EVALUATION

A. BASIS FOR AWARD

1. The Government reserves the right to eliminate from consideration for award any or all offers at any time prior to award of the contract; to negotiate with offerors in the competitive range; and to award the contract to the offeror submitting the proposal determined to represent the best value—the proposal most advantageous to the Government, price and other factors considered.

2. As stated in the solicitation, the Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). The Government reserves the right to conduct discussions if the CO later determines them to be necessary. In addition, if the CO determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the CO may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

3. The tradeoff process is selected as appropriate for this acquisition. The Government considers it to be in its best interest to allow consideration of award to other than the lowest priced offeror or other than the highest technically rated offeror.

4. As stated in the solicitation, all technical factors when combined are of equal importance to the performance confidence assessment (past performance) rating; and all technical factors and the performance confidence assessment (past performance) rating, when combined are significantly more important than cost.

5. Any proposal found to have a deficiency in meeting the stated solicitation requirements or performance objectives will be considered ineligible for award, unless the deficiency is corrected through discussions. An Unacceptable rating in any of the non-cost/price factors and/or sub-factors will result in an overall rating of “Unacceptable” for the non-cost/price factors, unless corrected through discussions. Proposals may be found to have either a significant weakness or multiple weaknesses that impact either the individual factor rating or the overall rating for the proposal. The evaluation report must document the evaluation board’s assessment of the identified weakness(s) and the associated risk to successful contract performance resulting from the weakness(s). This assessment must provide the rationale for proceeding to award without discussions.

B. ADJECTIVAL RATINGS/DESCRIPTIONS

1. TECHNICAL EVALUATION:

The technical rating reflects the degree to which the proposed approach meets or does not meet the minimum performance or capability requirements through an assessment of the strengths, weaknesses, significant weaknesses, deficiencies, and risks of a proposal.

a. A combined technical/risk evaluation includes consideration of risk in conjunction with the significant strengths, strengths, weaknesses, significant weaknesses, uncertainties, and deficiencies in determining technical ratings shall be used. The technical risk evaluation shall utilize the combined technical/risk ratings listed in the following table. Adjectival ratings and

rating descriptions will be used to assign an overall rating to each technical proposal and to assign a rating for each technical factor. Use upper case letter ratings for major technical factors as well as the overall rating. The addition of plus (+) or minus (-) to an adjective rating is not allowed.

Table 1. Combined Technical/Risk Rating Method	
Adjectival Rating	**Description**
Outstanding (**O**)	Proposal demonstrates an exceptional approach and understanding of the requirements and contains multiple strengths and/or at least one significant strength, and risk of unsuccessful performance is low.
Good (**G**)	Proposal indicates a thorough approach and understanding of the requirements and contains at least one strength or significant strength, and risk of unsuccessful performance is low to moderate.
Acceptable (**A**)	Proposal meets requirements and indicates an adequate approach and understanding of the requirements, and risk of unsuccessful performance is no worse than moderate.
Marginal (**M**)	Proposal has not demonstrated an adequate approach and understanding of the requirements, and/or risk of unsuccessful performance is high.
Unacceptable (**U**)	Proposal does not meet requirements of the solicitation and, thus, contains one or more deficiencies and is unawardable unless corrected through discussions, and/or risk of performance is unacceptably high.

b. Definitions: The following definitions are provided to assist evaluators in the evaluation of each non-cost/price factor.

(i) Significant Strength: An aspect of an offeror’s proposal with appreciable merit or will exceed specified performance or capability requirements to the considerable advantage of the Government during contract performance.

(ii) Strength: An aspect of an offeror's proposal with merit or will exceed specified performance or capability requirements to the advantage of the Government during contract performance.

(iii) Weakness: A flaw in the proposal that increases the risk of unsuccessful contract performance.

(iv) Significant Weakness: A flaw that appreciably increases the risk of unsuccessful contract performance.

(v) Uncertainty: Any aspect of a non-cost/price factor proposal for which the intent of the offer is unclear (e.g., more than one way to interpret the offer or inconsistencies in the proposal indicating that there may have been an error, omission, or mistake).

(vi) Deficiency: A material failure of a proposal to meet a Government requirement or a combination of significant weaknesses in a proposal that increases the risk of unsuccessful contract performance to an unacceptable level.

2. PAST PERFORMANCE EVALUATION

a. The past performance evaluation results in an assessment of the offeror's ability of meeting the solicitation requirements. The past performance evaluation considers each offeror's demonstrated recent and relevant record of performance in supplying products and services that meet the contract's requirements. The currency and relevance of the information, source of the information, context of the data, and general trends in contractor's performance shall be considered. These are combined to establish one performance confidence assessment rating for each offeror.

b. There are three aspects to the past performance evaluation: recency, relevancy (including context of data), and quality (including general trends in contractor performance and source of information).

The first is to evaluate the recency of the offeror's past performance. The second is to determine how relevant a recent effort accomplished by the offeror is to the effort to be acquired through the source selection. The third is to establish the overall quality of the offeror's past performance. Recency is generally expressed as a time period during which past performance references are considered relevant and is critical to establishing the relevancy of past performance information. In establishing what is relevant for the acquisition, consideration should be given to those aspects of an offeror's contract history that would give the greatest ability to measure whether the offeror will satisfy the current procurement. Common aspects of relevancy include, but are not limited to, the following: similarity of service/support, complexity, dollar value, contract type, use of key personnel (for services) and extent of subcontract/teaming. The third aspect of the past performance evaluation is to establish the overall quality of the offeror's past performance (see FAR 15.304[c][2]). The past performance evaluation conducted in support of a current source selection does not establish, create, or change the existing record and history of the offeror's past performance on past contracts; rather, the past performance evaluation process gathers information from customers on how well the offeror performed those past contracts. A separate quality assessment rating is not required; rather, the past performance rating using the confidence assessment rating, is based on the offeror's overall record of recency, relevancy, and quality of performance.

c. This source selection will evaluate past performance relevancy in accordance with the ratings in Table 3 below:

Table 3. Past Performance Relevancy Rating Method

Adjectival Rating	Description
Very Relevant	Present/past performance effort involved essentially the same scope and magnitude of effort and complexities this solicitation requires.
Relevant	Present/past performance effort involved similar scope and magnitude of effort and complexities this solicitation requires.
Somewhat Relevant	Present/past performance effort involved some of the scope and magnitude of effort and complexities this solicitation requires.

Not Relevant	Present/past performance effort involved little or none of the scope and magnitude of effort and complexities this solicitation requires.

d. The SSEB will review all past performance information collected and determine the quality of the offeror's performance, general trends, and usefulness of the information and incorporate these into the performance confidence assessment. A separate quality assessment rating is not required; rather, the past performance confidence assessment rating is based on the offeror's overall record of recency, relevancy and quality of performance.

In the case of offerors for which there is no information on past contract performance or where past contract performance is not available, the offeror may not be evaluated favorably or unfavorably on the factor of past contract performance. In this case, the offeror's past performance is unknown and assigned a confidence rating of "neutral." Although the SSEB may not rate an offeror that lacks recent, relevant past performance favorably or unfavorably with regard to past performance, the SSA may determine, that a "Substantial Confidence" or "Satisfactory Confidence" past performance rating is worth more than a "Neutral Confidence" past performance rating in a best value tradeoff as long as the determination is consistent with stated selection criteria.

e. Performance Confidence Assessment. This source selection requires a greater level of discrimination within the past performance evaluation, therefore, the SSEB shall use all confidence ratings identified in Table 4 below.

Table 4. Performance Confidence Assessments

Adjectival Rating	Description
Substantial Confidence	Based on the offeror's recent/relevant performance record, the Government has a high expectation that the offeror will successfully perform the required effort.
Satisfactory Confidence	Based on the offeror's recent/relevant performance record, the Government has a reasonable expectation that the offeror will successfully perform the required effort.
Neutral Confidence	No recent/relevant performance record is available or the offeror's performance record is so sparse that no meaningful confidence assessment rating can be reasonably assigned. The offeror may not be evaluated favorably or unfavorably on the factor of past performance.
Limited Confidence	Based on the offeror's recent/relevant performance record, the Government has a low expectation that the offeror will successfully perform the required effort.
No Confidence	Based on the offeror's recent/relevant performance record, the Government has no expectation that the offeror will be able to successfully perform the required effort.

C. EVALUATION FACTORS FOR AWARD

1. **The solicitation requires the evaluation of cost and the following non-cost/price factors:**

- Factor 1 – Experience
- Factor 2 – Program and Project Management and Coordination
- Factor 3 – Technical Approach and Sample Research Outlines
- Factor 4 – Personnel
- Factor 5 – Environment – Facilities, Equipment, and Security
- Factor 6 - Small Business Utilization
- Factor 7 – Past Performance

The distinction between experience and past performance is that experience pertains to the volume of work completed by a contractor that is comparable to the types of work described under the definition of recent, relevant projects, in terms of size, scope, and complexity. Past performance pertains to both the relevance of recent efforts and how well a contractor has performed on the contracts.

In order to be considered for award, offerors must clearly demonstrate that the following mandatory requirements can be met by the time of contract award. Offerors shall include all information that documents and/or supports the qualification criterion in one clearly marked section of the Technical Proposal.

MANDATORY QUALIFICATION CRITERIA

Listed below are mandatory qualification criteria. THE OFFEROR SHALL INCLUDE ALL INFORMATION WHICH DOCUMENTS AND/OR SUPPORTS THE QUALIFICATION CRITERIA IN ONE CLEARLY MARKED SECTION OF ITS TECHNICAL PROPOSAL.

The qualification criteria establishes conditions that must be met at the time of receipt of Technical Proposals by the Contracting Officer in order for your proposal to be considered any further for award.

1. **Mandatory Requirement: Good Laboratory Practices (GLP) Compliance**

All work performed under this contract for any assignment that directly supports a GLP Toxicology study shall comply with Food and Drug Administration Good Laboratory Practices for Nonclinical Laboratory Studies (FDA GLP Regulations; 21 CFR 58 Link: CFR Code of Federal Regulations Title 21 unless specifically authorized by the COR.
Organizations supporting proposals shall include information and documentation that demonstrates evidence of the testing laboratory's current compliance with the provisions of 21 CFR 58. Such documentation may include (but is not limited to):
FDA 482-Notice of Inspection forms, as evidence that general surveillance inspections and/or directed inspections have occurred.
Establishment Inspection Report (EIR) forms issued to document the results of any inspections.
Any adverse findings or Form 483 reports issued.
History (number, time-frame, and evidence) of GLP studies conducted if documentation from a regulatory agency such as the above a, b, or c, cannot be provided.

2. **Mandatory Requirement: Animal Welfare**

The work conducted must be in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the AWRs, the current edition of the Guide for the Care and Use of Laboratory Animals (the Guide), and all local, state, or federal regulations. The contractor must be accredited by AAALAC International. Organizations supporting proposals must have an approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW) at the time of contract award. (Note: *an offeror that does not have a PHS Assurance may be selected but the CO will have to initiate the process of obtaining an assurance from OLAW, and contract funds may not be expended for animal work, until the assurance has been approved*).

The Offeror and any proposed subcontractors shall be accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

Further information may be obtained from the following source:

Office of Laboratory Animal Welfare
Office of Extramural Research
National Institutes of Health
Rockledge Center I, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20817
Phone: (301) 496-7163, ext. 234

Copies of the PHS policy are available by fax at 301-402-2803 and on the internet at URL: http://grants.nih.gov/grants/olaw/olaw.htm

LIVE VERTEBRATE ANIMALS EVALUATION

The offerors proposal must include, as a separate section of the Technical Proposal titled "Vertebrate Animal Section," (VAS) a complete, concise (no more than 1-2 pages) description addressing the following criteria. (See NIH Guide Notice NOT-OD-16-006 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html):

a. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Request for Proposal (RFP) Statement of Work. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.

b. Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).

c. Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.

d. Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

As part of the overall technical evaluation of proposals, the reviewers will consider the acceptability of the offeror's description in the VAS of the technical proposal. The discussion of all criteria will be addressed and evaluated. Based on the evaluation of this Section, the VAS may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the description addressing each of the criteria, or no discussion can be found regarding the VAS), or "acceptable." If the reviewers find that this Section of the technical proposal is "unacceptable" they will provide a narrative supporting their findings.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed description under the VAS is still found to be unacceptable, then your proposal may not be considered further for award.

3. <u>Mandatory Requirement:</u> EVALUATION OF DATA MANAGEMENT AND SHARING PLAN

An Offeror's plan for the management and sharing of final research data (Data Management and Sharing Plan) shall be assessed for appropriateness, adequacy, and reasonableness.

If an Offeror's proposal does not include a Data Management and Sharing Plan (Plan) or if the Plan in an Offeror's proposal is considered "unacceptable," and the Government includes Offeror's proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), the Offeror will be afforded the opportunity to further discuss, clarify, and/or modify its Plan during discussions and in its Final Proposal Revision (FPR). However, if the Plan is still considered "unacceptable" by the Government after discussions, the Offeror may not be further considered for award.

2. The relative order of importance of the non-cost/price evaluation factors is the technical factors (Factors 1-5) are of equal importance to each other and, when combined are equal in importance to the past performance evaluation/performance confidence assessment factor (Factor 6). When the proposal is evaluated as a whole, the technical factors and past performance/performance confidence assessment factor combined (i.e., the non-cost/price evaluation factors) are significantly more important than cost.

   The importance of price will increase if the offerors' non-cost/price proposals are considered essentially equal in terms of overall quality, or if price is so high as to significantly diminish the value of a non-cost/price proposal's superiority to the Government. Award will be made to the responsible offeror(s) whose offer conforms to the solicitation and represents the best value to the Government, price and non-price factors considered.

3. Basis of Evaluation and Submittal Requirements for Each Factor.

   a. Cost:

      (1) *<u>Solicitation Submittal Requirements</u>:* Five sample Research Outlines (RO 1,2,3,4, and 5) are included in the Source Selection Plan (Attachment B) to provide offerors example research activities that might be conducted under the contract. When the actual contract award is made, the type and number of research activities may vary from the sample ROs, and options may be unilaterally exercised by the Government at any time during the contract.

Table 5 lists the activities that the offeror shall assume will be conducted during the base and optional periods (assumes an Option Year to extend the period of performance is exercised each year of the contract) and during the option to add labor hours (Option 1). Option 1 can be exercised at any time for level of effort (LOE) up to a ceiling defined by cost assumptions listed in Table 5 and the Independent Government Cost Estimate (IGCE). Option1 to perform additional work in eight Functional Areas, may be exercised up to 1 time per year with costs capped at 30% of the base contract proposal. Offerors shall prepare a cost proposal for Option 1 based on a maximum of 30% of the level of effort, and the prorated assignment mix anticipated in the base optional periods during the year the assignment is exercised. To estimate the total effort and cost over the 10-year period of the contract, Offerors are to utilize sample ROs to estimate cost for each Functional Activity listed in Table 5 and those activities in full will be conducted in the contract year listed (assume a starting date of January 18, 2027). Activities associated with overall contract management and coordination, such as preparing monthly status reports, monthly budget summary reports, invoices, and annual reports; maintaining contract and research records etc. shall be captured under an administrative category.

