Attachment 1 - Packaging and Delivery of Proposals for Use with the NIH electronic Contract Proposal Submission (eCPS) Website

I. PROPOSAL SUBMISSION

A. eCPS

1. Proposals must be submitted via the electronic Contract Proposal Submission (eCPS) website at https://ecps.nih.gov.

2. Proposals submitted by facsimile or e-mail will not be accepted.

3. Follow the "How to Submit an Electronic Proposal" instructions provided on the eCPS website at: https://ecps.nih.gov/home/howto. **Please note that creating an account to submit may take up to three (3) business days.** Please apply for a new account early to allow enough time for the registration process.

4. Offerors are solely responsible for submitting proposals and any modifications or revisions so as to reach the Government office designated above by the date and time specified in the solicitation. If your proposal is not received by the date and time specified in the solicitation, it will be considered a "late proposal," in accordance with **FAR Clause 52.215-1 Instructions to Offerors – Competitive Acquisition.**

B. Creating and Naming Files:

1. **Create one PDF file of your Technical Proposal, including all attachments**. The Technical Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring signature(s) may be scanned, but must be merged into the Technical Proposal PDF file.

2. **Create one PDF file of your Business Proposal, including all attachments**: The Business Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring signature(s) may be scanned, but must be merged into the Business Proposal PDF file. Additionally, the "Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet" (http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx) must be included in the Business Proposal.

3. **Create your Business Document Excel**. The Excel file should be the "Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet" (http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx) included in the Business Proposal in its original Excel format, not PDF. Multiple Excel files may be included, as necessary.

4. Each of the proposals, Technical and Business, must be separate and complete in itself. Do not reference one proposal in another.

5. File naming convention: It is requested that the filenames for your Technical Proposal, Business Proposal, and Excel Workbook include the name of the offeror, the solicitation number and the type of proposal (i.e., Technical, Business, or Excel Workbook).

   Examples:
   Technical Proposal: *XYZ Company_NIHAI2012001_Technical.pdf*
   Business Proposal: *XYZ Company_NIHAI2012001_Business.pdf*
   Excel Workbook: *XYZ Company_NIHAI2012001_Business.xlsx*

II. FORMATTING AND PAGE LIMITATIONS:

A. Formatting for proposals

1. Proposal page layout shall be letter size 8.5” x 11" for all pages.

2. Proposals shall not include links to internet web site addresses (URLs) or otherwise direct readers to alternate sources of information.

3. Proposals shall not include audio or video files of any type.

4. Font size must be 10 to 12 points.

5. Spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.

6. Margins must be at least one-inch on all sides.

7. **Failure to adhere to the formatting requirements above may impact whether your proposal is reviewed in its entirety.**

B. Page limitations:

See Attachment 24 for page limitations.

PROPOSAL INTENT RESPONSE SHEET

RFP No: 75N94026R00002

Title: Chemistry Research for the Division of Translational Toxicology (DTT)

Please review the Request for Proposals (RFP). Furnish the information requested below and return this page to the Contracting Officer at the email address below by **July 24, 2026.**

Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation. **Note: Proposals may NOT be submitted via e-mail, but rather through the NIH e-CPS** and you will need to allow several days for the registration process.

Choose one of the following:

[ ] Do intend to submit a proposal

[ ] Do Not intend to submit a proposal.

If you are not responding to this RFP, please provide your reason(s):

Please provide the following contact information:
COMPANY/INSTITUTION NAME:
FULL ADDRESS:
POINT OF CONTACT and TELEPHONE NUMBER:
POC E-MAIL ADDRESS:

Please submit this Proposal Intent Response sheet to the email address below:

sarah.bank@nih.gov

STATEMENT OF WORK (SOW)
Chemistry Research for the Division of Translational Toxicology (DTT)

1. General Information

1.1 General

This is a non-personal service(s) contract under which the personnel rendering the service(s) are not subject, either by the contract's terms or by the manner of its administration, to the supervision and control usually prevailing in relationships between the Government and its employees. The purpose of this contract is to provide chemistry research for the National Institute of Environmental Health Sciences (NIEHS), Division of Translational Toxicology (DTT) research. The type and extent of chemistry research provided by this contract will be tailored to specific DTT research needs.

1.2 Description of Services

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, procedures, materials, equipment, and facilities not otherwise provided by the Government to perform the objectives set forth below. In general, studies shall be conducted according to the requirements described in the *Specifications for the Conduct of Chemistry Activities for Toxicology Research Performed by the Division of Translational Toxicology at the National Institute of Environmental Health Sciences* (DTT Chemistry Specifications) (https://ntp.niehs.nih.gov/data/research/chemistry/rfp).

1.3 Background and Scope

The mission of NIEHS is to discover how the environment affects people to promote healthier lives. DTT is an intramural division at NIEHS, and DTT scientists use a variety of traditional and cutting-edge approaches to better understand how factors in our environment may impact our health. One of DTT's goals is to lead the transformation of toxicology through the development and application of innovative tools and strategies. This contract will provide required chemistry research at each step of the DTT toxicological evaluation process.

Performance of this contract will involve program management procedures and chemistry technical activities in up to 8 Functional Areas as given below. Functional Activities under Functional Areas may be performed individually or in one or more combinations (see Functional Area 5, Special Studies below). Detailed requirements for Functional Areas and corresponding Functional Activities are given in the DTT Chemistry Specifications.

Recognizing the evolution and integration of data science remains crucial to the study of environmental health, the scope of this Research and Development (R&D) contract aligns with the DTT research portfolio and NIEHS strategic plan. The objective of this R&D contract is to provide scientific, operational, and administrative chemistry research for DTT/NIEHS research.

1.4 Overview of Required Capabilities

The Contractor shall provide scientific and administrative research support to conduct chemistry activities in the following Functional Areas. Activities include, but are not limited to, the Functional Activities described in the DTT Chemistry Specifications and shall be performed in accordance with the requirements set forth there.

Functional Area 1: Logistics and Handling
Logistics and Handling include all activities pertaining to procurement, handling, and shipment of test articles and samples produced for all DTT research.

Functional Area 2: Characterization
Characterization includes all activities related to establishing the identity and determining the purity of test articles, including developing methods needed to perform the analysis.

Functional Area 3: Formulation
Formulation includes all activities related to preparation, mixing, and analysis of dose formulations containing one or more test articles in a vehicle (e.g., corn oil, water, feed).

Functional Area 4: Biosample Analysis
Biosample analysis includes all activities related to determination of the concentration of an analyte (e.g., test article, a metabolite of the test article, DNA adduct, endogenous analyte) in a variety of matrices (e.g., blood, plasma, tissue).

Functional Area 5: Special Studies
Special studies include activities that are part of the overall scope of the contract but may or may not be contained within a single functional activity or represent only a portion of a functional activity.

Functional Area 6: Animal Studies
Animal studies include all activities related to determining absorption, distribution, metabolism, and excretion (ADME) parameters and toxicokinetic (TK) parameters of a test article administered to animals, typically rodents, via a route or routes of interest (e.g., oral gavage, drinking water, feed, and/or intravenous). Animal studies will use either non-labelled (e.g., TK studies) or radiolabelled (e.g., ADME studies) test articles.

Functional Area 7: Omics
Omics activities typically include exposomics, proteomics, and metabolomics analyses, using state-of-the-art techniques, in biological matrices (e.g., cell lysates, urine, plasma) and/or environmental samples (e.g., water).

Functional Area 8: In Vitro Assays
In vitro assays include all activities related to determining ADME of test article(s) typically in in vitro rodent and human models.

1.5 Policies and Procedures

The Contractor and applicable subcontractor facilities shall comply with the below regulations and specifications. Refer to DTT Chemistry Specifications Chapters 2 Facilities), 3, (Health and Safety) and 4 (Animal Care and Use) for details.

- All work performed under this contract by the Contractor or any Subcontractor for any assignment that directly supports a DTT GLP study (e.g., toxicology study) shall comply with Food and Drug Administration Good Laboratory Practices for Nonclinical Laboratory Studies (FDA GLP Regulations; Federal Register, 12/22/78, Part II et seq. (CFR Code of Federal Regulations Title 21) unless specifically authorized by the contracting officer's representative (COR) or specifically excluded in the DTT Chemistry Specifications.

- Health and Safety
    a. The Contractor shall establish procedures to protect the health and safety of contract personnel performing work under this contract and provide staff with on-going training to ensure that they are aware of any potential hazards.
    b. The Contractor's Health and Safety Program shall:
        i. Provide a qualified Health and Safety Officer.
        ii. Obtain and maintain full Drug Enforcement Agency (DEA) licensing (Schedules 1-5) that provides for procurement, receipt, storage, and shipment of Schedule 1-5 substances.
        iii. Develop and implement a detailed health and safety plan (HASP) that demonstrates compliance with the Occupational Safety and Health Act (Public Law 91-596 84 STAT 1590 1970, amended 2004) and applicable state and local safety and health codes, standards, and regulations. A DTT approved HASP is required prior to any work commencing under the contract and a copy of the proposed HASP shall be included in the contract proposal.
        iv. Include safely dispose of hazardous wastes.
        v. The Contractor shall comply with all federal, state, and local regulations for receipt, storage, handling, and shipping of hazardous chemicals, and with the National Cancer Institute (NCI) Safety Standards for Research Involving Chemical Carcinogens, DHEW Publication no. (NIH) 77-900 (1975), and subsequent revisions; and the NIH Guidelines for the Laboratory Use of Chemical Carcinogens, NIH Publication no 81-2385 (May 1981), and subsequent revisions.
        vi. All shipments must comply with Department of Transportation (DOT) regulations and the DTT Specifications requirements for chemical shipments. International shipments must comply with all applicable regulations for the recipient's location

- Animal Care and Use
    a. Contractor shall comply with requirements in Chapter 4 of the DTT Chemistry Specifications and Chapter 6 of the Specifications for the Conduct of Toxicity Studies by the Division of Translational Toxicology at NIEHS

(https://ntp.niehs.nih.gov/data/research/toxicology).

i. For required animal record information, the contractor shall comply with the requirements in Chapter11, Appendix A, Section 3, unless otherwise specified.

b. The contract shall be conducted in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the Animal Welfare Act Regulations, the current edition of the Guide for the Care and Use of Laboratory Animals (the Guide), and all local, state or federal regulations and policies.

c. Animal experimental protocols, approved by the contractor's IACUC, shall be deliverables to the COR prior to the commencement of work. These contractor-approved protocols shall also be available to the NIEHS ACUC.

d. The Contractor shall utilize a qualified Laboratory Animal Veterinarian to supervise the care and health of the animals.

1.6 Reporting Requirements

1.6.1. Reports and Deliverables

- The contractor shall comply with the requirements in DTT Chemistry Specifications Chapter 7. A summary of required reports is given in Table 1.

Table 1. Summary of Required Reports

Report Type	Report	Due	Submit to
Contract Management Reports	Quality Management Plan (QMP)	Within 60 days of the award of the contract	COR, CO, CS
	Health and Safety Plan (HASP)	Within 60 days of the award of the contract	COR, CO, CS
	IT Security Plan	Within 60 days of the award of the contract	COR, CO, CS
	Standard Operating Procedures	Within 6-months of the award of the contract	COR
	Chemical Inventory	On the 15th day of each month of this contract, beginning with the second month after award	COR
	Annual Water Analysis Report	Within 30 days of the start of the contract and annually thereafter	COR
	Monthly Status Report	On the 15th day of the second month after the start of the contract, and each month thereafter	COR, CO, CS
	Monthly Level of Effort Spreadsheet	Before the 15th day of the following month	COR
	Annual Report	Within 60 calendar days of the end of each year of the contract	COR, CO, CS
	Final Report	On or before the expiration of the contract	COR, CO, CS
Functional Activity Reports	Interim Data	Within one week of data generation	COR

	Draft Final Report[1]	From 8 weeks to 12 weeks of laboratory work completion. Period varies depending on the Functional Activity	COR
	Final Report	Within 2 weeks of COR approval	COR
	Letter reports	Within 8 weeks of laboratory work completion	COR
	Study Files (hard copies and pdfs)	Within 60 calendar days of the end of each year of the contract	COR

[1]Includes any applicable data summaries and data files

- All reports submitted under this contract shall reference the contract number, the title and type of report, any applicable DTT assignment number, and the represented period on the first page of the report.
- Posting Electronic Reports
    a. Electronic copies of all final chemistry reports shall be submitted to the DTT information management system (DTT PMS, currently Microsoft Dynamics 365 Program Operations) drop box at a URL specified by the COR.
    b. Electronic copies of contract management and status reports shall be submitted to the DTT PMS.
    c. Electronic copies of financial reports shall be emailed to the Contracting Officer. The Contracting Officer will provide the email address to the Contractor.
- If paper copies of fiscal, status, and technical reports are required, they shall be delivered to the COR or the CO as directed.
- When reporting subcontracted work, the Contractor shall summarize the work in a report to the DTT and attach as an appendix the original report submitted to the Contractor by the Subcontractor.

