This is a combined synopsis/solicitation for commercial products or commercial services prepared in accordance with FAR RFO part 12. This announcement constitutes the only solicitation. Offers are being requested and a separate written solicitation will not be issued. The solicitation number is 75F40126Q134171. This solicitation is issued as a Request for Quote (RFQ) for CNS Organoid Neuropharmacological Analysis.

This acquisition is not set-aside for small business concerns. This solicitation incorporates provisions and clauses by reference. The full text of provisions and clauses may be accessed electronically at https://www.acquisition.gov/far-overhaul.

The associated North American Industry Classification System (NAICS) Code is- 541380 - Testing Laboratories and Services; the applicable Small Business Size Standard is $19 million.

The FDA intends to award a sole-source, firm-fixed-price purchase order to 28Bio, 4224 Houma Boulevard, Suite 224, Metairie, LA 70006, pursuant to FAR RFO 12.102(a). FDA has documented that only one source is available and the basis for that decision. The requirement is for CNS organoid neuropharmacological analysis involving characterization of acute and chronic neuromodulatory effects of a marketed small molecule drug and related transcriptomic changes in human CNS-3D brain organoids. No other source is available to satisfy the requirement because the required CNS-3D human brain organoid analysis must use organoids and testing methods consistent with prior FDA research data generated with 28Bio's specialized human iPSC-derived 3D cortical organoid model, which includes demonstrated serotonergic pathway activity and supports the required customized neuropharmacological endpoints, including FLIPR calcium influx analysis. Continued use of 28Bio is necessary to maintain comparability and continuity with the existing dataset and ongoing research effort. Use of a different source at this stage could introduce variability in organoid composition, assay performance, and analytical interpretation, and could require additional bridging or revalidation work that would delay the study and reduce comparability to the existing data. All responsible sources may submit capability information or a quotation, as appropriate, which will be considered by the agency by the response date identified in this notice.

Schedule of Items (all shipping and handling shall be included in the price)

Contract Line Item	Description	Quantity	Unit	Unit Price	Extended Price
1	CNS Organoid Neuropharmacological Analysis as specified herein.	1	Job	$_____	$_____
Grand Total				$_____	

Statement of Work: CNS Organoid Neuropharmacological Analysis

Background

The U.S. Food and Drug Administration's (FDA) National Center for Toxicological Research (NCTR), Jefferson, AR requires functional examination of neuromodulatory effects of a drug and related transcriptomic changes in human Central Nervous System (CNS)-3D brain organoids. Specifically, the CNS-3D human brain organoid testing includes (1) characterizing acute and chronic neuromodulatory effects of a marketed small molecule drug in human CNS-3D brain organoids, including spontaneous Ca2+ burst and induced variability in Ca2+ burst timing; (2) characterizing the role of the 5-HT5A receptor in drug-induced effects in human CNS-3D brain organoids using co-treatment with the 5-HT5A receptor inhibitor SB-699551; and (3) evaluating transcriptional changes induced by chronic exposure to the drug in human CNS-3D brain organoids. This work is in coordination with FDA review teams and directly supports patient safety, regulatory product center review work, and the Food, Drug and Cosmetics Act.

Objectives

The objectives of the lab analysis service are:
Characterizing acute and chronic neuromodulatory effects of a marketed small molecule drug (drug cost up to $1,000) in human CNS-3D brain organoids, including spontaneous Ca2+ burst and induced variability in Ca2+ burst timing.
Characterizing the role of the 5-HT5A receptor in drug-induced effects in human CNS-3D brain organoids using co-treatment with the 5-HT5A receptor inhibitor SB-699551.
Evaluating transcriptional changes induced by chronic exposure to the drug in human CNS-3D brain organoids.

Scope

Reports will be delivered for the functional examination of neuromodulatory effects of a marketed small molecule drug and related transcriptomic changes in human CNS-3D brain organoids. Data shall be provided electronically, including study design, experimental conditions, and results analyzed. This analysis will be conducted at the contractor lab, no installation/training is needed. This is also a one-time analysis; there are no option periods.

Tasks

CNS-3D human brain organoid testing includes (1) characterizing acute and chronic neuromodulatory effects of a marketed small molecule drug in human CNS-3D brain organoids, including spontaneous Ca2+ burst and induced variability in Ca2+ burst timing; (2) characterizing the role of the 5-HT5A receptor in drug-induced effects in human CNS-3D brain organoids using co-treatment with the 5-HT5A receptor inhibitor SB-699551; and (3) evaluating transcriptional changes induced by chronic exposure to the drug in human CNS-3D brain organoids.