An optional 6-month extension of the period of performance may be exercised after Option Year 9. Offerors shall prepare a separate cost proposal for the optional 6-month extension based on the level of effort anticipated in Option Year 9 of the base contract.

Table 5. Anticipated Research Activities per Year

Research Activity	Anticipated Number per Year for Base Year and Option Years (Option Years 1-9)[1]	Anticipated Number per Year for Option 1
Contract management and administration	Ongoing	Ongoing
Activities Captured in Sample ROs		
Logistics and Handling – Chapter 6.2 DTT Chemistry Specifications[2]		
Chemical Handling (CH)	3	1
Chemical Procurement (CP)	3	1
Chemical Storage (CS)	2	1
Shipment (SHIP)	10	3
Protocols Development (PD)	1	0
Multiple Chemical Handling (MCH)	3	1
Multiple Chemical Procurement (MCP)	3	1
Characterization – Chapter 6.3 DTT Chemistry Specifications		
Comprehensive Chemical Analysis (CCA)	3	1
Chemical Identity and Purity Screen (CIPS)	3	1
Chemical Reanalysis (CRA)	2	1
Multiple Chemical Identity and Purity (MIPS)	3	1

Research Activity	Anticipated Number per Year for Base Year and Option Years (Option Years 1-9)[1]	Anticipated Number per Year for Option 1
Formulation – Chapter 6.4 DTT Chemistry Specifications		
Preliminary Formulation Studies (PFS)	1	0
Formulation Analysis (FA)	2	1
Formulation Development (FD)	3	1
Formulation Preparation, Analysis, and Shipment (FPAS)	3	1
Vehicle Analysis (VA)	3	1
Biosample Analysis – Chapter 6.5 DTT Chemistry Specifications		
Biosample Method Development (BMD)	3	1
Biosample Analysis (BSA)	5	1
Special Studies – Chapter 6.6 DTT Chemistry Specifications		
Annual Water Analysis (AWA)	1	0
Special Chemical Activity (SCA)	8	2
Animal Studies – Chapter 6.7 DTT Chemistry Specifications		
Toxicokinetic Study (TKS)	2	1
Absorption, Distribution, Metabolism, and Distribution Study (ADMES)	1	0
Omics – Chapter 6.8 DTT Chemistry Specifications		
Omics Studies (OMICS)	2[3]	1
In Vitro Assays – Chapter 6.9 DTT Chemistry Specifications		
In Vitro Assays (IVA)	2[4]	1

[1]Assume 30% of base contract for Option 1 to perform additional work.

[2]Refer to DTT Chemistry Specifications https://ntp.niehs.nih.gov/data/research/chemistry/rfp for detail descriptions of each Functional Area and Functional Activity.

[3]Assume that one assignment includes all activities found in Sample Research Outline 3 (OMICS) for costing purposes.

[4]Assume that one assignment includes all activities found in Sample Research Outline 4 (In Vitro Assays) for costing purposes.

Description of Cost and Effort Summaries: Offerors must provide detailed effort and cost breakdowns to include the following. Refer to the NIH *Breakdown of Proposed Estimated Cost (Plus Fee) and Labor Hours* (https://oamp.od.nih.gov/content/breakdown-proposed-estimated-cost-plus-fee-and-labor-hours) **(Section J - Attachment 13: NIH Breakdown of Proposed Estimated Costs- Business Proposal) for guidance and for the required Business Proposal Spreadsheet submission:**

- Direct labor hours, including labor classification (professional/technical), labor category, individual, and hourly rate
- Other direct costs, including subcontracts, consulting, travel, etc.
- Material and supply costs
- Indirect rates
- Fee

Offerors shall provide detailed effort and cost breakdowns by filling out **NIEHS Level of Effort Worksheet (Section J - Attachment 24: Sub Attachment E)** according to the provided instructions. A complete NIEHS Level of Effort Worksheet (Attachment E) shall include effort and cost information for overall summary cost estimate (base year + 9 option years + Option 1 to add labor hours) for all research activities per Table 5 and sample ROs and associated administrative costs.

The following Business Proposal Spreadsheets are required with Proposal submission:

1. Section J - Attachment 13: NIH Breakdown of Proposed Estimated Costs- Business Proposal) for guidance and for the required Business Proposal Spreadsheet submission.
2. NIEHS Level of Effort Worksheet (Section J - Attachment 24: Sub Attachment E)

<u>Additional Costing Assumptions</u>

(a) Chemical Procurement (CP) Cost Assumption
   1. For costing purposes, Offerors shall assume that Chemical Procurement (CP) chemicals will be procured in quantities of < 200 kg. For purposes of cost estimation only, Offerors shall assume that an average procurement under the Base contract costs $11,000.
   2. For costing purposes, Offerors shall assume that Multiple Chemical Procurement (MCP) of 90 chemicals will be procured in quantities of 10 g. For purposes of cost estimation only, Offerors shall assume an average procurement cost of $500 per chemical.

(b) Multiple Chemical Handling (MCH) Cost Assumption
   For costing purposes Offerors shall assume that a MCH assignment will involve handling 90 chemicals.

(c) Chemical Shipment (SHIP) Cost Assumptions
   For costing purposes, Offerors shall assume an average cost of $3,500 per shipment.

(d) Multiple Chemical Identity and Purity Screen (MIPS)
   For costing purposes Offerors shall assume that a MIPS assignment will involve identity and purity determination for 90 chemicals. Chemical and biosample inventory transfer.

(e)Chemical and biological Sample inventory Receipt and Storage
   For costing purposes Offerors shall assume that quantities given in Attachment F will need to be stored. Offerors will need to plan for shipping and other required costs.

(2) *Basis of Evaluation:* The Government will evaluate price based on the total price. Total price consists of the basic requirements and all option items (see Section B of the solicitation). The Government intends to evaluate all options and has included the provision FAR 52.217-5, Evaluation of Options (JUL 1990) in Section M of the solicitation. In accordance with FAR 52.217-5, evaluation of options will not obligate the Government to exercise the option(s). Analysis will be performed by one or more of the following techniques to ensure a fair and reasonable price:

(a) Comparison of proposed prices received in response to the RFP.

(b) Comparison of proposed prices with the IGCE.

(c) Comparison of proposed prices with available historical information.

(d) Comparison of market survey results.

b. Non-cost/price Factors:

(1) Factor 1, Experience:

(a) *Solicitation Submittal Requirements:* The offeror shall provide a minimum of one (1) and a maximum of three (3) examples of recent and relevant contract actions to be documented through use of the Corporate Experience Project Data Form (Attachment A). The offeror shall clearly demonstrate past experience to perform the services described in the Statement of Work (SOW). Examples submitted shall be recent and relevant contract actions that were similar in size, scope, and complexity to the requirements described in the SOW completed within the last five (5) years preceding the release date of the solicitation. To meet the minimum standard acceptable for this evaluation, offerors shall demonstrate through their examples experience in items one (i) through seven (vii) either separately or combined to demonstrate relevancy per requirements in DTT Chemistry Specifications:

(i) Logistics and Handling
(ii) Characterization
(iii) Formulation
(iv) Biosample Analysis
(v) Animal Studies (Absorption, Distribution, Metabolism, Excretion, and Toxicokinetics, ADME/TK)
(vi) OMICS
(vii) In Vitro Assays

Offerors that demonstrate through their experience an understanding and proficiency in ADME/TK study design and conduct may be viewed more favorably than offerors without such experience. Relevant experience performed by the offeror as a prime contractor may be considered more favorably than experience performed by the offeror as a subcontractor.

For each contract action the offeror shall complete the Corporate Experience Project Data Form included as Attachment A. All information shall be provided as requested on the form.

If the offeror uses affiliates/subsidiaries/parent/LLC/LTD member companies or subcontractors to demonstrate corporate experience, the offeror shall clearly demonstrate that the affiliates/subsidiaries/parent/LLC/LTD member companies or subcontractors will have meaningful involvement in the performance of this contract.

IMPORTANT: It is the offeror's responsibility to clearly explain and demonstrate to the Government how its work experience, and the experience of each teaming partner (if applicable) in each submitted contract action is relevant to the contract requirements in this solicitation. If the offeror does not clearly explain how its experience(s) are relevant to the contract requirements in this specification, the Government may determine that the submitted contract experience is not relevant.

(b) *Basis of Evaluation:* Offeror demonstrates experience in performing work of similar size, scope, and complexity to this requirement. The assessment of the offeror's recent and relevant experience will be used as a means of evaluating the capability of the offeror to successfully meet the requirements of the RFP. At a minimum, the offeror must submit contract actions demonstrating experience in:

(i) Logistics and Handling
(ii) Characterization
(iii) Formulation
(iv) Biosample Analysis
(v) Animal Studies (Absorption, Distribution, Metabolism, Excretion, and Toxicokinetics, ADME/TK)
(vi) OMICS
(vii) In Vitro Assays

The Government will review only the first three (3) contract actions submitted. Any contract actions submitted in excess of the three (3) contract action limit will not be considered in the evaluation.

Offerors that demonstrate through their experience an understanding and proficiency conducting literature-based evaluations may be viewed more favorably than offerors without such experience.

Offerors that submit contract actions demonstrating experience performing the other requirements outlined in the SOW that are above and beyond those required to meet the minimum standard may be rated more favorably than offerors who only meet the minimum standard.

(2) Factor 2, Program and Project Management and Coordination:

(a) *Solicitation Submittal Requirements:* The contract requires a Principal Investigator (PI) and Deputy PI both as key personnel. The offerors shall propose a delineation of the day-to-day roles and responsibilities of the PI and Deputy PI. Collectively, the PI and Deputy PI are expected to be knowledgeable and involved in all aspects of the contract, including project status, record keeping, reporting, and detailed analysis of budget for all contract functions. The offeror shall submit a detailed plan, not to exceed 100 pages (excluding QMP, see below), addressing all areas below. Any information exceeding the 100-page limit for this factor will not be considered in the evaluation.

(i) Management Plan and Approach

- Proposed approach to program and project management and coordination.
- A functional organization chart, including lines of reporting.
- Details on the scope of the program, how work will be scheduled, how progress will be monitored, and how project status will be communicated to the Government.
- Management of staff responsibilities and interactions, including provision of a functional organization chart, showing lines of reporting.
- Proposed project staff working together as a team. The daily interaction and constant coordination of efforts needed amongst these discipline areas throughout the performance of work makes it critical that they be physically and organizationally together.
- Documentation of procedures applied to the allocation of facilities and equipment required to achieve timely completion of assigned laboratory work, including health and safety aspects.
- Documentation of offeror's flexibility to perform a large number (>50) of multidisciplinary Functional Activity assignments. Note that these assignments will often occur simultaneously. Describe how staffing will be handled during periods of peak activity (e.g., close to deadlines) to ensure continued progress on all ongoing assignments.
- A Quality Management Plan (QMP; submit as an appendix to this factor, not to exceed 60 pages). A QMP identifies the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and its processes for planning, implementing, documenting, and assessing all activities conducted under the organization's quality system. Discuss within the QMP a process for assessing possible conflicts of interest. For additional information on QMPs, see https://www.epa.gov/irmpoli8/quality-management-plan-qmp-standard.
- Summary of corporate experience in the conduct and management of programs and projects of similar size, scope, and complexity, including those of any proposed subcontractors, to those described in the SOW.
- Summary of the approach for avoiding real and perceived conflict of interest for all staff.
- Documentation of procedures for acquisition and oversight of any proposed subcontractors/consultants. If any subcontractors/consultants are proposed, the offeror must clearly define how any proposed subcontract/consultant arrangements would meet program needs. A letter of commitment from each subcontractor/consultant must be provided. If subcontracting is proposed, details must be given as to how this would be structured, organized, managed, and monitored.

(ii) Principal Investigator (PI) and Deputy PI

- The PI and Deputy PI shall both be employees of the contractor and designated as key personnel, considered essential to the contract.
- Provide a description (limited to 2 pages for each personnel) to be included in the proposal body.

- Provide a biographical sketch for both the PI and the Deputy PI (in an appendix) using the form in Attachment D. Include information to document relevant training, experience, scientific expertise, accomplishments, and competency including selected references for publications relevant to the scope of the SOW and sample ROs (limited to 5 pages; see RFP), necessary for the successful completion of all contract requirements.
- Provide details on the experience in the management and coordination of multidisciplinary projects similar to those described in the sample ROS and SOW.
- Provide details on specific duties on the SOW and sample ROs, and availability to the contract.
- The PI must be responsible for the daily management of the contract, point of contact for communication with the Government officials and serves as an on-staff expert and technical resource for chemistry and chemistry-related issues, which may from time-to-time arise during the contract. The PI must be knowledgeable in all aspects of the Program/Contract, including the status of all active assignments, record keeping, reporting, and detailed analysis of cost for any or all functions which make up the total operation
- General qualifications expected of a PI and Deputy PI include: a Doctorate, or the equivalent relevant experience in a key scientific discipline applicable to the Program/Contract (e.g., chemistry, biochemistry, ADME and TK); significant experience in managing large-scale programs in multiple disciplines; demonstrated capability for effective written and oral communication

(b) *Basis of Evaluation:* Each offeror will be evaluated on the extent to which the offeror demonstrates an understanding of the three (3) below areas.

(i) Management Plan and Approach: Appropriateness of the proposed approach to program and quality management strategy, including: functional organization chart; Quality Management Plan; management of staff, experience of staff working together as a team, and communication between the project staff and Government staff; details of project scope; scheduling and monitoring of progress; relevancy of corporate experience in projects of similar size, scope and complexity; evaluation of the Offeror's flexibility to perform various multidisciplinary assignments; adequacy of details for arrangement and oversight for any proposed subcontractors/consultants.

(ii) PI and Deputy PI: Appropriateness of the education, training, experience, scientific expertise, competency, and accomplishments of the proposed PI and Deputy PI (as demonstrated in the biographical sketch) familiar with in the management and coordination of multidisciplinary projects covering the activities under the Functional Areas given in DTT Chemistry specifications; proposed specific duties, effort on, and availability to the program. Appropriateness of the education, training, experience, scientific expertise, competency, and accomplishments of the proposed deputy PI (as demonstrated in the biographical sketch) familiar with the organization, management and coordination of multidisciplinary projects; proposed specific duties, effort on, and availability to the program.

(iii) Quality Control and Quality Assurance: Appropriateness of the proposed approach and procedures for quality control and quality assurance, including details of the organization and operating procedures of the Quality Assurance Unit and evaluation of the Offeror's schedule for quality assurance audits and inspections. Appropriateness of the training, experience, and competency of the proposed Quality Assurance Officer (as demonstrated in the biographical sketch- Attachment D) and support staff, including proposed specific duties and effort on the program; include those of any proposed subcontractors/consultants.

(3) Factor 3, Technical Approach and Sample Research Outlines:

(a) *Solicitation Submittal Requirements:* The criteria described here apply to both the overall technical approach as demonstrated in response to the RFP and the required capabilities, in addition to proposals for the specific requirements in each of the sample ROs. The responses to all sample ROs should be very detailed and describe how all aspects of the work would be conducted. The offeror shall submit a detailed plan, not to exceed 200 pages, addressing all areas below. Any information exceeding the 200-page limit for this factor will not be considered in the evaluation.