1.7. Post Award Conference/Periodic Progress Meetings

The Contractor shall attend any post award conference convened by the contracting activity or contract administration office in accordance with FAR Subpart 42.5. The CO, COR, and other Government personnel, as appropriate, may meet periodically with the Contractor to review the Contractor's performance. At these meetings the CO will apprise the Contractor of how the Government views the Contractor's performance and the Contractor shall apprise the Government of problems, if any, being experienced. Appropriate action shall be taken to resolve outstanding issues. These meetings shall be at no additional cost to the Government.

1.8. Progress Meetings

The Contractor shall attend, participate in, and furnish input to scheduled and unscheduled meetings, conferences, and briefings that relate to the functions and services herein as required by the Government to provide effective communication and impart necessary information. The Principal Investigator and/or Deputy Principal Investigator shall attend meetings as requested by the Government. Meeting attendees shall at times include Contractor

managerial, supervisory, and other personnel knowledgeable of the subject matter. Meetings may start or end outside of regular duty hours.

1.9. Personnel

The Contractor shall ensure that all Contractor personnel are adequately trained, possess the required credentials, and are fully qualified and skilled to perform the activities outlined in this SOW. The Contractor shall be responsible for all costs associated with technical training and necessary travel to ensure that staff maintain required certifications and proficiency to perform assigned duties. Refer to DTT Chemistry Specifications Chapter 1 for details.

In accordance with HHSAR 352.237-75, the following personnel are considered key personnel by the Government.

Contractor shall identify a Principal Investigator who shall be responsible for the performance of the work and provide the name of this person and that of a Deputy Principal Investigator, who shall act for the Contractor when the Principal Investigator is absent. The Principal Investigator and Deputy Principal Investigator shall have full authority on all contract matters relating to daily operation of this contract.

Each Functional Area Leads (e.g. Logistics and Handling, Characterization, Formulation, Biosample analysis, Animal Studies, Omics, and in Vitro Assays) shall be designated Key Personnel. For ADME and TK studies that Contractor shall have a subject matter expert (SME) on staff with relevant ADME and TK experience.

For activities involving animals, the Contractor shall employ a Lab Animal Veterinarian to monitor the study.

Key Personnel, along with the Health and Safety and Quality Assurance Officers and the Lab Animal Veterinarian shall be employees of the contractor (i.e., not consultants or subcontractors). Acceptance of the CV by the CO is required before these individuals are permitted to perform any task on this contract.

All subcontracted work (e.g., DNA barcoding of botanical materials for authentication; imaging mass spectrometry to determine xenobiotic distribution in tissues) must have a responsible staff member employed by the prime contractor who will oversee activities at the subcontractor. Subcontractors shall designate a project manager (PM) or SME with experience relevant to the subcontracted activities to oversee the work and serve as the point of contact for the prime contractor's staff. When subcontracted work constitutes a significant fraction of an activity, the subcontractor must designate a QA SME to monitor the subcontracted work.

Any change in personnel that might have an impact on the conduct and results of studies shall be reported immediately to the DTT.

1.10. Data Rights, Patents, and Copyrights

The Government has unlimited rights to all documents and materials produced under this

contract. All documents and materials produced under this contract shall be Government-owned and are the property of the Government with all rights and privileges of ownership and copyright belonging exclusively to the Government. These documents and materials may not be used or sold by the Contractor without written permission from the CO. All materials supplied to the Government shall be the sole property of the Government and may not be used for any other purpose. This right does not abrogate any other Government rights.

1.11. Source Documentation

All original source documentation is the property of NIEHS. Data summaries and other relevant information generated during the performance of this contract shall be submitted to the COR in the form of status reports and project specific reports as specified under the Deliverables in the DTT Chemistry Specifications. In addition, annual reports shall be submitted as described in DTT Chemistry Specifications. To the extent possible, the Government will retain unlimited access and rights to all materials, data, and technical information generated under the contract. The Contractor shall arrange for delivery of all raw data and study files for archival annually as directed by the COR.

1.12. Non-Disclosure Requirements

Performance under this contract may require the Contractor to access data and information proprietary to a Government agency, another Government Contractor, or of such nature that its dissemination or use other than as specified in this work statement would be adverse to the interests of the Government or others. The Contractor and Contractor's employees shall not divulge, or release data or information developed, or obtained under performance of this contract, except to authorized Government personnel or upon written approval of the CO. The Contractor shall not use, disclose, or reproduce proprietary data, which bears a restrictive legend, other than as specified in this contract. All documentation showing individual names or other personal information shall be controlled and protected under the provisions of the Privacy Act of 1974, Public Law 93-579, 5 United States Code (U.S.C.) Section 552a.

1.13. Replication, Dissemination, or Use of the Results

It is anticipated that the results of the research conducted under the Contract shall be published in the open, peer-reviewed scientific literature and/or in a NTP or NIEHS technical report series. Specific details concerning authorship and technical issues surrounding the publication of the research shall be discussed and agreed upon by the PI and the DTT COR on a case-by-case basis.

Because premature release of information developed under the contract could be harmful to the public, the Contractor and the Government agree that it is important to consider issues related to the timing of the release of research results when submitting information for publication. With regard to public disclosures of the research to be carried out pursuant to this contract, the Contractor agrees to submit all proposed articles to the COR at least thirty (30) days in advance of submission for publication. Within this thirty-day period the COR shall inform the Contractor if there are serious concerns raised by the timing of said publication. Upon receipt of a notification that the Government objects to the publication of said information the Contractor agrees to withhold submission of said publication while the author

and the COR discuss the issues of concern. The Contractor agrees to give good faith consideration to all such issues and further agrees that it will not knowingly submit for publication any article, abstract or other item that would be harmful to the public welfare. The final decision on whether to submit an article for publication shall rest with the DTT COR after the procedures set forth above are followed. Similar procedures shall apply for scientific presentations and meeting abstracts.

1.14. Protection of Government and Contract Information

The Contractor shall not cite any information (e.g., contract information, pictures, locations, etc.) obtained through this contract on any hard copy or digital marketing tools to include on its company website.

1.15. Non-Disclosure Statements

The Contractor shall provide signed non-disclosure agreements to the Government no later than five (5) days prior to commencement of work under the contract. Disclosure of information by Contractor personnel may result in removal of Contractor personnel from performance under this contract.

2. Required Capability Areas

2.1. General Requirements

The Contractor shall provide services, qualified personnel, materials, equipment, and facilities needed to conduct chemistry services in Functional Areas given below. Detailed requirements for Functional Areas and Functional Activities are given in DTT Chemistry Specifications Chapter 6.

2.2. Required Capabilities

2.2.1. Functional Area 1: Logistics and Handling

Logistics and Handling include all activities pertaining to procurement, handling, and shipment of test articles and samples produced for all DTT research. Activities in this area include, but are not limited to, the Functional Activities described in Chapter 6.2 of the DTT Chemistry Specifications and shall be performed in accordance with the requirements set forth there. Logistics and Handling typically involve performing any or all of the following activities:

- Procure and/or receive test articles, analytical standards, or samples (e.g., rodent plasma) from commercial and/or non-commercial sources.
- Handle test articles to include, but are not limited to repackage, mill blend, prepare solutions, aliquot, homogenize, or photograph of procured material.
- Store materials (e.g., test articles, formulations, biological matrices).
- Maintain test article inventories.
- Ship and/or arranging for shipment of analytical standards, test articles, or samples to DTT-designated research laboratories.

- Develop protocols for test article, handling and reanalysis, and dose formulation and analysis.

2.2.2. Functional Area 2: Characterization

Characterization includes all activities related to establishing the identity and determining the purity of test articles, including developing methods needed to perform the analysis. Activities in this area include, but are not limited to, the Functional Activities described in Chapter 6.3 of the DTT Chemistry Specifications and shall be performed in accordance with the requirements set forth there.

Characterization typically involves performing any or all of the following activities:

- Determine physical properties (e.g., melting point, color, optical rotation)
- Establish identity and/or structure.
- Establish purity.
- Determine long-term storage stability.

2.2.3. Functional Area 3: Formulation

Formulation includes all activities related to preparation, mixing, and analysis of dose formulations containing one or more test articles in a vehicle (e.g., corn oil, water, feed). Activities in this area include, but are not limited to, the Functional Activities described in Chapter 6.4 of the DTT Chemistry Specifications and shall be performed in accordance with the requirements set forth there.

Formulation typically involves performing any or all of the following activities

- Determine solubility, suspendability, and/or syringeability of a test article in a vehicle or vehicles designated by the COR.
- Develop methods for the formulation of a test article in a vehicle. For similar test articles (e.g., a chemical class), a common preparation method shall be considered.
- Develop, qualify, and/or validate methods needed to perform an analysis of a formulation for test article concentration. For similar test articles (e.g., a chemical class), a common analysis method shall be considered.
- Evaluate physical and chemical properties of a formulation, e.g., pH, suspendability.
- Evaluate the homogeneity of formulations that are not solutions.
- Evaluate the stability of a formulation under several storage regimes, e.g., ambient temperature, refrigerator, and/or freezer conditions.
- Evaluate the stability of a formulation under conditions of dosing.
- Prepare and/or analyze formulations using qualified and/or validated analytical methods. Formulations to be analyzed may be prepared by the Contractor or supplied to the Contractor from a DTT-designated laboratory. Ship formulations to a DTT-designated laboratory as directed.
- Analyze vehicles used in formulations for conformance to DTT, US Pharmacopeia (USP),

or other specified requirements.

2.2.4. Functional Area 4: Biosample Analysis

Biosample analysis includes all activities related to determination of the concentration of an analyte (e.g., test article, a metabolite of the test article, DNA adduct, endogenous analyte) in a variety of matrices (e.g., blood, plasma, tissue). Activities in this area include, but are not limited to, the Functional Activities described in Chapter 6.5 of the DTT Chemistry Specifications and shall be performed in accordance with the requirements set forth there.

Biosample analysis typically involves performing any or all of the following activities:

- Develop, qualify, and/or validate methods needed to quantitate analytes.
- Evaluate the stability of the analyte in one or more matrices during storage.
- Determine the concentration of an analyte in one or more matrices.

2.2.5. Functional Area 5: Special Studies

Special studies include activities that are part of the overall scope of the contract but may or may not be contained within a single functional activity or represent only a portion of a functional activity. Activities in this category include, but are not limited to, the Functional Activities described in Chapter 6.6 of the DTT Chemistry Specifications and shall be performed in accordance with the requirements set forth there.

Special studies include, but are not limited to, performing any or all of the following activities:

- Performance of a portion or subset of any functional activity. For example, only determining the stability of the formulation would be a special task, because the formulation development and validation activity requirement includes developing and validating a formulation development and analysis method, in addition to determining stability.
- Performance of a combination of several portions or subsets of two or more functional activities as a single activity. For example, determining the test article identity and purity and formulation preparation and analysis is a combination of parts of the characterization and formulation analysis activities.
- Performance of activities such as extraction and analysis of samples other than biological matrices (e.g., PM2.5 filters), nontargeted analysis of mixtures (e.g., botanical dietary supplements), identification of a metabolite of a test article in a biological matrix, partition coefficient determination of an analyte between two matrices, protein binding of an analyte, and inhalation feasibility studies conducted in a small chamber to determine the ability of a chemical or test article to be generated as a uniform atmosphere in an inhalation chamber.
- Performance of activities to determine enzyme activity using probe substrates (e.g., use of midazolam to determine CYP 3A4 activity) and enzyme inhibition or induction following exposure to a test article (e.g., induction of CYP 1A1 following exposure to

benzo(a)pyrene).

- Development and application of prediction models such as Physiologically Based Pharmacokinetic (PBPK) Models to predict disposition of chemicals in animal or human models.
- In vitro to in vivo extrapolation (IVIVE) of data to predict phenomena in vivo in biological systems.
- Performance of the annual water analysis required to confirm the acceptability of water supplied to animals under study in the Contractor's animal facility.
- Preparation of products per DTT COR request (e.g., manuscripts for submittal to peer reviewed journals, meeting abstracts and presentations for scientific conferences).

2.2.6. Functional Area 6: Animal Studies

To support animal studies, some Functional Activities in Functional Areas 1-4 shall be conducted as appropriate including preparation and analysis of formulations for the study and analysis of study samples for analyte concentrations as described above or as directed by the COR.

Animal studies include all activities related to determining absorption, distribution, metabolism, and excretion (ADME) parameters and toxicokinetic (TK) parameters of a test article administered to animals, typically rodents, via a route or routes of interest (e.g., oral gavage, drinking water, feed, and/or intravenous). Animal studies will use either non-labelled (e.g., TK) or radiolabelled (e.g., ADME) test articles. All animal studies require a signed study protocol, which has been reviewed and approved by the Contractor's Institutional Animal Care and Use Committee (or equivalent) and the DTT COR. Animal studies include the Functional Areas described in Chapter 6.7 of the DTT Chemistry Specifications and shall be performed in accordance with the requirements set forth there.