- Human iPSC-derived CNS-3D organoids at 10 weeks of differentiation will be treated with a drug (25 µM and 100 µM), serotonin (positive control) (25 µM and 100 µM), and DMSO (negative control) with or without a SB-699551 for 2 weeks. A total of 10 treatment groups shall be tested.
- Each treatment group shall have 32 organoids (n=32/group).
- The CNS-3D brain organoids shall be characterized and consistent with the organoids previously used in related FDA research. Use of 28Bio organoids is required in order to maintain continuity and comparability with prior research data. The organoids shall be comprised of serotonergic neurons and astrocytes and confirmed expression of 5-HT5A receptor. Expression profile of serotonin receptors and other GPCRs shall be available. The

organoids shall exhibit spontaneous and coordinated neuronal network activity such as spontaneous Ca2+ bursts, which can be captured in real-time with FLIPR analysis.

- Ca2+ flux shall be measured longitudinally on Day 1 (pre-exposure, 30, 60, and 240 minutes post-exposure), Day 3 and Day 14, using the FLIPR Tetra® High-Throughput Cellular Screening System.
- Waveform analysis of Ca2+ flux data shall be performed for the features that describe the number (peak frequency), size (peak height), and shape (peak skew) of spontaneous calcium oscillations in each organoid, along with variability of the burst strength, burst timing, and the calcium influx rate.
- Viability shall be assessed by quantifying the amount of released lactate dehydrogenase (LDH) using the LDH-GloTM cytotoxicity assay at each media change on Day 1 (prior to exposure) and during chronic exposure on Days 3, 5, 7, 12 and 14.
- Transcriptomic analysis shall be conducted to evaluate differences between the treatment groups after chronic exposure for 2 weeks. The analysis can be done for pooled organoids (8 organoids/pool, n = 4 pools/group).
- Transcriptomic analysis shall be performed using RNA sequencing techniques (RNAseq). Data analysis shall be performed to find differential expression of genes (DEG), and gene ontology (GO) analysis shall be conducted to find pathways associate with chronic drug treatment.
- Statistical analyses shall be performed for each treatment time point and dose group.
- Results shall be comparable with our preliminary data.
- Data provided shall include study design, experimental conditions, and results.
- All data shall be provided to NCTR via email or a secure internet site for downloading. The service company does not own the data (i.e., intellectual property). NCTR/FDA is the owner of the data.

Delivery
Delivery address: to be completed at time of award.

Deliverable Schedule

Deliverable	Description	Quantity/Media	Date Completed
1	Final Study design including experimental design, methods, and data analysis methods, identification of the 28Bio organoids to be used and available organoid characterization information demonstrating the required features identified in the SOW.	1 study proposal: electronic file	Two weeks after award date
	Government review		One week
	Resubmit with Government comments	1 study proposal: electronic file	One month after award date

2	Acute and chronic neuromodulatory effects of a drug in human CNS-3D brain organoids, including spontaneous Ca2+ burst and induced variability in Ca2+ burst timing	Electronic files of data for each of 32 organoids per group (n=32/group) for 5 treatment groups and group data. Time points: Day 1 at 0, 30, 60, 120, and 240 minutes post-exposure, Day 3 and 14 post-exposure.	1/31/2027
3	Role of the 5-HT5A receptor in drug-induced effects in human CNS-3D brain organoids using co-treatment with the 5-HT5A receptor inhibitor SB-699551	Electronic files of data for each of 32 organoids per group (n=32/group) for 5 treatment groups and group data. Time points: Day 1 at 0, 30, 60, 120, and 240 minutes post-exposure, Day 3 and 14 post-exposure.	1/31/2027
4	LDH (Viability)	Electronic files of data for each of 32 organoids per group (n=32/group) for 10 treatment groups and group data. Time points: Pre-exposure and on Days 3, 5, 7, 12, and 14.	1/31/2027
5	Transcriptomic data	Electronic files of data for 10 treatment groups with 4 pools/group (a total of 40 data sets) on Day 14.	3/31/2027

Government-Furnished Property, Material, Equipment, or Information (GFP, GFM, GFE, or GFI)
No government-furnished property, material, equipment, or information will be provided in the scope of this acquisition.

Security
Security requirements are not applicable to this contract.