(i) Project Approach

- Describe the overall strategy to accomplish the goals of the SOW and for each of the sample ROs. Throughout the sample ROs, there are additional specific outputs that offerors shall include in their Technical Proposal.
- Identify potential problems that may be encountered during performance of work under the SOW and for each of the sample ROs, and solutions to these problems.
- Identify alternative strategies to accomplish the goals of the SOW and sample ROs; identify benchmarks for success.

(ii) Overall Technical Approach

- Demonstrate technical approach, including demonstrated understanding of the scope of the contract and overall strategy, procedures and approaches, and services, including those that are novel or innovative; technical capability in the conduct of chemistry activities under Functional Areas in the DTT Chemistry Specifications.
- Include detail and provide documentation to demonstrate how all aspects of the SOW and sample ROs will be implemented, including methodologies, analyses, technologies, and services to meet the goals of the program, including those that are novel or innovative.
- The offeror must clearly define how subcontractor and/or consultant arrangements would contribute to the success of the offeror's technical approach.
- Include copies of the Standard Operating Procedures to be used in the management and technical activities

(iii) Organizational Details

- Include organizational details for how projects will be staffed, managed, and organized, and details for submission of all reports/deliverables.

- Describe how work will be coordinated between functional areas (e.g., Animal study conduct).
- Describe how work will be coordinated between the contractor and proposed subcontractors.

(b) *Basis of Evaluation:* Each offeror will be evaluated on the extent to which the offeror demonstrates an understanding of the three (3) below areas.

(i) Project Approach: Appropriateness of the demonstrated understanding of how all aspects of the SOW and sample ROs per DTT Chemistry Specifications will be achieved, including identification of problems, solutions, alternative strategies, and benchmarks for success.

(ii) Overall Technical Approach: Appropriateness and feasibility of the demonstrated technical approach, including overall strategy, methodologies, analyses, technologies, and services, including those that are novel or innovative; technical capability in the conduct of scientific information management and literature-based evaluations; including all aspects of the work performed by contractor staff and any proposed subcontractors or consultants. Appropriateness of the demonstrated understanding of the information provided in the Sample Research Outlines (Attachment B).

(iii) Organizational Details: Appropriateness of organizational details, including how projects are staffed, managed, and organized, and details for the submission of deliverables, including all aspects of the work to be performed by contractor staff and any proposed subcontractors/consultants. Appropriateness of the proposed approach to coordinate work between functional areas and provide independence for peer reviews.

(4) Factor 4, Personnel:

(a) *Solicitation Submittal Requirements:* The offeror shall address the areas below. Tables summarizing personnel and years of experience are not limited.

(i) Professional/Key personnel

- For professional staff, provide a table of proposed staff that will work on the contract, including major roles/disciplines and qualifying criteria (e.g., years of experience, skill sets appropriate for the contract). All key personnel and shall be employees of the offeror.
- Provide a description (limited to 1 page for professional/key personnel; ½ page for other professional personnel) to be included in the proposal body. If professional/critical staff are committed to other Government-supported projects, include their time commitment to these projects.
- Provide a biographical sketch for all personnel (submit using Attachment D) with a Master's or Doctorate degree, or the equivalent in experience and/or responsibility. Include information to document relevant training, experience, scientific expertise, and competency including selected references for publications relevant to the scope of the SOW and Sample Research Outlines

(limited to 5 pages; see RFP), necessary for the successful completion of all contract requirements.

- Document specific duties on, and availability to the program.

(ii) Technical Personnel: Technical personnel job functions include all activities under Functional Areas in the DTT Chemistry Specifications. All job functions proposed by the offeror to support the SOW and sample ROs shall be described as outlined below.

- Provide a table of technical personnel that will work on the contract. Include major roles/discipline on the contract, highest degree, years of experience, proposed effort of (percent effort), and availability to the contract,
- Include information to document relevant training, experience, and competency necessary for the successful completion of all contract requirements; these should be separated by Functional Areas per DTT Chemistry Specifications.
- List additional technical personnel and total effort to the project by job function (e.g., analysts, animal care technicians, lab staff). Subcontractors/consultants shall be included and designated as such.
- Subcontractors/consultants shall be described similarly to contractor staff and designated as such.

(b) *Basis of Evaluation:* Each offeror will be evaluated on the extent to which the offeror demonstrates an understanding of the two (2) below areas.

(i) Professional/Key Personnel: Appropriateness of the demonstrated understanding of how all aspects of the SOW and sample ROs will be achieved, including identification of problems.

- *Logistics and Handling Functional Area Discipline Lead*; appropriateness of the education, training, and experience in the conduct and reporting of all Functional Activities under the Logistics and Handling Functional Area. Detailed requirements for chemistry Functional Activities are given in the DTT Chemistry Specifications Chapter 6.2. The Materials and Handling Discipline Lead shall also have experience managing a sample-handling program or facility and performing sample handling, including sample shipments of biological materials and biohazards, sample tracking, and handling of hazardous chemicals. This individual shall have a Master's or Bachelor's degree and any combination of graduate work and equivalent relevant experience, in a key scientific discipline applicable to the Program/Contract (e.g., chemistry, biology, and/or materials science)
- *Characterization Functional Area Discipline Lead*; appropriateness of the education, training, and experience in the design, conduct, data analysis and interpretation, and reporting of all Functional Activities under the Characterization Functional Area. Detailed requirements for chemistry Functional Activities are given in the DTT Chemistry Specifications Chapter 6.3. This individual shall have a Bachelor of Science degree in chemistry or a related science or any combination of years of experience in chemistry and full-time college-level study in the field totaling 4 years. This individual shall also have analytical chemistry experience, which includes trace analysis.
- *Formulation Functional Area Discipline Lead*; appropriateness of the education, training, and experience in the design, conduct, data analysis and interpretation, and reporting of all Functional Activities under the Formulation

Functional Area. Detailed requirements for chemistry Functional Activities are given in the DTT Chemistry Specifications Chapter 6.4. This individual shall have a Bachelor of Science degree in chemistry or a related science or any combination of years of experience in chemistry and full-time college-level study in the field totaling 4 years. This individual shall also have analytical experience related to formulation analysis and experience formulating test articles for toxicology studies.

- *Biosample Analysis Functional Area Discipline Lead*; appropriateness of the education, training, and experience in the design, conduct, data analysis and interpretation, and reporting of all Functional Activities under the Biosample Analysis Functional Area. Detailed requirements for chemistry Functional Activities are given in the DTT Chemistry Specifications Chapter 6.5. This individual shall have a Doctoral or a Master's degree with 5 year's of experience in bioanalytical chemistry especially with trace analysis of biological samples using state-of-the art analytical instrumentation.
- *Animal Studies Functional Area Discipline Lead;* appropriateness of the education, training, and experience in the design, conduct, data analysis and interpretation, and reporting of all Functional Activities under the Animal Studies Functional Area. Detailed requirements for chemistry Functional Activities are given in the DTT Chemistry Specifications Chapter 6.7. This individual shall have a Doctoral or a Master's degree experience in ADME and toxicokinetics or a related science totaling 5 years. The ADME/TK Discipline Lead shall also have experience designing, conducting time course (toxicokinetic or pharmacokinetic) studies, including analyzing and modeling and interpreting ADME and TK data.
- *OMICS Functional Area Discipline Lead;* appropriateness of the education, training, and experience in the design, conduct, data analysis and interpretation, and reporting of all Functional Activities under the OMICS Functional Area. Detailed requirements for chemistry Functional Activities are given in the DTT Chemistry Specifications Chapter 6.8. The individual shall have a Master's or any combination of graduate experience totaling 5 years of experience in a key scientific discipline (e.g., chemistry (environmental, analytical, or bioanalytical); significant experience in managing programs of comparable scope and size; experience performing metabolomics, proteomics, and/or exposomics analyses; and demonstrated ability to provide effective written and oral communication.
- *In Vitro Assays Functional Area Discipline Lead*; appropriateness of the education, training, and experience in the design, conduct, data analysis and interpretation, and reporting of all Functional Activities under the In Vitro Assays Functional Area. Detailed requirements for chemistry Functional Activities are given in the DTT Chemistry Specifications Chapter 6.9. The *In Vitro* Project Manager shall have a Master's or any combination of graduate experience in a key scientific discipline applicable to the conduct of assignments (e.g., chemistry, biochemistry, toxicology); significant experience in managing programs of comparable scope and size; experience conducting *in vitro* assays; and demonstrated ability to provide effective written and oral communication. Document the training and experience of the proposed Discipline Lead to conduct *in vitro* cell-based studies to determine in vitro intestinal and dermal absorption, hepatic metabolism and clearance, and bioaccumulation following repeated exposure.

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.

(ii) Technical Personnel: Appropriateness of the education, training, experience, and competency of the proposed technical personnel with the knowledge and ability to conduct chemistry activities under the Functional Areas given in DTT Chemistry specifications; effort on, and availability to projects; include those of any proposed subcontractors/consultants.

(5) Factor 5, Environment – Facilities, Equipment, and Security:

(a) *Solicitation Submittal Requirements*: The offeror shall address the areas below. The offeror shall submit a detailed plan (no page limit), addressing all areas below.

(i) Facilities

- Provide detailed facility floor plans and a description of all facilities relevant to technical conduct of work on the project. Include all disciplines relevant to the project (e.g., materials handling; chemical characterization, formulation, bioanalysis, ADME/TK) with clear labels as to the location of equipment and function/use of all rooms.
- Animal facility floor plans shall include airflow direction and corridor system/traffic flow for personnel as well as animals, equipment and supplies through all facilities proposed for use. Information on the air handling system and back-up generator and other pertinent features shall be included. Describe available space for the performance of work. Document compliance with all applicable Federal and state regulations and guidelines for all aspects of the project. Include the above for any proposed subcontractors/consultants.
- Describe the hazard containment facility(ies) (HCF) proposed for the safe and secure handling of hazardous materials, including biohazards. Provide detailed floor plans for the HCF that include air flows, designations of clean and dirty corridors/rooms as appropriate and shall indicate ingress and egress routes. Information on the HCF air handling system and back-up generator and other pertinent features shall be included. The availability of the HCF to the project shall be documented. See Government Furnished Materials Attachment F for additional storage and space requirements.
- Describe offeror's approach and procedures to provide adequate health and safety needed for the proposed program in accordance with the Health and Safety requirements found in the DTT Chemistry Specifications and per Sample Research Outlines 1-5.
    a. Document the adequacy of the proposed procedures for safe handling of chemicals, test articles, biological and environmental samples, including implementation of hazard containment procedures, including the potential chemical and biological hazards commencing from the receipt of a chemical, test article, and/or biological or environmental sample to the ultimate disposal of residual chemicals, test articles, and samples,

and handling and disposal of contaminated waste in general, and as related to the specific chemicals and requirements.

b. Demonstrate the adequacy of the proposed administrative controls, personal protective equipment (PPE), and work practices to protect contract staff.
c. Demonstrate the appropriateness of the procedures described for the operation of the proposed chemical containment, storage, and handling facility, including facility access policies and procedures.
d. Provide a Health and Safety Chemical Hygiene Plan (in an appendix).
e. Document location(s) of health and safety equipment.

(ii) Equipment and Physical Resources

- Provide equipment and physical resources available onsite for use in performance of the work outlined in the SOW. Demonstrate the ability to obtain any other necessary equipment as needed to fulfill the requirements of the SOW. Include for any proposed subcontractors/consultants as appropriate.
  a. Describe equipment and physical resources needed for each functional area of the SOW and DTT Chemistry Specifications per Sample Research Outline 1-5 including descriptions and locations, including those of any proposed subcontractors/consultants.
  b. Provide a table showing availability, storage capacity and location, of all controlled access ambient and sub-ambient storage systems, including but not limited to ambient storage rooms, refrigerators and cold rooms, sub-ambient freezers, and walk-ins (list -20ºC and < -70ºC storage separately) proposed.
  c. Provide a table showing location and availability of each instrument proposed for performance of the bioanalysis requirements of the project.
  d. Provide documentation of the capacity of the proposed instrumentation and equipment to develop up to four bioanalytical methods and analyze up to 120 samples for a single biological matrix, e.g., plasma, per method developed, per year.
  e. Provide documentation showing the AAALAC certification of the proposed animal facility.
  f. Document the appropriateness and adequacy of the proposed facilities for proper storage of small amounts (≤ 100 g) of large numbers (up to 10,000) of substances, including dietary supplements, drugs (including DEA Schedule 1-5 substances), and potentially toxic, reactive, and/or flammable chemicals.
  g. Indicate ambient and sub-ambient storage areas and equipment on the floor plans to be submitted with the proposal.
  h. Document the procedures to be used to ensure that instrumentation is available to perform assignments.
  i. Describe how conflicting demands on the use of specific equipment, instrumentation and/or facilities will be resolved. Address conflicts between assignments within the project and conflicts with the needs of other contracts and contract options.

(iii) Policies, Procedures, and Information Technology (IT) Processes

- Provide information to document policies and procedures surrounding data collection, management, and security.
- Provide a draft IT Security Plan for ensuring integrity and security of information. Include the draft plan as an appendix to this factor (not to exceed 50 pages).
- Document relevant training, experience, and competency of the proposed IT professional (as demonstrated in the biographical sketch- Attachment D) and support staff, including proposed specific duties and effort on the SOW and sample ROs.
- Include the above for of any proposed subcontractors/consultants as appropriate.

(b) *Basis of Evaluation*: Each offeror will be evaluated on the extent to which the offeror demonstrates an understanding of the three (3) below areas.

(i) Facilities: Appropriateness of facilities relevant to technical conduct of work all aspects of the project, including available capacity for the performance of work; include those of any proposed subcontractors/consultants.

(ii) Equipment, and Physical Resources: Appropriateness of equipment and physical resources for all aspects of the SOW and sample ROs, including descriptions and locations; include those of any proposed subcontractors/consultants.

(iii) Policies, Procedures, and IT Processes: Appropriateness of the proposed policies and procedures relating to security of data management, including compliance requirements; data security, storage, archiving, and transmission; and adequacy of the proposed IT security plan. Appropriateness of the training, experience, and competency of the proposed IT professional (as demonstrated in the biographical sketch- Attachment D) and support staff, including proposed specific duties and effort on the SOW and sample ROs; include those of any proposed subcontractors/consultants.

(6) Factor 6, Small Business Utilization

It is the policy of the Government to provide maximum practicable opportunities in its acquisitions to Small Business (SB) concerns, including Small Disadvantaged Business (SDB), Woman-Owned Small Business (WOSB), Historically Underutilized Business Zone Small Business (HUBZone SB), Veteran-Owned Small Business (VOSB), Service-Disabled Veteran-Owned Small Business (SDVOSB), and other small business concerns. Further, it is the policy of the Government that such concerns will have the maximum practicable opportunity to participate in contract performance consistent with its efficient performance.