Animal studies typically involve performing any or all of the following activities:

TK Studies

- The test article may be administered following single or repeated exposure via the route(s) of interest.
- Typically measure concentration of analyte(s) (e.g., test article, metabolites) in a matrix (e.g., plasma, serum, tissues) over time following administration of test article.
- Typically consist of studies with number of animals <100 per species.
- Studies typically obtain samples from multiple animals (e.g., 3) per time point. Definitive studies typically utilize up to 3 doses, 2 species, and both sexes following single or repeated exposure via the route of interest.
- A preliminary study may be conducted using limited doses and number of animals per time points. Results of preliminary studies may be used to establish doses and time points for definitive studies, and, if needed, analyte concentration ranges to be validated in the biosample analysis method.
- Analysis of data and determination of TK parameters from analyte concentration versus time course data are described in the DTT Chemistry Specifications.

ADME Studies

- The test article may be administered following single or repeated exposure via the route(s) of interest.
- Typically consist of studies with numbers of animals <100 per species.
- Studies typically utilize up to 3 doses, 2 species, and both sexes and obtain samples from multiple animals (e.g., 3) per end point.
- Typically measure radiolabel equivalents (e.g., total, bound) in blood, excreta, and tissues, over the study duration.
- Qualitatively and/or quantitatively determine the test article-specific metabolites or products in blood, plasma, serum, tissues, or urine, as directed by the COR.
- ADME parameters determined are described in the DTT Chemistry Specifications

2.2.7. Functional Area 7: Omics

Omics activities typically include exposomics, proteomics, and metabolomics analyses, using state-of-the-art techniques, in biological matrices (e.g., cell lysates, urine, plasma) and/or environmental samples (e.g., water). Activities in this category include, but are not limited to, the Functional Activities described in Chapter 6.8 of the DTT Chemistry Specifications and shall be performed in accordance with the requirements set forth there.

Omics analyses typically involve performing any or all of the following activities:

- Utilizing state-of -the art analytical systems and nontargeted analysis approaches using state-of-the-art analytical systems (e.g., high resolution mass spectrometry, tandem mass spectrometry) to identify and/or quantify analytes (e.g. xenobiotics and/or their metabolites) in biological or environmental matrices (e.g., exposomics), as directed by the COR.
- Utilizing state-of-the-art analytical systems and nontargeted analysis approaches to identify and/or quantify perturbations in the endogenous metabolome (i.e., metabolomics) following an insult (e.g., exposure to a test article).
- Utlizing state-of-the-art analytical systems (e.g., high resolution mass spectrometry, tandem mass spectrometry) and approaches to identify and/or quantify changes of the proteome (e.g., proteins, protein adducts) following an insult (e.g., exposure to a test article).

2.2.8. Functional Area 8: In Vitro Assays

In vitro assays include all activities related to determining in vitro ADME of a test article typically in rodent and human models, as directed by the COR. Activities in this category include, but are not limited to, the Functional Activities described in Chapter 6.9 of the DTT Chemistry Specifications and shall be performed in accordance with the requirements set forth there. Examples of activities that fall under this Functional Area include, but not limited to:

- Performance of assay(s) using suitable model(s) to determine absorption of a test article (e.g., Caco-2 monolayer model to determine intestinal absorption).
- Performance of assay(s) using suitable model(s) to identify transporters responsible for ADME of a test article (e.g., Pgp GloTM assay to determine Pgp substrates).
- Performance of assay(s) using suitable model(s) to determine clearance and metabolism of a test article (e.g., HepaRG cells, 3D liver organoids, or primary hepatocytes to determine hepatic clearance and metabolism).
- Performance of assay(s) using suitable model(s) to determine bioaccumulation of a test article following repeated exposure (e.g., HepatoPac® or plateable hepatocyte model to determine bioaccumulation).
- Performance of assays using suitable model(s) to determine in vitro percutaneous absorption of a test article (e.g., Franz diffusion cells, Flow Through Diffusion Cells).

3. Operating Procedures

3.1. Project Management

The Contractor shall comply with the Project Management requirements described below and in Chapters 2-5 of the DTT Chemistry Specifications during performance of all work under this contract and apply appropriate staff expertise and facilities to ensure that assigned work is completed in a timely and cost-effective manner.

3.1.1. Contract Servicing

- To ensure timely start-up of contract work, the Contractor shall:
  I. Ensure that all proposed staff are in place within 60 days after contract award.
  II. Ensure that all the proposed management documents are in place, including but not limited to, the IT Security Plan, the Health and Safety Plan (HASP) and the Quality Management Plan (QMP) within 60 days after award. All management documents shall conform to the requirements, including delivery requirements, set forth in the DTT Chemistry Specifications.
  III. Ensure that facilities are as proposed and in good working order within 15 calendar days after contract award.
- Coordination and Continuity of Services
  I. The Contractor shall provide for effective and efficient coordination of contract performance with DTT personnel and other DTT-designated contractors.

3.1.2. Scheduling and Information Management

- The Contractor's work in this area shall comply with the requirements described in the DTT Chemistry Specifications.
- The Contractor shall use a DTT program management system (PMS) specified by the Government to document assignments, including, but not limited to, assignment descriptions and activities under the contract; and to communicate with the COR regarding the status of ongoing assignments. DTT will provide access to this system.

The Contractor shall provide the computer hardware, appropriate software (e.g., browser, MS365, MS D365), and a high-speed internet connection to access these systems.

- The Contractor shall employ an internal information management system (IMS) to track the work performed under the contract. This system shall:
  I. Monitor the status of all on-going work, including schedule, hours, and costs.
  II. Serve as a Master Schedule for all assignments performed under U.S. Food and Drug Administration (FDA) Good Laboratory Practice (GLP) compliance requirements.
  - The Contractor shall provide schedules and assignment cost estimates that accurately reflect the work to be performed for all assigned work. The Contractor shall update the estimated assignment costs and schedules in their internal IMS and the DTT PMS when there are changes to cost and/or schedule (e.g., assignments that do not proceed as planned or assignment priorities change).
  - The Contractor shall develop and implement an IT security plan that demonstrates compliance of their data management systems and practices with the Federal Information Security Management Act of 2002 (FISMA) and the Federal Information Technology Acquisition Reform Act of 2014 (FITARA). A DTT approved IT Security Plan is required prior to any work commencing under the contract and a copy of the proposed IT Security Plan shall be included in the contract proposal.
  - The Contractor shall comply with all applicable NIEHS/DTT Data Management Plans when submitting data to or holding/archiving data for the Government

3.1.3. Quality Program

- The Contractor shall establish an effective Quality Program, which addresses the requirements described below for any assignment that directly supports a DTT GLP study, including for work performed by any Subcontractor.
- The Contractor's quality program shall:
  - Conform to the requirements set forth in the DTT Chemistry Specifications.
  - Implement a comprehensive quality management plan (QMP), which addresses the requirements of the DTT Chemistry Specifications (see Chapter 5). A DTT approved QMP is required prior to commencement of any work under the contract and a copy of the proposed QMP must be included in the contract proposal.
  - Establish an effective quality control (QC) program to ensure that data obtained under this contract is of high quality.
  - Establish an independent Quality Assurance Unit (QAU) headed by a qualified Quality Assurance Officer (QAO).
  - Establish Standard Operating Protocols (SOPs) for all activities performed under this contract, as required by the DTT Chemistry Specifications.
  - Provide appropriate, ongoing staff training to ensure that all work conforms to contract requirements, DTT Chemistry Specifications, and where appropriate, to FDA GLP requirements.

3.2. Technical Activities

3.2.1. General Requirements

- Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, procedures, materials, equipment, and facilities not otherwise provided by the Government, as needed to perform the work set forth below.
    - The Contractor shall have a fully functional facility adequate to conduct the work described herein. An on-site evaluation of facilities and equipment may be made prior to award.
- Ongoing, recurring chemistry services are assigned as required for DTT research activities. The requirements described in the DTT Chemistry Specifications for each functional activity are typical of the work to be performed. The Contractor shall perform each assignment according to the requirements described at the time of assignment, and in compliance with the requirements of the DTT Chemistry Specifications for each Functional Activity.

3.2.2. Management of Technical Activities

- The day-to-day work performed under this contract will be managed as assignments, governed by assignment memos describing the work to be performed. Assignments shall be initiated by the COR to perform the Functional Activities described in the DTT Chemistry Specifications. The assignment description shall be provided by the COR to the Contractor, who shall document the assignment scope and description in the DTT PMS as described below. If a specific conflict arises between the SOW and the Chemistry Specifications, the Chemistry Specifications requirements shall take precedence.
    I. The Contractor shall consult with the COR to develop a schedule for the proposed work that includes, at minimum, the following milestones.
        - The estimated start date of work for the assignment.
        - The estimated completion date of lab work for the assignment. If no lab work is involved, the estimated lab work completed date will reflect the date the data package will be completed and work on the draft report will begin.
        - The estimated date of issuance of the Draft Final report.
        - The Contractor shall enter the agreed milestones into the DTT PMS.
    II. The Contractor shall provide an estimated cost and hours budget, based on the work to be performed and post the estimated hours and cost to the DTT PMS.
    III. The Contractor may not proceed with work on an assignment until the COR has reviewed and approved the proposed schedule and estimated cost in the DTT PMS.
- During performance of an assignment, the Contractor shall develop and follow assignment- or test article-specific SOPs for all work that employs validated analysis methods.
    I. As work on an assignment proceeds, the Contractor shall update the DTT PMS with actual milestone dates as they are completed and revise estimated

milestones when necessary. The Contractor's intention to revise milestone dates must be communicated to the COR, who must approve any change to a milestone date.

II. As work on an assignment proceeds, the Contractor shall update the DTT PMS cost and hours budget on a regular basis and/or requested by the COR. The Contractor's intention to revise the cost and hours budget for an assignment must be communicated to the COR.

III. The Contractor shall update the assignment workflow (e.g., status flag updated from 'lab work in progress' to 'lab work complete') in the DTT PMS when an assignment's status changes. Specific status flags corresponding to assignment milestones will be established in the DTT PMS for all assignments.

IV. The Contractor shall provide to the COR updated information on progress and/or changes in approach during the performance of each assignment.
   - Updates shall be posted to the DTT PMS in the form of notes and threaded discussions as they occur, or at least weekly, whichever is more frequent.
   - Updates may also be required by the COR via other communication methods as needed (e.g., telephone). The Contractor shall summarize these communications in the DTT PMS.
   - Updates shall include data, when applicable, in the form of tables, graphs, spreadsheets, and/or other documents, as specified by the COR.

- The Contractor shall update the assignment workflow as work proceeds, compile all data supporting the assignment, and prepare and submit data and report per requirements set forth in the DTT Chemistry Specifications.

3.2.3. Ongoing Activities

The Contractor is expected to perform a combination of Functional Activities under any or all of the Functional Areas. Requirements for each Functional Area are described in detail in the DTT Chemistry Specifications.

- Required Base and Option Years
  I. Ongoing activities for the base contract and option years (Option Years 1 through 9) may include any or all Functional Activities under the Functional Areas 1-8. Assignments may vary from year to year.
- Option 1 for additional work
  I. One Option 1 for additional work may be exercised per year.
  II. If required, may include any Functional Activity or combination of Functional Activities under Functional Areas 1-8. The requirements for Option 1 will therefore vary each time Optional Item 1 is exercised.
- A 6-month extension of period of performance may be exercised after Option Year 9
  I. Includes all of the chemistry services in Functional Areas 1-8 under the base contract.

3.3. Data Management

The Contractor shall provide a data management plan for the management, sharing, backup,

storage, and security of all paper and electronic files and information collected and generated as part of completing the products outlined in this SOW.

All software and databases used or secured must be PC and MAC compatible unless approved by the COR.

All electronic deliverables must be PC and MAC compatible unless approved by the COR. Once projects are completed, all paper and electronic files will be transferred to the Government upon the COR's request for long term storage.

All data derived or collected by Contractor shall reside in a data management system approved by the Government after acceptance by the COR.

The Government will have unlimited data rights ownership of all data and information generated during the Contract. The Government retains the right to access all information and data generated under this Contract at any time.

The Contractor shall plan for or acquire any subscriptions needed for accessing databases and/or information resources upon COR's approval. All software and databases used to carry out the project objectives and requirements for scientific data management shall be approved by the CORs.

3.4. Contractor Travel

Under this contract, travel is authorized for activities pursuant to contract requirements, in accordance with the Office of Management and Budget (OMB) Memo, M-12-12. Travel is authorized, with prior approval of the COR, to professional meetings for the purpose of presenting work conducted under this contract, for meetings with DTT staff, or as specified by the COR.

Contract staff will be reimbursed at the Federal Government per diem rate for the city/state of the venue. Sponsored travel shall not be reimbursed as no travel costs are incurred. However, level of effort may be reimbursed if pre-approved by the COR and CO.

3.5. Contract Management and Monitoring

Contract performance will be monitored through periodic site visits to inspect facilities, study data and records; meetings with the Principal Investigator and contractor staff; review of laboratory study protocols, interim data, final data, and study reports. The COR will monitor laboratory performance.

3.6. Government Furnished Property and Services

- Access to Government specified information management systems (currently Microsoft

Dynamics 365 Program Operations) (DTT PMS).