Travel

Travel is not applicable to this contract.

Special Material Requirements
The contract shall buy the test article (drug) as specified by the government.

Other Unique Requirements
Data Deliverables and Use of Information
The Contractor shall provide all deliverable data generated under this contract in electronic format, including study design, experimental conditions, raw data, analyzed results, statistical analyses, and final study reports, as required by the contract.

Data and information provided by the Government to the Contractor, or generated by the Contractor in performance of this contract, shall be used only for purposes of performing this contract and shall not be released, disclosed, or used for any other purpose except as authorized in writing by the Contracting Officer or as otherwise required by law.

The Government's rights in delivered data shall be governed by the contract clause or clauses included in the contract.

Publication and Disclosure Restriction
The Contractor shall not publish, present, or otherwise publicly disclose nonpublic information, data, or results generated under or provided in connection with this contract without prior written approval from the Contracting Officer, except as otherwise required by law.

Confidentiality and Nondisclosure of Information. Any information provided to the contractor (and/or any subcontractor) by FDA or collected by the contractor on behalf of FDA shall be used only for the purpose of carrying out the provisions of this contract and shall not be disclosed or made known in any manner to any persons or entity except as may be necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and shall ensure that all work performed by its employees and subcontractors shall be under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any FDA records may be made available or disclosed shall be notified in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein. The information shall not be disclosed to any other entity without prior FDA approval.

Contractor Non-Disclosure Agreement (NDA). Contractor must submit signed FDA form 3398 with quote submission and prior to any other contractor employee performing work on the contract. Each Contractor (and/or any subcontractor) employee having access to non-public government information (Government provided samples) and sequencing data under this contract shall complete the FDA non-disclosure agreement (3398 Form), as applicable. A copy of each signed and witnessed NDA shall be submitted to the CO and/or COR prior to performing any work under this acquisition.

Sanitization of Government Files and Information. The Contractor shall securely maintain all Government data, files, records, and related information for up to five years after completion of the analysis, or for another period as directed in writing by the Government, to support NCTR's

planned publication of the results in a scientific journal and any reasonable Government requests for additional analysis details.

Contract closeout shall not relieve the Contractor of its obligation to retain, protect, return, dispose of, or sanitize Government records and information as required by this section. Before contract closeout, the Contractor shall provide the COR with written documentation identifying the Government data, files, records, media, and devices that have been returned, retained, transferred, disposed of, or sanitized.

At the end of the retention period, or earlier upon written direction from the Government, the Contractor, including any subcontractor, shall dispose of all remaining Government records and information and sanitize all applicable devices and media in accordance with NIST SP 800-88, Guidelines for Media Sanitization, and FDA IS2P Appendix T, Sanitization of Computer-Related Storage Media. The Contractor shall provide written certification to the COR confirming completion of the required disposal and sanitization.

The confidentiality, integrity, and availability of such information shall be protected in accordance with HHS and FDA policies. Unauthorized disclosure of information will be subject to the HHS/FDA sanction policies and/or governed by the following laws and regulations:

a. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);
b. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and
c. 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

Place of Performance
Performance will be at the Contractor's facility.

Period of Performance
The period of performance is estimated be from 8/1/2026-4/30/2027. This date may be adjusted based on the actual award date.

FOB Point Destination. All items shall include shipping and handling to the destination identified herein.

Holidays and Government Closures

Service/Delivery shall not be scheduled during Federal Holidays or Federal Closures as determined by Executive Orders or opm.gov. Federal Holidays are as follows:

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

Independence Day

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

Required:
52.212-4, Contract Terms and Conditions-Commercial Items (Deviation SEP 2025)
Applicable:
52.203-17, Contractor Employee Whistleblower Rights (Nov 2023)
52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017)
52.204-13 System for Award Management and Maintenance (Deviation) (RFO Aug 2025)
52.209-6, Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, Proposed for Debarment, or Voluntarily Excluded. (Deviation) (RFO NOV 2025)
52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Deviation) (RFO NOV 2025)
52.219-4, Notice of Price Evaluation preference for HUBZone Small Business Concerns (DEVIATION) (RFO SEP 2025)
52.222-3, Convict Labor (DEVIATION) (RFO SEP 2025)
52.222-19, Child Labor-Cooperation with Authorities and Remedies (Deviation) (RFO Sep 2025)
52.222-36, Equal Opportunity for Workers with Disabilities (Deviation) (RFO Sep 2025)
52.222-50, Combating Trafficking in Persons (Deviation) (RFO Sep 2025)
52.222-53 Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (Deviation) (RFO Sep 2025)
52.222-90, Addressing DEI Discrimination by Federal Contractors (DEVIATION) (RFO APR 2026)
52.223-23, Sustainable Products and Services (Deviation) (RFO Sep 2025)
52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act Alt II (DEVIATION) (RFO NOV 2025)
52.226-8, Encouraging Contractor Policies to Ban Text Messaging While Driving (May 2024)
52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct 2018)
52.232-40, Providing Accelerated Payments to Small Business Subcontractors (Mar 2023)
52.233-3, Protest After Award (Deviation) (RFO Aug 2025)
52.233-4, Applicable Law for Breach of Contract Claim (Deviation) (RFO Aug 2025)
52.240-91 Security Prohibitions and Exclusions (Deviation) (RFO Aug 2025)
52.244-6, Subcontracts for Commercial Products and Commercial Services (Deviation) (RFO Sep 2025)

Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

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

HHSAR Clause 352.224-71 Confidential Information (FEB 2024) (DEVIATION)
(a) [*Definition*. As used in this clause—
Confidential Information, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
(b) *Identification of information.* Specific confidential information or categories of information that the Government will furnish to the Contractor, or that the Contractor is expected to generate, is identified this contract.
(c) *Disclosure.* The Contractor shall not disclose confidential information or records until Written notice is provided to the Contracting Officer at least 45 days in advance of the Contractor's intent to release findings of studies or research, to which an agency response may be appropriate to protect the public interest or that of the agency. The Contractor shall not disseminate or publish such information without the written consent of the Contracting Officer.
(d) *Government furnished or provided information:* For information provided by or on behalf of the government—
(1) The publication or dissemination of the following types of information are restricted under this contract: All data related to this procurement is restricted
(2) The reason(s) for restricting the types of information identified in subparagraph (d)(1)(i) is/are: The national security risk to the Government that process Americans' plasma samples, genome or exome data in any foreign country or entity or potentially provide that information to a foreign country or other foreign entities. The Federal Bureau of Investigation (FBI) has identified national security risks that could undermine U.S. companies and steal intellectual property and trade secrets related to sharing genomic data, and recognizes foreign countries and entities as a primary source of those risks.
(e) The Contractor shall consult with the Contracting Officer when there is uncertainty with regard to the confidentiality of,or a property interest in, information under this contract, prior to the release, disclosure, dissemination, or publication of such information.

HHSAR Clause 352.232-71 Electronic Submission of Payment Requests (APR 2026) (RFO DEVIATION)

(a) Definitions. As used in this clause-

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

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

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

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

(END OF CLAUSE)

HHSAR Clause 352.239-79 Information and Communication Technology Accessibility (Feb 2024) (Deviation)

(a) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all information and communication technology (ICT) supplies, products, platforms, information, documentation, and services support developed, acquired, maintained or delivered under this contract or order must comply with the Revised 508 Standards, which are located at 36 C.F.R. 1194.1 and Appendices A, B, and C, and are available at https://www.access-board.gov/ict/. Information about Section 508 is available at https://www.hhs.gov/web/section-508/index.html.
(b) Additional Section 508 accessibility standards applicable to this contract or order may be identified in the specification, statement of work, or performance work statement. If it is determined by the Government that ICT supplies, products, platforms, information, documentation, and services support provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.
(c) In the event of a modification(s) to this contract or order, which adds new ICT supplies or services or revises the type of, or specifications for, supplies, products, platforms, information, documentation, or services support, the Contracting Officer shall require that the Contractor submit a completed HHS Section 508 Accessibility Conformance Checklist (see *https://www.hhs.gov/web/section-508/accessibility-checklists/index.html*) or an Accessibility Conformance Report (ACR) (based on the Voluntary Product Accessibility Template (VPAT) see https://www.itic.org/policy/accessibility/vpat), and any other additional information necessary to assist the Government in determining that the ICT supplies or services conform to Section 508 accessibility standards. If it is determined by the Government that ICT supplies, products, platforms, information, documentation, and services support provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.
(d) If this is an Indefinite-Delivery type contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include ICT supplies, products, platforms, information, documentation, or services support will define the specifications and accessibility standards for the order. In those cases, the Contractor shall be required to provide a completed HHS Section 508 Accessibility Conformance Checklist (see *https://www.hhs.gov/web/section-508/accessibility-checklists/index.html*) or an ACR (based on the VPAT see https://www.itic.org/policy/accessibility/vpat), and any other additional information necessary to assist the Government in determining that the ICT supplies, products, platforms, information, documentation, or services support conform to Section 508 accessibility standards. If it is determined by the Government that ICT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies, products, platforms, information, documentation, or

services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.
(e) The contractor shall identify to the Contracting Officer any perceived exception or exemption to Section 508 requirements.
(End of clause)]