This Factor assesses both the historical achievements in utilizing small business concerns and the proposed small business participation commitment for this requirement. The offeror is required to demonstrate its previous commitment to SBs through its record of past utilization of SBs and the level of commitment to small business if awarded a contract under this solicitation.

(a) *Solicitation Submittal Requirements:*

(i) **All** offerors (large, non-profits, **AND** small businesses) shall use **Attachment G** (Historical Small Business Utilization) to demonstrate their historical utilization of SBs. Each project submitted under **Factor 1, Experience**, shall be included on **Attachment G**. Failure to include each project submitted under **Factor 1, Experience**, on **Attachment G**, or the failure to fully complete **Attachment G** for each project may result in a deficiency. Only complete **Attachment G**. Information provided in a different format and/or on a form created by the offeror will not be evaluated. Attachments or addendums to **Attachment G** will not be evaluated. Offerors are permitted to expand portions of the form, as needed, to provide sufficient response. Instructions regarding how to complete **Attachment G** are included at the beginning of the attachment.

(ii) **All** offerors (large, non-profits, **AND** small businesses) shall use **Attachment H** (Small Business Participation Commitment Document (SBPCD) to submit the following required information for evaluation of this factor:

- To demonstrate commitment to use small business concerns in the performance of this contract, identify by name the subcontractors that will be used to support each small business category, including SDB, WOSB, HUBZone SB, VOSB, and SDVOSBs. Identify the type and complexity of product/service to be subcontracted, and the type of commitment (i.e., teaming agreement, joint venture agreement, mentor protégé agreement, letter of commitment, etc.) with each subcontractor.
    - If subcontractors are not identified by name, offerors shall provide a detailed explanation why subcontractors are not identified. If firm written commitments with SBs are not in place, offerors shall provide an explanation and rationale on the ability to achieve the proposed participation. (See **Attachment H**, paragraph 5)
    - If a LB offeror does not intend to subcontract, provide a **detailed explanation** why subcontracting would not result in efficient contract performance. SBs intending to 100% self-perform are not required to provide an explanation. (See **Attachment H**, paragraph 6)

- To demonstrate maximum practicable participation of small businesses, identify (**in terms of dollar value and <u>percentage of the total contract value</u>**) the offeror's proposed small business participation. The minimum required small business participation (i.e., work to be performed by small business as the prime contractor and/or work to be performed by small business subcontractors) is **5%**. Offerors who are not able to meet the minimum total small business participation requirement of **5%** (of the total contract value) shall provide a detailed explanation why the minimum total small business participation requirement cannot be achieved.

- Only complete **Attachment H**. Information provided in a different format and/or on a form created by the offeror will not be evaluated. Attachments or addendums to **Attachment H** will not be evaluated.

- Large business offerors may achieve the minimum total small business participation requirement through subcontracting to small businesses.

- Small business offerors may achieve the minimum total small business participation requirement through their own performance/participation as a prime as well as through a joint venture, teaming arrangement, and/or subcontracting with other small business concerns.

(b) *Basis of Evaluation:*

The Government will evaluate the likelihood of success in achieving the small business objectives of this acquisition based on the following:

(i) The extent to which the offeror is able to demonstrate a history of supporting Government policies concerning the utilization of small business concerns, including SDB, WOSB, HUBZone SB, VOSB, and SDVOSB and the success in achieving goals established by subcontracting plans on prior contracts. For projects submitted for **Factor 1 - Experience**, that did not have established small business goals, consideration will be given to the utilization of the small business concerns and the degree of usage of small business relative to the total contract value. Historical Small Business Utilization will only be evaluated if performed by the offeror.

(ii) The extent to which the offeror has demonstrated an achievable commitment to use small businesses, including SDB, WOSB, HUBZone SB, VOSB, and SDVOSB in the performance of this contract within the SBPCD.

- The minimum small business participation requirement, through work performed by the small business prime and/or subcontracting with small businesses, shall meet or exceed **5%** of the total contract value, unless the offeror provides a reasonable and well-documented explanation for why the minimum **5%** small business participation requirement cannot be achieved.
    - Offerors that demonstrate a commitment to providing maximum practical opportunity to small businesses may be rated higher.
    - Proposing less than **5%** total small business participation requirement may result in a deficiency.
    - Offerors that do not demonstrate commitment to providing maximum practical opportunity to small businesses may result in a deficiency.

- The SBPCD will be evaluated to determine the extent to which small business concerns are specifically identified by name and socioeconomic category in the document and the degree to which small business concerns, including SDB, WOSB, HUBZone SB, VOSB, and SDVOSB will participate relative to the total contract value. The complexity and variety of the work small business concerns will perform and the degree of commitment to use named sources through formal teaming agreements, joint venture agreements, mentor protégé agreements, written/signed letters of /commitment, etc. will be evaluated to assess achievability of the commitment.
    - The offeror may receive a deficiency if firm commitments with subcontractors are not provided and the offeror fails to provide a detailed explanation for how the proposed small business participation requirement will be achieved.

- The offeror may be rated lower, if they fail to provide a detailed explanation for why subcontracting would not result in efficient contract performance. (Not applicable to SBs intending to 100% self-perform or LBs and non-profits who intend to subcontract.)

(7) Factor 7, Past Performance:

(a) *Solicitation Submittal Requirements:* Submit a completed CPARS evaluation for each project submitted under Factor 1, Experience. If there is not a completed CPARS evaluation, the Past Performance Questionnaire (PPQ) included in the solicitation is provided for the offeror or its team members to submit to the client for each contract the offeror includes in its proposal for Factor 1 – Experience. AN OFFEROR SHALL NOT SUBMIT A PPQ WHEN A COMPLETED CPARS IS AVAILABLE.

IF A CPARS EVALUATION IS NOT AVAILABLE, ensure correct phone numbers and email addresses are provided for the client point of contact. Completed PPQs should be submitted with your proposal. If the offeror is unable to obtain a completed PPQ from a client for a project(s) before proposal closing date, the offeror should complete and submit with the proposal the first page of the PPQ (Attachment C), which will provide contract and client information for the respective contract(s). Offerors should follow-up with clients/references to ensure timely submittal of questionnaires. If the client requests, questionnaires may be submitted directly to the Government's point of contact, Sarah Bank, via email at sarah.bank@nih.gov prior to proposal closing date. Offerors shall not incorporate by reference into their proposal PPQs or CPARS previously submitted for other RFPs. However, this does not preclude the Government from utilizing previously submitted PPQ information in the past performance evaluation.

Also include performance recognition documents received within the last 5 (five) years such as awards, award fee determinations, customer letters of commendation, and any other forms of performance recognition. For performance recognition documents to be considered under this factor, they are required to be dated and contain the signature and position of the individual signing. Further, performance recognition documents solicited especially for the purposes of this factor may be considered less favorably than documents contemporaneously received for the work performed.

In addition to the above, the Government may review any other sources of information for evaluating past performance. Other sources may include, but are not limited to, past performance information retrieved through CPARS using all CAGE/UEI numbers of team members (partnership, joint venture, teaming arrangement, or parent company/subsidiary/affiliate) identified in the offeror’s proposal, inquiries of owner representative(s), Federal Awardee Performance and Integrity Information System (FAPIIS), Electronic Subcontract Reporting System (eSRS), and any other known sources not provided by the offeror.

While the Government may elect to consider data from other sources, the burden of providing detailed, current, accurate and complete past performance information rests with the offeror.

A copy of the blank Past Performance Questionnaire to be used for requesting client

references is included as Attachment C.

The definition of a recent. relevant project is a contract that has been completed in the past five (5) years with services similar to those described in the attached statement of work.

(b) *Basis of Evaluation:* The Government will evaluate how well the offeror performed on the recent and relevant contracts submitted under Factor 1 - Experience and on other recent and relevant contracts documented in known sources. There are three (3) aspects of the past performance evaluation: recency, relevancy, and quality. The first is to evaluate the recency of the offeror's past performance. The second aspect is to determine whether the offeror's performance is relevant or not relevant to the effort to be acquired. For purposes of this evaluation, a recent and relevant contract is a contract as defined in Factor 1 - Experience. The third aspect of the evaluation is to establish the overall quality of the offeror's past performance and how well the contractor performed on the contracts. The past performance evaluation performed in support of a current source selection does not establish, create, or change the existing record and history of the offeror's past performance on past contracts; rather, the past performance evaluation process gathers information from customers on how well the offeror performed those past contracts.

The Government will also evaluate the degree to which past performance evaluations and all other past performance information reviewed by the Government (e.g., CPARS, FAPIIS, eSRS, performance recognition documents, and information obtained from any other source) reflect a trend of satisfactory performance considering:

- A pattern of successful completion of tasks;
- A pattern of deliverables that are timely and of good quality;
- A pattern of cooperativeness and teamwork with the Government at all levels (task managers, contracting officers, auditors, etc.); and
- Recency of tasks performed that are identical to, similar to, or related to the task at hand.

In the case of offerors without a record of relevant past performance or for whom information on past performance is not available or so sparse that no meaningful past performance rating can be reasonable assigned, the offeror may not be evaluated favorably or unfavorably on past performance (see FAR 15.305(a)(2)(iv)), and will receive a Neutral Confidence Rating.

V. ATTACHMENTS

Attachment A – Experience Form
Attachment B – Sample Research Outlines
Attachment C – Past Performance Questionnaire (PPQ)
Attachment D- Biographical Sketch Form
Attachment E- NIEHS Level of Effort Worksheet
Attachment F- Government Furnished Materials

Attachment G – Historical Small Business Utilization
Attachment H – Small Business Participation Commitment

Experience Form

CORPORATE EXPERIENCE PROJECT DATA SHEET
Project No. (check one) : ☐ #1 ☐ #2 ☐ #3 ☐ ☐
1. Experience for: ☐ Offeror ☐ Joint-Venture ☐ Other (Explain) **Firm Name:** **Address:** **Phone Number:** **Point of Contact:** **Contact Phone Number:**
2. Work Performed as: ☐ Prime Contractor ☐ Sub Contractor ☐ Joint Venture ☐ **Other (Explain)** **Percent of project work performed:** **If subcontractor, who was prime (Name/Phone #):**
3. Contract Number: **Delivery/Task Order Number:** **Title:** **Location:**
4. Award Date (mm/dd/yy): **Completion Date (mm/dd/yy):**
5. Type of work: ☐ Professional Services ☐ Studies and Assessments ☐ Other (explain):
6. Type of Contract/Task Order: (Check ALL that apply) ☐ Firm-Fixed Price ☐ Cost Reimbursement ☐ Other (explain):
7. Award Amount including all modifications: **Final Price:** **Note: Award amount includes value at award and amount added/deducted by modification and final price/cost.**

8. Provide a detailed description of the project and the relevancy to the project requirements of this RFP
9. Provide a detailed description of what work your firm self-performed on this project:
10. Other Information:

Chemistry Research for the Division of Translational Toxicology (DTT)

Sample Research Outlines

Background

The following instructions and Sample Research Outline are in reference to the Request for Proposal for the Chemistry Support for the Division of Translational Toxicology. Each offeror shall submit the completed assignments and submit with their proposal for this effort.

Work for each Functional Activity performed shall comply with the relevant chapters of the DTT Chemistry Specifications and where applicable, with FDA GLP requirements (CFR Code of Federal Regulations Title 21). Refer to the Specifications for the Conduct of Studies to Toxicity Studies by the Division of Translational Toxicology at NIEHS (https://ntp.niehs.nih.gov/sites/default/files/ntp/test_info/toxspecs/dtt_specs_compiled_508.pdf as appropriate, for additional information on Toxicology Study Support.

List of Functional Activities and corresponding acronyms are given in Table 1.

1) ***Sample Research Outline 1 – Support for Toxicology Studies***

i) For each Activity (1A-1J) listed in Sample Research Outline 1, describe the procedure(s) you would follow in performing the work. Include a timeframe for completion of each Activity and for all Activities in each subsection taken together. Include discussion of the following items for each Activity and describe how each is addressed in your proposal.

(1) Anticipated problems unique to each Activity.

(2) Special considerations related to the availability of suitably pure chemical, physical/chemical properties of Allura Red AC (disodium 6-hydroxy-5-((2-methoxy-5-methyl-4-sulfophenyl)azo)-2-naphthalenesulfonate; CASRN: 25956-17-6; DTXSID4024436), and applicable regulations specific to Allura Red AC and/or azo-dyes as a compound class.

(3) Scheduling of Activities to complete work prior to the anticipated study start date, including the availability of staff and appropriate instrumentation.

(4) Scheduling sample receipt, sample handling, and analysis during the study, including the availability of staff and appropriate instrumentation to analyze the samples during the demonstrated period of stability.

(5) Reporting requirements applicable to Sample Research Outline 1, including report formats and timelines for each Activity.

2) ***Sample Research Outline 2 – Absorption, Distribution, Metabolism, Excretion (ADME) and Toxicokinetic (TK) Studies***

i) Include discussion of the following items for all activities needed to perform Sample Research Outline 2 (ADME and TK Studies) and describe how each is addressed in your proposal.

(1) Anticipated problems related to each activity.

(2) Specific concerns related to the physical/chemical properties of Allura Red AC.

(3) Scheduling of work to complete the assignment, including the availability of staff and appropriate instrumentation.

(4) Reporting requirements applicable to Sample Research Outline 2, including report formats and timelines for each Activity.

3) ***Sample Research Outline 3 – Omics***

a) Include discussion of the following items for each activity and describe how each is addressed in your proposal.

i) Anticipated problems related to each Omics activity.

ii) Special considerations related to the test article(s) and analysis to be performed.

iii) Scheduling of work to complete the assignment in the allotted time frame, including the availability of staff and appropriate instrumentation.

iv) Reporting requirements applicable to Sample Research Outline 3 (Omics), including report formats and timelines for each Activity.

4) ***Sample Research Outline 4 – In Vitro Assays***

a) Include discussion of the following items for each activity and describe how each is addressed in your proposal.

i) Anticipated problems related to each activity performed for an in vitro assay.

ii) Special considerations related to the assays and analysis to be performed.

iii) Scheduling of work to complete the assignment in the allotted time frame, including the availability of staff and appropriate instrumentation.

iv) Reporting requirements applicable to Sample Research Outline 4, including report formats and timelines for each Activity.

5) ***Sample Research Outline 5 – Support for Medium to High Throughput Toxicity Screening***

a) For each Functional Activity (5A-D) listed in Sample Research Outline 5, describe the procedure(s) you would follow in performing the work described. Include a timeframe for completion of each Activity and for all Activities taken together. Include discussion of the following and describe how each is addressed in your proposal.

i) Anticipated problems unique to each Activity.

ii) Considerations for chemicals in the set, including but not limited to, chemical/physical properties of the chemicals involved; applicable regulations, including Customs, DEA Schedule, and DOT requirements; and scheduling/timeline concerns, for each Activity.

iii) Applicable labelling requirements for racks and samples.

iv) Reporting requirements, including report formats and timelines for each Activity.

b) The sample chemical list applicable to Sample Research Outline 5 can be found in Table 2.