- Training in the use of the DTT PMS.
- Research outlines for activities under Animal Studies Functional Area.
- Test article inventories
    - Bulk quantity test articles along with Safety Data Sheets (SDS) (refer to business proposal template for quantity information)
    - Small quantity test articles along with SDS

4. Contractor Furnished Property and Services

The Contractor shall provide all materials, equipment, space, and facilities necessary to perform the work described in this SOW per Chapter 2 of DTT chemistry Specifications.

5. Definitions and Acronyms

Refer to the DTT Chemistry Specifications for definitions of terms and acronyms used throughout this Statement of Work.

6. Applicable References

The following publications, manuals, regulations, etc. are mentioned in this SOW and are listed below.

Specifications for the Conduct of Chemistry Activities for Toxicology Research Performed by the Division of Translational Toxicology at the National Institute of Environmental Health Sciences (DTT Chemistry Specifications) (https://ntp.niehs.nih.gov/data/research/chemistry/rfp).

Gargas, M.L., Burgess, R.J., Voisard, D.E., Cason, G.H. and Andersen, M.E. (1989). Partition coefficients of low-molecular weight volatile chemicals in various liquids and tissues. Toxicology and Applied Pharmacology:98, 87-99.

Dose Vehicle Analysis of Ethanol, DTT Chemistry Specifications Appendix 3.1. HYPERLINK: https://ntp.niehs.nih.gov/ntp/test_info/chemspecs2013/appendix3_120130920_508.pdf

The United States Pharmacopeia, Twenty-third Revision, (USP XXIII), Physical Tests/Chromatography 621, System Suitability, (1995) p. 1776.

U.S. Environmental Protection Agency (EPA) Requirements for Quality Management Plans (EPA QA/R-2). HYPERLINK: https://www.epa.gov/sites/default/files/2016-06/documents/r2-final.pdf

The EPA Quality System Website: HYPERLINK "http://www.epa.gov/quality1/index.html" http://www.epa.gov/quality1/index.html

The FDA GLP regulations are available from the Code of Federal Regulations, 21 CFR Ch.1 (4/1/1999 Edition). Website: HYPERLINK "http://www.gpoaccess.gov/cfr/index.html" http://www.gpoaccess.gov/cfr/index.html

Additional information about FDA GLP regulations is available from the FDA/ORA Compliance Program Guidance: GLP Supporting Documents. Website: HYPERLINK "http://www.fda.gov/ora/compliance_ref/bimo/GLP/default.htm" http://www.fda.gov/ora/compliance_ref/bimo/GLP/default.htm

Specifications for the Conduct of Toxicity Studies by the Division of Translational Toxicology at the National Institute of Environmental Health Sciences
https://ntp.niehs.nih.gov/data/research/toxicology

Bookshelf ID: NBK591148PMID: 37676988 DOI: 10.22427/NIEHS-00

Technical Reporting Requirements and Deliverables

The items specified below may be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below:

a. Technical Reports Delivery and Distribution Schedule:

See Item (16) for required DTT Chemistry Specifications Link and additional reporting requirement details.*

Item	Description	Due Date	Recipients & Number of Copies
	Contract Management Reports		
(1)	Quality Management Plan (QMP)	Within 60 days of the award of the contract	One electronic copy to the COR, CO and CS.
(2)	Health and Safety Plan (HASP)	Within 60 days of the award of the contract	One electronic copy to the COR, CO and CS.
(3)	IT Security Plan	Within 60 days of the award of the contract	One electronic copy to the COR, CO and CS.
(4)	Standard Operating Procedures	Within 6-months of the award of the contract	One electronic copy to the COR.
(5)	Chemical Inventory	On the 15th day of each month of this contract, beginning with the second month after award	One electronic copy to the COR.
(6)	Annual Water Analysis Report	Within 30 days of the start of the contract and annually thereafter	One electronic copy to the COR.
(7)	Monthly Status Report	On the 15th day of the second month after the start of the contract, and each month thereafter	One electronic copy to the COR, CO and CS.
(8)	Monthly Level of Effort Spreadsheet	Before the 15th day of the following month	One electronic copy to the COR.
(9)	Annual Report	Within 60 calendar days of the end of each year of the contract	One electronic copy to the COR, CO and CS.
(10)	Final Report	On or before the expiration of the contract	One electronic copy to the COR, CO and CS.
	Functional Activity Reports		
(11)	Interim Data	Within one week of data generation	One electronic copy to the COR.
(12)	Draft Final Report[1]	From 8 weeks to 12 weeks of laboratory work completion. Period varies depending on the Functional Activity	One electronic copy to the COR.
(13)	Final Report	Within 2 weeks of COR approval	One electronic copy to the COR.
(14)	Letter reports	Within 8 weeks of laboratory work completion	One electronic copy to the COR.

(15)	Study Files (hard copies and pdfs)	Within 60 calendar days of the end of each year of the contract	COR
*(16)	Specifications for the Conduct of Chemistry Activities for Toxicology Research Performed by the Division of Translational Toxicology at the National Institute of Environmental Health Sciences (DTT Chemistry Specifications) (Chapter 7)	See Specifications: https://ntp.niehs.nih.gov/data/research/chemistry/rfp	See Specifications. One electronic copy to the COR.

[1]Includes any applicable data summaries and data files

b. The above items shall be addressed and delivered to:

Addressee	Email Address
Contracting Officer (CO), NIH, OALM, OD, R&D and Professional Services- Division B	(To be inserted at contract award)
Contracting Officer Representative (COR), NIEHS, DTT	(To be inserted at contract award)
Interagency Edison (iEdison), Extramural Inventions and Technology Resources Branch, OPERA, NIH	http://www.iedison.gov/

SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS

Update per FAC 2025-03
FAR CD 2025-02
Last updated: 05/25

This SECTION is made up of eight parts as follows:

1. **Annual Representations and Certifications, FAR 52.204-8**
2. **Commercial and Government Entity Code Reporting, FAR 52.204-16**
3. **Information Regarding Responsibility Matters, FAR 52.209-7**
4. **Cost Accounting Standards**
5. **Certification Regarding Environmental Tobacco Smoke**
6. **Certification of Institutional on Financial Conflicts of Interest**
7. **Disaster or Emergency Area Representation**
8. **Alternate – Representation by Corporations Regarding an Unpaid Delinquent Tax Liability or a Felony Conviction Under Any Federal Law**

To Be Completed by the Offeror: This document must be completed and included as part of your Business Proposal. By submission of its signed offer, the offeror makes the following Representations and Certifications:

1. ANNUAL REPRESENTATIONS AND CERTIFICATIONS (Jan 2025) (Deviation Feb 2025)

(a) (1) The North American Industry Classification System (NAICS) code for this acquisition is_____ *[insert NAICS code]*.

(2) The small business size standard is _____ *[insert size standard]*.

(3) The small business size standard for a concern that submits an offer, other than on a construction or service acquisition, but proposes to furnish an end item that it did not itself manufacture, process, or produce is 500 employees, or 150 employees for information technology value-added resellers under NAICS code 541519, if the acquisition—

(i)Is set aside for small business and has a value above the simplified acquisition threshold;

(ii)Uses the HUBZone price evaluation preference regardless of dollar value, unless the offeror waives the price evaluation preference; or

(iii)Is an 8(a), HUBZone, service-disabled veteran-owned, economically disadvantaged women-owned, or women-owned small business set-aside or sole-source award regardless of dollar value.

(b) (1) If the provision at 52.204-7, System for Award Management, is included in this solicitation, paragraph (d) of this provision applies.

(2) If the provision at 52.204-7, System for Award Management, is not included in this solicitation, and the Offeror has an active registration in the System for Award Management (SAM), the Offeror may choose to use paragraph (d) of this provision instead of completing the corresponding

individual representations and certifications in the solicitation. The Offeror shall indicate which option applies by checking one of the following boxes:

(i) □ Paragraph (d) applies.

(ii) □ Paragraph (d) does not apply and the offeror has completed the individual representations and certifications in the solicitation.

(c) (1) The following representations or certifications in SAM are applicable to this solicitation as indicated:

(i) 52.203-2, Certificate of Independent Price Determination. This provision applies to solicitations when a firm-fixed-price contract or fixed-price contract with economic price adjustment is contemplated, unless–

(A) The acquisition is to be made under the simplified acquisition procedures in part 13;

(B) The solicitation is a request for technical proposals under two-step sealed bidding procedures; or

(C) The solicitation is for utility services for which rates are set by law or regulation.

(ii) 52.203-11, Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions. This provision applies to solicitations expected to exceed $150,000.

(iii) 52.203-18, Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation. This provision applies to all solicitations.

(iv) 52.204-3, Taxpayer Identification. This provision applies to solicitations that do not include the provision at 52.204-7, System for Award Management.

(v) 52.204-5, Women-Owned Business (Other Than Small Business). This provision applies to solicitations that-

(A) Are not set aside for small business concerns;

(B) Exceed the simplified acquisition threshold; and

(C) Are for contracts that will be performed in the United States or its outlying areas.

(vi) 52.204-26, Covered Telecommunications Equipment or Services-Representation. This provision applies to all solicitations.

(vii) 52.209-2, Prohibition on Contracting with Inverted Domestic Corporations-Representation.

(viii) 52.209-5, Certification Regarding Responsibility Matters. This provision applies to solicitations where the contract value is expected to exceed the simplified acquisition threshold.

(ix) 52.209-11, Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law. This provision applies to all solicitations.

(x) 52.214-14, Place of Performance-Sealed Bidding. This provision applies to invitations for bids except those in which the place of performance is specified by the Government.

(xi) 52.215-6, Place of Performance. This provision applies to solicitations unless the place of performance is specified by the Government.

(xii) 52.219-1, Small Business Program Representations (Basic, Alternates I, and II). This provision applies to solicitations when the contract will be performed in the United States or its outlying areas, or when the contracting officer has applied part 19 in accordance with 19.000 (b)(1)(ii).

(A) The basic provision applies when the solicitations are issued by other than DoD, NASA, and the Coast Guard.

(B) The provision with its Alternate I applies to solicitations issued by DoD, NASA, or the Coast Guard.

(C) The provision with its Alternate II applies to solicitations that will result in a multiple-award contract with more than one NAICS code assigned.

(xiii) 52.219-2, Equal Low Bids. This provision applies to solicitations when contracting by sealed bidding and the contract is for supplies to b delivered or services to be performed in the United States or its outlying areas, or when the contracting officer has applied part 19 in accordance with 19.000 (b)(1)(ii).

(xiv) 52.222-22, Previous Contracts and Compliance Reports. This provision applies to solicitations that include the clause at 52.222-26, Equal Opportunity.

(xv) 52.222-25, Affirmative Action Compliance. This provision applies to solicitations, other than those for construction, when the solicitation includes the clause at 52.222-26, Equal Opportunity.

(xvi) 52.222-38, Compliance with Veterans' Employment Reporting Requirements. This provision applies to solicitations when it is anticipated the contract award will exceed the simplified acquisition threshold and the contract is not for acquisition of commercial products or commercial services.

(xvii) 52.223-1, Biobased Product Certification. This provision applies to solicitations that require the delivery or specify the use of biobased products in USDA–designated product categories; or include the clause at 52.223-2, Reporting of Biobased Products Under Service and Construction Contracts.

(xviii) 52.223-4, Recovered Material Certification. This provision applies to solicitations that are for, or specify the use of, EPA–designated items.

(xix) 52.225-2, Buy American Certificate. This provision applies to solicitations containing the clause at 52.225-1.

(xx) 52.225-4, Buy American Agreements-Israeli Trade Act Certificate. (Basic, Alternates II and III.) This provision applies to solicitations containing the clause at 52.225-3.

(A) If the acquisition value is less than $50,000, the basic provision applies.

(B) If the acquisition value is $50,000 or more but is less than $100,000, the provision with its Alternate II applies.

(C) If the acquisition value is $100,000 or more but is less than $102,280, the provision with its Alternate III applies.

(xxi) 52.225-6, Trade Agreements Certificate. This provision applies to solicitations containing the clause at 52.225-5.

(xxii) 52.225-20, Prohibition on Conducting Restricted Business Operations in Sudan-Certification. This provision applies to all solicitations.

(xxiii) 52.225-25, Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran-Representation and Certifications. This provision applies to all solicitations.

(xxiv) 52.226-2, Historically Black College or University and Minority Institution Representation. This provision applies to solicitations for research, studies, supplies, or services of the type normally acquired from higher educational institutions.

(2) The following representations or certifications are applicable as indicated by the Contracting Officer:

[*Contracting Officer check as appropriate.*]

__ (i) 52.204-17, Ownership or Control of Offeror.

__ (ii) 52.204-20, Predecessor of Offeror.

__ (iii) 52.222-18, Certification Regarding Knowledge of Child Labor for Listed End Products.

__ (iv) 52.222-48, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment- Certification.

__ (v) 52.222-52, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Certification.

__ (vi) 52.227-6, Royalty Information.

__ (A) Basic.

__ (B) Alternate I.

__ (vii) 52.227-15, Representation of Limited Rights Data and Restricted Computer Software.

(d) The offeror has completed the annual representations and certifications electronically in SAM website accessed through https://www.sam.gov. After reviewing the SAM information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically that apply to this solicitation as indicated in paragraph (c) of this provision have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this

solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below [*offeror to insert changes, identifying change by clause number, title, date*]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR Clause #	Title	Date	Change

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on SAM.