The supplies and/or services delivered hereunder shall be inspected and accepted at destination by the Contracting Officer's Representative (COR) specified at award. If the supplies or services are acceptable, the COR shall promptly forward a report of inspection and acceptance to the paying office. If the supplies or services are not acceptable, the COR shall document the nonconforming items/services and immediately notify the contracting officer.

Contract Administration

a. Contracting Officer/Contract Administrator
Nick Sartain, Contracting Officer
Phone: 301-796-1988
Email: nick.sartain@fda.hhs.gov

b. COR –
The following COR will represent the Government for the purpose of this contract:
(To be completed at time of award)
Name:
Phone:
Email:

The COR 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.

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 statement of work;
(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.

Payments

Payment terms Net 30 days after government acceptance. No advance payments will be made.

Invoice Submission

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

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

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

c.

1. The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 - 5 business days of the contract award for new contracts or date of modification for existing contracts.
2. Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.
3. The Contractor POC will receive two emails from **IPP Customer Support**, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.
4. If your company is already registered to use IPP, you will not be required to re-register.
5. If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

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

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

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

f. Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:

(a) list of all invoices submitted to date under the subject award, including the following:

(1) invoice number, amount, & date submitted
(2) corresponding payment amount & date received

(b) total amount of all payments received to date under the subject contract or order

(c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance.

g. Payment of invoices will be made based upon acceptance by the Government of the entire task or the tangible product deliverable(s) invoiced. Payments shall be based on the Government certifying that satisfactory services were provided, and the Contractor has certified that labor charges are accurate.

h. If the services are rejected for failure to conform to the technical requirements of the delivery order, or any other contractually legitimate reason, the Contractor shall not be paid, or shall be paid an amount negotiated by the CO.

i. Payment to the Contractor will not be made for temporary work stoppage due to circumstances beyond the control of U.S. Food and Drug Administration such as acts of God, inclement weather, power outages, and results thereof, or temporary closings of facilities at which Contractor personnel are performing. This may, however, be justification for excusable delays.

j. The Contractor agrees that the submission of an invoice to the Government for payment is a certification that the services for which the Government is being billed, have been delivered in accordance with the hours shown on the invoices, and the services are of the quality required for timely and successful completion of the effort.

k. Questions regarding invoice payments that cannot be resolved by the IPP Helpdesk should be directed to the FDA Employee Resource and Information Center (ERIC) Helpdesk at 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742); or, by email at ERIC@fda.hhs.gov. Refer to the Call-in menu options and follow the phone prompts to dial the option that corresponds to the service that's needed. All ERIC Service Now Tickets will either be responded to or resolved within 48 hours (2 business days) of being received. When emailing, please be sure to include the contract number, invoice number and date of invoice, as well as your name, phone number, and a detailed description of the issue.

Notice Regarding the Use of Macros in Submitted Documents

Be advised that FDA does not accept documents which contain the use of macros. When submitting documents via email, DO NOT include .exe, .mso, or any other executable file types that could potentially trigger email security protections (i.e. email blocks, quarantine). Document submissions required throughout the award period(s) shall not have macro enabled functionality and any document delivered having that functionality will be deemed delinquent, if not corrected prior to the due date.

List of Attachments:
Attachment 1: FDA 3398

Solicitation provisions
Contract Type: Commercial Item-Firm Fixed Price.

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

FAR Provisions.
52.203-18 Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation (Jan 2017)
52.204-7 System for Award Management (Deviation) (RFO Aug 2025)
52.222-18 Certification Regarding Knowledge of Child Labor for Listed End Products (FEB 2021)

52.225-4 Buy American-Free Trade Agreements-Israeli Trade Act Certificate Alt II (DEVIATION) (RFO SEP 2025)

HHSAR Provisions

352.239-7~~3~~[8] ~~Electronic~~ Information and [Communication] Technology Accessibility Notice (~~Dec 2015~~[Feb 2024]) [(Deviation)]

(a) Any offeror responding to this solicitation must comply with established HHS Information and Communication Technology (ICT) accessibility standards. Information about Section 508 is available at https://www.hhs.gov/web/section-508/index.html.