Sample Research Outlines

1. Sample Research Outline 1 – Support for Animal Toxicology Studies

a. *Introduction*

i. Sample Research Outline1 involves chemistry support services needed for a 90-day perinatal study of disodium 6-hydroxy-5-((2-methoxy-5-methyl-4-sulfophenyl)azo)-2-naphthalenesulfonate (Allura Red AC; CASRN: 25956-17-6; DTXSID4024436) to be conducted at a DTT-designated laboratory.

1) Study Design:

The study will be conducted at a DTT-designated toxicology contract laboratory. Timed-pregnant HSD:Sprague-Dawley®SD® (HSD) rats (assume body weights at the start of the study will be ~300 g) will be administered Allura Red in NTP-2000 diet or via corn oil gavage beginning on gestation day 6 (GD6) through weaning on postnatal day 28 (PND28) with terminal sacrifice on PND91. Dose concentrations in NTP-2000 will be 0, 200, 600, 1,800, 5,000, and 15,000 ppm with 5 dams per dose group. Gavage doses will be 0, 10, 33, 100, 333, and 1,000 mg/kg body weight with 5 dams per dose group and a dose volume of 5 mL/kg body weight. Biosamples will be collected on ice from controls and all dose groups at GD18, PND4, and PND28, stored at -70ºC, and shipped to the chemistry support contractor for later analysis. Whole blood will be collected into K_3EDTA treated tubes and separated into plasma. A minimum of 5, 100-µL aliquots of maternal and pup plasma will be collected from each animal at each time point. Fetuses will be pooled by dam for each dose group. All samples will be stored at -70ºC and shipped to the chemistry contractor on dry ice. Samples collected at each time point are as follows:

GD18: Dam plasma and fetus (n=30)

PND4: Maternal plasma (n=30); pup plasma (n=30/sex)

PND28: Pup plasma (n=30/sex)

ii. Activities anticipated for Sample Research Outline 1 refer to the requirements found in Chapter 6.2 Logistics and Handling, 6.3 Characterization, 6.4 Formulation, and 6.5 Biosample Analysis in the DTT Chemistry Specifications.

b. Pre-Study

i. Activity 1A: Chemical Procurement (CP)

1) Source suppliers for 5 kg of Allura Red with a minimum purity of 98%. If no supplier meets minimum purity requirements, recommend the best available supplier based on cost, purity, and availability.

2) Procure 5 kg of Allura Red from the recommended supplier.

ii. Activity 1B: Chemical Handling (CH)

1) Homogenize and repackage the appropriate containers upon receipt.

iii. Activity 1C: Comprehensive Chemical Analysis (CCA)

1) Unambiguously identify the received material as Allura Red and determine the purity of the chemical.

2) Determine physical properties of the chemical.

3) Determine the stability of the chemical.

iv. Activity 1D: Vehicle Analysis (VA)

1) Select and qualify a suitable vehicle for use in dose formulations of Allura Red according to the requirements set forth in the DTT Chemistry Specifications.

v. Activity 1D: Formulation Development (FD)

1) Develop and validate methods for the quantitation of Allura Red and determine homogeneity, storage stability, and stability under conditions of dosing for Allura Red in each study vehicle according to the requirements set forth in the DTT Chemistry Specifications.

vi. Activity 1E: Biosample Method Development (BMD)

1) Develop and validate methods for the quantitation of Allura Red and/or anticipated major metabolite in the matrices specified in the study design at the lowest level of quantitation achievable (LLOQ) (e.g., LLOQ) of ≤ 1 ng/mL in blood or plasma).

2) Determine stability of Allura Red and anticipated major metabolite in study matrices during analysis and storage stability for 60 days according to the DTT Chemistry Specifications.

vii. Activity 1F: Protocol Development (PD)

1) Develop mixing and analysis protocols for Allura Red as required by the DTT Chemistry Specifications.

2) Develop analytical standard operating procedures (SOP) for chemical reanalysis and dose analysis of Allura Red.

c. In-Study

i. Activity 1G: Chemical Reanalysis (CRA)

1) Perform a chemical reanalysis of Allura Red prior to shipment, within 30 days of the start of the study and during the study in accordance with the Specifications for the Conduct of Toxicity Studies by the Division of Translational Toxicology at NIEHS (https://ntp.niehs.nih.gov/sites/default/files/ntp/test_info/toxspecs/dtt_specs_compiled_508.pdf).

ii. Activity 1H: Formulation Preparation, Analysis, and Shipping (FPAS)

1) Prepare gavage formulations of Allura Red in corn oil 2 L batches at the doses described above, following the mixing protocol developed in Assignment 1E. Dispense formulations and archive samples into appropriate dosing containers prior to shipment in accordance with the Specifications for the Conduct of Toxicity Studies by the Division of Translational Toxicology at NIEHS (https://ntp.niehs.nih.gov/sites/default/files/ntp/test_info/toxspecs/dtt_specs_compiled_508.pdf).

2) Analyze all doses of the formulations prepared above using the formulation analysis protocol developed in Assignment 1E. Describe procedures you would follow in the event of out-of-specification dose concentrations and reporting of interim results.

3) Package and ship the prepared formulations to a DTT Contract Laboratory designated by the COR (Study Lab, see below). The dose formulations must arrive at the designated laboratory within seven days of the mix date.

a) Study Lab
Battelle Memorial Institute

505 King Avenue Columbus, OH 43201-2696

iii. Activity 1I. Biosample Analysis (BSA)

1) Analyze plasma and fetus samples specified in the Study Design to be received from the Study Lab after GD18, PND4, and PND28, using the validated method developed for Allura Red and anticipated major metabolite.

d. Post-Study

i. Activity 1J: Chemical Storage (CS)

ii. Receive surplus chemical from the Study Lab and process according to the requirements of the DTT Chemistry Specifications.

2. Sample Research Outline 2 –ADME and TK Studies

a. Introduction

i. This assignment involves the evaluation of the toxicokinetics and ADME of disodium 6-hydroxy-5-((2-methoxy-5-methyl-4-sulfophenyl)azo)-2-naphthalenesulfonate (Allura Red AC; CASRN: 25956-17-6; DTXSID4024436) administered via intravenous (IV) and oral routes to Hsd:Sprague Dawley® SD® (HSD) rats and B6C3F1 mice. The assignment includes A) toxicokinetic studies, the analysis of plasma samples resulting from these studies, TK modeling, and interpretation and reporting of the data and B) ADME studies, the analysis of blood, excreta, and tissues resulting from these studies, data analysis, and interpretation and reporting of data. The following sections describe a sample study protocol that would be provided to the Contractor by the COR for conduct of these studies.

ii. The Contractor shall use this information to develop a working study protocol, which shall be submitted to the COR for signature approval, prior to the commencement of work on this assignment.

iii. The Contractor's IACUC shall review and approve the study protocol and a copy of the approved IACUC protocol shall be provided.

iv. The Contractor shall comply with the animal care and use requirements in the DTT Chemistry Specifications.

v. Activities anticipated for Sample Research Outline 2 refer to the requirements found in Chapters 6.2 through 6.7 in the DTT Chemistry Specifications.

b. Objectives

i. Determine plasma toxicokinetic parameters of Allura Red (non-radiolabeled) and anticipated major metabolite in male and female HSD rats and B6C3F1 mice following a single oral gavage and IV administration.

ii. Determine plasma toxicokinetic parameters of Allura Red and anticipated major metabolite in male and female HSD rats and B6C3F1 mice following 7-day repeat administration of Allura Red (non-radiolabelled) in NTP 2000 diet.

iii. Determination of ADME parameters of 14C-labelled Allura Red ([^{14}C]Allura Red) in male and female HSD rats following a single gavage administration.

c. Test Article

i. Allura Red (disodium 6-hydroxy-5-((2-methoxy-5-methyl-4-sulfophenyl)azo)-2-naphthalenesulfonate (CASRN: 25956-17-6; DTXSID4024436))

1) Test article shall be procured, characterized, and purity determined by the Contractor according to the requirements of the DTT Chemistry Specifications. Purity of the chemical shall be ≥ 98%.

2) Formulation

a) The Contractor shall develop and validate methods to formulate and analyze test article in vehicle(s) suitable for administration in animals.

3) Biosample analysis

a) The Contractor shall develop and validate a bioanalytical method for quantitation of test article concentration in plasma. Pooled control plasma from male and female rats shall be used to construct standard curves if no species differences are noted in the blank plasma.

ii. [^{14}C]Allura Red

1) Test article shall be procured, characterized, and radiolabel purity determined by the contractor according to the requirements of the DTT Chemistry Specifications. Radiolabel purity of the chemical shall be ≥ 95%.

2) Formulation

a) The contractor shall develop a method to formulate radiolabeled and unlabeled test articles at the desired concentrations and determine the concentration using appropriate method(s) for administration in animals.

3) Biosample Analysis

a) The Contractor shall develop and/or utilize appropriate method(s) to determine total radioactivity in blood, plasma, tissues, and excreta to determine disposition and mass balance.

b) The Contractor shall utilize suitable method(s) to profile plasma and urine and identify 5 most abundant test-article specific metabolites.

d. Animals

i. Male and female HSD rats and B6C3F1 mice shall be procured by the Contractor from a NIEHS-approved Harlan Laboratory. Prior to study start animals shall be quarantined for a minimum of 7 days to a maximum of 14 days after arrival at the study site under conditions simulating those in the test situation. Animals shall be 10-12 weeks old at the time of dosing. NTP-2000 diet (Zeigler Bros. Inc.; Gardners, PA) and municipal water shall be provided ad libitum throughout the experiment and shall comply with DTT Toxicology Specifications regarding contaminant levels.

e. Study Design, Sample Collection and Analysis: TK Study (TKS)

i. General information

1) Blood shall be collected with K_3EDTA as an anticoagulant. After collection, blood shall be put on ice until separated into plasma. Plasma shall be stored at or below -70°C, as identified in preliminary studies, until analysis. Test article concentration in plasma shall be quantified using the analytical method validated above. Pooled control plasma from male and female rats shall be used to construct standard curves if no species differences are noted in the blank plasma. The tabulated results from the preliminary study shall be sent to the COR via DTT PMS upon completion of analyses. The COR shall determine whether the subsequent studies is to be performed or not after reviewing the preliminary study results.

2) Preliminary studies using limited dose groups and animals shall be conducted to determine the feasibility and/or timepoints for sample collection in subsequent studies.

3) Single administration studies:

a) Rat studies: Groups of male and female rats shall be dosed IV at 0.3 mg/kg bwt. Groups of male and female rats shall be dosed via oral gavage at three dose concentrations (0.03, 0.3, and 3.0 mg/kg). Blood samples shall be taken at a minimum of 8 time points after administration with 3 animals bled at each time point. In each case the number of animal groups required and the exact time points for blood collection shall be decided based on preliminary study results. When feasible, each rat can be sampled more than once.

b) Mouse studies: Groups of male and female mice shall be dosed IV at 0.3 mg/kg bwt. Groups of male and female mice shall be dosed via oral gavage at three dose concentrations (0.03, 0.3, and 3.0 mg/kg bwt). Blood samples shall be taken at a minimum of 8 time points after administration with 3 animals bled per time point. In each case the number of animal groups required and the exact time points for blood collection shall be decided based on the preliminary study results.

4) 7-Day Repeated Dose Study

a) Definitive 7-Day Rat studies: Groups of male and female rats shall be dosed via feed for seven days at three exposure concentrations (0.3, 3.0, and 30 ppm). Blood samples shall be taken every 3 hours for a 24-hour period beginning at 7:00 AM the morning of Day 8 with 3 animals bled at each time point. When feasible, each rat can be sampled more than once.

b) Definitive 7-Day Mouse studies: Groups of male and female mice shall be dosed via feed for seven days at three dose concentrations (0.3, 3, 30 ppm). Blood samples shall be taken every 3 hours for a 24-hour period beginning at 7:00 AM the morning of Day 8 with 3 animals bled at each time point.

f. Study Design, Sample Collection and Analysis: ADME Study (ADMES)

i. General information

1) SOPs pertaining to the analysis of formulation and biological samples shall be enclosed with the study protocol. Blood shall be collected with K_3EDTA as an anticoagulant. All samples shall be stored as appropriate following collection. All samples to determine ADME, including mass balance, shall be analyzed using appropriate methods. The tabulated results shall be sent to the COR via DTT PMS upon completion of analyses.

ii. Single administration studies

1) Groups of male and female rats shall be administered a single gavage dose at three dose concentrations (0.03, 0.3, and 3.0 mg/kg). Excreta (urine, feces, exhaled volatile organics and CO_2) shall be collected up to 72 at predetermined time intervals. Blood and tissues shall be collected at the study termination.

g. Data Analyses

1) TKS

a) All measurements shall be reported as mean ± standard deviation. Other descriptive statistics shall be calculated as needed per direction of the COR. The Contractor shall evaluate the plasma time data for each single administration and repeated dose study using compartmental (when appropriate) and non-compartmental toxicokinetic models and report data using the best fitting model.

2) ADMES

a) All measurements shall be reported as mean ± standard deviation. Other descriptive statistics shall be calculated as needed per direction of the COR.

b) Mass balance tables containing recovery in excreta and tissues, and total administered dose recovered shall be generated.

c) Proposed metabolic pathway of Allura Red shall be included.

3. Sample Research Outline 3 – Omics (OMICS)

a. Introduction

i. Omics activities may involve all or parts of any Functional Activity described in Chapter 6.8 (Omics) of the DTT Chemistry Specifications, and where applicable, with FDA GLP requirements.

ii. This assignment includes analysis of Yohimbe bark extract (CASRN 85117-22-2) and samples from HSD male rats following oral administration of Yohimbe bark extract (CASRN 85117-22-2) for 7 days. The contractor shall assume that the animal study from which samples were obtained was conducted elsewhere.

b. Activities

i. Exposomics

1) The Contractor shall utilize appropriate analytical approaches (e.g., nontargeted analysis using mass spectrometry techniques) to identify absorbed constituents and their metabolites in serum and urine of male rats following exposure to Yohimbe bark extract.

2) The Contractor may utilize data from the analysis of Yohimbe bark extract to aid in this identification.

3) The Contractor shall quantitate up to 10 major constituents and/or their metabolites using suitable approaches.

ii. Metabolomics

1) The Contractor shall analyze serum samples to:

a) Identify patterns of behavior of the endogenous metabolome due to exposure compared to corresponding controls using appropriate analytical approaches and data mining (e.g., metabolomics workflow)

b) Identify whether the endogenous metabolome is up or downregulated due to exposure to Yohimbe bark extract with a significance value $p < 0.1$ compared to the control group using state-of-the art approaches (e.g., high-resolution mass spectrometry).

2) The Contractor shall quantitate up to 10 major endogenous metabolites upregulated and up to 10 major endogenous metabolites downregulated due to chemical exposure using applicable techniques and approaches.

iii. Proteomics

1) The Contractor shall analyze serum samples to identify the changes in proteome (e.g., globulins) due to exposure to Yohimbe bark extract.

2) The Contractor shall analyze serum samples to identify the modification of serum albumin by Yohimbe-specific reactive metabolites (e.g., protein adducts of reactive metabolites).