(End of provision).

Alternate I (MAR 2023). As prescribed in 4.1202(a), substitute the following paragraph (a) for paragraph (a) of the basic provision:

(a)(1) The North American Industry Classification System (NAICS) codes and corresponding size standards for this acquisition are as follows; the categories or portions these NAICS codes are assigned to are specified elsewhere in the solicitation:

NAICS Code	Size standard

[*Contracting Officer to insert NAICS codes and size standards*].

(2) The small business size standard for a concern that submits an offer, other than on a construction or service acquisition, but proposes to furnish an end item that it did not itself manufacture, process, or produce, (i.e., nonmanufacturer), is 500 employees, or 150 employees for information technology value-added resellers under NAICS code 541519, if the acquisition—

(i) Is set aside for small business and has a value above the simplified acquisition threshold;

(ii) Uses the HUBZone price evaluation preference regardless of dollar value, unless the offeror waives the price evaluation preference; or

(iii) Is an 8(a), HUBZone, service-disabled veteran-owned, economically disadvantaged women-owned, or women-owned small business set-aside or sole-source award regardless of dollar value.

(End of provision).

COST ACCOUNTING STANDARDS

2. COST ACCOUNTING STANDARDS NOTICES AND CERTIFICATION (Jun 2020), FAR Provision 52.230-1

Note: This notice does not apply to small businesses or foreign governments. This notice is in three parts, identified by Roman numerals I through III.

Offerors shall examine each part and provide the requested information in order to determine Cost Accounting Standards (CAS) requirements applicable to any resultant contract.

If the offeror is an educational institution, Part II does not apply unless the contemplated contract will be subject to full or modified CAS coverage pursuant to 48 CFR 9903.201-2(c)(5) or 9903.201-2(c)(6), respectively.

I. DISCLOSURE STATEMENT-COST ACCOUNTING PRACTICES AND CERTIFICATION

(a) Any contract in excess of the lower CAS threshold specified in Federal Acquisition Regulation (FAR) 30.201-4(b) resulting from this solicitation will be subject to the requirements of the Cost Accounting Standards Board (48 CFR chapter 99), except for those contracts which are exempt as specified in 48 CFR 9903.201-1.

(b) Any offeror submitting a proposal which, if accepted, will result in a contract subject to the requirements of 48 CFR chapter 99must, as a condition of contracting, submit a Disclosure Statement as required by 48 CFR 9903.202. When required, the Disclosure Statement must be submitted as a part of the offeror's proposal under this solicitation unless the offeror has already submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal. If an applicable Disclosure Statement has already been submitted, the offeror may satisfy the requirement for submission by providing the information requested in paragraph (c) of Part I of this provision.

Caution: In the absence of specific regulations or agreement, a practice disclosed in a Disclosure Statement shall not, by virtue of such disclosure, be deemed to be a proper, approved, or agreed-to practice for pricing proposals or accumulating and reporting contract performance cost data.

(c) Check the appropriate box below:

(1) □ *Certificate of Concurrent Submission of Disclosure Statement*. The offeror hereby certifies that, as a part of the offer, copies of the Disclosure Statement have been submitted as follows:

(i) Original and one copy to the cognizant Administrative Contracting Officer (ACO) or cognizant Federal agency official authorized to act in that capacity (Federal official), as applicable; and

(ii) One copy to the cognizant Federal auditor.

(Disclosure must be on Form No. CASB DS-1 or CASB DS-2, as applicable. Forms may be obtained from the cognizant ACO or Federal official.)

Date of Disclosure Statement: [_____] Name and Address of Cognizant ACO or Federal Official Where Filed: [_____]

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the Disclosure Statement.

(2) □ *Certificate of Previously Submitted Disclosure Statement*. The offeror hereby certifies that the required Disclosure Statement was filed as follows:

Date of Disclosure Statement: [_____] Name and Address of Cognizant ACO or Federal Official Where Filed: [_____]

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the applicable Disclosure Statement.

(3) □ *Certificate of Monetary Exemption*. The offeror hereby certifies that the offeror, together with all divisions, subsidiaries, and affiliates under common control, did not receive net awards of negotiated prime contracts and subcontracts subject to CAS totaling $50 million or more in the cost accounting period immediately preceding the period in which this proposal was submitted. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

(4) □ *Certificate of Interim Exemption*. The offeror hereby certifies that (i) the offeror first exceeded the monetary exemption for disclosure, as defined in (3) of this subsection, in the cost accounting period immediately preceding the period in which this offer was submitted and (ii) in accordance with 48 CFR 9903.202-1, the offeror is not yet required to submit a Disclosure Statement. The offeror further certifies that if an award resulting from this proposal has not been made within 90 days after the end of that period, the offeror will immediately submit a revised certificate to the Contracting Officer, in the form specified under paragraph (c)(1) or (c)(2) of Part I of this provision, as appropriate, to verify submission of a completed Disclosure Statement.

Caution: Offerors currently required to disclose because they were awarded a CAS-covered prime contract or subcontract of $50 million or more in the current cost accounting period may not claim this exemption (4). Further, the exemption applies only in connection with proposals submitted before expiration of the 90-day period following the cost accounting period in which the monetary exemption was exceeded.

II. Cost Accounting Standards-Eligibility for Modified Contract Coverage

If the offeror is eligible to use the modified provisions of 48 CFR 9903.201-2(b) and elects to do so, the offeror shall indicate by checking the box below. Checking the box below shall mean that the resultant contract is subject to the Disclosure and Consistency of Cost Accounting Practices clause in lieu of the Cost Accounting Standards clause.

□ The offeror hereby claims an exemption from the Cost Accounting Standards clause under the provisions of 48 CFR 9903.201-2(b) and certifies that the offeror is eligible for use of the Disclosure and Consistency of Cost Accounting Practices clause because during the cost accounting period immediately preceding the period in which this proposal was submitted, the offeror received less than $50 million in awards of CAS-covered prime contracts and subcontracts. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

Caution: An offeror may not claim the above eligibility for modified contract coverage if this proposal is expected to result in the award of a CAS-covered contract of $50 million or more or if, during its current cost accounting period, the offeror has been awarded a single CAS-covered prime contract or subcontract of $50 million or more.

III. Additional Cost Accounting Standards Applicable to Existing Contracts

The offeror shall indicate below whether award of the contemplated contract would, in accordance with paragraph (a)(3) of the Cost Accounting Standards clause, require a change in established cost accounting practices affecting existing contracts and subcontracts.

☐ YES ☐ NO

(End of provision).

3. COST PROPOSAL DISCLOSURE-COST ACCOUNTING PRACTICE CHANGES, (Apr 2005), FAR Provision 52.230-7

The offeror shall check "yes" below if the contract award will result in a required or unilateral change in cost accounting practice, including unilateral changes requested to be desirable changes.

□ Yes □ No

If the offeror checked "Yes" above, the offeror shall-

(1) Prepare the price proposal in response to the solicitation using the changed practice for the period of performance for which the practice will be used; and

(2) Submit a description of the changed cost accounting practice to the Contracting Officer and the Cognizant Federal Agency Official as pricing support for the proposal.

(End of provision).

4. CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE (December 1994)

Public Law 103-227, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, early childhood development services, education or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law also applies to children's services that are provided in indoor facilities that are constructed, operated, or maintained with such federal funds. The law does not apply to children's services provided in private residences; portions of facilities used for inpatient drug or alcohol treatment; service providers whose sole source of applicable federal funds is Medicare or Medicaid; or facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 for each violation and/or the imposition of an administrative compliance order on the responsible entity.

By submission of its signed offer, the offeror/contractor (for acquisitions) or applicant/grantee (for grants) certifies that the submitting organization will comply with the requirements of the Act and will not allow smoking within any portion of any indoor facility used for the provision of services for children as defined by the Act.

The submitting organization agrees that it will require that the language of this certification be included in any subawards which contain provisions for children's services and that all subrecipients shall certify accordingly.

6. CERTIFICATION OF INSTITUTIONAL POLICY ON FINANCIAL CONFLICTS OF INTEREST

Note: This certification is applicable to all Research and Development (R&D) Contracts except Phase I SBIR/STTR and Contracts with Federal Agencies.

By Submission of its signed offer, the offeror certifies that:

(1) there is in effect at the Institution (the term Institution includes any contractor, public or private, excluding a Federal agency) an up-to-date, written and enforced administrative process to identify and manage, financial conflicts of interest with respect to all research projects for which funding is sought or received from the NIH;

(2) the Institution shall promote and enforce Investigator compliance with this part's requirements including those pertaining to disclosure of significant financial interests;

(3) the Institution shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to NIH consistent with this part;

(4) the Institution agrees to make information available, promptly upon request, to the Contracting Officer relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest; and

(5) the Institution shall fully comply with the requirements of 45 CFR Part 94.

7. DISASTER OR EMERGENCY AREA REPRESENTATION, (Nov 2007), FAR Provision 52.226-3

Note: This provision is applicable for acquisitions that are set-aside for a Disaster or Emergency Area under FAR Subpart 26.2. See Section L.1. of the Solicitation, paragraph entitled "Notice of Disaster or Emergency Area Set-Aside."

(a) *Set-aside area.* The area covered in this contract is: _____
[Contracting Officer to fill in with definite geographic boundaries.]

(b) *Representations.* The offeror represents that it □ does □ does not reside or primarily do business in the designated set-aside area.

(c) An offeror is considered to be residing or primarily doing business in the set-aside area if, during the last twelve months-

(1) The offeror had its main operating office in the area; and

(2) That office generated at least half of the offeror's gross revenues and employed at least half of the offeror's permanent employees.

(d) If the offeror does not meet the criteria in paragraph (c) of this provision, factors to be considered in determining whether an offeror resides or primarily does business in the set-aside area include-

(1) Physical location(s) of the offeror's permanent office(s) and date any office in the set-aside area(s) was established;
(2) Current state licenses;
(3) Record of past work in the set-aside area(s) (*e.g.*, how much and for how long);
(4) Contractual history the offeror has had with subcontractors and/or suppliers in the set-aside area;
(5) Percentage of the offeror's gross revenues attributable to work performed in the set-aside area;
(6) Number of permanent employees the offeror employs in the set-aside area;
(7) Membership in local and state organizations in the set-aside area; and
(8) Other evidence that establishes the offeror resides or primarily does business in the set-aside area. For example, sole proprietorships may submit utility bills and bank statements.

(e) If the offeror represents it resides or primarily does business in the set-aside area, the offeror shall furnish documentation to support its representation if requested by the Contracting Officer. The solicitation may require the offeror to submit with its offer documentation to support the representation.

(End of provision).

8. ALTERNATE - REPRESENTATION BY CORPORATIONS REGARDING AN UNPAID DELINQUENT TAX LIABILITY OR A FELONY CONVICTION UNDER ANY FEDERAL LAW

The Consolidated and Further Appropriations Act, 2015 Pub. L 113-235, Division E, Sections 744 and 745 prohibit covered agencies from using funds to enter into contracts with corporations with unpaid federal tax delinquencies or certain felony convictions unless certain conditions are met.

The Offeror represents that:

(1) It is □ is not □ a corporation that was convicted of a felony criminal violation under a Federal or State law within the preceding 24 months.

(2) It is □ is not □ a corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability.

(End of provision).

HHSAR 352.204-74 Supply Chain Risk Assessment (OCT 2024) (DEVIATION)

Instructions to Offerors:
As a part of its proposal, the offeror must submit the completed HHSAR provision 352.204-74, Supply Chain Risk Assessment (Deviation), found below, including all potential subcontractor information and representations as required by paragraph (g) of the provision.

As prescribed 304.7304(a) insert the following provision:

(a) *Definitions*. As used in this provision—
Contract means as defined in FAR 2.101.
Foreign person means as defined in 31 CFR 800.224.
Mission-critical acquisition means the acquisition of products, materials, information, or services that are identified as—

(1) Contract support or development services for HHS or OpDiv/StaffDiv research and development;

(2) Contract support or development services for HHS or OpDiv/StaffDiv financial databases and services;

(3) Contract support services that require utilization or sharing of HHS or OpDiv/StaffDiv Intellectual property;

(4) Contract services supporting HHS or OpDiv/StaffDiv continuity of operations (COOP) mission essential functions;

(5) Contract support services or development initiatives for HHS or OpDiv/StaffDiv critical infrastructure;

(6) An HHS or OpDiv/StaffDiv high-value/dollar acquisition; or

(7) Other acquisitions for critical assets or services as identified by OpDiv/StaffDiv leadership.

Office of National Security (ONS) means the HHS office responsible for the management, oversight, policy, guidance, and implementation of the HHS Enterprise Supply Chain Risk Management (E-SCRM) Program, including the conducting of supply chain risk assessments.

State-owned enterprise means a legal entity that is created by a government in order to partake in commercial activities on the government's behalf. A state-owned enterprise or government-owned enterprise is a business enterprise where the government or state has significant control through full, majority, or significant minority ownership.