(b) The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-79 Information and Communication Technology Accessibility. In order to facilitate the Government's determination whether proposed ICT supplies, products, platforms, information, and documentation meet applicable Section 508 accessibility standards, offerors must submit an appropriate HHS Section 508 Accessibility Conformance Checklist (see *https://www.hhs.gov/web/section-508/accessibilitychecklists/index.html*) or an Accessibility Conformance Report (ACR) (based on the Voluntary Product Accessibility Template (VPAT) see https://www.itic.org/policy/accessibility/vpat), in accordance with the completion instructions. The purpose of the checklists and conformance reports are to assist HHS acquisition and program officials in determining whether proposed ICT supplies, products, platforms, information, and documentation conform to applicable Section 508 accessibility standards. Checklists and ACRs evaluate—in detail—whether the ICT conforms to specific Section 508 accessibility standards and identifies remediation efforts needed to address conformance issues.

(c) If an offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, *i.e.*, after award of a contract or order, that supplies, products, platforms, information, documentation, or services support delivered do not conform to the described accessibility standards, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(d) In order to facilitate the Government's determination whether proposed ICT supplies meet applicable Section 508 accessibility standards, offerors must submit an Accessibility Conformance Report, in accordance with its completion instructions and tailored to the requirements in the solicitation. The purpose of the Report is to assist HHS acquisition and program officials in determining whether proposed ICT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document, in detail, whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available at https://section508.gov/.

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

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

(g) Items delivered as electronic content must be accessible to HHS acceptance criteria. Checklist for various formats are available at https://section508.gov/. Materials, other than items incidental to contract management, that are final items for delivery should be accompanied by the appropriate checklist, except upon approval of the Contracting Officer or Contracting Officer's Representative.

(END OF PROVISION).

The provision at FAR 52.212-1 Instructions to Offerors-Commercial Items (Deviation) (RFO Aug 2025) The following addenda have been added to this provision:

Technical Capability/Risk (paragraph (b)(4): Will be determined by review of information submitted by the offeror which must provide sufficient technical information necessary for the Government to conclusively determine that the offered CNS-3D human brain organoid analysis meets or exceed the technical requirements identified above. Offerors shall specifically address the performance specifications and support same with submitted technical specifications, descriptive material, literature, brochures, scientific publications where proposed solution has been used for same or similar purposes, and other information which demonstrates the capability of the offered solution at meeting or exceeding the stated needs of the FDA. The Government's determination of technical acceptability in no way relinquishes the Awardee's contractual obligation to ensure the services meet the FDA's stated need. Provide (1) the place of performance for the services that process Americans' plasma, genome or exome data (stored or transmitted electronically), to include a specification of whether that processing will occur through or in any foreign country or entity, (2) whether the plasma, genome or exome will be provided to any other country or entity, or (3) whether any information technology capabilities used to receive, process, or respond to this contract, to include but not limited to servers, data storage, cloud storage, or analytics tools, are located in any foreign country or entity.

Past Performance (paragraph (b)(10): Past performance information shall clearly demonstrate recent (within the past 3 years) and relevant experience in providing CNS-3D human brain organoid analysis services similar to this requirement. For each reference include a brief description of service performed, contract number(s), dollar value, client points of contact names, and client points of contact email addresses and phone numbers. The Government reserves the right to look to other sources of information (e.g., the Contractor Performance Assessment Reporting System (CPARS), etc.) to support past performance evaluations.

Price: Provide detailed price quote for each item proposed to meet the Schedule of Items. Price shall be detailed and supported by a breakdown of all items required. (Offerors shall fill in the schedule above with the total prices and provide a detailed quote in their own format.) Include the firm's SAM Unique Entity ID (UEI) number with quote.