4. <u>Sample Research Outline 4 – In Vitro Assays (IVA)</u>

a. Introduction

i. In Vitro Assays may involve all or parts of any Functional Activity described in Chapter 6.9 (In Vitro Assays) of the DTT Chemistry Specifications.

ii. This assignment involves the evaluation of ADME properties of disodium 6-hydroxy-5-((2-methoxy-5-methyl-4-sulfophenyl)azo)-2-naphthalenesulfonate (Allura Red; CASRN: 25956-17-6; DTXSID4024436)) in vitro in rat and human models.

iii. The Contractor may utilize commercially or other available assays/models to conduct the work.

iv. The Contractor may utilize suitable analytical approaches to analyze samples.

v. Include discussion of the following items for each activity and describe how each is addressed in your proposal.

b. Activities

i. Absorption

1) The Contractor shall utilize appropriate assays and/or models to determine intestinal and dermal absorption of Allura Red.

2) The Contractor shall utilize appropriate assays to determine transporters responsible for absorption.

ii. Clearance and metabolism

1) The Contractor shall utilize appropriate assays and/or models to determine hepatic clearance of Allura red.

2) The Contractor shall utilize appropriate assays to determine hepatic metabolism of Allura Red.

3) The Contractor shall utilize appropriate analysis methods from the literature or develop methods as needed for sample analysis.

iii. Bioaccumulation

1) The Contractor shall utilize appropriate assays and/or models to determine bioaccumulation of Allura Red following repeated exposure.

iv. The Contractor shall utilize appropriate analysis methods from the literature or develop methods as needed for sample analysis.

5. <u>Sample Research Outline 5 – Support for Medium to High Throughput Toxicity Screening</u>

a. Introduction

i. All work performed under this assignment shall comply with the relevant sections of the DTT Chemistry Specifications and, where applicable, with FDA GLP requirements.

1) Activities anticipated for Sample Research Outline 5 refer to the requirements found in Chapters 6.2 Logistics and Handling and 6.3 Characterization of the DTT Chemistry Specifications, as applicable to Sample Research Outline 5—support for medium to high throughput toxicity screening (MHTS).

ii. Sample Research Outline 5 includes the multiple chemical procurement (MCP), multiple chemical handling (MCH), multiple chemical identification and purity screening (MIPS) and shipping (SHIP) of a set of 90 chemicals (Table 2) required to complete a 96-tube rack that would be sent to 3 research facilities.

1) Assume that the plate will require the procurement of all 90 test articles referenced above.

2) Chemical handling activities (Assignment 5B, below) shall apply to all 90 chemicals in the set referenced above.

3) Identity and purity determination will be required for all 90 chemicals in the set referenced above.

iii. Assume that all 90 chemicals will need to be added to the MHTS Chemical Inventory.

b. Assignment 5A: Multiple Chemical Procurement (MCP)

i. Source 10 g of each chemical in the set and recommend an optimal source and/or quantity for each chemical, based on availability, vendor past performance, and cost.

ii. Procure 10 g (or recommended quantity) of each chemical from the recommended source, and complete receiving as required by the DTT Chemistry Specifications.

c. Assignment 5B: Multiple Chemical Handling (MCH)

i. Homogenize chemicals received in multiple containers.

ii. Enter all chemicals into the MHTS Inventory with appropriate metadata.

iii. Curate inventory entries such that all information entered for each chemical is correct, including, identifying numbers (e.g., CASRN, DTXSID, etc.), and chemical names and synonyms. Determine the solubility of each chemical up to 100 mM in DMSO.

iv. Prepare 50-mL solutions of each chemical in DMSO. The specified solution concentration is 20 mM or maximum soluble concentration if below 20 mM. Recommend suitable replacement chemicals for any chemicals found to be insoluble at or above 1 mM.

v. Dispense test article solutions into 96-tube racks. Assume amount to be dispensed is the maximum working volume for a Micronic 96-Q1 tube rack. For this assignment assume that 5 duplicate racks are to be produced.

d. Assignment 5C: Multiple Chemical Identity and Purity Screen (MIPS)

i. Determine the identity and purity of each of the 90 chemicals in the set.

e. Assignment 5D: Shipping (SHIP)

i. Ship one rack of this 90-chemical set, along with 50 mL of DMSO, to each of the following research facilities.

1) University of Oregon
Sinnhuber Aquatic Research Laboratory
Oregon State University
28645 East Highway 34
Corvallis, OR 97333

2) ZeClinics
IGTP Edifici Muntanya,
Carretera de Can Ruti, Camí de les Escoles s/n; Lab P-08
08916 Badalona (Barcelona), Spain

3) Health Canada

Aquatic and Crop Resource Development

National Research Council Canada

1411 Oxford Street | Halifax, Nova Scotia | B3H 3Z1

Table1. Functional Areas and Functional Activities and acronyms

Functional Area and Functional Activities	Functional Activity Acronym
Logistics and Handling – Chapter 6.2 DTT Chemistry Specifications	
Chemical Handling	CH
Chemical Procurement	CP
Chemical Storage	CS
Shipment	SHIP
Protocols Development	PD
Multiple Chemical Handling	MCH
Multiple Chemical Procurement	MCP
Characterization – Chapter 6.3 DTT Chemistry Specifications	
Comprehensive Chemical Analysis	CCA
Chemical Identity and Purity Screen	CIPS
Chemical Reanalysis	CRA
Multiple Chemical Identity and Purity	MIPS
Formulation – Chapter 6.4 DTT Chemistry Specifications	
Preliminary Formulation Studies	PFS
Formulation Analysis	FA
Formulation Development	FD
Formulation Preparation, Analysis, and Shipment	FPAS
Vehicle Analysis	VA
Biosample Analysis – Chapter 6.5 DTT Chemistry Specifications	
Biosample Method Development	BMD
Biosample Analysis	BSA
Special Studies – Chapter 6.6 DTT Chemistry Specifications	
Special Chemical Activity	SCA
Animal Studies – Chapter 6.7 DTT Chemistry Specifications	
Toxicokinetic Study	TKS
Absorption, Distribution, Metabolism, and Distribution Study	ADMES
Omics – Chapter 6.8 DTT Chemistry Specifications	
Omics Studies	OMICS
In Vitro Assays – Chapter 6.9 DTT Chemistry Specifications	
In Vitro Assays	IVA

Table 2. **Chemical List for Sample Research Outline 5 (Support for Medium to High Throughput Screening)**

Chemical Name	DTXSID	CAS Number	Molecular Wt. (g/mol)	Molecular Formula	Target Conc (mM)	Plate Volume (µL)[1]
Cyclohexanol, 4-(1,1-dimethylethyl)-	DTXSID5026623	98-52-2	156.2652	$C_{10}H_{20}O$	20.0	
3,4'-Dichloro-2-methylacrylanilide	DTXSID2020424	2164-09-2	230.0906	$C_{10}H_9Cl_2NO$	20.0	
Hexanoic acid	DTXSID7021607	142-62-1	116.1583	$C_6H_{12}O_2$	20.0	
2,7-Acetylaminofluorene	DTXSID9021479	304-28-9	280.3211	$C_{17}H_{16}N_2O_2$	20.0	
Di-n-pentylphthalate	DTXSID5031131	131-18-0	306.3966	$C_{18}H_{26}O_4$	20.0	
Isophorone diisocyanate	DTXSID0023826	4098-71-9	222.2835	$C_{12}H_{18}N_2O_2$	20.0	
2-Aminoanthraquinone	DTXSID6020068	117-79-3	223.2268	$C_{14}H_9NO_2$	20.0	
2,4-Dichloroaniline	DTXSID1024966	554-00-7	162.0166	$C_6H_5Cl_2N$	20.0	
3,4-Dimethyl phenol	DTXSID4024062	95-65-8	122.1644	$C_8H_{10}O$	20.0	
p-Xylenol blue	DTXSID8026303	125-31-5	410.4828	$C_{23}H_{22}O_5S$	20.0	
Dimethyldisulfide	DTXSID4025117	624-92-0	94.199	$C_2H_6S_2$	20.0	
Acrylamide	DTXSID5020027	79-06-1	71.0779	C_3H_5NO	20.0	
Melatonin	DTXSID1022421	73-31-4	232.2783	$C_{13}H_{16}N_2O_2$	20.0	
4-Nonylphenol, branched	DTXSID5029055	84852-15-3	220.3505	$C_{15}H_{24}O$	20.0	
Phenol, 2,2'-methylenebis[6-(1,1-dimethylethyl)-4-methyl-	DTXSID4020870	119-47-1	340.499	$C_{23}H_{32}O_2$	20.0	
Bifenthrin	DTXSID9020160	82657-04-3	422.8678	$C_{23}H_{22}ClF_3O_2$	20.0	
Fenpropathrin	DTXSID0024002	39515-41-8	349.4229	$C_{22}H_{23}NO_3$	20.0	
3-Sulfolene	DTXSID6021294	77-79-2	118.1542	$C_4H_6O_2S$	20.0	
4-ethylphenol	DTXSID4021977	123-07-9	122.1644	$C_8H_{10}O$	20.0	
Dimethyl methylphosphonate	DTXSID0020494	756-79-6	124.0755	$C_3H_9O_3P$	20.0	
2-Ethyl 2-methyl-2-propenoate	DTXSID3027293	688-84-6	198.3019	$C_{12}H_{22}O_2$	20.0	
2,4,5-Trichlorophenoxyacetic acid	DTXSID5021388	93-76-5	255.4825	$C_8H_5Cl_3O_3$	20.0	
Methenamine	DTXSID6020692	100-97-0	140.1863	$C_6H_{12}N_4$	20.0	
Trichlorfon	DTXSID0021389	52-68-6	257.4367	$C_4H_8Cl_3O_4P$	20.0	
Dimethyl malonate	DTXSID4029145	108-59-8	132.1146	$C_5H_8O_4$	20.0	
(4-Chloro-6-(2,3-xylidino)-2-pyrimidinylthio) acetic acid (WY-14643)	DTXSID4020290	50892-23-4	323.7979	$C_{14}H_{14}ClN_3O_2S$	20.0	
5-Aminosalicylic acid	DTXSID5024506	89-57-6	153.1354	$C_7H_7NO_3$	20.0	
N-Phenylbenzenamine	DTXSID4021975	122-39-4	169.2224	$C_{12}H_{11}N$	20.0	

Tolbutamide	DTXSID8021359	64-77-7	270.3479	$C_{12}H_{18}N_2O_3S$	20.0	
3,4-Dichloronitrobenzene	DTXSID8024999	99-54-7	191.9995	$C_6H_3Cl_2NO_2$	20.0	
Sodium dodecyl sulfate	DTXSID1026031	151-21-3	288.3793	$C_{12}H_{25}NaO_4S$	20.0	
Anise Oil	DTXSID3024528	8007-70-3	148.21	Not applicable	20.0	
Diethylene glycol	DTXSID8020462	111-46-6	106.1204	$C_4H_{10}O_3$	20.0	
Dichlorvos (Vapona)	DTXSID5020449	62-73-7	220.9757	$C_4H_7Cl_2O_4P$	20.0	
1,2-Dimethyl-5-nitroimidazole	DTXSID5020497	551-92-8	141.128	$C_5H_7N_3O_2$	20.0	
Cyanazine	DTXSID1023990	21725-46-2	240.6927	$C_9H_{13}ClN_6$	20.0	
Sodium benzenethiolate	DTXSID1027342	930-69-8	132.1587	C_6H_5NaS	20.0	
Sodium thiocyanate	DTXSID4021343	540-72-7	81.0722	CNNaS	20.0	
Bis(2-ethylhexyl) phosphate	DTXSID1027134	298-07-7	322.4205	$C_{16}H_{35}O_4P$	20.0	
3-Ethylphenol	DTXSID0022480	620-17-7	122.1644	$C_8H_{10}O$	20.0	
6-Phenyl-1,3,5-Triazine-2,4-diamine	DTXSID1020142	91-76-9	187.2013	$C_9H_9N_5$	20.0	
2-Octanol	DTXSID0027014	123-96-6	130.2279	$C_8H_{18}O$	20.0	
Benzotrifluoride	DTXSID2024589	98-08-8	146.11	$C_6H_5CF_3$	20.0	
1,1,1-Trimethoxy-ethane	DTXSID8027400	1445-45-0	120.147	$C_5H_{12}O_3$	20.0	
Orthanilic acid	DTXSID1024463	88-21-1	173.1897	$C_6H_7NO_3S$	20.0	
Chloroacetonitrile	DTXSID7021524	107-14-2	75.497	C_2H_2ClN	20.0	
1-Methyl-3-phenoxybenzene	DTXSID8027537	3586-14-9	184.2338	$C_{13}H_{12}O$	20.0	
2-Biphenylamine	DTXSID3030189	90-41-5	169.2224	$C_{12}H_{11}N$	20.0	
Pyridine	DTXSID9021924	110-86-1	79.0999	C_5H_5N	20.0	
2,2'-Thiobis(4-chlorophenol)	DTXSID4026137	97-24-5	287.1617	$C_{12}H_8Cl_2O_2S$	20.0	
p-Synephrine	DTXSID0030588	94-07-5	167.205	$C_9H_{13}NO_2$	20.0	
Dehydroepiandrosterone 3-acetate	DTXSID3020380	853-23-6	330.4611	$C_{21}H_{30}O_3$	20.0	
Diethylene glycol dibutyl ether	DTXSID8025046	112-73-2	218.333	$C_{12}H_{26}O_3$	20.0	
1,3-Dichloro-2-butene	DTXSID7027338	926-57-8	124.9964	$C_4H_6Cl_2$	20.0	
4-Chloro-3,5-dinitro-a,a,a-trifluorotoluene	DTXSID8024781	393-75-9	270.55	$C_7H_2ClF_3N_2O_4$	20.0	
Ribavirin	DTXSID8023557	36791-04-5	244.2047	$C_8H_{12}N_4O_5$	20.0	
6-Amino-1,3-dimethyl-5-nitrosouracil	DTXSID8029280	6632-68-4	184.1527	$C_6H_8N_4O_3$	20.0	
p-Bromotoluene	DTXSID7024661	106-38-7	171.0345	C_7H_7Br	20.0	
1,2-Dibromo-4-(1,2-dibromoethyl)cyclohexane	DTXSID8024947	3322-93-8	427.7969	$C_8H_{12}Br_4$	20.0	
1,4-Dioxane	DTXSID4020533	123-91-1	88.1051	$C_4H_8O_2$	20.0	
Chlorothiazide	DTXSID0022800	58-94-6	295.7232	$C_7H_6ClN_3O_4S_2$	20.0	
4,4'-Thiodiphenol	DTXSID9047960	2664-63-3	230.3669	$C_{12}H_{22}O_2S$	20.0	

