and claims	(Dec 2015)

INSTRUCTIONS TO OFFERORS

COVER PAGE

Offeror shall include a cover page which shall include a point of contact (name, telephone number, and email address). Dun and Bradstreet (DUNS) 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 (to include updated representations and certifications in accordance with FAR 52.212-3).

The technical proposal shall be submitted electronically via email to the Contract Specialist Telisha Wilson, at telisha.wilson@fda.hhs.gov and ensure the solicitation number is visible in the subject of the email transmission of their proposal.

The proposal submitted shall describe in detail a full understanding on the evaluation factors listed below.

The offeror or applicant shall submit all electronic documents for Microsoft Office suite products without the use of “macros”. If the offeror or applicant submits documents that contain macros

the Government will not be able to view or open such documents and the submission will be considered non-responsive to the solicitation. No additional time will be given to an offeror or applicant to correct the document submission and the Government will not inform the offeror or applicant that their submission is non-responsive prior to award. It is the offeror's or applicant's responsibility to ensure all electronic documents are submitted without the use of macros.

FACTOR 1: UNDERSTANDING OF THE REQUIREMENT

The Offeror shall demonstrate by explanation a general, but thorough, understanding of the tasks within the SOW.

- The Offeror shall describe their ability the application of pulsed electric fields to biological tissue or cells within a Biosafety Level 2 (BSL-2) or higher laboratory environment.
- Dedicated personnel for this project, including a Principal Investigator and at least one full time PhD student or Post-Doctoral researcher.
- Demonstrated access to animal and/or human blood for use within 48 hours of collection to maintain biological viability.
- Access to and operational knowledge of a spectrophotometer to measure the released plasma free hemoglobin

FACTOR 2: COST/PRICE

The offeror shall provide an annual firm fixed price for this requirement, to be billed once annually at the end of the period of performance for the current contracting year. IN order to assist the Government in determining price reasonableness, the offeror's price proposal shall include a breakdown of all of the applicable time and material costs needed to complete the requirement.

The Offeror's proposal shall demonstrate and clearly describe an effective and efficient cost approach for accomplishing stated requirements. Unrealistically low or high proposed costs or prices, initially or subsequently, may be grounds for eliminating a proposal from competition, either on the basis that the offeror does not understand the requirement, or has made an unrealistic proposal. Offerors should be sufficiently detailed to demonstrate their price reasonableness. The burden of proof for credibility of proposed cost/prices rests with the offeror.

EVALUTATION FACTORS

The Government will evaluate offerors for technical acceptability in the following four technical factors (Understanding of Requirement and Cost/Price) For these factors, Offerors will be evaluated as either technically acceptable or unacceptable. Price will be evaluated for fairness and reasonableness.

FACTOR 1-UNDERSTANDING OF REQUIREMENT

The Government will evaluate the extent to which the offerors proposal demonstrates a cohesive understanding of the requirements and demonstrated experience and expertise. Specifically, the Government will evaluate the extent to which the offeror's proposal addresses the following questions:

- Did the offeror demonstrate by explanation a general, but thorough, understanding of the tasks within the SOW.
- Did the offeror document their experience.
- Did the offeror provide documentation of experience related to the statement of work.

FACTOR 2: COST/PRICE

The FDA will be evaluated for fairness and price reasonableness.

BASIS FOR AWARD

Award shall be made to a single responsible party with the lowest priced technically acceptable offer. More specifically, the Government intends to evaluate only the lowest priced proposals until the point at which it determines that a technically acceptable proposal has been received, and at that point, no further technical evaluations will be conducted.

RESPONSE DATES

Questions are due by email to Telisha Wilson; Telisha.Wilson@fda.hhs.gov on or before 10AM EST on 07/10/2026 to Telisha When responding, please include in the subject line "Questions for **RFP-SB-ALP 134042**.

Proposals are due by email to Telisha Wilson; 10AM EST on or before 07/20/2026. When responding, please include in the subject line "Proposals for **RFP-SB-ALP 134042.**

Faxed quotes and late responses will not be accepted.

Quotes must be valid through September 30, 2026.