The Quoter shall submit a written Accessibility Conformance Report (ACR) for each item not in compliance with 508 standards identified in clause 352.239-74, describing how the item(s) will fully address the accessibility requirements outlined in the solicitation; and a description of the evaluation methods the offeror will use to validate for conformance to the Revised 508 Standards. The ACR should be based on the Voluntary Product Accessibility Template Version 2.0 (MS Word) provided by the Industry Technology Industry Council (ITIC). For this requirement we anticipate only invoices to be applicable to the requirement

NOTE: Submission of the ACR is required for documentation purposes. In accordance with agency purchasing procedures, solutions which do not conform fully to the applicable 508 standards may still be purchased by FDA if the FDA Requiring Office obtains the appropriate approval. In order to obtain approval, the FDA must have an ACR from the vendor documenting the level of conformance of the items being purchased.

The government is not responsible for locating or securing any information, which is not identified in the proposal however the Government reserves the right to obtain information for use in the evaluation from any and all sources including sources outside of the Government. The Government reserves the right to request additional information from a quoter at any time.

Service Contract Act Exemption
This solicitation is being issued under the premise that the offeror will certify that the service it will propose to fulfill this requirement is exempt from the Service Contract Act per the conditions set forth in FAR 52.222-52 & FAR 22.1002-1(f)(3). If the Contractor certifies that the company is exempt under the terms and conditions of 52.222=52, then clause 52.222-53 will be applicable to the resulting order. In the event that a contractor does not make this certification, the traditional Service Contract Act clause 52.222-41 shall be included and the applicable SCA wage determination at the delivery location shall become part in any resultant contract. Wage Determination No.: WD 2015-5189 (Rev. 33) dated 4/29/2026 which is located at: https://sam.gov/wage-determination/2015-5189/33.

52.222-52 Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Certification (Deviation) (RFO Sep 2025)
(a) The offeror must check the following certification:
Certification
The offeror □ does □ does not certify that-
(1) The services under the contract are offered and sold regularly to non-Governmental customers, and are provided by the offeror (or subcontractor in the case of an exempt subcontract) to the general public in substantial quantities in the course of normal business operations;

(2) The contract services are furnished at prices that are, or are based on, established catalog or market prices. An "established catalog price" is a price included in a catalog, price list, schedule, or other form that is regularly maintained by the manufacturer or the offeror, is either published or otherwise available for inspection by customers, and states prices at which sales currently, or were last, made to a significant number of buyers constituting the general public. An "established market price" is a current price, established in the usual course of ordinary and usual trade between buyers and sellers free to bargain, which can be substantiated from sources independent of the manufacturer or offeror;
(3) Each service employee who will perform the services under the contract will spend only a small portion of his or her time (a monthly average of less than 20 percent of the available hours on an annualized basis, or less than 20 percent of available hours during the contract period if the contract period is less than a month) servicing the Government contract; and
(4) The offeror uses the same compensation (wage and fringe benefits) plan for all service employees performing work under the contract as the offeror uses for these employees and for equivalent employees servicing commercial customers.
(b) Certification by the offeror as to its compliance with respect to the contract also constitutes its certification as to compliance by its subcontractor if it subcontracts out the exempt services. If the offeror certifies to the conditions in paragraph (a) of this provision, and the Contracting Officer determines in accordance with FAR 22.1002-1(f)(3) that the Service Contract Labor Standards statute-
(1) Will not apply to this offeror, then the Service Contract Labor Standards clause in this solicitation will not be included in any resultant contract to this offeror; or
(2) Will apply to this offeror, then the clause at FAR 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements, in this solicitation will not be included in any resultant contract awarded to this offer, and the offeror may be provided an opportunity to submit a new offer on that basis.
(c) If the offeror does not certify to the conditions in paragraph (a) of this provision-
(1) The clause of this solicitation at 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements, will not be included in any resultant contract to this offeror; and
(2) The offeror must notify the Contracting Officer as soon as possible if the Contracting Officer did not attach a Service Contract Labor Standards wage determination to the solicitation.
(d) The Contracting Officer may not make an award to the offeror, if the offeror fails to execute the certification in paragraph (a) of this provision or to contact the Contracting Officer as required in paragraph (c) of this provision.
(End of provision)

Microsoft Suite Documents Containing Macros
The offeror or applicant shall submit all electronic documents for Microsoft Office suite products without the use of “macros”. ***When submitting proposals via email, DO NOT include .exe, .mso, or any other executable file types that could potentially trigger email security protections (i.e. email blocks, quarantine).*** If the offeror or applicant submits documents that contain macros**,** ***macro referenced files, and/or executable files***, the Government will not be able to view or open such documents and the submission will be considered non-responsive to the solicitation. No additional time will be given to an offeror or applicant to correct the document

submission and the Government will not inform the offeror or applicant that their submission is non-responsive prior to award. It is the offeror's or applicant's responsibility to ensure all electronic documents are submitted without the use of macros.