4-Hydroxy-4'-chlorobenzophenone	DTXSID4047961	42019-78-3	232.6624	$C_{13}H_9ClO_2$	20.0	
Isobutyl alcohol	DTXSID0021759	78-83-1	74.1216	$C_4H_{10}O$	20.0	
2-Oxobutanedioic acid	DTXSID8021646	328-42-7	132.0716	$C_4H_4O_5$	20.0	
(Tetrapropenyl)succinic anhydride	DTXSID8027905	26544-38-7	266.3758	$C_{16}H_{26}O_3$	20.0	
2,4-Dichlorobenzaldehyde	DTXSID1022130	874-42-0	175.0121	$C_7H_4Cl_2O$	20.0	
2,3-Butanedione	DTXSID6021583	431-03-8	86.0892	$C4H_6O_2$	20.0	
1,4-Diacetylbenzene	DTXSID7021657	1009-61-6	162.1852	$C_{10}H_{10}O_2$	20.0	
Dibenzoyl-L-tartaric acid	DTXSID6033401	2743-38-6	358.299	$C_{18}H_{14}O_8$	20.0	
1-methoxy-4-methyl-2-nitrobenzene	DTXSID3029152	119-10-8	167.162	$C_8H_9NO_3$	20.0	
1,1,1-Trichloropropanone	DTXSID5021679	918-00-3	161.4143	$C_3H_3Cl_3O$	20.0	
Chlorobenzene	DTXSID4020298	108-90-7	112.5569	C_6H_5Cl	20.0	
Toluene	DTXSID7021360	108-88-3	92.1384	C_7H_8	20.0	
S-Ethy chlorothioformic acid	DTXSID6025278	2941-64-2	124.5892	C_3H_5ClOS	20.0	
Nitazoxanide	DTXSID5033757	55981-09-4	307.282	$C_{12}H_9N_3O_5S$	20.0	
3-Chloropivaloyl chloride	DTXSID0027567	4300-97-4	154.01	$C_5H_8Cl_2O$	20.0	
2-Methyl-3-nitrobenzoic acid	DTXSID7025637	1975-50-4	181.1455	$C_8H_7NO_4$	20.0	
4-Hydroxybenzophenone	DTXSID5036684	1137-42-4	198.2173	$C_{13}H_{10}O_2$	20.0	
2,4-Dimethoxyaniline hydrochloride	DTXSID1020483	54150-69-5	189.6394	$C_8H_{12}ClNO_2$	20.0	
6-Azacytidine	DTXSID4020117	3131-60-0	244.2047	$C_8H_{12}N_4O_5$	20.0	
Hydroxypropyl methacrylate	DTXSID5027936	27813-02-1	144.1684	$C_7H_{12}O_3$	20.0	
1-Ethyl-3-methylimidazolium methanesulfonate	DTXSID7049219	145022-45-3	206.26	$C_7H_{14}N_2O_3S$	20.0	
1-Hexyl-3-methylimidazolium tetrafluoroborate	DTXSID8049252	244193-50-8	254.08	$C_{10}H_{19}BF_4N_2$	20.0	
1-Butyl-1-methylpyrrolidinium tetrafluoroborate	DTXSID6049276	345984-11-4	229.07	$C_9H_{20}BF_4N$	20.0	
1-Ethylpyridinium tetrafluoroborate	DTXSID1049279	350-48-1	194.97	$C_7H_{10}BF_4N$	20.0	
N-Phenyl-1-naphthylamine	DTXSID2025892	90-30-2	219.2811	$C_{16}H_{13}N$	20.0	
7-Diethylamino-4-methylcoumarin	DTXSID9025035	91-44-1	231.2903	$C_{14}H_{17}NO_2$	20.0	
4-Chloro-1,2-diaminobenzene	DTXSID5020283	95-83-0	142.5862	$C_6H_7ClN_2$	20.0	
Thiocarbanilide	DTXSID4026139	102-08-9	228.3128	$C_{13}H_{12}N_2S$	20.0	

[1]Assume Micronic 96-Q1 rack, tube volume 0.5 mL

ATTACHMENT C

NIEHS PAST PERFORMANCE QUESTIONNAIRE (Form PPQ-0)

CONTRACT INFORMATION (Contractor to complete Blocks 1-4)

1. Contractor Information

Firm Name: CAGE Code:
Address: Entity Identifier Number:
Phone Number:
Email Address:
Point of Contact: Contact Phone Number:

2. Work Performed as: ☐ Prime Contractor ☐ Sub Contractor ☐ Joint Venture ☐ Other (Explain)
Percent of project work performed:
If subcontractor, who was the prime (Name/Phone #):

3. Contract Information

Contract Number:
Delivery/Task Order Number (if applicable):
Contract Type: ☐ Firm Fixed Price ☐ Cost Reimbursement ☐ Other (Please specify):
Contract Title:
Contract Location:

Award Date (mm/dd/yy):
Contract Completion Date (mm/dd/yy):
Actual Completion Date (mm/dd/yy):
Explain Differences:

Original Contract Price (Award Amount):
Final Contract Price (*to include all modifications, if applicable*):
Explain Differences:

4. Project Description:

Complexity of Work ☐ High ☐ Med ☐ Routine
How is this project relevant to project of submission? (*Please provide details such as similar equipment, requirements, conditions, etc.*)

CLIENT INFORMATION (Client to complete Blocks 5-8)

5. Client Information

Name:
Title:
Phone Number:
Email Address:

6. Describe the client's role in the project:

7. Date Questionnaire was completed (mm/dd/yy)**:**

8. Client's Signature:

NOTE: NIEHS REQUESTS THAT THE CLIENT COMPLETES THIS QUESTIONNAIRE AND SUBMITS DIRECTLY BACK TO THE OFFEROR. THE OFFEROR WILL SUBMIT THE COMPLETED QUESTIONNAIRE TO NIEHS WITH THEIR PROPOSAL, AND MAY DUPLICATE THIS QUESTIONNAIRE FOR FUTURE SUBMISSION ON NIEHS SOLICITATIONS. CLIENTS ARE HIGHLY ENCOURAGED TO SUBMIT QUESTIONNAIRES DIRECTLY TO THE OFFEROR. HOWEVER, QUESTIONNAIRES MAY BE SUBMITTED DIRECTLY TO NIEHS. PLEASE CONTACT THE OFFEROR FOR NIEHS POC INFORMATION. THE GOVERNMENT RESERVES THE RIGHT TO VERIFY ANY AND ALL INFORMATION ON THIS FORM.

ADJECTIVE RATINGS AND DEFINITIONS TO BE USED TO BEST REFLECT YOUR EVALUATION OF THE CONTRACTOR'S PERFORMANCE

RATING	DEFINITION	NOTE
(E) Exceptional	Performance meets contractual requirements and exceeds many to the Government/Owner's benefit. The contractual performance of the element or sub-element being assessed was accomplished with few minor problems for which corrective actions taken by the contractor was highly effective.	An Exceptional rating is appropriate when the Contractor successfully performed multiple significant events that were of benefit to the Government/Owner. A singular benefit, however, could be of such magnitude that it alone constitutes an Exceptional rating. Also, there should have been NO significant weaknesses identified.
(VG) Very Good	Performance meets contractual requirements and exceeds some to the Government's/Owner's benefit. The contractual performance of the element or sub-element being assessed was accomplished with some minor problems for which corrective actions taken by the contractor were effective.	A Very Good rating is appropriate when the Contractor successfully performed a significant event that was a benefit to the Government/Owner. There should have been no significant weaknesses identified.
(S) Satisfactory	Performance meets minimum contractual requirements. The contractual performance of the element or sub-element contains some minor problems for which corrective actions taken by the contractor appear or were satisfactory.	A Satisfactory rating is appropriate when there were only minor problems, or major problems that the contractor recovered from without impact to the contract. There should have been NO significant weaknesses identified. A fundamental principle of assigning ratings is that contractors will not be assessed a rating lower than Satisfactory solely for not performing beyond the requirements of the contract.
(M) Marginal	Performance does not meet some contractual requirements. The contractual performance of the element or sub-element being assessed reflects a serious problem for which the contractor has not yet identified corrective actions. The contractor's proposed actions appear only marginally effective or were not fully implemented.	A Marginal is appropriate when a significant event occurred that the contractor had trouble overcoming which impacted the Government/Owner.
(U) Unsatisfactory	Performance does not meet most contractual requirements and recovery is not likely in a timely manner. The contractual performance of the element or sub-element contains serious problem(s) for which the contractor's corrective actions appear or were ineffective.	An Unsatisfactory rating is appropriate when multiple significant events occurred that the contractor had trouble overcoming and which impacted the Government/Owner. A singular problem, however, could be of such serious magnitude that it alone constitutes an unsatisfactory rating.
(N) Not Applicable	No information or did not apply to your contract	Rating will be neither positive nor negative.

Contractor Information (Firm Name): _____

Client Information (Name): _____

TO BE COMPLETED BY CLIENT

PLEASE CIRCLE THE ADJECTIVE RATING WHICH BEST REFLECTS YOUR EVALUATION OF THE CONTRACTOR'S PERFORMANCE.

1. QUALITY:						
a) Quality of technical data/report preparation efforts	E	VG	S	M	U	N
b) Ability to meet quality standards specified for technical performance	E	VG	S	M	U	N
c) Timeliness/effectiveness of contract problem resolution without extensive customer guidance	E	VG	S	M	U	N
d) Adequacy/effectiveness of quality control program and adherence to contract quality assurance requirements (without adverse effect on performance)	E	VG	S	M	U	N
2. SCHEDULE/TIMELINESS OF PERFORMANCE:						
a) Compliance with contract delivery/completion schedules including any significant intermediate milestones. *(If liquidated damages were assessed or the schedule was not met, please address below)*	E	VG	S	M	U	N
b) Rate the contractor's use of available resources to accomplish tasks identified in the contract	E	VG	S	M	U	N
3. CUSTOMER SATISFACTION:						
a) To what extent were the end users satisfied with the project?	E	VG	S	M	U	N
b) Contractor was reasonable and cooperative in dealing with your staff (including the ability to successfully resolve disagreements/disputes; responsiveness to administrative reports, businesslike and communication)	E	VG	S	M	U	N
c) To what extent was the contractor cooperative, businesslike, and concerned with the interests of the customer?	E	VG	S	M	U	N
d) Overall customer satisfaction	E	VG	S	M	U	N
4. MANAGEMENT/ PERSONNEL/LABOR						
a) Effectiveness of on-site management, including management of subcontractors, suppliers, materials, and/or labor force?	E	VG	S	M	U	N
b) Ability to hire, apply, and retain a qualified workforce to this effort	E	VG	S	M	U	N
c) Government Property Control	E	VG	S	M	U	N
d) Knowledge/expertise demonstrated by contractor personnel	E	VG	S	M	U	N
e) Utilization of Small Business concerns	E	VG	S	M	U	N
f) Ability to simultaneously manage multiple projects with multiple disciplines	E	VG	S	M	U	N
g) Ability to assimilate and incorporate changes in requirements and/or priority, including planning, execution and response to Government changes	E	VG	S	M	U	N
h) Effectiveness of overall management (including ability to effectively lead, manage and control the program)	E	VG	S	M	U	N
5. COST/FINANCIAL MANAGEMENT						
a) Ability to meet the terms and conditions within the contractually agreed price(s)?	E	VG	S	M	U	N

Client Information (Name): _____

b) Contractor proposed innovative alternative methods/processes that reduced cost, improved maintainability or other factors that benefited the client	E	VG	S	M	U	N
c) If this is/was a Government cost type contract, please rate the Contractor's timeliness and accuracy in submitting monthly invoices with appropriate back-up documentation, monthly status reports/budget variance reports, compliance with established budgets and avoidance of significant and/or unexplained variances (under runs or overruns)	E	VG	S	M	U	N
d) Is the Contractor's accounting system adequate for management and tracking of costs? *If no, please explain in Remarks section.*		Yes			No	
e) If this is/was a Government contract, has/was this contract been partially or completely terminated for default or convenience or are there any pending terminations? *Indicate if show cause or cure notices were issued, or any default action in comment section below.*		Yes			No	
f) Have there been any indications that the contractor has had any financial problems? *If yes, please explain below.*		Yes			No	
6. SAFETY/SECURITY						
a) To what extent was the contractor able to maintain an environment of safety, adhere to its approved safety plan, and respond to safety issues? (Includes: following the users rules, regulations, and requirements regarding housekeeping, safety, correction of noted deficiencies, etc.)	E	VG	S	M	U	N
b) Contractor complied with all security requirements for the project and personnel security requirements.	E	VG	S	M	U	N
7. GENERAL						
a) Ability to successfully respond to emergency and/or surge situations (including notifying COR, PM or Contracting Officer in a timely manner regarding urgent contractual issues).	E	VG	S	M	U	N
b) Compliance with contractual terms/provisions *(explain if specific issues)*	E	VG	S	M	U	N
c) Would you hire or work with this firm again? *(If no, please explain below)*		Yes			No	
d) In summary, provide an overall rating for the work performed by this contractor.	E	VG	S	M	U	N

Please provide responses to the questions above (*if applicable*) and/or additional remarks. Furthermore, please provide a brief narrative addressing specific strengths, weaknesses, deficiencies, or other comments which may assist our office in evaluating performance risk *(please attach additional pages if necessary)***:**

Modified form OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME:
ORGANIZATION:
POSITION TITLE:
EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY

NOTE: The Biographical Sketch may not exceed five pages. Follow the formats and instructions below.

A. Personal Statement

Briefly describe why you are well-suited for your role(s) in the project described in this proposal. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project.

B. Positions and Honors

List in chronological order previous positions, concluding with the present position. List any honors. Include professional society membership(s). Include present membership on any Federal Government public advisory committee.

C. Experience and Accomplishments (Contributions to Science)

Briefly describe up to five of your most significant accomplishments/experience. For each contribution, indicate the background that frames the scientific problem; the central finding(s) or outcome(s); and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.

D. Research & Development Projects

List both selected ongoing and completed research projects for up to the past ten years (Federal or non-Federally-supported), notably those with a similar scope, size and complexity. *Begin with the projects that are most relevant to the research proposed in the RFP.* Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

Attachment F. Government Furnished Materials

Attachment F. Government Furnished Materials

1. Bulk test articles in containers currently stored under contracts with Battelle, Columbus, OH; MRIGlobal, Kansas City, MO; and RTI International, RTP, NC. Upon award these chemicals must be transferred to the successful offerors. Each successful offeror shall be responsible for the immediate and safe transfer of the stored chemicals from the current Contractors to their own facilities. Table 1 lists the numbers and sizes of containers that will need to be transferred per award. Safety Data Sheets (SDS) will be provided for all chemicals to be transferred at the time of award.
2. Small quantity test article inventory currently stored at MRIGlobal, Kansas City, MO. The successful offeror shall be responsible for the immediate and safe transfer of the stored chemicals from the current Contactor's facility to their own facility. Table 2 lists the numbers and sizes of containers that will need to be transferred. Safety Data Sheets (SDS) will be provided for all chemicals to be transferred at the time of award.