Supply chain risk means the potential for harm or compromise that arises as a result of security risks from suppliers, their supply chains, and their products, materials, information, or services. Supply chain risks include exposures, threats, and vulnerabilities associated with the products and services traversing the supply chain as well as the exposures, threats, and vulnerabilities to the supply chain.

Supply chain risk assessment means a systematic examination of supply chain risks, likelihoods of their occurrence, and potential impacts.

Supply chain risk management (SCRM) means a systematic process for managing risk to the integrity, trustworthiness, and authenticity of products, materials, information, and services within the supply chain. It addresses the activities of foreign and other adversaries aimed at compromising the supply chain, which may include the introduction of counterfeit or malicious items into the supply chain. It is conducted through identification of threats, vulnerabilities, and consequences throughout the supply chain and development of mitigation strategies to address the respective risks presented by the supplier, the supplied products, materials, information, and services, or the supply chain at any point during the life cycle.

(b) *Supply chain risk assessment*. The Office of National Security (ONS) or delegated designee may perform a supply chain risk assessment of the Offeror's proposal. In performing the supply chain risk assessment, the Government may consider public and non-public information relating to the Offeror's supply chain.

(c) *Required information submittal*. The Offeror shall provide the following information for products, materials, information, or services provided under their proposal:

(1) Description of the type of products, materials, information, or services provided.

Services in support of coordination and management of multiple-site clinical trials (clinical sites are under separate NIAAA contracts).

(2) Vendor and manufacturer's company, if applicable, including name and address.

(3) If known, vendor's and manufacturer's web site, and the Commercial and Government Entity (CAGE) code and Unique Entity Identifier (UEI).

(d) *Representations*. The Offeror represents that—

(1) It [ ] does, [ ] does not have any foreign ownership, outside of retail shareholders, who control more than 10% of the company's total shares. If yes, identify the legal name of the owning organization/individual and their country of affiliation.

(2) It [ ] does, [ ] does not have any of the following business affiliations with foreign entities: technology development partnerships, strategic partnerships, joint ventures, foreign subsidiaries, grants from a foreign entity. If yes, identify the legal name of the organization, its foreign address, and the nature of the relationship.

(3) It [ ] does, [ ] does not have any foreign governments, or state-owned enterprises that have investments or ownership interest in the company. If yes, identify the foreign government, the ownership stake percentage, and the nature of the relationship.

_____

(4) The company leadership (C-Suite executives, Board members, etc.) [ ] does, [X] does not have any substantial ties to foreign countries, including being citizens of a foreign country, graduates of a foreign university, or investments in a foreign country. If yes, identify the individual, the nature of the tie, and the country they are tied to.

_____

(5) It [ ] has, [ ] has not violated export controls or the Foreign Corrupt Practices Act within 5 years. If yes, enter the event, the date, and any remediation the company committed after the event.

_____

(6) It [ ] has, [ ] has not been prohibited from doing business with the government of the US or any of its administrative subdivisions to include agencies, states, territories or municipalities. If yes, enter the event, the date, and any remediation the company committed after the event.

_____

(7) It [ ] has, [ ] has not been prohibited from doing business with any foreign governments or subdivisions thereof. If yes, enter the event, the date, and any remediation the company committed after the event.

_____

(8) It [ ] has had, [ ] has not had affiliations with any entities prohibited (e.g. Huawei, see SAM.gov "exclusions" page for additional information regarding prohibited entities) from doing business with the government of the US or any of its administrative subdivisions to include agencies, states, territories or municipalities? If yes, enter the event, the date, and any remediation the company committed after the event.

_____

(9) It [ ] has, [ ] has not been suspended or debarred at any point while doing business with the U.S. Government or any of its administrative subdivisions to include agencies, states, territories or municipalities. If yes, enter the event, the date, and details below.

_____

(10) It [ ] has previously filed for or is currently in, [ ] has not previously filed for or is not currently in bankruptcy in the last 10 years. If yes, enter the event, the date, and details below.

_____

(11) It | | was or is currently in, | | was not or is not currently in litigation in the last 10 years. If yes, enter the event, the date, and details below.

_____

(e) *Supply chain risk determination.* Findings from the supply chain risk assessment will be considered in connection with a determination of the Offeror's responsibility and eligibility for award. Failure of the Offeror to furnish the information required in this provision or provide additional information as requested by the Contracting Officer may render the Offeror non-responsible and ineligible for award. The Government reserves the right to limit the disclosure of information to the Offeror regarding the risk in accordance with all applicable laws or regulations.

(f) *Mitigation plans*. Any mitigation plans and amendments determined necessary and to be implemented and sustained during contract performance will be incorporated into the contract.

(g) *Subcontracts*. The Offeror shall include the substance of this provision, including the information and representations at paragraphs (c) and (d), and including this paragraph (g), in subcontracts with persons or entities proposed to be used involving the development or delivery of any mission-critical products, materials, information, or services. The Offeror shall submit all potential subcontractor information and representations with its proposal for any mission-critical products, materials, information, or services provided for in the proposal.

(End of provision)

SBCX

HHS Government User Guide for Subcontracting Plan Reviews

Table of Contents

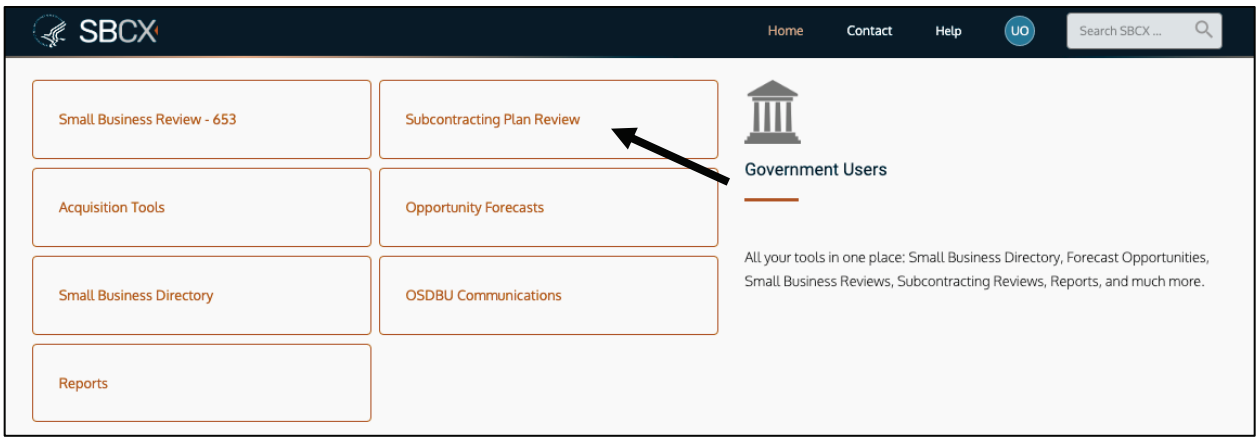
Introduction 1
Navigation 1
Creating a Subcontracting Plan Request 2
Invitations to Offerors 3
Communications 4
Evaluation 5

Introduction

SBCX allows you to complete the Subcontracting Plan Review process from start to finish with one or more offerors and reviewers.

Navigation

Access Subcontracting Plan Reviews from the Government User section of SBCX. Users can create Subcontracting plans and evaluate them when assigned to the Subcontracting Plan Review.

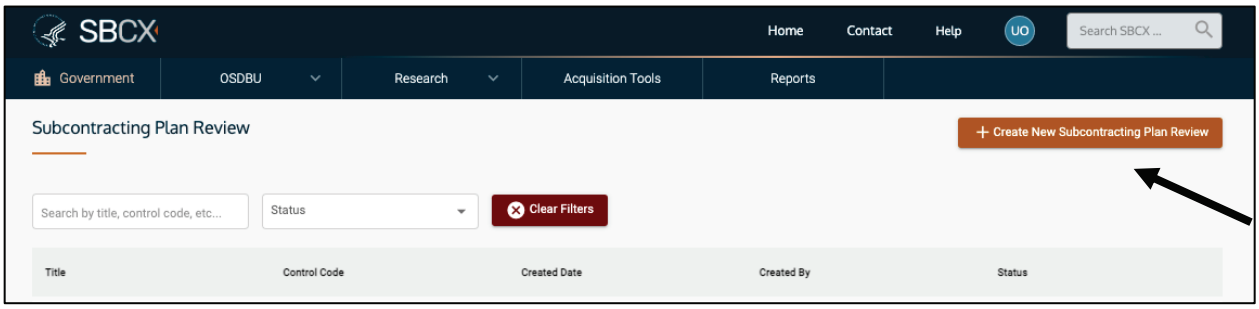


APEXLOGIC

SBCX

Creating a Subcontracting Plan Request

Use the Create New Subcontracting Plan Review button to create the Summary for a Subcontracting Plan review.



The SBCX Subcontracting Plan is created in four steps.

1. **Search** for a 653 Control Code or Create a Subcontracting Plan without it.
2. **Project Information** requires identifying information.
3. **Proposal Details** requires the Submission deadline for the subcontracting plans. SBCX enforces the deadline and sends a notification when the evaluation process can begin.
4. **Complete** the summary to invite offerors to submit plans or get a link to include in your solicitation documents.

If you do not know which offerors you would like to invite to submit Subcontracting Plans, the following information may be helpful.

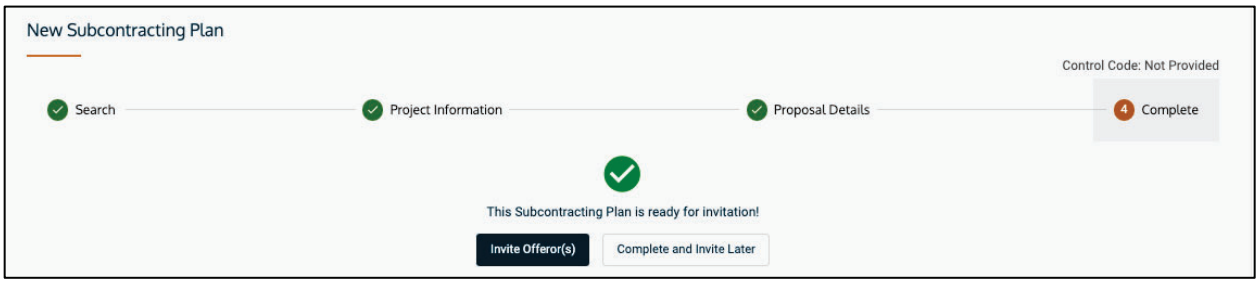
- **Save** keeps the Subcontracting Plan in the *Started* status
- **Copy Link** to save the Subcontracting Plan link to your clipboard.
- **Complete and Return to Subcontracting Plans** publishes the link. Offerors can only respond when the status is *Ready for Offerors*.

SBCX

Invitations to Offerors

Two questions will lead to the invitation option.

1. **Multiple Awards.** Choose the Yes or No option that applies.
2. **Do you know which Offerors you would like to invite to submit Subcontracting Plans?** Choose "Yes" to send invitations to offerors.

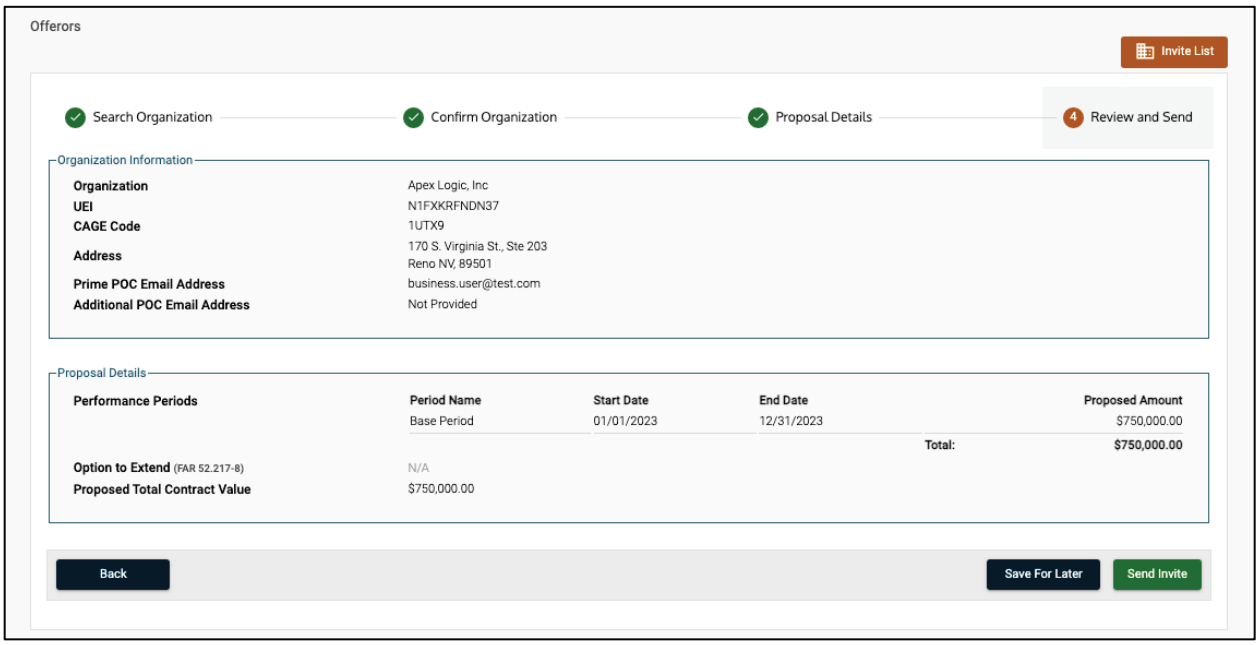


- **Save** keeps the Subcontracting Plan in the *Started* status
- **Complete and Invite Later** places the Subcontracting Plan in the *Ready for Invitation* status. This means that you are waiting to invite offerors.
- **Invite Offeror(s)** to go to the Invitation page. Click + Invite Offeror. Once an Offeror is invited, the status becomes *Sent to Offeror.*

APEXLOGIC

The Offeror Invitation process is four steps.