Buy American Act and Executive Order 14005
If applicable, respondent shall provide place (country) of product/service manufacture or performance and any other applicable information to enable review and analysis pertaining to the requirements under the Buy American Act and requirements relating to Executive Order 14005 Ensuring the Future is Made in All of America by All of America's Workers, in the event that a nonavailability waiver request submitted through the Made in America Office (MIAO) Digital Waiver Portal is required. If the respondent does not provide a response for a line item, or if the respondent's SAM.gov online representation for FAR provision 52.225-4, Buy American-Free Trade Agreements-Israeli Trade Act Certificate, is not completed or is unclear, the Government will presume that the item is made in America..

Line Item No.	Country of Origin
_____	_____
_____	_____

Period for Acceptance of Offers. The offeror agrees to hold the prices in its quote firm through September 30, 2026.

The provision at FAR 52.212-2 Evaluation-Commercial Items (Deviation) (RFO Aug 2025) . The specific evaluation criteria to be included in paragraph (a) of that provision are as follows:

The Government intends to award a contract resulting from this solicitation to the lowest priced technically acceptable responsible quoter/offeror whose quote, conforming to the solicitation, will be most advantageous to the Government, price and other factors considered. Quotes will be evaluated on their ability to meet the requirements provided herein.

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

(i) Technical Capability/Risk (see FAR Provision 52.212-1 (b)(4) and addenda thereto). As part of the technical capability the national security risk to the Government will also be considered for entities that process Americans' plasma, genome or exome data in any foreign country or entity or potentially provide that information to a foreign country or other foreign entities. The national security risks related to sharing genomic data will be considered in the trade-off award decision. The Federal Bureau of Investigation (FBI) has identified national security risks that could undermine U.S. companies and steal

intellectual property and trade secrets related to sharing genomic data, and recognizes foreign countries and entities as a primary source of those risks.

(ii) Past Performance (see FAR Provision 52.212-1 (b)(10) and addenda thereto)

(iii) Price

Technical Capability/Risk (i.e., how well the proposed service will meet or exceed the Government's requirements), past performance (i.e. when, what and how well), and when combined is significantly more important than price in determining the best value to the government. However, if the Government determines non-price factors to be essentially equal among competing offerors price becomes more important as a discriminating factor.

The Government reserves the right to request additional information or conduct discussions at any time. Once the Government determines the offeror that is the best-suited (i.e., the apparent successful offeror), the Government reserves the right to communicate with only that offeror to address any remaining issues, if necessary, and finalize a contract with that offeror. These issues may include technical, price or other issues.

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

The Government's determination of technical acceptability in no way relinquishes the Awardee's contractual obligation to ensure the quoted products meet the FDA's stated need.

Notice to Offerors:

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

- System updates may lag policy updates. The System for Award Management (SAM) may continue to require entities to complete representations based on provisions that are not included in agency solicitations, including 52.223-22, Public Disclosure of Greenhouse Gas Emissions and Reduction Goals—Representation, and paragraph (t) of 52.212-3, Offeror Representations and Certifications—Commercial Products and Commercial Services. Agencies will not consider or use these representations. Entities are not required to, nor are they able to, update their entity registration to remove these representations in SAM.

- Notice to Offerors or Quoters: Funds are not presently available for this effort. No award will be made under this solicitation until adequate funds are available for it. The Government reserves the right to cancel this solicitation, either before or after the closing date of it. If the Government cancels this solicitation, the Government has no obligation to reimburse an offeror or quoter for any costs associated with it, including proposal or quote preparation costs

One or more of the items under this acquisition is subject to Free Trade Agreements.

It is the offeror's responsibility to monitor sam.gov for the release of any information related to this acquisition, e.g., questions and answers, amendments, award notice, etc. Offerors that fail to complete the required representations and certifications or reject the terms and conditions of the solicitation may be excluded from consideration.

All responsible sources may submit an offer, which if timely received, shall be considered. The offer must reference solicitation number 75F40126Q134171. The offers are due by email to nick.sartain@fda.hhs.gov on or before July 6, 2026 by 1:00 P.M. (Central Time in Jefferson, Arkansas).

For information regarding this solicitation, please contact Nick Sartain at (301) 796-1988 or email nick.sartain@fda.hhs.gov.