Table 1. Bulk test article containers

	Container Size					
Storage Temperature	**0.5 -1 gal**	**1-5 gal**	**10 gal**	**33-55 gal**	**Total**	**%**
Ambient (~25ºC)	1000	125	10	15	1150	43
Refrigerated (4ºC)	250	20	<1	<2	273	10
Frozen (–20ºC)	1000	250	3	0	1253	47
Ultracold (-80ºC)	10	5	0	0	15	<1
TOTALS	**2260**	**400**	**14**	**17**	**2691**	**100**

Table 2. Small quantity test article containers

	Container Size					
Storage Temperature	**≤ 1 g**	**≤ 5 g**	**≤ 25 g**	**> 25 g**	**Total**	**%**
Ambient (~25°C)	684	386	386	381	1837	66%
Refrigerated (4°C)	234	182	150	51	617	22%
Frozen (–20°C)	274	16	11	32	333	12%
Ultracold (–80°C)	10	6	0	0	16	1%
				Total containers	2803	

ATTACHMENT G
HISTORICAL SMALL BUSINESS UTILIZATION
75N94026R00002

This form is to be completed by **ALL** offerors (both large **AND** small businesses) in order to provide supporting information for the evaluation of Factor 6, Small Business Utilization and Participation. **Attachment D** documents the offeror's historical small business utilization and achievements for each project submitted under Factor 1, Experience. **Round all percentages to the nearest tenth of a percent (i.e., include only 1 number after the decimal point)**.

Information provided in a different format and/or on a form created by the offeror will not be evaluated. Attachments or addendums to **Attachment D** will not be evaluated. Only complete **Attachment D**. Offerors are permitted to expand portions of the form, as needed, to provide sufficient response.

INSTRUCTIONS FOR COMPLETING ATTACHMENT D:

- Complete the "PROJECT DETAILS" section for each Project submitted under Factor 1, Experience.
  - Include contract or task order number; project title; the offeror's business size; whether the contract was performed as a prime, subcontractor, or JV member; and whether a subcontracting plan was required.
- Complete the "ACTUAL" column (required for all projects regardless of whether goals were established)
  - Enter dollar values actually subcontracted for each of the categories listed.
  - Provide actual percentages calculated as a percentage of total subcontract value, unless goals were calculated as a percentage of total contract value.
- Complete the "GOAL" column - Enter goals, if applicable.
  - If the project was a task order and no goals were established at the task order level, only complete the "ACTUAL" column. Goals for the overarching IDIQ contract should not be included in the "GOAL" column for task orders.
  - Goals shall be included for standalone contracts when established.
  - Goals can be entered as a percentage of total subcontract value or total contract value based on how the goals were established in the contract award.
- If goals were not established for the project submitted, or if goals were not established for a specific socioeconomic category, check N/A where applicable. The N/A block does not apply to the "ACTUAL" column, as actual subcontracted values are required for **ALL** projects, regardless of whether goals were established.
- If a goal was unmet for a Project, complete the section below titled "TO BE COMPLETED AS REQUIRED" under item #1.
  - Explanation is required for each unmet goal.
  - Item #1 is to be completed for each Project with unmet goal(s).
- If a Project has no small business subcontracting achievement (i.e.: $0 subcontracting in (d)), compete the "TO BE COMPLETED AS REQUIRED" under item #2.
  - Item #2 is to be addressed for each Project with no small business subcontracting achievement.
- Enter zeroes (0) where applicable.

DEFINITION OF TERMS IN ATTACHMENT D:

- Total Project Dollar Value: the total contract or task order value; this is the actual value of the contract or task order, rather than a "Not To Exceed" dollar value on an IDIQ type contract.
- Total Self-Performed Value: the contract or task order dollar amount performed by the prime contractor, subcontractor or JV.
- Total Subcontract Value: the dollar amount of the contract or task order performed by subcontractors.

PROJECT DETAILS: Project #1 Contract/Project Number/Task Order Number:_____ Project Title: _____ Offeror Size: Large Business ☐ Small Business ☐ Performed as: Prime Contractor ☐ Subcontractor ☐ JV Member ☐ Subcontracting Plan Required: ☐ Yes ☐ No	**ACTUAL**		**GOAL** (if applicable)		
(a) Total Project Dollar Value: $_____ (b) Total Self-Performed Value: $_____ (c) Total Subcontracted Value: $_____	Whole Dollars	Percent of line (a) or (c)	Whole Dollars	Percent of line (a) or (c)	N/A
SUBCONTRACTING BREAKDOWN:					
(d) Small Business Concerns (Includes overall SB subcontracting and subcontracting values from f-j below)	$	%	$	%	☐
(e) Large Business Concerns	$	%	$	%	☐
(f) Small Disadvantaged Business Concerns (SDB)	$	%	$	%	☐
(g) Women-Owned Small Business Concerns (WOSB)	$	%	$	%	☐
(h) HUBZone Small Business Concerns	$	%	$	%	☐
(i) Veteran-Owned Small Business Concerns (VOSB)	$	%	$	%	☐
(j) Service-Disabled Veteran-Owned Small Business Concerns (SDVOSB)	$	%	$	%	☐

TO BE COMPLETED AS REQUIRED:

1. Provide a detailed explanation for each unmet goal. Simply acknowledging that a goal was missed is not considered an adequate explanation: _____

2. Provide a detailed explanation for no small business subcontracting achievement (i.e.: $0 subcontracting in (d)) (if applicable): _____

PROJECT DETAILS: Project #2 Contract/Project Number/Task Order Number:_____ Project Title: _____ Offeror Size: Large Business ☐ Small Business ☐ Performed as: Prime Contractor ☐ Subcontractor ☐ JV Member ☐ Subcontracting Plan Required: ☐ Yes ☐ No	**ACTUAL**		**GOAL** (if applicable)		
(a) Total Project Dollar Value: $_____ (b) Total Self-Performed Value: $_____ (c) Total Subcontracted Value: $_____	Whole Dollars	Percent of line (a) or (c)	Whole Dollars	Percent of line (a) or (c)	N/A
SUBCONTRACTING BREAKDOWN:					
(d) Small Business Concerns (Includes overall SB subcontracting and subcontracting values from f-j below)	$	%	$	%	☐
(e) Large Business Concerns	$	%	$	%	☐
(f) Small Disadvantaged Business Concerns (SDB)	$	%	$	%	☐
(g) Women-Owned Small Business Concerns (WOSB)	$	%	$	%	☐
(h) HUBZone Small Business Concerns	$	%	$	%	☐
(i) Veteran-Owned Small Business Concerns (VOSB)	$	%	$	%	☐
(j) Service-Disabled Veteran-Owned Small Business Concerns (SDVOSB)	$	%	$	%	☐

TO BE COMPLETED AS REQUIRED:

1. Provide a detailed explanation for each unmet goal. Simply acknowledging that a goal was missed is not considered an adequate explanation: _____

2. Provide a detailed explanation for no small business subcontracting achievement (i.e.: $0 subcontracting in (d)) (if applicable): _____

PROJECT DETAILS: Project #3 Contract/Project Number/Task Order Number:_____ Project Title: _____ Offeror Size: Large Business ☐ Small Business ☐ Performed as: Prime Contractor ☐ Subcontractor ☐ JV Member ☐ Subcontracting Plan Required: ☐ Yes ☐ No	**ACTUAL**		**GOAL** (if applicable)		
(a) Total Project Dollar Value: $_____ (b) Total Self-Performed Value: $_____ (c) Total Subcontracted Value: $_____	Whole Dollars	Percent of line (a) or (c)	Whole Dollars	Percent of line (a) or (c)	N/A
SUBCONTRACTING BREAKDOWN:					
(d) Small Business Concerns (Includes overall SB subcontracting and subcontracting values from f-j below)	$	%	$	%	☐
(e) Large Business Concerns	$	%	$	%	☐
(f) Small Disadvantaged Business Concerns (SDB)	$	%	$	%	☐
(g) Women-Owned Small Business Concerns (WOSB)	$	%	$	%	☐
(h) HUBZone Small Business Concerns	$	%	$	%	☐
(i) Veteran-Owned Small Business Concerns (VOSB)	$	%	$	%	☐
(j) Service-Disabled Veteran-Owned Small Business Concerns (SDVOSB)	$	%	$	%	☐

TO BE COMPLETED AS REQUIRED:

1. Provide a detailed explanation for each unmet goal. Simply acknowledging that a goal was missed is not considered an adequate explanation: _____

2. Provide a detailed explanation for no small business subcontracting achievement (i.e.: $0 subcontracting in (d)) (if applicable): _____

PROJECT DETAILS: Project #4 Contract/Project Number/Task Order Number:_____ Project Title: _____ Offeror Size: Large Business ☐ Small Business ☐ Performed as: Prime Contractor ☐ Subcontractor ☐ JV Member ☐ Subcontracting Plan Required: ☐ Yes ☐ No	**ACTUAL**		**GOAL** (if applicable)		
(a) Total Project Dollar Value: $_____ (b) Total Self-Performed Value: $_____ (c) Total Subcontracted Value: $_____	Whole Dollars	Percent of line (a) or (c)	Whole Dollars	Percent of line (a) or (c)	N/A
SUBCONTRACTING BREAKDOWN:					
(d) Small Business Concerns (Includes overall SB subcontracting and subcontracting values from f-j below)	$	%	$	%	☐
(e) Large Business Concerns	$	%	$	%	☐
(f) Small Disadvantaged Business Concerns (SDB)	$	%	$	%	☐
(g) Women-Owned Small Business Concerns (WOSB)	$	%	$	%	☐
(h) HUBZone Small Business Concerns	$	%	$	%	☐
(i) Veteran-Owned Small Business Concerns (VOSB)	$	%	$	%	☐
(j) Service-Disabled Veteran-Owned Small Business Concerns (SDVOSB)	$	%	$	%	☐

TO BE COMPLETED AS REQUIRED:

1. Provide a detailed explanation for each unmet goal. Simply acknowledging that a goal was missed is not considered an adequate explanation: _____

2. Provide a detailed explanation for no small business subcontracting achievement (i.e.: $0 subcontracting in (d)) (if applicable): _____

PROJECT DETAILS: Project #5 Contract/Project Number/Task Order Number:_____ Project Title: _____ Offeror Size: Large Business ☐ Small Business ☐ Performed as: Prime Contractor ☐ Subcontractor ☐ JV Member ☐ Subcontracting Plan Required: ☐ Yes ☐ No	**ACTUAL**		**GOAL** (if applicable)		
(a) Total Project Dollar Value: $_____ (b) Total Self-Performed Value: $_____ (c) Total Subcontracted Value: $_____	Whole Dollars	Percent of line (a) or (c)	Whole Dollars	Percent of line (a) or (c)	N/A
SUBCONTRACTING BREAKDOWN:					
(d) Small Business Concerns (Includes overall SB subcontracting and subcontracting values from f-j below)	$	%	$	%	☐
(e) Large Business Concerns	$	%	$	%	☐
(f) Small Disadvantaged Business Concerns (SDB)	$	%	$	%	☐
(g) Women-Owned Small Business Concerns (WOSB)	$	%	$	%	☐
(h) HUBZone Small Business Concerns	$	%	$	%	☐
(i) Veteran-Owned Small Business Concerns (VOSB)	$	%	$	%	☐
(j) Service-Disabled Veteran-Owned Small Business Concerns (SDVOSB)	$	%	$	%	☐

TO BE COMPLETED AS REQUIRED:

1. Provide a detailed explanation for each unmet goal. Simply acknowledging that a goal was missed is not considered an adequate explanation: _____

2. Provide a detailed explanation for no small business subcontracting achievement (i.e.: $0 subcontracting in (d)) (if applicable): _____

(ATTACHMENT H)
SMALL BUSINESS PARTICIPATION
COMMITMENT DOCUMENT (SBPCD)

OFFEROR'S NAME
ADDRESS

RFP No.
PROJECT DESCRIPTION
Date Prepared

1. Instructions. The SBPCD includes the minimum level of commitment to subcontract with the SBs identified herein. This form is to be completed by **ALL** offerors (both large **AND** small businesses) in order to provide supporting information for evaluation of Factor 6, Small Business Utilization and Participation. This is the **only** form that will be evaluated to determine the offeror's small business participation commitment. Information provided in a different format and/or on a form created by the offeror will **not** be evaluated. Attachments or addendums to this form will **not** be evaluated. Round dollars to nearest whole dollar and percentages to the nearest tenth of a percent.

2. Offeror Information. Prime contractor size based on the NAICS Code identified in the solicitation (check one):

   ☐ Large Business (LB)
   ☐ Small Business (SB)

   For offerors that identify as a SB, check all applicable socioeconomic categories that apply or check "None" if the offeror does not qualify under any of the socioeconomic categories:

   ☐ Small Disadvantaged Business (SDB)
   ☐ Woman-Owned Small Business (WOSB)
   ☐ Economically Disadvantaged Woman-Owned Small Business (EDWOSB)
   ☐ Historically Underutilized Business Zone Small Business (HUBZone SB)
   ☐ Veteran-Owned Small Business (VOSB)
   ☐ Service-Disabled Veteran-Owned Small Business (SDVOSB)
   ☐ None

3. Subcontracting Breakdown.
   a. Total contract value (TCV)(including options) $ ____
   b. Total value of the work to be self-performed by the prime offeror $ ____
   c. Total value of work to be subcontracted $ ____

4. Small Business Participation.

   a. Complete the participation table below with dollars and % of total contract value to be subcontracted.

Small Business Participation
(Including Small Business prime offeror's participation)

Business Category	Dollar Value	% of TCV
Total Small Business (SB) (including all SB socio-economic categories and work self-performed as a SB) The minimum total small business subcontracting requirement for this contract is **5%.** If this minimum small business participation requirement is not met, a detailed explanation **is required** below.	$	%
Small Disadvantaged Business (SDB)	$	%
Woman-Owned Small Business (WOSB)	$	%
Historically Underutilized Business Zone Small Business (HUBZone)	$	%
Veteran-Owned Small Business (VOSB)	$	%
Service-Disabled Veteran-Owned Small Business (SDVOSB)	$	%

If the offeror has **not** proposed a minimum of 5% for small business participation, provide a **detailed explanation**:

_____
_____
_____
_____
_____
_____
_____
_____

   b. To the greatest extent possible, the table below should identify SBs where firm commitments are in place, to support the minimum small business participation requirement identified in paragraph 4.a (above). **If subcontracting firm commitments are NOT in place, do not add the subcontractor to the table below.** A SB commitment is a written agreement between a prime and small business to work together on this contract. This commitment in writing is considered the nature of commitment, which can include written teaming agreement, joint venture agreement, mentor-protégé agreement, written/signed letter of commitment from the small business, etc. This table can be expanded as needed.

Company Name	Small Business Category(ies)*	Products/Services, including type & variety of work	Nature of Commitment

*SB, SBD, WOSB, HUBZone SB, VOSB, SDVOSB

5. Explanation/Rationale. If no subcontractors are identified in paragraph 4.b. above, provide **detailed explanation** for why subcontractors are not identified with firm commitments **AND** how your firm will be able to achieve the proposed small business participation.

_____
_____
_____
_____
_____
_____
_____
_____
_____

6. If a LB offeror does not intend to subcontract, provide a **detailed explanation** why subcontracting would not result in efficient contract performance. SBs intending to 100% self-perform are not required to provide an explanation.

_____
_____
_____
_____
_____
_____
_____
_____