1. **Search** for the Offeror's organization by UEI and Cage code if applicable.
2. **Confirm** the Offeror's organization is found or try again.
3. **Proposal Details** allows only those on the invitation to respond to the request. A notification email will go to the Prime POC and an additional POC if needed.
4. **Review** and **Send** the invitation to the Offeror(s). Saving for later places the invitation in a *Created* Status.



Communications

Use the company link in the Subcontracting plan to monitor Offeror progress. Use the **Notes** tab to communicate with the parties involved in the review. The Contracting Officer may request a clarification and return the subcontracting plan for revision before the deadline occurs.

Evaluation

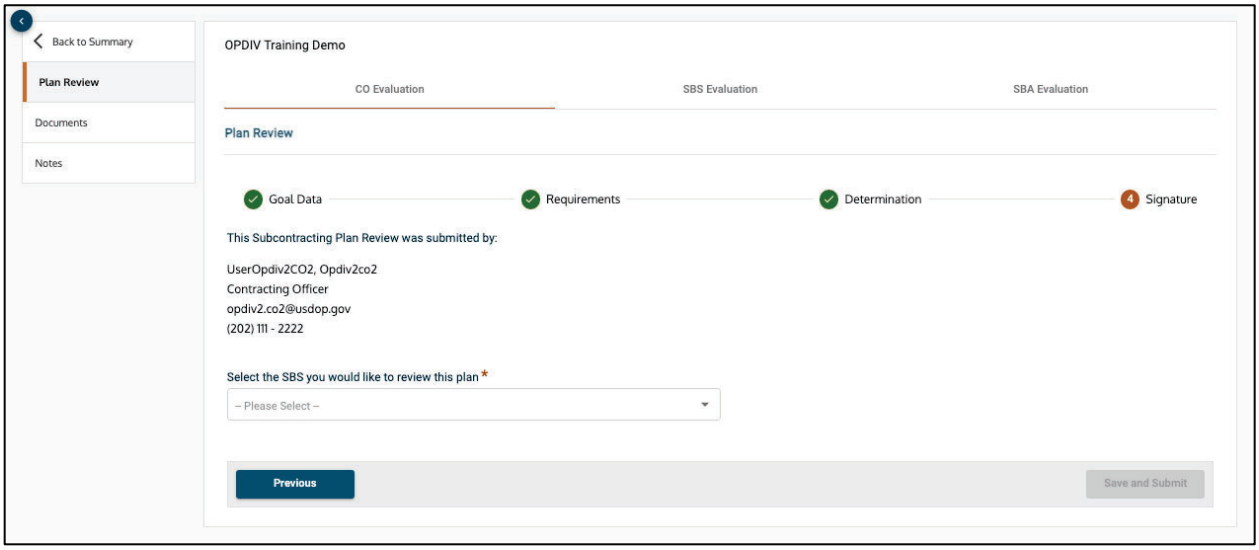
When the Subcontracting Plan is in Evaluation status, the offerors plans are ready for review. Use the Organization link view the Subcontracting Plans ready for review.

1. **Subcontracting Goal Data:** SBCX provides calculations for your review and flags amounts above or below the agency goals. There is also space for comments for any items that are unacceptable.

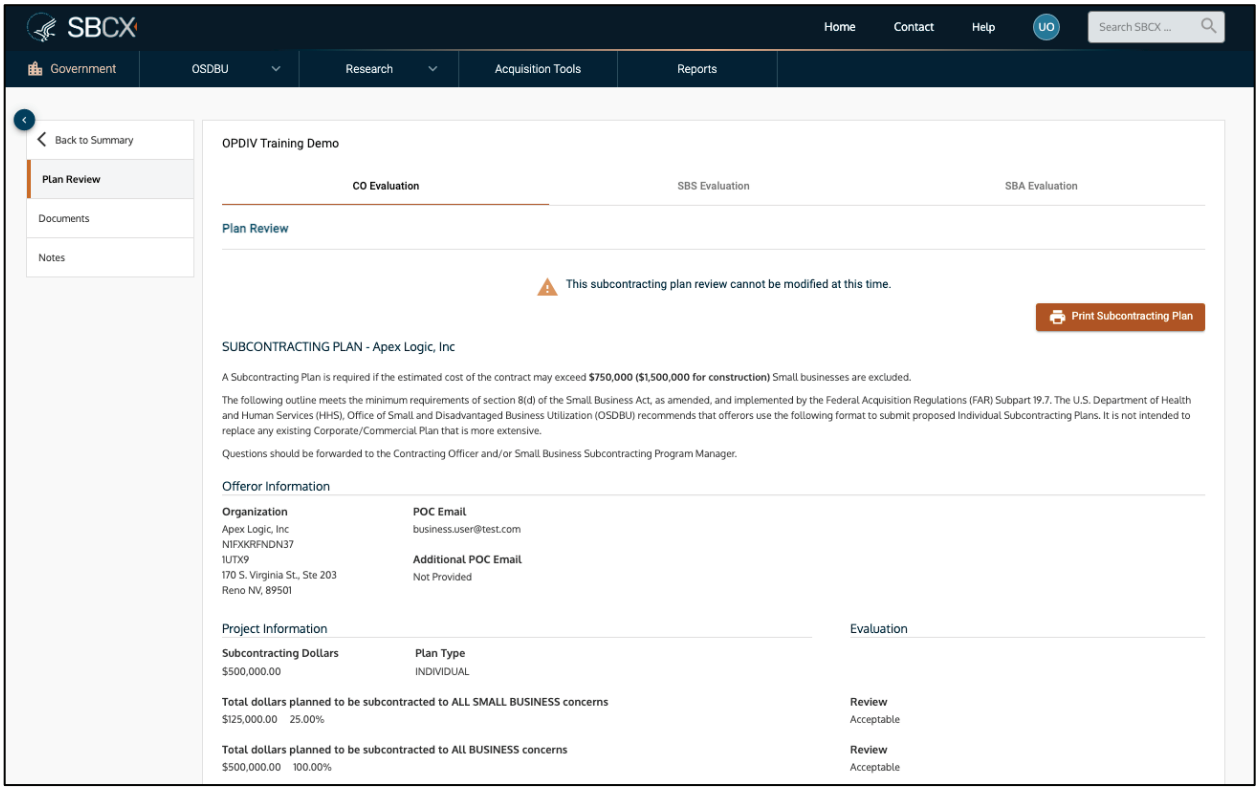
2. **Requirements:** This step applies to Individual and Master Plan evaluations. Verify whether the Offeror's answers are acceptable or unacceptable.

3. **Determination:** Answer the question(s) to complete the evaluation.

4. **Signature and Submission:** Identify the next reviewer (if applicable) in the process and confirm the evaluation by saving and submitting the evaluation. The Subcontracting Plan Review process involves three approvers.
    1. Evaluation CO
    2. Evaluation SBS
    3. Evaluation SBA



A PDF version of each approver's evaluation is available when the information is in Read-Only status.



If you still need technical help, contact us at client.support@apexlogic.com.

INVOICE/FINANCING REQUEST INSTRUCTIONS
FOR NIH COST-REIMBURSEMENT TYPE CONTRACTS, NIH(RC)-1

Format: Submit payment requests on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

Number of Copies: Submit payment requests in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Billing of Costs Incurred: If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall cite the amount(s) and month(s) in which the costs were incurred.

Contractor's Fiscal Year: Prepare payment requests in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

Currency: All NIH contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract shall not exceed the United States dollars authorized.

Costs Requiring Advance Approval: Costs requiring advance approval by the Contracting Officer, which are not set forth in the Contract Schedule shall be identified by the Contracting Officer's Authorization (COA) Number as a separate expenditure category on the payment request. In addition, the Contractor shall show any cost limitation or ceiling set forth in the Contract Schedule, i.e. an Advance Understanding, as a separate expenditure category on the payment request.

Invoice/Financing Request Identification, Frequency and Timeliness: The contractor must identify each payment request as either:

(a) Interim Invoice/Contract Financing Request: These are interim payment requests submitted during the contract performance period.

i. **Frequency:** Payment requests must not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks. At a minimum, the payment requests must be submitted on a monthly basis.

ii. **Timeliness:** Invoices must be submitted NLT 30 days following the period for which the services are being billed.

(b) Completion Invoice: A completion invoice must be submitted after the completion of the base period of performance, as well as after the completion of each Option period of performance, as set forth in Section F of the contract. The Contractor must submit the completion invoice when all costs have been assigned to the contract, and all performance has been completed for the period of performance.

Timeliness: The completion invoice shall be considered timely when submitted within six (6) months of the completion date for that period of performance, or within 120 days after settlement of the final indirect cost rates covering that period of performance (whichever date is later).

(c) Final Invoice: A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

Timeliness: The final invoice shall be considered timely when submitted no later than 30 days after the effective date of the contract settlement.

The contractor's failure to submit timely invoice(s) to the Government, as set forth in paragraphs (a)–(c) above, waives the contractor's rights to receive payment pursuant to this contract. In the event of the contractor's failure to submit timely invoice(s), the Government is not obligated to make such payment, and the Contracting Officer shall have the authority to unilaterally deobligate the funds in accordance with the requirements at 31 U.S.C. 1552(a) and downwardly adjust the total amount of the award by the amount of the deobligation. The contractor shall be given an opportunity to request the excusal of a late invoice from the Contracting Officer. If excused, the Contracting Officer will respond in writing to confirm that the contactor's right to receive payment has not been waived.

Preparation and Itemization of the Invoice/Financing Request:

The Contractor shall furnish the information set forth in the instructions below. The instructions are arranged to match the entries on the Sample Invoice/Financing Request. ***All information must be legible, or the invoice will be considered improper and returned to the Contractor.***

(a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(b) **Contractor's Name, Address, Point of Contact, TIN, and Unique Entity Identifier (UEI):** Show the Contractor's name and address exactly as they appear in the contract. Any invoice identified as improper will be sent to this address. Also include the name, title, phone number, and e-mail address of the Point of Contact in case of questions. If the remittance name differs from the legal business name, both names must appear on the invoice. Provide the Contractor's Federal Taxpayer Identification Number (TIN) and Unique Entity Identifier (UEI). The UEI must identify the Contractor's name and address exactly as stated in the contract and as registered in the System for Award Management (SAM) database.

When an approved assignment of claims has been executed, the Contractor shall provide the same information for the assignee as is required for the Contractor (i.e., name, address, point of contact, TIN, and UEI), with the remittance information clearly identified as such.

(c) **Invoice/Financing Request Number:** Identify each payment request by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization. For example, if a Contractor has already submitted invoice number 05 on one of its contracts or orders, it cannot use that same invoice number on any other contract or order. Payment requests with duplicate invoice numbers will be considered improper and returned to the Contractor.

The NIH does not prescribe a particular numbering format but suggests using a job or account number for each contract and order followed by a sequential invoice number (example: 8675309-05). Invoice numbers are limited to 30 characters. There are no restrictions on the use of special characters, such as colons, dashes, forward slashes, or parentheses.

If all or part of an invoice is suspended and the Contractor chooses to reclaim those costs on a supplemental invoice, the Contractor may use the same unique invoice number followed by an alpha character, such as "R" for revised (example: 8675309-05R).

(d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (if applicable).

(f) **Contract Title: Insert** the contract title listed on the cover page of the contract and/or Section G of the Contract Schedule.

(g) **Current Contract Period of Performance:** Insert the contract start date/effective date through the current completion date of the contract.

(h) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fee. If billing under an order, insert the total estimated cost of the order, exclusive of fee. For contracts/orders with options or incremental funding provisions, enter the amount currently obligated and available for payment.

(i) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable). For contracts/orders with options or incremental funding provisions, enter the amount currently obligated. ***Note:*** *If the contract provides for another type of Fee, i.e. Award or Incentive Fee, insert the amount available to be earned as identified in the contract and indicate the type of fee to be billed on the payment request.*

(j) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.

(k) **Office of Acquisitions: Insert** the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(l) **Central Point of Distribution: Insert** the Central Point of Distribution, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(m) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(n) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(o) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(p) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract.

   For Level of Effort contracts only, the Contractor shall provide the following information on a separate page attached to the payment request:

   - hours or percentage of effort and cost by labor category (as specified in the Level of Effort Article in Section F of the Contract Schedule) for the current billing period, and

   - hours or percentage of effort and cost by labor category from contract inception through the current billing period. (NOTE: The Contracting Officer may require the Contractor to provide additional breakdown for direct labor, such as position title, employee name, and salary or hourly rate.)

2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Cite the rate(s) used to calculate fringe benefit costs, if applicable.

3) **Accountable Personal Property:** Include permanent research equipment and general purpose equipment having a unit acquisition cost of $1,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS *Contractor's Guide for Contract of Government Property*). Show permanent research equipment separate from general purpose equipment.

   On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. Precede the item with an asterisk (*) if the equipment is below the $1,000 approval level. Include reference to the following (as applicable):

   - item number for the specific piece of equipment listed in the Property Schedule, and
   - Contracting Officer Authorization (COA) Number, if the equipment is not covered by the Property Schedule.

   The Contracting Officer may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

4) **Materials and Supplies:** Include equipment with unit costs of less than $1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

5) **Premium Pay:** List remuneration in excess of the basic hourly rate.

6) **Consultant Fee:** List fees paid to consultants. Identify consultant(s) by name or category as set forth in the contract or Contracting Officer Authorization (COA), as well as the effort (i.e., number of hours, days, etc.) and rate billed.

7) **Travel:** Include domestic and foreign travel. Foreign travel is travel outside of the United States and its territories and possessions. However, for an organization located outside the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

8) **Subcontract Costs:** List subcontractor(s) by name and amount billed.

9) **Other:** List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(q) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(r) **Indirect Costs:** Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.

(s) **Fixed-Fee:** Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract. ***Note:*** *If the contract provides for another type of Fee, i.e. Award or Incentive Fee, provide the same documentation for the amount claimed.*

(t) **Total Amounts Claimed:** Insert the total amounts claimed for the current and cumulative periods.

(u) **Adjustments:** Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(v) **Grand Totals**

(w) **Certification:** The Contractor shall include the following certification at the bottom of each payment request:

"Pursuant to authority vested in me, I certify that this voucher is correct and proper for payment."

Note: The *contract may require additional certifications (See Invoice Submission Instructions in Section G of the Contract Schedule)*

The Contracting Officer may require the Contractor to submit detailed support for costs claimed on one or more interim payment requests.

SAMPLE INVOICE/FINANCING REQUEST

(a) Designated Billing Office Name and Address: National Institutes of Health (NIH) Office of Financial Management (OFM) E-mail: See Section G (b) Contractor's Name, Address, Point of Contact, TIN, and DUNS or DUNS+4 Number: **ABC CORPORATION** 100 Main Street Anywhere, U.S.A. Zip+4 Name, Title, Phone Number, and E-mail Address of Contractor's Point of Contact. UEI: _____ TIN: _____	(c) Invoice/Financing Request No.: _____ (d) Date Invoice/Financing Request Prepared: _____ (e) Contract No. and Order No. (if applicable): _____ (f) Contract Title: _____ (g) Current Contract Period of Performance: _____ (h) Total Estimated Cost of Contract/Order: _____ (i) Total Fixed Fee (if applicable):_____ (j) Two-Way Match: ____ Three-Way Match: ____ (k) Office of Acquisitions:_____ (l) Central Point of Distribution:_____

(m) This invoice/financing request represents reimbursable costs for the period from _____ to _____.

Expenditure Category*	(n) Amount Billed Current Period	(o) Amount Billed Cumulative
(p) Direct Costs	$ 3,400	$ 6,800
1) Direct Labor	600	1,200
2) Fringe Benefits _____%		
3) Accountable Personal Property	3,000	6,000
Permanent Research	2,000	2,000
General Purpose	2,000	4,000
4) Materials and Supplies	100	150
5) Premium Pay	100	100
6) Consultant Fee: Dr. Jones, 1 day @ $100 (COA #3)	200	200
7) Travel (Domestic) (Foreign)	200	200
8) Subcontract Costs	-0-	-0-
9) Other	-0-	-0-
Total Direct Costs	$11,600	$20,650
(q) Cost of Money (Factor) of (Appropriate Base)	2,400	3,600
(r) Indirect Costs_____% of IDC Base (Formula)	4,000	6,000
(s) Fixed Fee (Formula)	700	1,400
(t) Total Amount Claimed (u) Adjustments	$19,700	$31,650
Outstanding Suspensions		(1,700)
(v) Grand Totals	$19,700	$29,950

"Pursuant to authority vested in me, I certify that this voucher is correct and proper for payment."

_____ _____

(Name of Official (Title)

*Attach additional details as specified in the contract or requested by the Contracting Officer

Safety and Health, HHSAR 352.223-70 (DEC 2015)

a. To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State, and local laws and regulations applicable to the work being performed under this contract. These laws are implemented or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration (OSHA) and other regulatory/enforcement agencies at the Federal, State, and local levels.

   1. In addition, the Contractor shall comply with the following regulations when developing and implementing health and safety operating procedures and practices for both personnel and facilities involving the use or handling of hazardous materials and the conduct of research, development, or test projects:
      I. 29 CFR 1910.1030, Bloodborne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by OSHA and included in 29 CFR part 1910. These regulations are available at https://www.osha.gov/.
      II. Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.). The Contractor may obtain copies from the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

   2. The following Government guidelines are recommended for developing and implementing health and safety operating procedures and practices for both personnel and facilities:
      I. Biosafety in Microbiological and Biomedical Laboratories, CDC. This publication is available at http://www.cdc.gov/biosafety/publications/index.htm.
      II. Prudent Practices for Safety in Laboratories (1995), National Research Council, National Academy Press, 500 Fifth Street NW., Lockbox 285, Washington, DC 20055 (ISBN 0-309-05229-7). This publication is available at http://www.nap.edu/catalog/4911/prudent-practices-in-the-laboratory-handling-and-disposal-of-chemicals.

b. Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer, in conjunction with the Contracting Officer's Representative or other appropriate officials, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, the Contracting Officer will make an equitable adjustment in accordance with the applicable ``Changes'' clause set forth in this contract.

c. The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to

toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report citing all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State, or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

d. If the Contractor fails or refuses to comply with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State, or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any such stop work order shall form the basis for a request for extension or costs or damages by the Contractor.

e. The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. The Contractor is responsible for the compliance of its subcontractors with the provisions of this clause.

(End of clause)

INSTRUCTIONS FOR COMPLETING FORM NIH 2706
"FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT"

GENERAL INFORMATION

Purpose. Form NIH 2706 is designed to: (1) provide a management tool for use by be NIH in monitoring the application of financial and personnel resources to the NIH contracts; (2) provide contractors with financial and personnel management data which is usable in their management processes; (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel; and (4) obtain contractor's analysis of cause and effect of significant variations between actual and prior estimates of financial and personnel performance.

REPORTING REQUIREMENTS

Scope. The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may require the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

Number of Copies and Mailing Address. An original and two (2) copies of the report(s) shall be sent to the contracting officer at the address shown on the face page of the contract, no later than 30 working days after the end of the period reported. However, the contract may provide for one of the copies to be sent directly to the project officer.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not require reporting on a separate Form NIH 2706, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

Definitions and Instructions for Completing Form NIH 2706. For the purpose of establishing expenditure categories in Column A, the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

(1) **Key Personnel.** Include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.

(2) **Personnel--Other.** List as one amount unless otherwise required by the contract.

(3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.

(4) **Accountable Personal Property.** Include nonexpendable personal property with an acquisition cost of $1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See "Contractor's Guide for Control of Government Property."

(5) **Supplies.** Include the cost of supplies and material and equipment charged directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.

(6) **Inpatient Care.** Include costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.

(7) **Outpatient Care.** Include costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.

(8) **Travel.** Include all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure, destination and return, including time and dates; and (iii) Total cost of trip.

(9) **Consultant Fee.** Include fees paid to consultant(s). Identify each consultant with effort expended, billing rate, and amount billed.

(10) **Premium Pay.** Include the amount of salaries and wages over and above the basic rate of pay.

(11) **Subcontracts.** List each subcontract by name and amount billed.

(12) **Other Costs.** Include any expenditure categories for which the Government does not require individual line item reporting. It may include some of the above categories.

(13) **Overhead/Indirect Costs.** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(14) **General and Administrative Expense.** Cite the rate and the base. In the case of nonprofit organizations, this item will usually be included in the indirect cost.

(15) **Fee.** Cite the fee earned, if any.

(16) **Total Costs to the Government.**

PREPARATION INSTRUCTIONS

These instructions are keyed to the Columns on Form NIH 2706.

Column A--Expenditure Category. Enter the expenditure categories required by the contract.

Column B--Percentage of Effort/Hours Negotiated. Enter the percentage of effort or number of hours agreed to during contract negotiations for each labor category listed in Column A.

Column C--Percentage of Effort/Hours-Actual. Enter the cumulative percentage of effort or number of hours worked by each employee or group of employees listed in Column A.

Column D--Cumulative Incurred Cost at End of Prior Period. Enter the cumulative incurred costs up to the end of the prior reporting period. This column will be blank at the time of the submission of the initial report.

Column E--Incurred Cost-Current Period. Enter the costs which were incurred during the current period.

Column F--Cumulative Incurred Cost to Date. Enter the combined total of Columns D and E.

Column G--Estimated Cost to Complete. Make entries only when the contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column H--Estimated Costs at Completion. Complete only if an entry is made in Column G.

Column I--Negotiated Contract Amount. Enter in this column the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

Column J--Variance (Over or Under). Complete only if an entry is made in Column H. When entries have been made in Column H, this column should show the difference between the estimated costs at completion (Column H) and negotiated costs (Column I). When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column J by Column I, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications. List any modification in the amount negotiated for an item since the preceding report in the appropriate cost category.

Expenditures Not Negotiated. List any expenditure for an item for which no amount was negotiated (e.g., at the discretion of the contractor in performance of its contract) in the appropriate cost category and complete all columns except for I. Column J will of course show a 100 percent variance and will be explained along with those identified under J above.

ATTACHMENT 23b

National Institutes of Health FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT, NIH FORM 2706 ***Note: Complete this Form in Accordance with Accompanying Instructions.***	**Project Task:**	**Contract No.:**	**Date of Report:**	**0990-0134** **0990-0131**
	Reporting Period:	**Contractor Name and Address:**		

Expenditure Category	**Percentage of Effort/Hours**		**Cumulative Incurred Cost at End of Prior Period**	**Incurred Cost-- Current Period**	**Cumulative Cost to Date (D + E)**	**Estimated Cost to Complete**	**Estimated Cost at Completion (F + G)**	**Negotiated Contract Amount**	**Variance (Over or Under) (I - H)**
	Negotiated	**Actual**							
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**

NIH-2706 (5/97) (Formerly HHS-646)

Attachment 24 – Additional Proposal Instructions and Evaluation Criteria *See RFP PDF #3- Attachment 24 and Sub Attachments

1. Packaging and Delivery of Proposals- NIH Electronic Contract Proposal Submission (eCPS) Website

   See attached.

2. Proposal Intent Response Sheet

   See attached.

3. Statement of Work

   See attached.

4. Reporting Requirements and Deliverables

   See attached.

5. Section K- Representations, Certifications, and Other Statements of Offerors

   See attached.

6. Supply Chain Risk Management Certification- HHSAR 352.204.74

   See attached.

7. Technical Proposal Cost Summary

http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/tech-prop-cost-summ.pdf.

8. Summary of Related Activities

https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf

9. Contract Proposal Vertebrate Animal Section (VAS) Worksheet

https://grants.nih.gov/grants/olaw/VAScontracts.pdf

10. HHS Section 508 Product Assessment Template

HHS Digital Accessibility & Section 508

11. Proposal Summary and Data Record, NIH-2043

https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2043.pdf

12. Small Business Subcontracting Plan Submission Guide

   See attached.

Small Business Subcontracting Plan Form for reference:

https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/HHS%20SubK%20Plan%20Template%20-%20updated%20March%202022.pdf.

13a. Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet

See attached.

14. Offeror's Points of Contact

https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/point-of-contact.pdf

15. Certificate of Current Cost or Pricing Data

https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/cert-current-cost.pdf

16. Disclosure of Lobbying Activities, OMB Form SF-LLL

https://www.gsa.gov/reference/forms/disclosure-of-lobbying-activities

17. Invoice/Financing Request Instructions- CR - NIH (RC)-1

See attached.

18. Government Property Schedule

To be determined during negotiations.

19. Roster of Employees Requiring Suitability Investigations

https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Suitability%20Roster%202021%20Revised.xlsx

20. Employee Separation Checklist

https://ocio.nih.gov/sites/external/files/2024-01/Emp-sep-checklist.pdf

21. Commitment to Protect Non-Public Information Contractor Agreement

https://ocio.nih.gov/sites/external/files/2024-01/Nondisclosure04082020.pdf

22. Safety and Health, HHSAR Clause 352.223-70

See attached.

23a. NIH FORM 2706- Instructions NIH Form 2706

See attached.

23b. NIH FORM 2706- Financial Report of Individual Project/Contract

See attached.

24. Additional Proposal Instructions and Evaluation Criteria

See attached (Includes Sub Attachments A-E).

25. Attachments and Links

See attached.